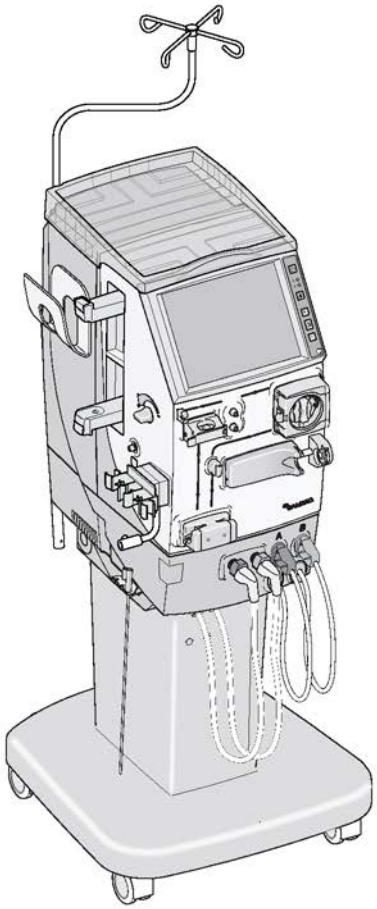
AK 98 Dialysis Machine



Operator’s Manual

Program version 2.xx

Order number:
MHCEN12745-10/16

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Manufacturer

Gambro Lundia AB

Box 10101 Magistratsvägen 16

SE-220 10 LUND

Sweden

Phone +46 46 169000

www.baxter.com

Questions or comments about this publication can be directed to your local representative or to the manufacturer.

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1.1 Important while reading the operator's manual

1.1.1 About this operator´s manual

This operator's manual provides instructions necessary for the proper operation of the AK 98 dialysis machine. It is not a guide for the administration of haemodialysis.

1.1.2 Safety definitions

Warning

WARNING!
A warning alerts the reader about a situation which, if not avoided, could result in an adverse reaction, injury or death.

Caution

CAUTION!
A caution alerts the reader about a situation which, if not avoided, could result in minor or moderate injury to the user or patient or damage to the equipment or other property.

Note

NOTE!
Notes are added to give more information.

1.1.3 Values and settings

Parameter values are set by the operator. For example treatment time and some alarm limits. See Section 1.1.5 "About the screen" on page A:11. All values and settings in this operator's manual are default values, which are set when the dialysis machine is manufactured. Check with the authorised service technician responsible for installing the dialysis machine if there are any values that are changed from the default settings.

Preset

When this symbol appears in the manual text, it indicates the possibility to preset the value of a parameter. Such a preset is done to adapt the settings of the machine to correspond with the routines of the user/clinic or specific patient prescription. A preset change shall always be done by an authorised service technician. For example, it is possible to preset the machine for which mode to start up in, some alarm limits, some functions and options. An authorised service technician shall, together with the user, confirm that the presets have been properly set.

1.1.4 Buttons

The buttons on the operator's panel, to the right of the screen, light up in different situations to guide the operator or to inform of actual status. See Figure 1-1 "The operator´s panel" on page A:11. The illustrations in the handling instructions do not normally show if the button is lit or unlit; the button figures are the same for lit, flashing and unlit buttons.

The buttons on the screen can be lit, disabled or flashing depending on the status and action but in this manual this state of the button is not reflected in the text or picture.

1.1.5 About the screen

The operator´s panel of the AK 98 dialysis machine has a colour touch screen. The screen allows the operator to interact with the dialysis machine by pressing various buttons.

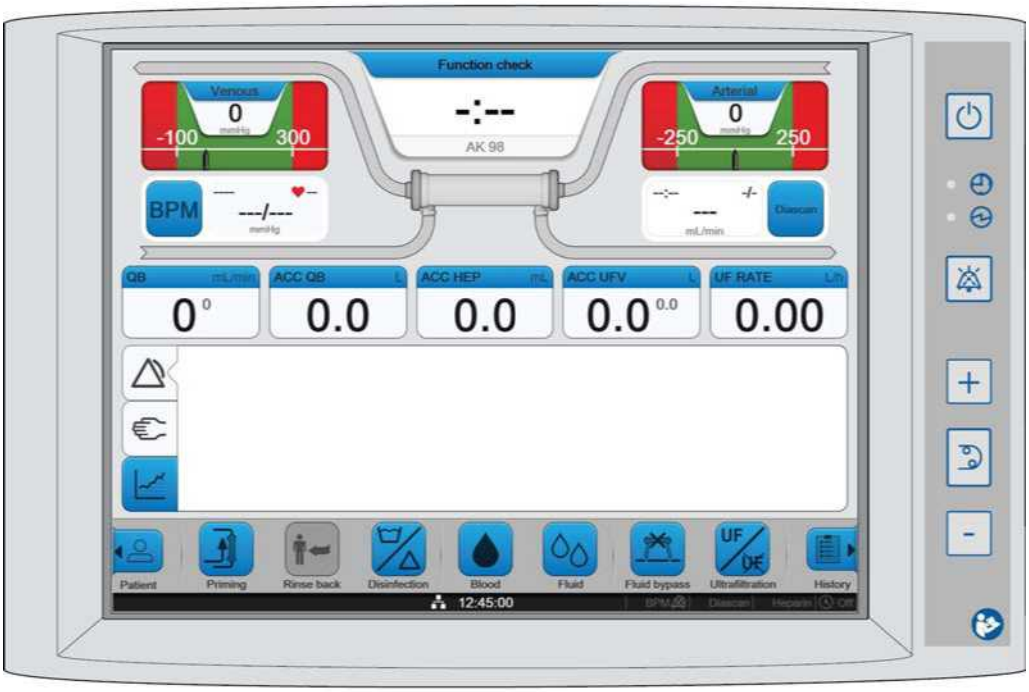
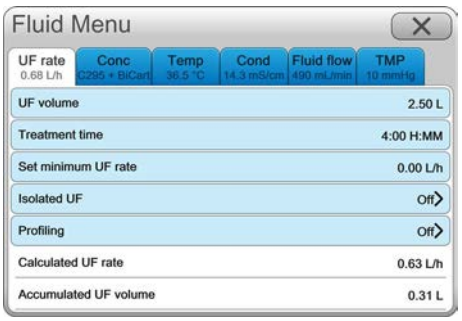


Figure 1-1. The operator´s panel

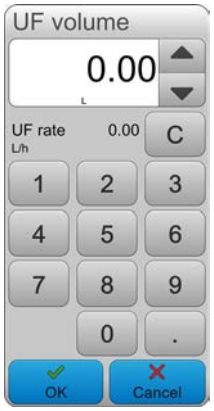
Press a button or menu item to activate its function.

Select a tab to reach the settings. The `UF rate` tab is selected in this picture.



Press a setting to adjust it. For example `UF volume`.

Use the **keypad** to adjust numeric values. The **keypad** will open automatically when needed.



1.1.6 Symbols

The symbols can be affixed to the machine or affixed/printed on the original packaging.

	Alternating current
	Protective earth (ground)
	Off (disconnection from the mains power)
	On (connection to the mains power)
	Equipotential connector
IP21	The AK 98 dialysis machine is protected against solid foreign objects ≥12.5 mm Ø and vertically falling water drops.
	Type B, applied part
	NIBP type BF applied part
	The product does not contain latex. The symbol frame and text are white.
	The product does not contain PVC. The symbol frame and text are white.
	The maximum stacking load permitted on the transport package
	Fragile – Handle with care
	This way up
	Keep dry

	Catalogue number
	Serial number
	Humidity limitation. Upper and lower limit is expressed with numeric values in %.
	Atmospheric pressure limitation. Upper and lower limit is expressed with numeric values in kPa.
	Temperature limitation. Upper and lower limit is expressed with numeric values in degree Celsius or Fahrenheit.
	Manufacturer. The date of manufacture as well as the name and address of the manufacturer are included in the symbol.
	Recycling symbol – Corrugated Cardboard. According to GB 18455–2001.
	This symbol indicates that the dialysis machine contains toxic or hazardous substances or elements according to GB/T26572-2011. The number 25 indicates the corresponding environmental protection use period of the dialysis machine.
	Separate collection for electrical and electronic equipment
	Warning, dangerous voltage. Contact may cause electric shock or burn. The symbol colour is black on a yellow background.
	Warning. Do not lean the AK 98 dialysis machine more than 5° from the horizontal plane. The symbol colour is black on a yellow background.
	Do not lean or push the AK 98 dialysis machine. Risk for overbalance. The symbol colours are red, white, and black.
	The weight of the AK 98 dialysis machine including equipment used for the treatment placed on the machine.
	Caution, consult accompanying documents
	Read instructions before use. The symbol colour is white on a blue background.
The following symbols are found on the cuff:	
	Index Line
	Artery symbol and arrow should be placed over brachial or femoral artery.
	Symbol indicating arm circumference.
	Cuff index line must fall within range markings.
The following symbols are found on the BICART cartridge holder:	

●	Shows where the top port of the BICART and CLEANCART cartridges connects with the upper arm during cartridge installation.
▼	A guide to ensure the correct upright positioning of the BICART and CLEANCART cartridges during its installation.

Cuff ranges/colours

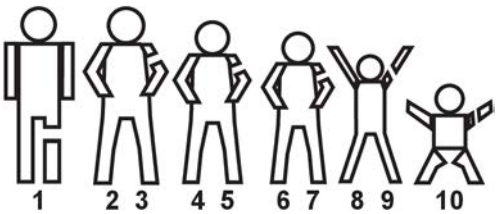


Table 1-1. Cuff ranges/colours

Number:	Size:	Colour:	Range:
1	Thigh	Brown	38-50 cm
2	Lg Adult Long	Burgundy	31-40 cm
3	Lg Adult	Burgundy	31-40 cm
4	Adult Long	Navy Blue	23-33 cm
5	Adult	Navy Blue	23-33 cm
6	Sm Adult Long	Royal Blue	17-25 cm
7	Sm Adult	Royal Blue	17-25 cm
8	Child Long	Green	12-19 cm
9	Child	Green	12-19 cm
10	Infant	Orange	8-13 cm

Certification marks

CE marking

CE
0086

The CE conformity mark indicates that the AK 98 dialysis machine conforms to the requirements in the EC Council Directive 93/42/EEC of 14 June, 1993 concerning medical devices. It also indicates that the notified body British Standards Institution (BSI, No. 0086) has approved the Quality Management System. The CE conformity mark is only valid for the AK 98 dialysis machine. Disposables and any accessories specified for use with the AK 98 dialysis machine are marked with CE conformity marks in their own right.

CSA marking

The CSA mark indicates that the AK 98 dialysis machine conforms to the requirements related to safety of medical devices for Canada and that the AK 98 dialysis machine has been evaluated to the applicable CSA standards for use in Canada.

1.2 General warning and precautions before use

1.2.1 General precautions before use

WARNING!
Unauthorised modifications, alterations or repair and lack of maintenance or calibration of the AK 98 dialysis machine may result in malfunctioning or have other serious consequences for the safe operation of the equipment.

WARNING!
The mains power cable from the AK 98 dialysis machine (cable length is 3.5 metres) shall be connected to a socket with protected earth (PE) to avoid risk of electrical shock.

WARNING!
To minimise the risk of arrhythmia due to leakage currents when a central venous catheter is used, and the tip of the catheter is close to the heart, it is necessary to connect the potential equalisation conductor between the AK 98 dialysis machine and the potential equalisation busbar in the electrical installation.

WARNING!
To minimise the risk of arrhythmia due to leakage currents from other electrical equipment when a central venous catheter is used, and the tip of the catheter is close to the heart, any equipment within the patient area shall have leakage current values below respective limit required by CF type applied parts.

WARNING!
To protect the children, never leave children unattended near the dialysis machine, its chemicals, disposables or accessories.

WARNING!
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING!
Never use multiple socket-outlet when connecting the dialysis machine or WRO 300 to mains supply since it might lead to too high leakage currents during fault conditions.

WARNING!
Do not use the AK 98 dialysis machine adjacent to or stacked with other equipment, other than specified by the manufacturer.

WARNING!
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING!
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) shall not be used no closer than 30 cm (12 inches) to any part of the ME EQUIPMENT, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could be the result.

CAUTION!
To avoid improper handling, the AK 98 dialysis machine may only be operated by persons trained in haemodialysis and who have studied the instructions in this manual. The user/operator should draw special attention towards the text valid for the safety philosophy of the machine. See Section 1.2.8 “Safety philosophy” on page A:19. Verify that the first digit of the program version of both the machine and the manual is the same. If the AK 98 dialysis machine does not perform as described in this manual, it should not be used until the condition is rectified.

CAUTION!
When unpacking, check the equipment for any signs of damage. If the equipment is in any way damaged, proper operation cannot be assured.

CAUTION!
Patients connected to the AK 98 dialysis machine should be monitored by competent personnel since life threatening situations can arise that may not activate alarms. The operator should pay attention to all appropriate alarms and follow the instructions, warnings, cautions, and notes given in this manual. It is imperative that the machine has passed the functional check before connecting a patient.

CAUTION!
To ensure proper functionality, all calibration checks must be completed during installation before the machine is used for dialysis treatment.

CAUTION!
The AK 98 dialysis machine needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in Section 14.6.3 “Electromagnetic environment” on page A:188.

CAUTION!
The use of mobile telephones or communication equipment in the vicinity of the AK 98 dialysis machine could adversely influence the performance of the machine. For further information, see Section 14 “Technical data and specifications” on page A:177.

CAUTION!
The AK 98 dialysis machine will perform as designed only if it is used and maintained in accordance with Baxter’s instructions. Any warranties made by Baxter with respect to the AK 98 dialysis machine are void if the equipment is not used in accordance with the instructions provided. Baxter will not accept responsibility for any damage or injury resulting from improper use or maintenance or unauthorised repair.

CAUTION!
To ensure proper functionality preventive inspection, maintenance and calibration of the AK 98 dialysis machine shall be performed by a fully trained authorised service technician according to the maintenance manual in the AK 98 Service manual which can be ordered from your Baxter representative. It is mandatory for preventive maintenance to be performed at least every other year. Yearly maintenance is recommended. The interval between preventive maintenance procedures might differ due to operating environment variations.

CAUTION!
Check the use environment before use as the AK 98 dialysis machine is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

CAUTION!
Make sure that any used chemical disinfectants are stored according to manufacturer's recommendations.

CAUTION!
Make sure not to position the AK 98 dialysis machine in a way that it becomes difficult to operate the mains power switch.

NOTE!
The AK 98 dialysis machine must be installed according to the Installation guide.

NOTE!
For accuracy ranges written as "(±1 mL/min or ±1%)", the widest range is valid.

NOTE!
It is recommended that the equipment is kept in its original packing during transportation and storage.

NOTE!
The service manual is only available for the authorised service technician.

NOTE!
It is important that the protective earth in the installation is of high quality.

NOTE!
For the purpose of protecting the environment the AK 98 dialysis machine shall be separately collected for dismantling and recovery. Where applicable, national regulations shall be applied. Consult your local Baxter distributor for information.

NOTE!
To protect the machine against spillage, the infusion stand must always be correctly mounted in the machine.

NOTE!
The WRO unit (WRO 300 or WRO 300 H) must be preset by an authorised service technician to work correctly with the dialysis machine.

1.2.2 Responsibility and disclaimer

The manufacturer accepts responsibility for the safety, reliability, and performance of this equipment only if the following conditions are fulfilled:

- Installation, operational procedures, maintenance, calibrations and repairs are carried out by appropriately trained and suitable qualified people.
- All equipment modifications are authorised in writing by the manufacturer and carried out by appropriately trained and suitable qualified people.
- The electrical installation of the relevant room complies with all applicable local electrical codes and, if applicable, IEC requirements.
- The equipment is used in accordance with the published operator's manual.

Baxter does not accept any responsibility or liability for use of accessories or disposables other than those specified in this manual or if any specified accessory or disposable is not used in accordance with this manual, online instructions and the instructions for use accompanying those accessories and disposables.

The patient's physician is responsible for counselling, home care follow-up and medical maintenance that comes with the treatment. Baxter has no responsibility for any of these activities.

1.2.3 Leakage current and potential equalisation connection

Definitions

Leakage current	Electrical current that leaks out of the intended circuit or current that is not functional.
Potential equalisation connection	A connection between the potential equalisation connector of the machine and the potential equalisation busbar of the electrical installation using a potential equalisation conductor. This connection shall be additional to the protective earth connection.

1.2.4 Treatment location

The user must make sure that the location where the AK 98 dialysis machine is installed, including the patient environment, is suitable for dialysis treatment. The location shall be maintained at a hygienic standard suitable for dialysis treatment and kept free from pets and pests.

The dialysis treatment shall not be performed in proximity to high-powered ME EQUIPMENT.

Any other electrical equipment used in the patient environment shall be marked with:

Any other electrical equipment not having this mark shall be located outside the patient environment. A potential equalisation connection has to be used when it is legally required.

1.2.5 Central venous catheter

If a central venous catheter is used during treatment with the tip of the catheter close to the heart a potential equalisation connection must be used.

1.2.6 Connection of external electrical equipment

The AK 98 dialysis machine is equipped with three interface contacts on the back side; a 25 pole D-Sub, a USB and an Ethernet connector. These connectors shall only be used by an authorised service technician. All other use is prohibited.

1.2.7 How to move the AK 98 dialysis machine

Always use the transportation handle when moving the dialysis machine. Take a firm hold on the transportation handle and gently pull the device over a step, do not push. Make sure the brakes are released before moving the dialysis machine.

WARNING!
If a remote Operator's Panel has been installed, fluid bags shall be removed from the infusion stand when transporting (moving) the machine to avoid overbalance. The fluid bags may be placed on the top tray.

CAUTION!
Do not move the dialysis machine during a treatment. If you need to move the dialysis machine to reach the side only do small adjustments and make sure not to overbalance or collide the dialysis machine as this could damage the equipment.

CAUTION!
When moving the dialysis machine, take a firm hold on the transportation handle and gently move the device over obstacles. Do not move the machine with anything hanging from the infusion stand or with anything standing at the base plate of the machine as this may make the dialysis machine unstable.

1.2.8 Safety philosophy

To maintain a safe treatment the AK 98 dialysis machine contains a control system and a protective system. Controllable treatment parameters (i.e. conductivity, temperature and ultrafiltration) are supervised by the control system.

The protective system triggers an alarm if a treatment value is outside its alarm limits. When an alarm is triggered, the protective system takes appropriate measures and puts the AK 98 dialysis machine into a patient-safe condition, for example by stopping the blood pump, closing the venous clamp or preventing the dialysis fluid from reaching the dialyzer.

The functionality of the protective system is checked by the AK 98 dialysis machine during functional check before each treatment. A fault detection during the pre-treatment tests will make it impossible to start the treatment.

Ultrafiltration
The ultrafiltration supervision feature uses an independent pair of flow sensors for the ultrafiltration protective system.

Venous pressure
The protective system checks the venous pressure to prevent patient blood loss.

WARNING!
Under certain circumstances the patient may suffer from blood loss, without the venous pressure passing any alarm limit. To avoid this, make sure that the blood circuit and the needle are correctly connected, tight and secure and that the low alarm limit is set as close as possible to the actual venous pressure.

Blood pump
The protective system checks how long time the blood pump is stopped during a treatment, to make sure the blood in the dialysis machine blood lines does not coagulate.

Blood leak detector
The protective system checks that the blood leak detector is able to detect the presence of blood in the dialysis fluid.

Air detector
Any air that enters the blood lines upstream of the air detector is trapped in the venous drip chamber. After a certain volume of air has been trapped an alarm is given.

1.3 Intended use

1.3.1 Intended use

The AK 98 dialysis machine is intended for use as a single patient machine to perform haemodialysis treatments of patients with renal failure or fluid overload upon prescription by a physician. Patient counselling and teaching of treatment techniques are directly under the supervision and discretion of the physician. The AK 98 dialysis

machine is intended for the in- center environment and care in a home healthcare environment.

WARNING!
Treatment in a home healthcare environment shall only be allowed if the operator has received proper training to enable her / him to prepare the machine, perform and end the treatment in a safe way, and disinfect and clean the machine between treatments. Training shall be based on a profile assuming maximum of eight years of operator's education. The physician is responsible to ensure that the competence of the operator is checked on regular basis. Records of the training and competence checks shall be archived by the responsible physician.

CAUTION!
Patient education, counselling, home care follow-up and medical maintenance must be performed under the direction and supervision of the physician prescribing the treatment. Baxter specifically denies any responsibility for patient education, counselling or home care and medical maintenance.

CAUTION!
When the AK 98 dialysis machine is used to produce bicarbonate containing dialysis fluid originating from non-liquid concentrates, the AK 98 dialysis machine is designed and validated for use with the BICART cartridge. Baxter does not accept responsibility for use of other non-liquid concentrate containers as the proper functionality cannot be guaranteed.

CAUTION!
The physician is responsible to ensure that the operator has access to the AK 98 operator's manual when performing haemodialysis in a home healthcare environment.

CAUTION!
Additional measures to supervise the patient weight loss is recommended when treating low weight patients or when performing long treatments. For Ultrafiltration details, refer to Technical data and specifications.

NOTE!
The AK 98 dialysis machine is intended for continuous operation.

1.3.2 Training

Everyone that works with the dialysis machine, its accessories or the patient, must go through proper training to learn about haemodialysis and how to handle the dialysis machine in a correct and safe way.

This operator's manual is the primary training material for anyone who is to operate the AK 98 dialysis system.

It is essential to read or being trained on the full content of the Operator's manual before operating the AK 98 dialysis machine.

Training can be arranged after request from your local Baxter representative.

1.3.3 Disinfection and functional check

Always perform a disinfection after installation, before initial use.

When the dialysis machine is new it needs to complete an extended functional check before you can connect the patient. See Section 4.2.2 "Start functional check" on page A:76

1.3.4 Inlet water requirements

The inlet water must meet a number of requirements regarding its quality. Normally this requires some technical equipment to purify the water.

Maintaining and disinfecting this equipment, including the distribution loop, regularly is essential.

The inlet water must comply with valid standards for water for dialysis; see Section 14.1.16 “Water supply” on page A:183.

Failure to meet the requirements of the inlet water may lead to hemolysis due to undesired substances in the water.

1.3.5 Hygienic quality of central delivery systems

The user is responsible for the hygienic quality of any delivery systems, e.g. central water supply system, central delivery systems, haemodialysis equipment connecting devices, including the fluid lines from connection points to the haemodialysis equipment.

1.3.6 Preparing dialysis fluid

The dialysis machine can prepare dialysis fluid from incoming water, acidic (A) concentrate and dry bicarbonate concentrate (BICART cartridge).

Dialysis fluid can also consist of incoming water, an acidic (A) concentrate and a liquid bicarbonate (B) concentrate. See Section 1.4.1 “Concentrates, chemical disinfectants, accessories and disposables” on page A:21.

1.4 Accessories

1.4.1 Concentrates, chemical disinfectants, accessories and disposables

Baxter does not accept responsibility if the dialysis machine is used with concentrates, chemical disinfectants, accessories, or disposables other than those specified in this section. Using other material may reduce Baxter’s warranties for the dialysis machine.

WARNING!
To ensure proper functionality of the AK 98 dialysis machine, use only concentrates, chemical disinfectants, accessories, and disposables specified as follows as these has been tested and validated for use with the AK 98 dialysis machine.

CAUTION!
Baxter does not accept any responsibility or liability for use of concentrates, chemical disinfectants, accessories, or disposables other than those specified as follows. Depending on the circumstances, use of concentrates, chemical disinfectants, accessories, or disposables other than those specified may also reduce Baxter’s warranties for the AK 98 dialysis machine.

CAUTION!
To ensure proper functionality of the dialysis machine, observe the manufacturer's instructions for use regarding blood lines and dialyzers for single use.

NOTE!
The user should make sure a current listing of concentrates, chemical disinfectants, accessories, and disposables is available.

NOTE!
The user should follow the facility procedures for proper disposal of used blood lines, dialyzers and other disposables per local regulations.

1.4.2 Concentrates

Accessories mentioned in this section are approved and required for use with the AK 98 dialysis machine.

CAUTION!
Incorrect choice of dialysis fluid concentrate may cause incorrect composition of the dialysis fluid. Incorrect composition may lead to electrolytic imbalance in the patient's blood.

Table 1-2. Liquid concentrates

Liquid concentrates	Intended use
SOFTPAC G- and C-series	The SOFTPAC product is an acid concentrate for bicarbonate based hemodialysis and is intended to be used together with the BICART cartridge for on-line preparation of hemodialysis, hemodiafiltration or hemofiltration fluids on compatible Baxter dialysis machines. To obtain a current listing of recommended concentrates contact your local sales office.
SOFTPAC Citrate G- and C-series	The SOFTPAC Citrate product is intended to be used as a citrate based acid concentrate together with the BICART cartridge for on-line preparation of hemodialysis, hemodiafiltration and hemofiltration fluids on compatible Baxter dialysis machines. To obtain a current listing of recommended concentrates contact your local sales office.

Table 1-3. Non-liquid concentrates

Non-liquid concentrates	Intended use
BICART cartridge	Dry bicarbonate concentrate for preparation of bicarbonate dialysis fluid together with proper liquid A-concentrate. To obtain a current listing of recommended concentrates contact your local sales office.

1.4.3 Chemical disinfectants

Accessories mentioned in this section are approved and required for use with the AK 98 dialysis machine.

Chemicals suitable for disinfection and concentrations thereof are listed in Section 14.1.10 “Disinfection and cleaning – chemical disinfection” on page A:180. Chemical disinfectants may be harmful to the materials used in the fluid path of dialysis machines. Therefore it is important to use the right disinfectant and be aware of the precautions for a certain chemical disinfectant before use, see Section 10.4.7 “About chemical disinfectants” on page A:152.

1.4.4 Blood lines

Accessories mentioned in this section are approved and required for use with the AK 98 dialysis machine.

CAUTION!
Do not use the neonatal blood lines: A-5.128-B4, V-5.127-X, A-5.129-B4 or V-5.129-X with AK 98 dialysis machine as these neonatal blood lines are not intended for use with the AK 98 dialysis machine.

Table 1-4. Blood lines

Line number	Area of use
The following blood lines manufactured by Gambro, are available for use on AK 98 dialysis machine:	
GMB S Series	Arterial and venous blood line set
GMB Series	Arterial and venous blood line set
CBL Series	Arterial and venous blood line set
BL 10 series	Arterial and venous blood line set
BL 95 SN	Arterial and venous blood line set
BL 120N	Arterial and venous blood line set
BL 100 Series	Arterial and venous blood line set
BL 200 Series	Arterial and venous blood line set
BL 200 S Series	Arterial and venous blood line set
A 5000 and V 5000 Series	Arterial and venous blood lines
The following blood lines manufactured by Vital, are available for use on AK 98 dialysis machine:	
BL 05	Arterial and venous blood line set
BL 24	Arterial and venous blood line set
BL 25	Arterial and venous blood line set
BL 90	Arterial and venous blood line set
BL 008	Arterial blood line set
BL 009	Venous blood line set
BL 10 R	Arterial and venous blood line set
BL 10	Arterial and venous blood line set
BL 90 D4	Arterial and venous blood line set
BL 14	Arterial and venous blood line set

1.4.5 Accessories

Table 1-5. Accessories

Line number	Area of use
C series	Haemodialysis accessories
C 705	A connection line with an expansion chamber. Used in single needle mode.
SP series	Haemodialysis accessories

1.4.6 Ultrafilter

Accessories mentioned in this section are approved and required for use with the AK 98 dialysis machine.

The dialysis machine has a holder for an ultrafilter. The purpose of the ultrafilter is to clean the dialysis fluid further from possible contamination by bacteria and endotoxins.

Table 1-6. Ultrafilter

Ultrafilter	Area of use
U9000	Ultrafilter used for preparation of ultra filtered dialysis fluid.

1.4.7 Dialyzers

Accessories mentioned in this section are approved and required for use with the AK 98 dialysis machine.

NOTE!
The listed dialyzers have been determined by Baxter to meet the specifications and instructions for use given for the AK 98 dialysis machine with regards to e.g. the recommended priming procedure; in addition, the connectors and the ports of the dialyzers comply with ISO 8637 and EN 1283.

Table 1-7. Dialyzers

Dialyzer	Area of use
POLYFLUX series	These hollow fiber dialyzers have been validated by Baxter for use with the AK 98 dialysis machine.
REVACLEAR series	
EVODIAL series	
THERANOVA series	

1.4.8 Blood pressure measurement accessories

Accessories mentioned in this section are approved and required for use with the AK 98 dialysis machine.

Table 1-8. Blood pressure measurement accessories

GAMBRO Cuff	**Size**
Adult	23 - 33 cm
Large Adult	31 - 40 cm
Small Adult	17- 25 cm
Child	12 - 19 cm
GAMBRO Cuff (single hand)	**Size**
Adult	28 - 37 cm
Large Adult	36 - 46 cm
Small Adult	21 - 29 cm
GAMBRO Cuff hose	
3.0 m	Cuff hose is used to connect cuff and AK 98 dialysis machine.

1.5 Glossary

1.5.1 Glossary

Table 1-9. Defintions

Authorised service technician	A service technician certified by Baxter.
CIS	Clinical Information System
Cleaning	Removing fats, proteins and organic material from the fluid path downstream of the dialyzer (post dialyzer). See Section 10.1 “Disinfection and cleaning – general” on page A:144.
Decalcification	Removing calcium and magnesium-carbonate from the fluid path, originating from the bicarbonate dialysis fluid. See Section 10.1 “Disinfection and cleaning – general” on page A:144.
Disinfection	A process that destroys or removes microorganisms. See Section 10.1 “Disinfection and cleaning – general” on page A:144.
Dwell Time	The period that the fluid path is filled with disinfectant.
Functional check	Before a treatment can be started the dialysis machine performs a functional check. The machine checks that internal functions are working. The machine performs either an extended functional check or a shorter basic functional check. See Section 4.2.2 “Start functional check” on page A:76. "Functional check" in this manual refers to either basic functional check or extended functional check. When a specific functional check is described "extended functional check" or "basic functional check" will be used.

Operator	A person who has knowledge of, and has been trained in haemodialysis. The operator is in charge of the machine, which means that the operator makes the machine settings, which have to be done before, during, and after the haemodialysis treatment. It is important that the operator has access to the AK 98 Operator's manual when performing haemodialysis treatment. The operator is sometimes referred to as ”you”. When performing haemodialysis treatment in a home healthcare environment, the operator can also be the patient.
Patient environment	The patient environment is the volume surrounding the patient during treatment. The size of this patient environment must be determined from case to case by the user and the authorised service technician.
Patient ID	A patient unique alphanumeric code, used to identify the patient in the Clinical Information System.
Physician	A person prescribing the treatment of the patient.
User	A person who has the comprehensive responsibility for how the AK 98 dialysis machine is being used. The user decides which local routines are applicable for the AK 98 dialysis machine.

2 Machine Description

2.1 Blood part **A:28**
2.1.1 Blood part components A:28
2.1.2 Blood part component details A:29

2.2 Fluid part **A:36**
2.2.1 Fluid part components A:36
2.2.2 Fluid part component details A:37

2.3 Rear component **A:44**
2.3.1 Rear components A:44
2.3.2 Rear component details A:45

2.1 Blood part

2.1.1 Blood part components

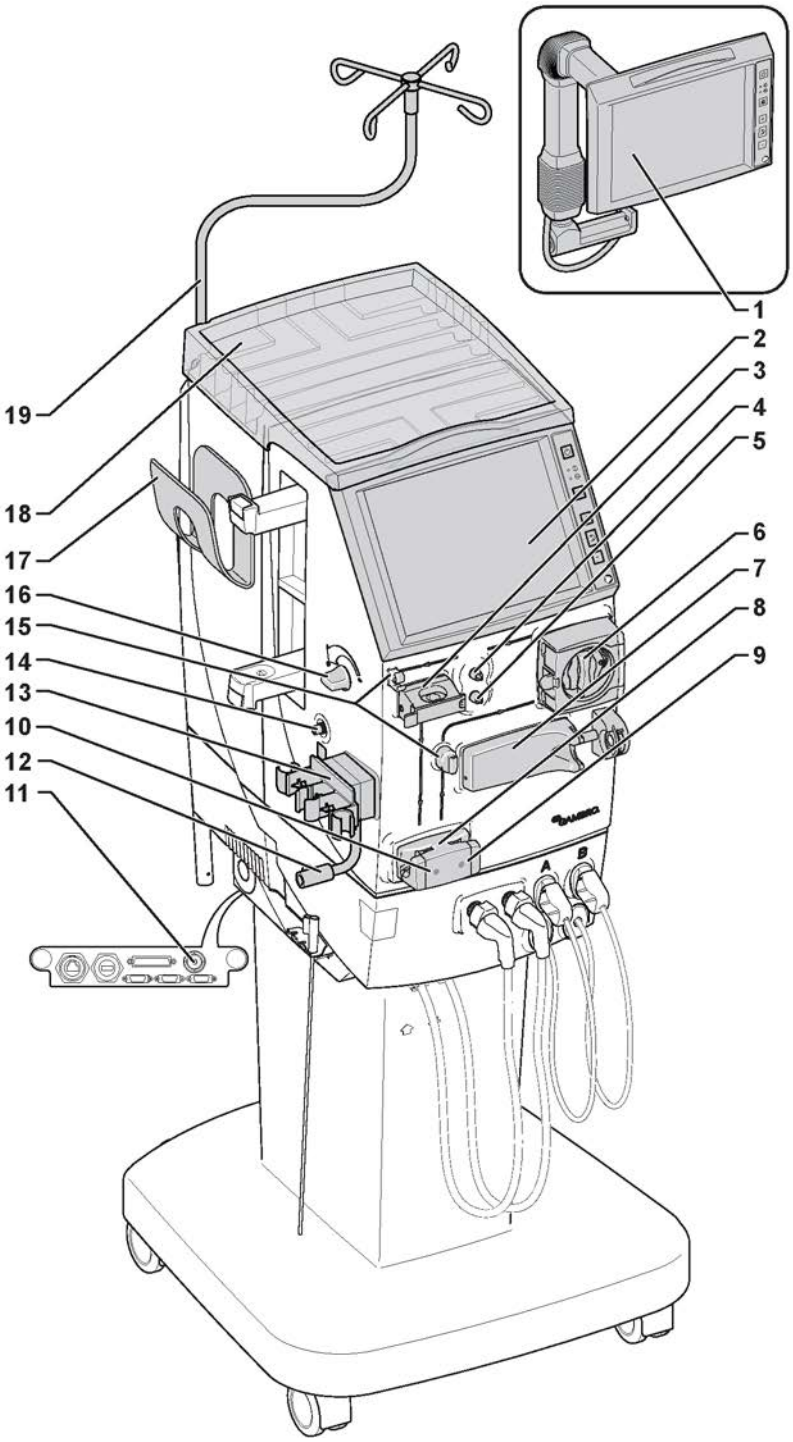
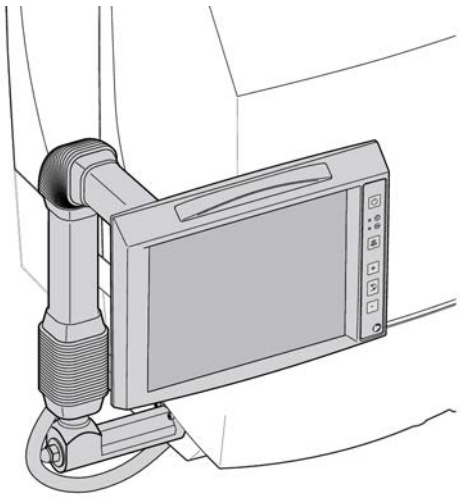


Figure 2-1. Blood part component terms

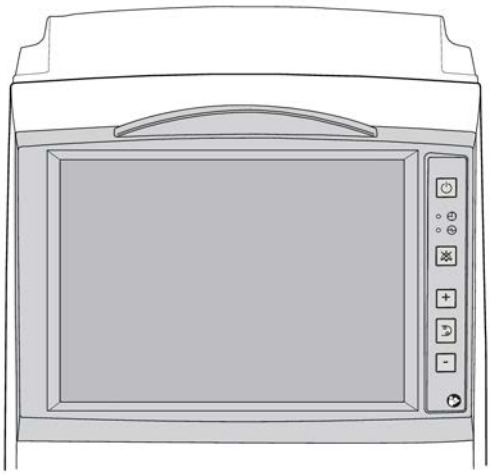
1. Remote operator's panel
2. Operator's panel
3. Air detector
4. Venous pressure transducer connector
5. Arterial pressure transducer connector
6. Blood pump
7. Heparin pump
8. Priming detector
9. Arterial blood line clamp
10. Venous blood line clamp
11. Potential equalisation connection
12. Arm for dialyzer holder
13. Expansion chamber holder
14. Blood pressure monitor (BPM) connector
15. Blood line guides
16. Level adjustment knob
17. BPM cuff holder
18. Top tray
19. Infusion stand

2.1.2 Blood part component details



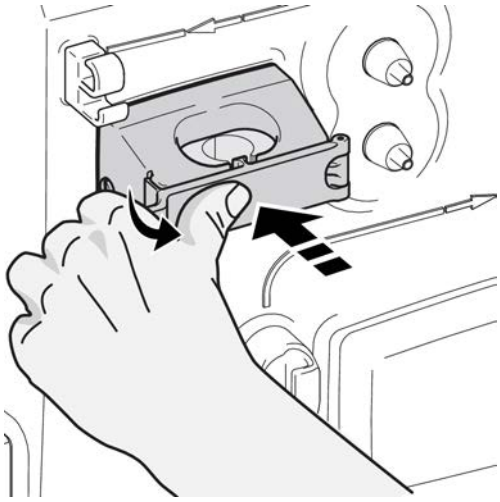
Remote operator's panel

The operator´s panel can be mounted in an external housing. The remote panel is easy to adjust in different positions. The controls on the remote panel are the same as when the operator's panel is mounted in the machine cabinet. See Section 3.4.1 “Screen overview” on page A:55 and Section 3.3.2 “Buttons on the operator´s panel” on page A:54.



Operator's panel

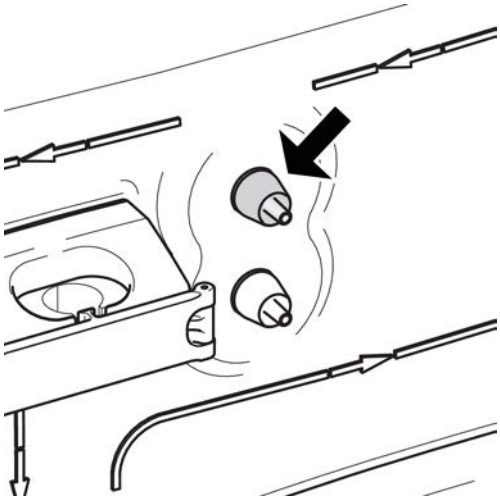
The controls on the operator's panel are described in Section 3.4.1 “Screen overview” on page A:55 and Section 3.3.2 “Buttons on the operator´s panel” on page A:54.



Air detector

The air detector holds a venous drip chamber. To open the air detector cover: pull the opening tab towards you, and at the same time press firmly at the middle of the cover.

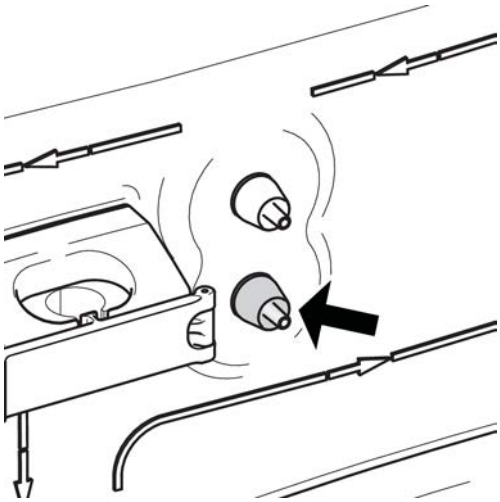
An alarm is issued if air or foam decreases the blood level in the drip chamber.



Venous pressure transducer connector

The venous pressure transducer protector on the venous blood line is connected to the venous pressure transducer connector.

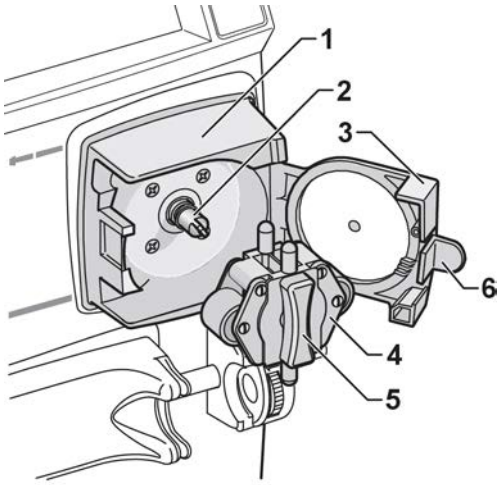
The venous pressure supervision measures and guards against too high or too low venous pressure.



Arterial pressure transducer connector

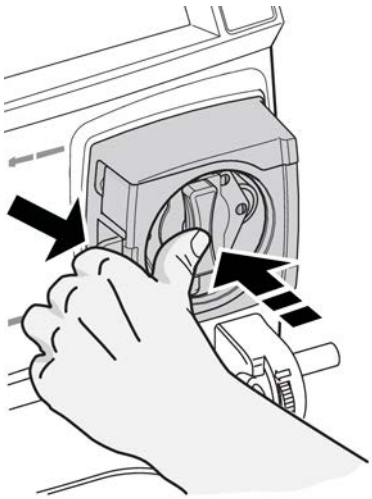
The arterial pressure transducer protector on the arterial blood line is connected to the arterial pressure transducer connector.

The arterial pressure supervision measures and guards against too high or too low arterial pressure.



Blood pump

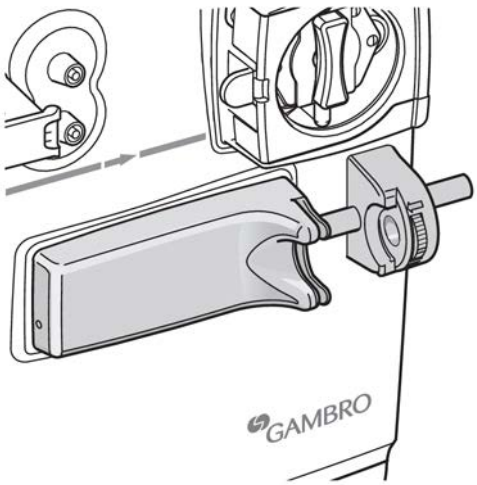
1. Pump housing
2. Pump shaft
3. Pump cover
4. Pump rotor
5. Pump handle
6. Pump cover opening tab



To open the pump cover: pull the opening tab towards you, and at the same time press firmly at the middle of the cover.

If you open the cover when the blood pump is running, the blood pump stops. The pump starts again when the cover is closed. See also Section 13.2.2 “Clean the blood pump rotor” on page A:172.

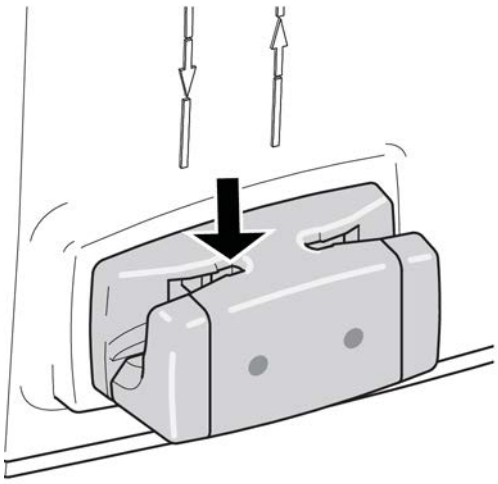
During a power failure you can turn the pump rotor manually (anticlockwise) by the handle to circulate the blood.



Heparin pump

The heparin pump holds a syringe containing heparin solution. The pump distributes heparin in the blood line to prevent the blood from clotting.

Syringes must comply with ISO 7886-2. Read more in Section 4.2.6 “Attach the heparin syringe” on page A:89.

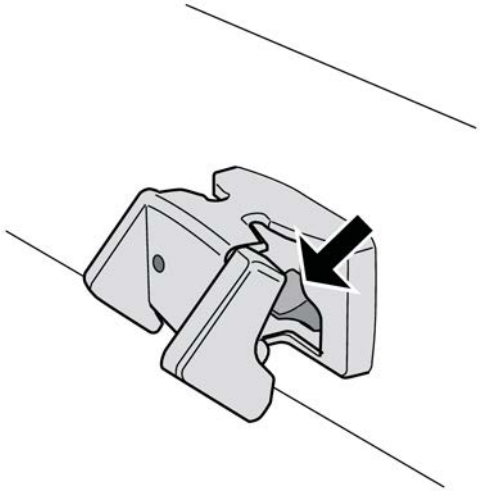


Priming detector

When the priming detector detects blood treatment mode is entered. When blood is detected in the venous blood line, the priming detector activates all alarms, which are suppressed during priming.

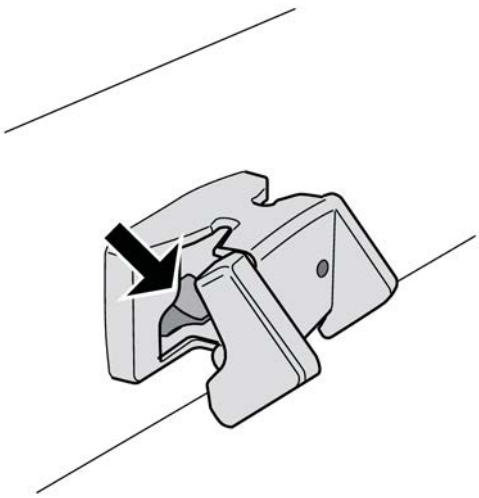
The priming detector is found inside the venous blood line clamp housing.

CAUTION!
Check carefully that the venous blood line is correctly placed in the priming detector to make sure that the supervision of alarms is activated.



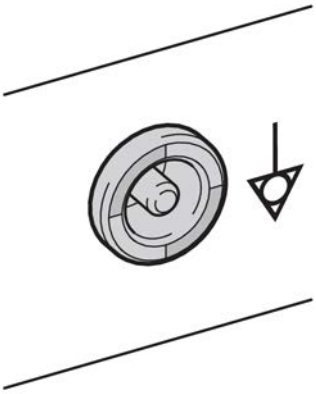
Arterial and venous blood line clamps

The arterial blood line clamp closes the arterial blood line in certain alarm situations, and is also used when performing single needle treatment.



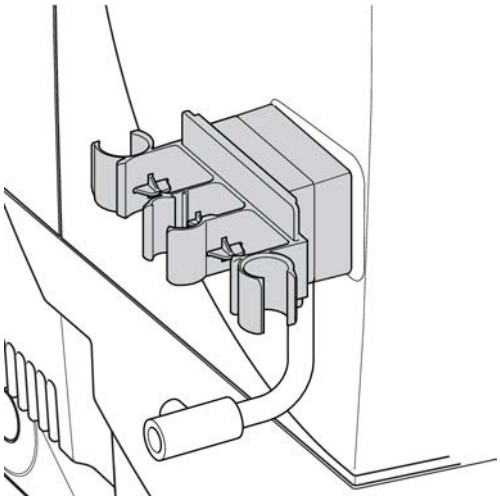
The venous blood line clamp closes the venous blood line in certain alarm situations, and is also used when performing single needle treatment.

Potential equalisation connection



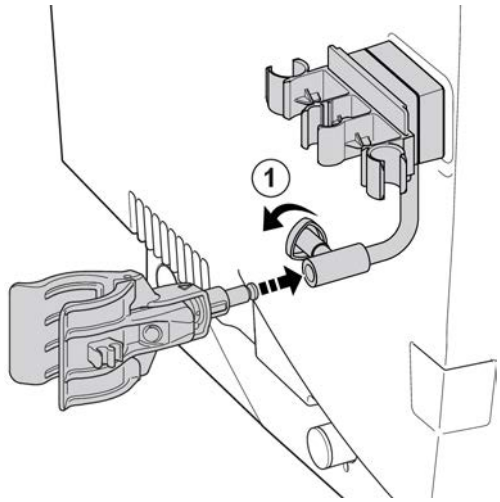
For patients with a central venous catheter this connector is used to connect to an equalisation conductor.

Expansion chamber holder



The holder is used to hold an expansion chamber, which is added into the venous blood line when performing single needle treatments. The holder is tilted during priming.

Dialyzer holder

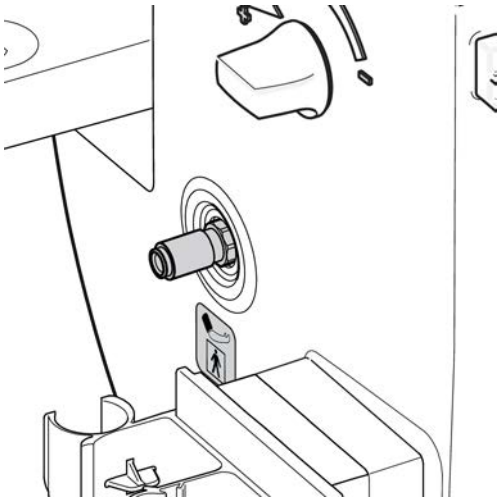


Attach the dialyzer holder to the arm and lock it into position with the locking screw (1).

You can swing the arm to change the position of the dialyzer.

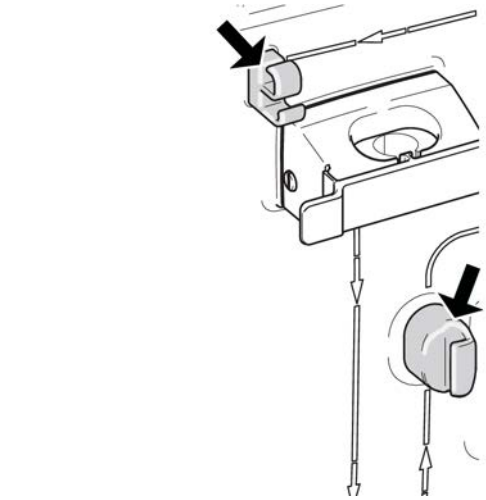
The holder can be rotated through 360°.

CAUTION!
Take care not to wrap the blood lines around the dialyzer holder when rotating it. This could cause kinking of the blood lines, and lead to hemolysis.



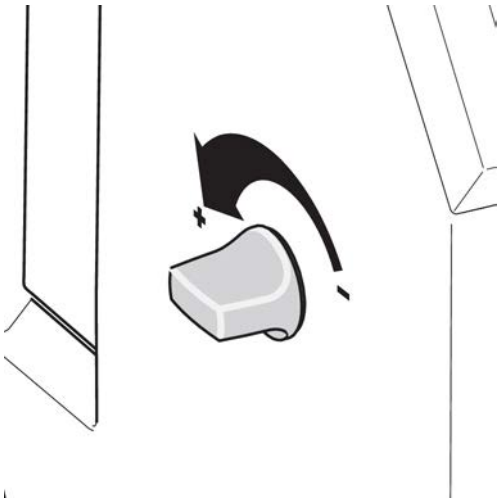
Blood pressure monitor (BPM) connector

The blood pressure cuff and hose connects directly to the BPM connector.



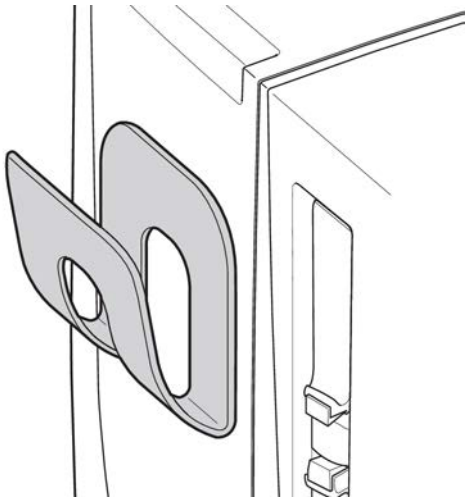
Blood line guides

The blood lines are placed in the blood line guides.



Level adjustment knob

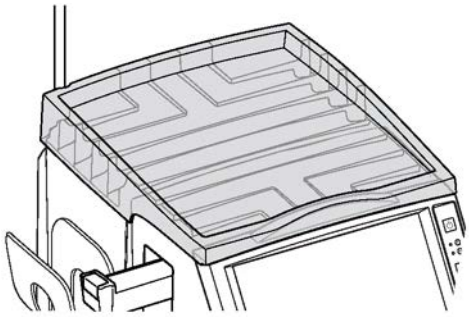
Turn the knob to raise or lower the level of blood in the venous drip chamber.



BPM cuff holder

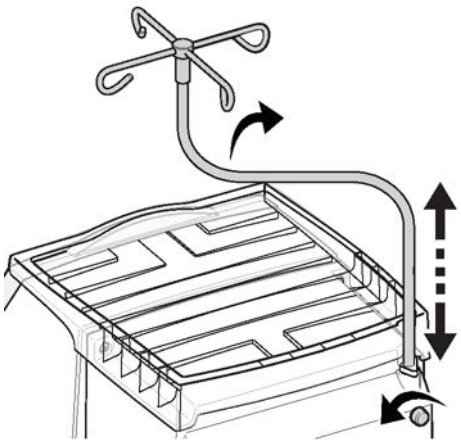
The holder is intended for the blood pressure cuff and its tube when not in use.

The holder has adhesive tape on the back which allows the user to place it anywhere appropriate on the machine.



Top tray

To protect the machine against spillage, the top tray must always be correctly placed on top of the machine.



Infusion stand

The infusion stand is used for fluid bags. Maximum permitted load is 3 kg.

The infusion stand can be turned between a position over the tray and to the left of the dialysis machine. A mechanical stop limits the movement.

The height of the infusion stand can also be adjusted.

2.2 Fluid part

2.2.1 Fluid part components

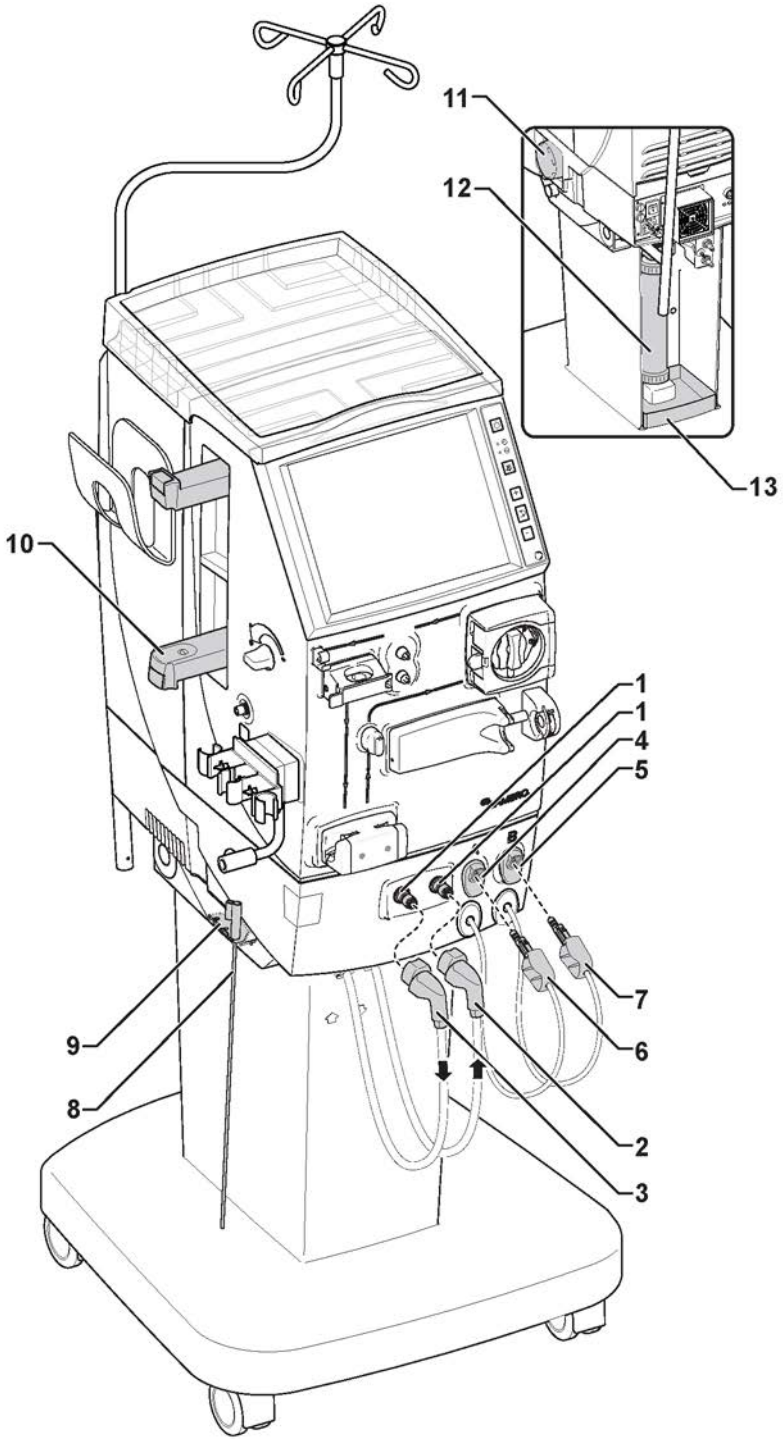
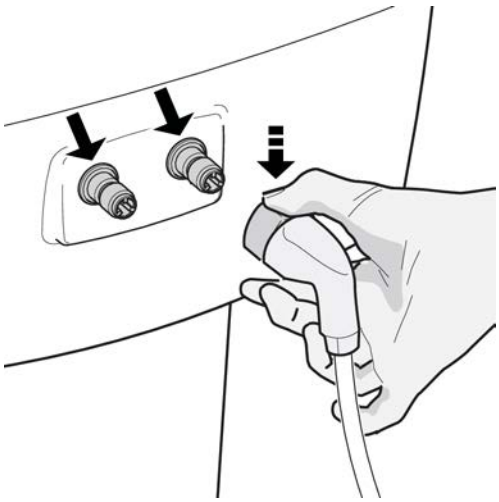


Figure 2-2. Fluid Part Component Terms

1. Safety couplings for dialysis fluid tubes
2. Dialysis fluid tube from machine to dialyzer (blue)
3. Dialysis fluid tube from dialyzer to machine (red)
4. Stand-by port for red concentrate connector
5. Stand-by port for blue concentrate connector
6. Concentrate connector, red
7. Concentrate connector, blue
8. Pick-up tube
9. Pick-up tube holder
10. BICART cartridge holder
11. Blood leak detector
12. Ultrafilter
13. Leakage detector tray

2.2.2 Fluid part component details

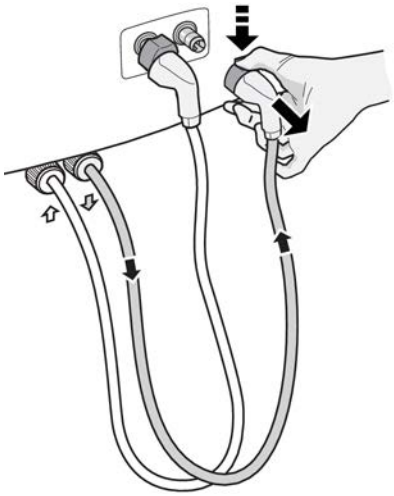


Safety couplings for dialysis fluid tubes

The safety couplings hold the dialysis fluid tubes during the functional check, the disinfection program, and the rinse program.

To attach a dialysis fluid tube to a safety coupling:

1. Press and hold the button on the dialysis fluid tube connector
2. Push the dialysis fluid tube connector onto the safety coupling. The connector locks into place with a click.
3. Release the button on the dialysis fluid tube connector.

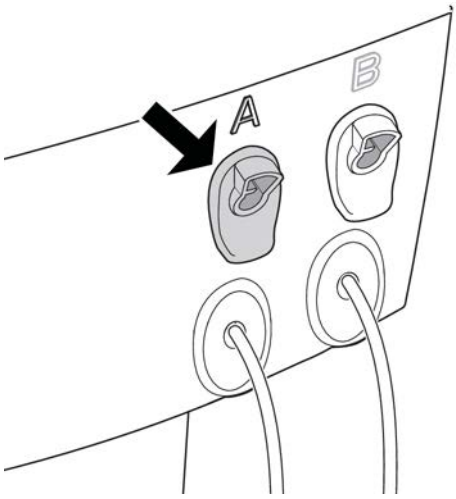


Dialysis fluid tubes

The blue connection is from the machine to the dialyzer. The newly prepared, fresh dialysis fluid, flows from the machine to the dialyzer via this tube.

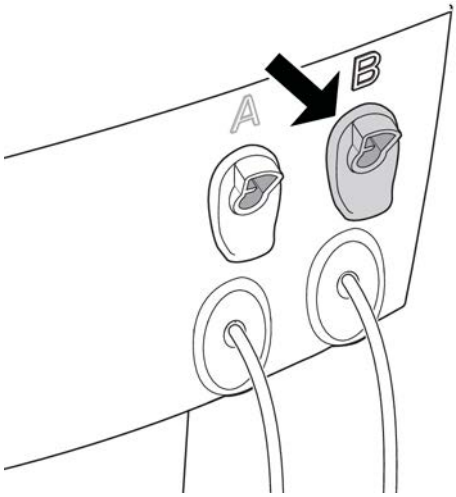
The red connection is from the dialyzer to the machine. The used dialysis fluid flows from the dialyzer to the machine via this tube.

To remove a dialysis fluid tube from a safety coupling; press and hold the button on the dialysis fluid tube connector and pull out.



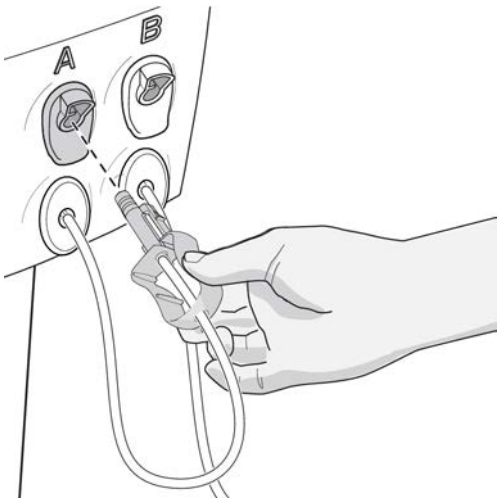
Stand-by port for red concentrate connector

This port holds the red concentrate connector when it is not used in treatment.



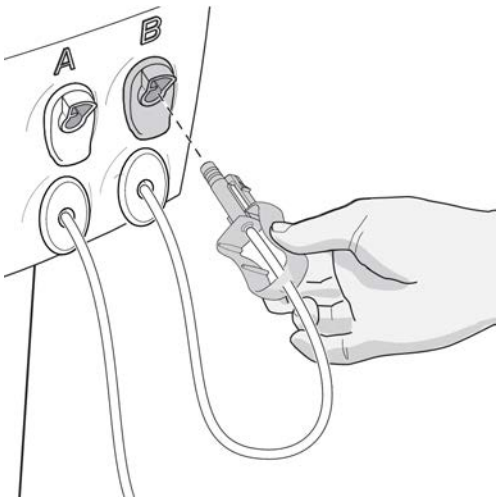
Stand-by port for blue concentrate connector

This port holds the blue concentrate connector when it is not used in treatment.



Concentrate connector, red

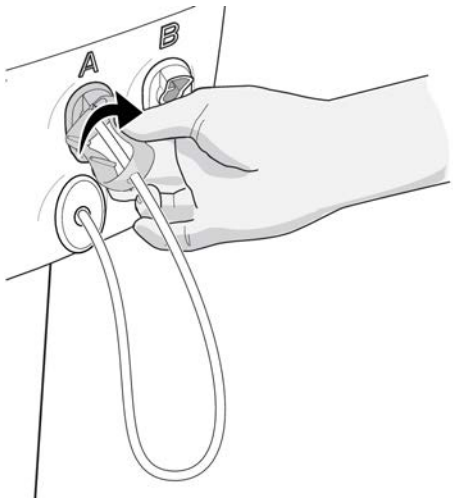
The red connector can be attached to a white pick-up tube and placed in a container with acidic concentrate. When this is done the dialysis machine can start to use the concentrate. See Section 4.2.3 “Set up the dialysis machine” on page A:77.



Concentrate connector, blue

The blue connector can be attached to a blue pick-up tube and placed in a container with liquid bicarbonate. Then the dialysis machine can start to use the liquid concentrate. See Section 4.2.3 “Set up the dialysis machine” on page A:77.

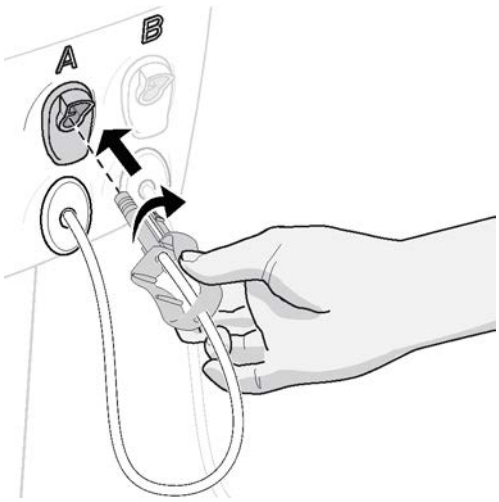
The blue concentrate connector is also used for chemical disinfectant. See Section 10.4.2 “Start a chemical disinfection” on page A:149. The blue connector is attached to the yellow pick-up tube when used for disinfectant.



To remove the connector from the port:

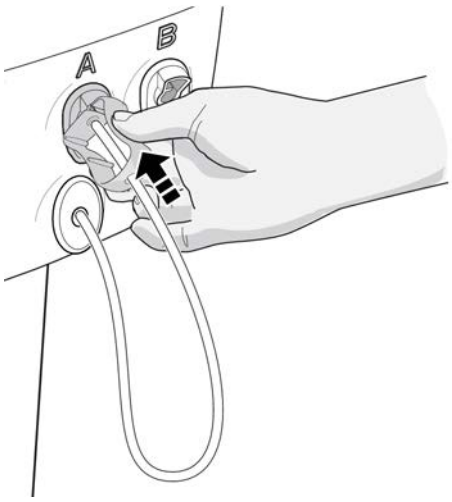
Turn the connector clockwise to unlock it.

Pull out the connector.

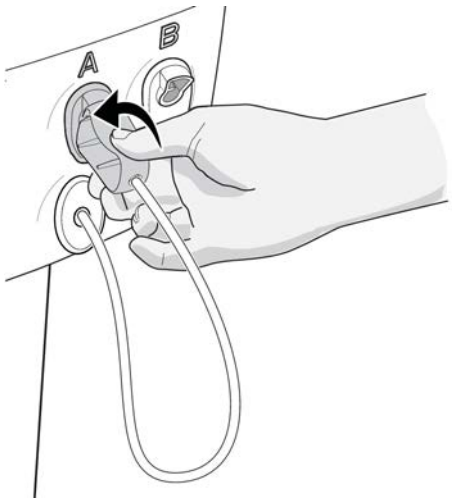


To attach a concentrate connector to its port:

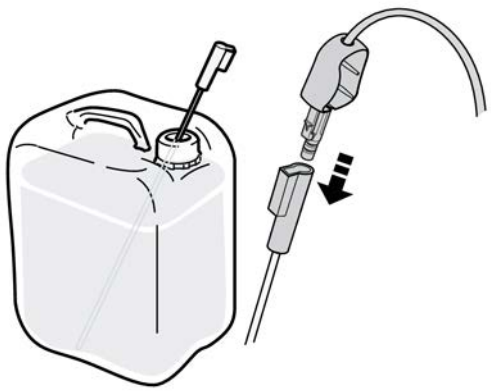
Hold the connector slightly turned clockwise in front of the port.



Insert the connector and push it into place.



Turn the connector anticlockwise to lock it.



Pick-up tube

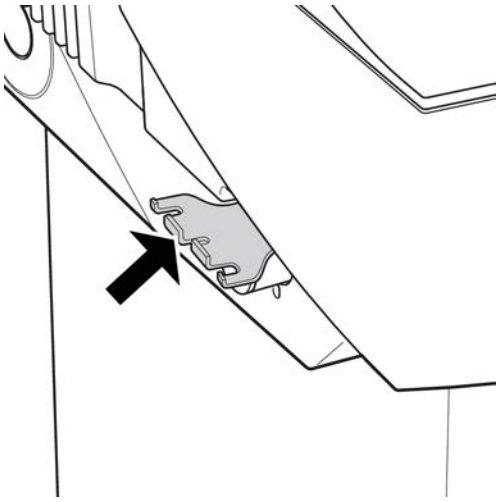
A pick-up tube is placed in a container with a dialysis fluid concentrate or a disinfectant solution.

Insert the concentrate connector to the proper pick-up tube and **push it into place until it clicks in**.

Use the **white** pick-up tube for acidic concentrate.

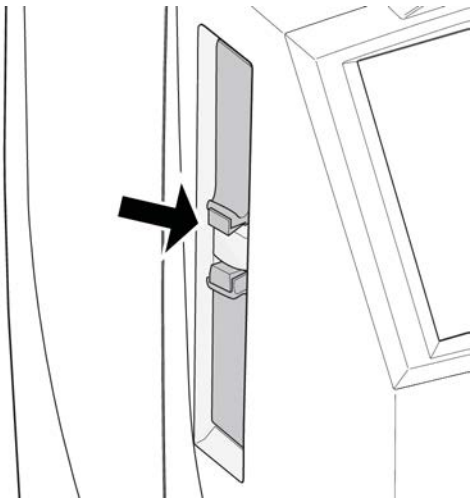
Use the **blue** pick-up tube for bicarbonate.

Use the **yellow** pick-up tube for chemical disinfectant.



Pick-up tube holder

The pick-up tubes not in use are kept in this holder.

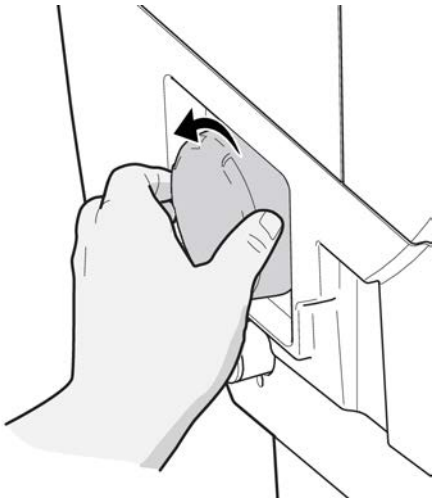


BICART cartridge holder

This holder is for the BICART cartridge. The holder is also used for CLEANCART cartridges (cleaning or decalcification).

To attach the BICART cartridge to the Holder, see Section 4.2.3 “Set up the dialysis machine” on page A:77.

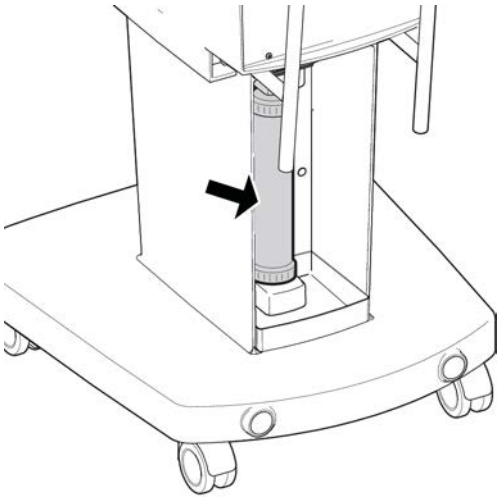
To attach a CLEANCART cartridge to the holder, see Section 10.3.4 “Start a heat disinfection with a CLEANCART cartridge” on page A:146



Blood leak detector

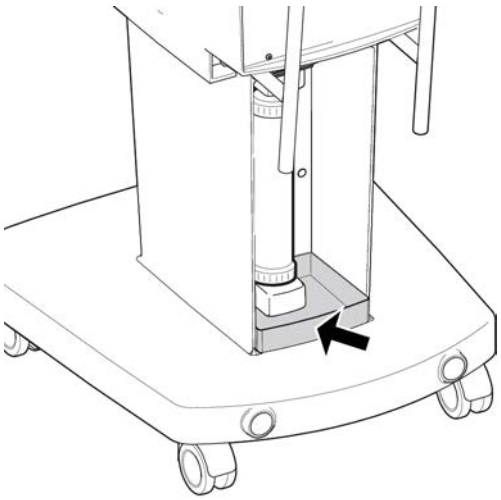
The blood leak detector checks for blood in the dialysis fluid.

To open the blood leak detector cover see Section 13.3 “Clean the blood leak detector” on page A:173.



Ultrafilter

The base of the dialysis machine cabinet contains the ultrafilter. The purpose of the ultrafilter is to further clean the dialysis fluid from possible contamination by bacteria and endotoxins.



Fluid leakage detector tray

If an internal leakage occurs in the dialysis machine, the fluid will be collected in the fluid leakage detector tray.

The detected volume could be an excessive UF volume.

An attention will be displayed if the fluid level reaches the level of the detector.

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2.3 Rear component

2.3.1 Rear components

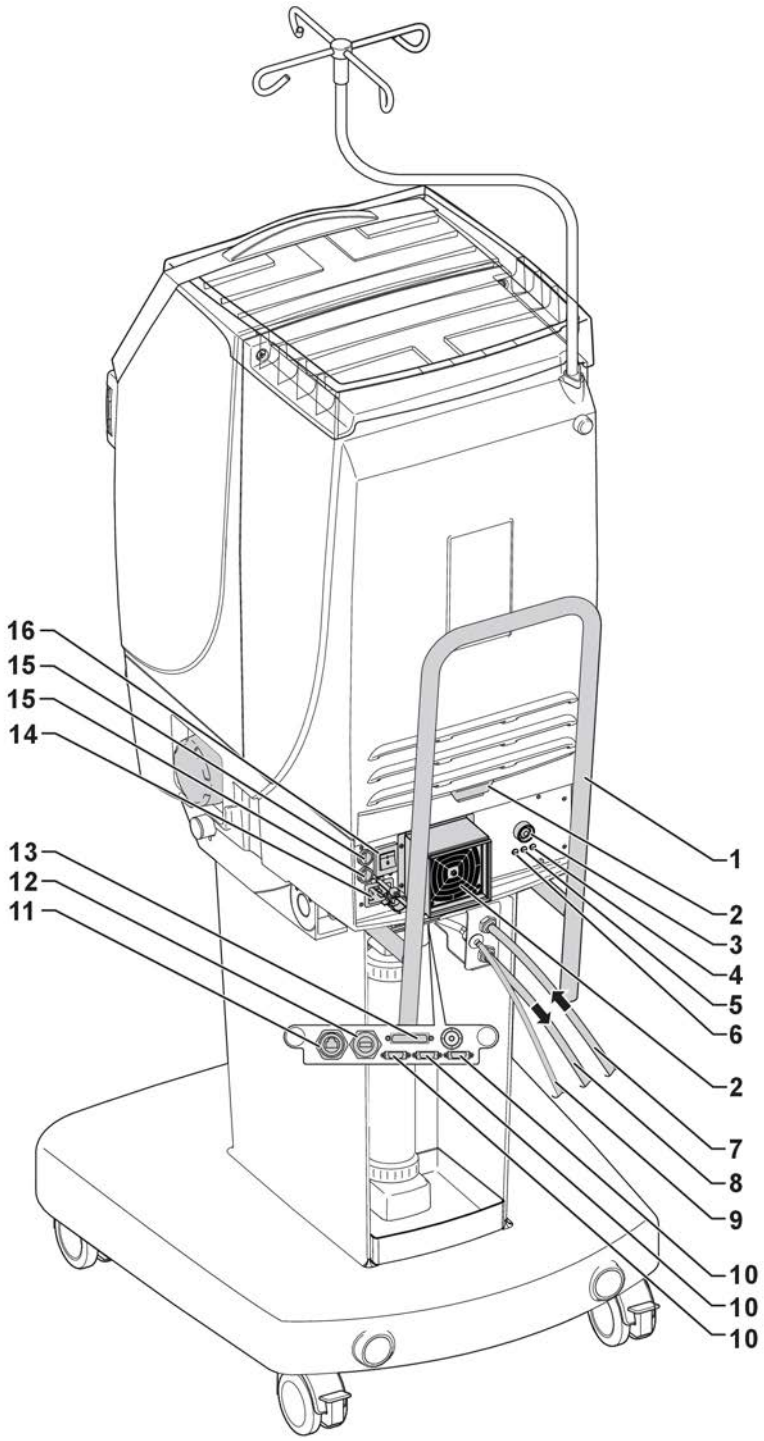
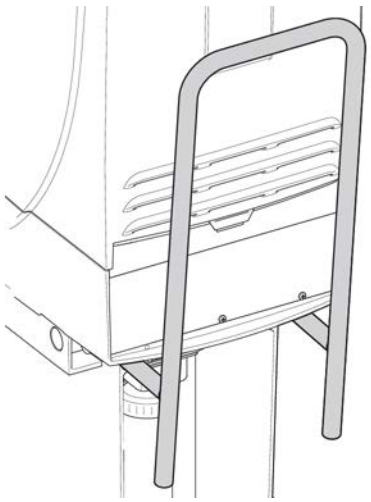


Figure 2-3. Rear Component Terms

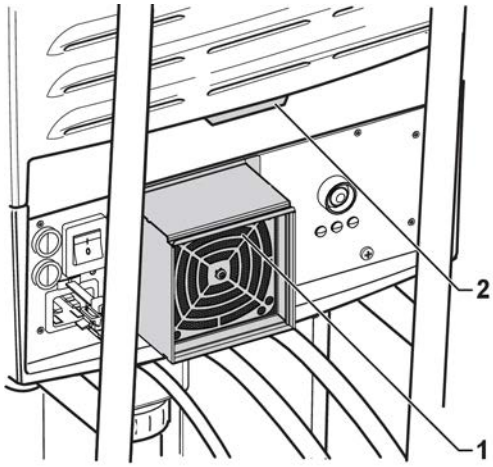
1. Transportation handle
2. Air filters
3. Halt button
4. Battery charge indicator
5. Battery connect indicator
6. Over temperature protection indicator
7. Inlet water tube
8. Outlet tube (drain)
9. Citric acid inlet tub
10. Remote panel contacts
11. Ethernet port
12. USB port
13. External communication port
14. Mains connection
15. Fuses
16. Main switch

2.3.2 Rear component details



Transportation handle

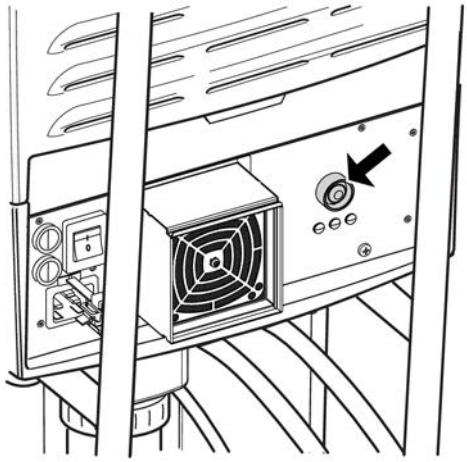
Always use this handle when moving the dialysis machine; see Section 1.2.7 “How to move the AK 98 dialysis machine” on page A:18



Air filters

Filter 1 protects the power supply unit.

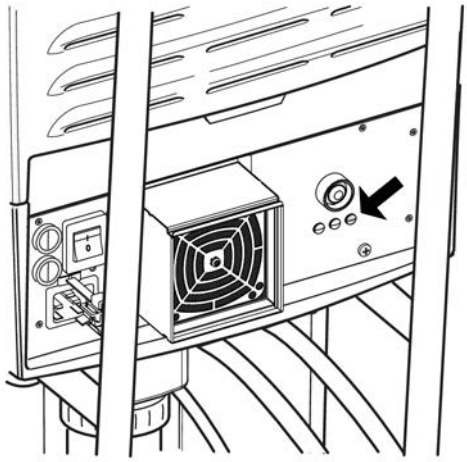
Filter 2 protects the inside of the dialysis machine from dust.



Halt button

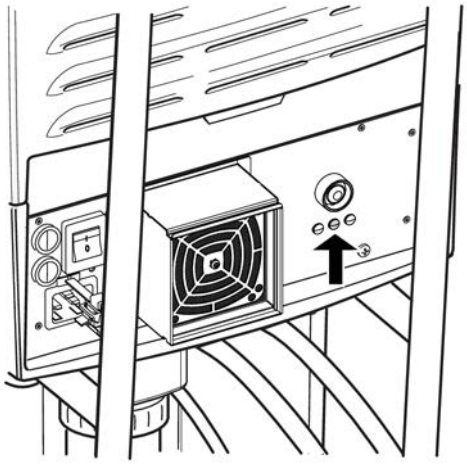
When this button is pressed, the power supply to the machine is interrupted. As soon as the button is released the power returns and the machine performs a recovery.

If this does not work, make a complete reset. Use the main switch to turn off the machine. Press and hold the halt button until the main switch indicator is unlit. Release the halt button. Switch on the machine and wait until the main switch indicator lights up. Press the **On/Off** button to start the machine.



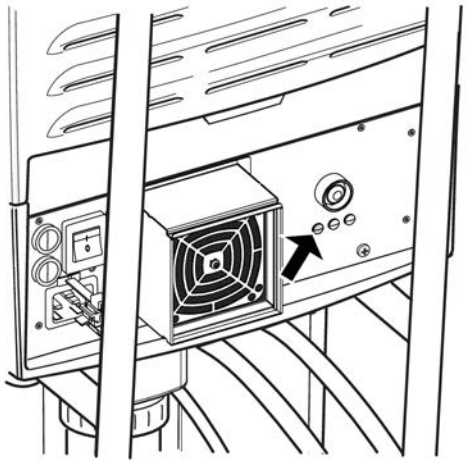
Battery charge indicator

This yellow lamp is lit when the mains cable is connected to the mains supply and the main switch is switched on. It indicates that the battery charge is ongoing. The lamp is marked BACH.



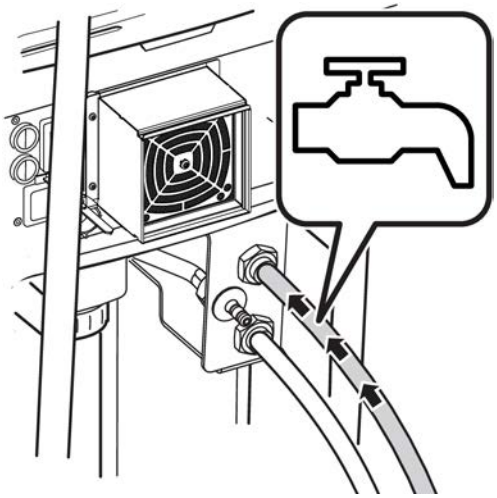
Battery connect indicator

This green lamp is lit if battery back-up has been installed. The lamp is marked BACO.



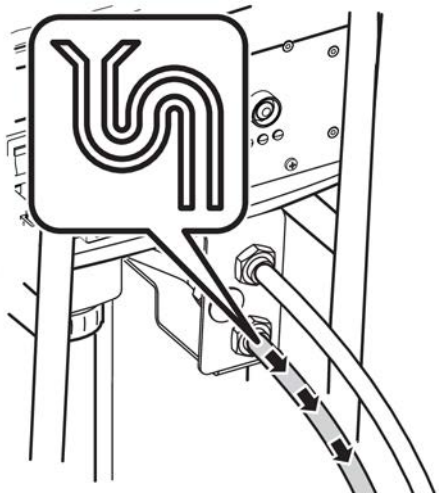
Over temperature protection indicator

This yellow lamp is lit when the temperature in the power supply is too high. The power supply cannot deliver power to the machine. The lamp is marked OTP.



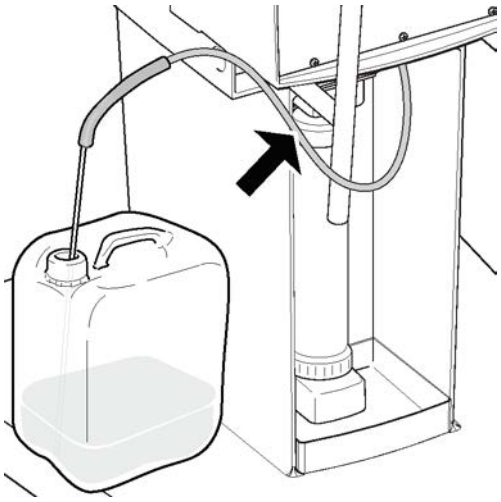
Inlet water tube

The inlet water tube is used to connect the dialysis machine to the water supply. Water is used for dialysis fluid preparation. See Section 14.1.16 “Water supply” on page A:183 for details on requirements for inlet water.



Outlet tube (drain)

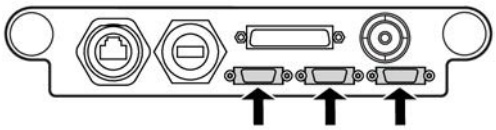
The outlet tube is used to transport used dialysis fluid out of the dialysis machine.



Citric acid inlet tube

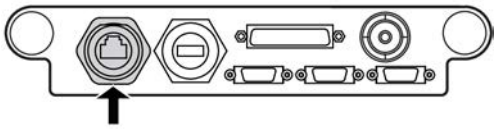
The liquid citric acid can be connected permanently to the dialysis machine via the citric acid inlet tube.

Do not connect any disinfectant to the citric acid inlet tube.



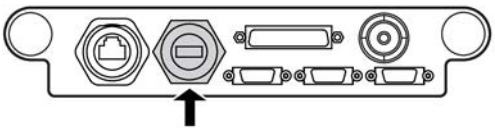
Remote panel contacts

These contacts shall only be used by an authorised service technician.



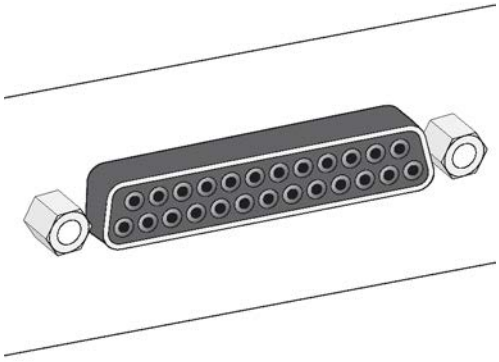
Ethernet port

This port is to be used by the authorised technician. See Section 1.2.6 “Connection of external electrical equipment” on page A:18.



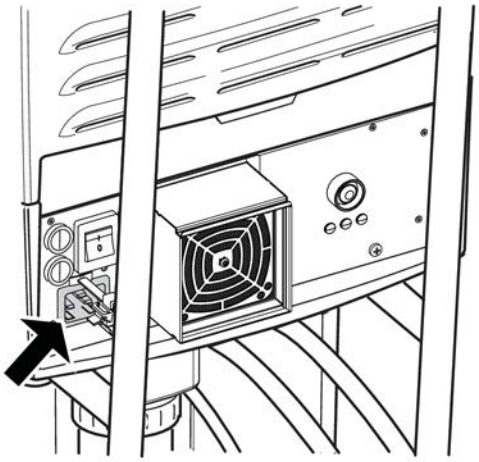
USB port

This port is to be used by the authorised technician. See Section 1.2.6 “Connection of external electrical equipment” on page A:18.



External communication port

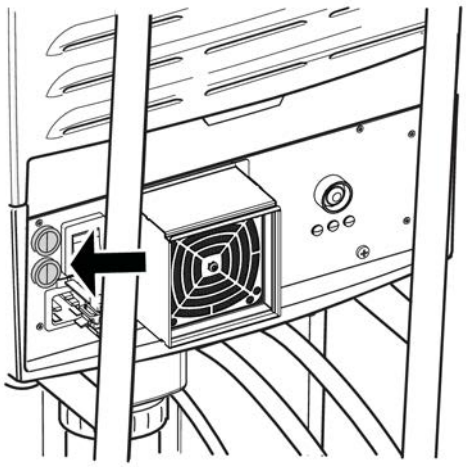
This port is to be used by the authorised technician. It can be used for service, connection to external computer systems and external alarms.



Mains connection

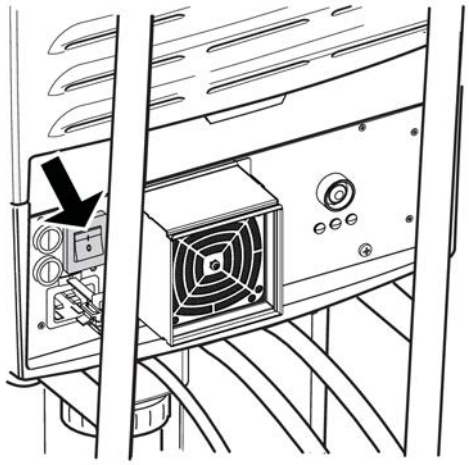
The mains cable is attached to this connector. The mains cable should always be connected, even when the dialysis machine is not used.

Make sure that the cable clip is properly fixed.



Fuses

The fuses shall only be exchanged by an authorised service technician.



Main switch

The main switch should always be on when plugged into mains power. This allows the battery to charge.

3 Handling the dialysis machine

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3.1 Operator's position

3.1.1 Operator's position

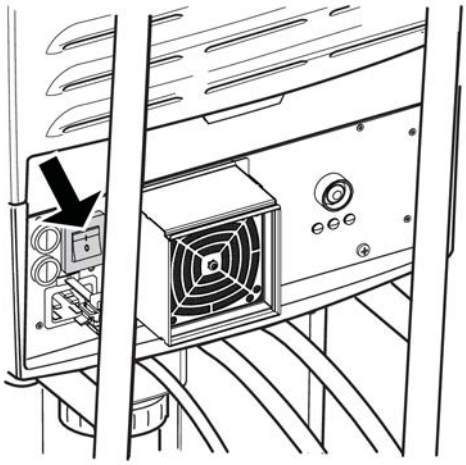
The operator shall be positioned so as to have a clear overview of the operator’s panel and other vital parts of the machine.

3.2 Switch the dialysis machine on and off

3.2.1 Main switch

The main switch is located at the back of the dialysis machine.

The main switch should always be on, to make sure the batteries are completely charged. It shall only be switched off when the dialysis machine is moved.



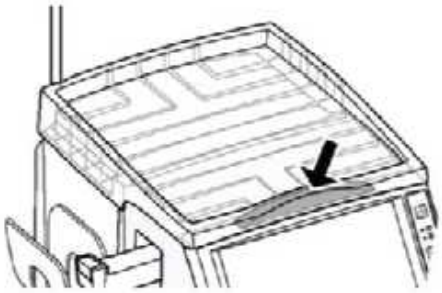
3.2.2 On/off button

The **On/Off** button is located on the operator's panel (to the right of the screen). See Figure 3- “” on page A:54.

Press the **On/Off** button lightly to turn the machine on or off.

3.3 Indication light and buttons

3.3.1 Indication light

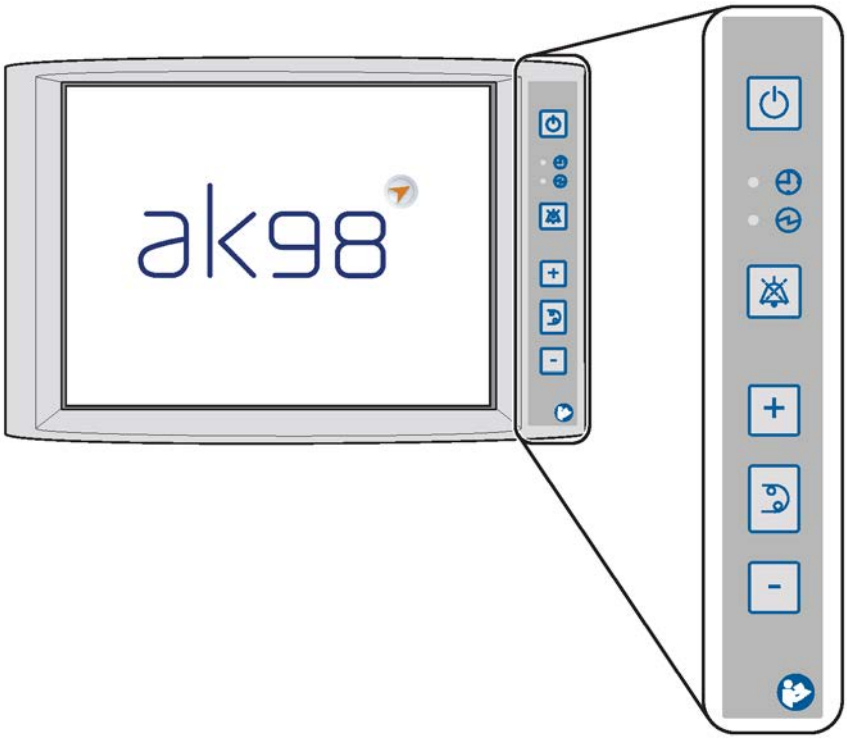


The indication light is placed above the touch screen. This flashing light indicates an alarm, or an attention condition. The light stops flashing when the cause of the alarm (or attention) is corrected.

- A flashing red light indicates a high priority alarm. When the cause of the alarm is corrected the light will stop flashing.
- A flashing yellow light indicates a medium priority alarm. When the cause of the alarm is corrected the light will stop flashing.
- A flashing blue light indicates an attention. When the cause of the attention is corrected the light will stop flashing.

3.3.2 Buttons on the operator´s panel

The buttons on the operator´s panel are placed to the right of the screen.



On/Off button

Press and hold to turn the dialysis machine on or off.

Schedule indicator

When this indicator is lit blue, a rinse or disinfection program is scheduled to run with automatic start.

Main switch indicator

When this indicator is lit green, the dialysis machine is connected to mains power supply and the main switch (at the rear of the machine cabinet) is on.

Mute button

Press the **Mute** button to mute the alarm or attention sound. Press and hold the **Mute** button to turn the alarm or attention sound on again.

Blood pump up button

Increase blood pump speed.

Blood pump button

Press the **Blood pump** button to start (or stop) the blood pump.

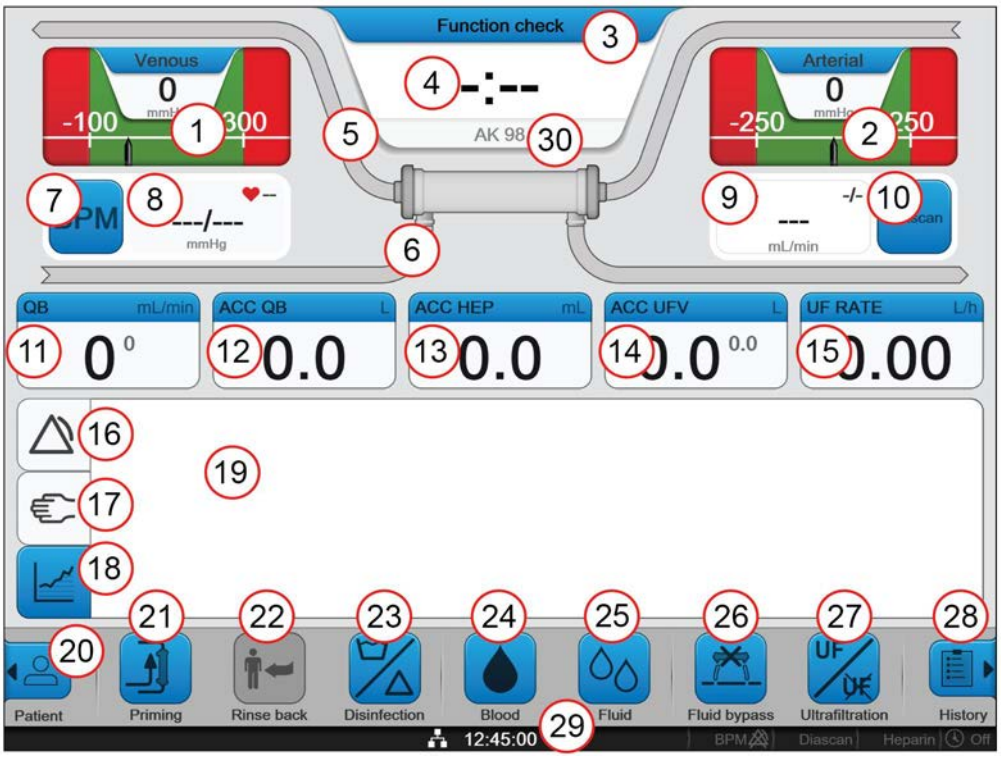
Blood pump down button

Decrease blood pump speed.

3.4 The screen

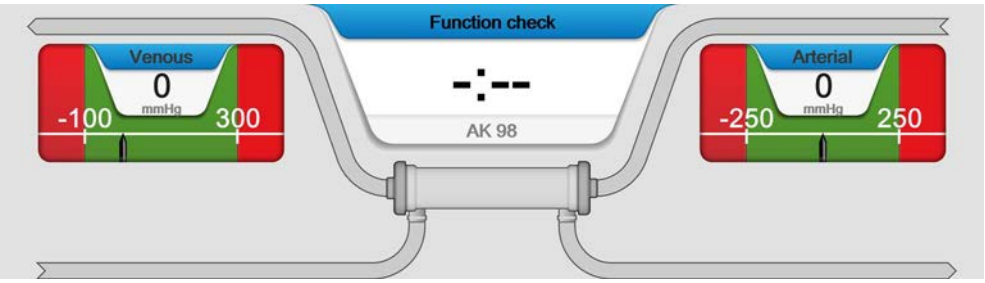
3.4.1 Screen overview

The touch screen contains of menues and buttons for preparing, running, finishing and maintaining the dialysis machine.



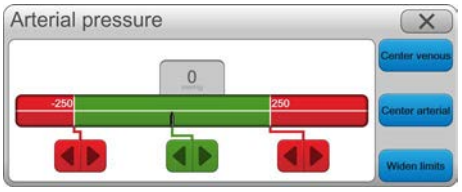
1. Venous pressure control
2. Arterial pressure control
3. Machine state indicator
4. Time indicator
5. Blood path
6. Fluid path
7. Blood pressure monitor (BPM) button
8. Blood pressure monitor (BPM) read out field
9. Diascan read out field
10. Diascan button
11. Treatment overview field
12. Treatment overview field
13. Treatment overview field
14. Treatment overview field
15. Treatment overview field
16. Alarm tab
17. Information tab
18. Treatement graph tab
19. Information field
20. Patient page
21. Priming button
22. Rinse back button
23. Disinfection button
24. Blood button
25. Fluid button
26. Fluid bypass button
27. Ultrafiltration (UF) button
28. Treatment history page
29. Status bar
30. Monitor identifier (Nickname)

3.4.2 Venous and arterial pressure controls (1, 2)



The pressure controls show the pressure in the blood line from the patient and the resistance of the blood returning to the patient. The corresponding alarm limits are also shown in the pressure controls.

Press the venous or the arterial pressure control to open the pressure control window. Use the pressure control window to adjust the alarm limit for the venous and the arterial pressure.



When a pressure control is flashing: Press the flashing pressure control to centralise the alarm limits. Press again to open the pressure control window.

When a red arrow is pressed the connected alarm limit is moving in the direction the arrow is pointing in. When the current value passes the alarm limit an alarm is triggered.

When a green arrow is pressed both connected alarm limits are moved in the direction of the arrow of the pressed button.

When center arterial button or center venous button is pressed a new centralisation will be performed.

When widen limits button is pressed the alarm limits will expand. The same behaviour as when adjusting the blood pump.

3.4.3 Machine state indicator (3)

The machine state indicator shows the actual machine state. For example functional check, treatment or disinfection.

3.4.4 Time (4)

The time indicator shows the remaining time during for example ongoing treatment and during a disinfection program. The time is shown as hh:min.

During treatment; remaining time of total treatment time.

3.4.5 Blood path (5)

When blood is detected in the venous blood line the blood path turns red, treatment starts and alarms are activated.

3.4.6 Fluid path (6)

When the correct conductivity is reached, the fluid path turns green, and the dialysis fluid can be directed to the dialyzer via the bypass button.

3.4.7 Bypass path

The machine will automatically bypass the dialyzis fluid to the dialyzer during certain alarm conditions and during self-calibration. The operator can also bypass the dialysis fluid using the `Fluid bypass` button.

3.4.8 Blood pressure area (7, 8)

Press the `BPM` button to open the blood pressure menu and control the settings for how to measure the patient's blood pressure. The latest measured blood pressure is available in the `BPM` read out field. Pulse rate (beats per minute) is shown next to the heart. Press the `BPM` read out field to do a single measurement. See Section 8 "Measuring blood pressure" on page A:127.

3.4.9 Diascan read out field and Diascan button (9, 10)

Press the `Diascan` button to open the Diascan menu and control the settings for how to measure the patient's clearance (K) and dialysis dose (Kt or Kt/V). You can see the latest measured value in the Diascan readout field. See Section 9 "DIASCAN" on page A:135 for more information.

3.4.10 Treatment overview (11–15)

In the treatment overview fields actual values from the treatment are shown. These fields are indicators of the treatment progress.

Press a field to open the menu that contains the corresponding function.

`QB`: Blood flow rate in mL/min. Press the field to open the `Blood Menu`.

`ACC QB`: Accumulated blood volume in L since treatment start. Press the field to open the `Blood Menu`.

`ACC HEP`: Accumulated heparin volume in mL since treatment start. Press the field to open the `Blood Menu`.

`ACC UFV`: Accumulated ultrafiltration volume in L since treatment start. Press the field to open the `Fluid Menu`.

`UF rate`: Ultrafiltration rate in L/h. Press the field to open the `Fluid Menu`.

3.4.11 Alarm tab (16)

When an alarm is generated the alarm tab is flashing and the alarm information is shown.

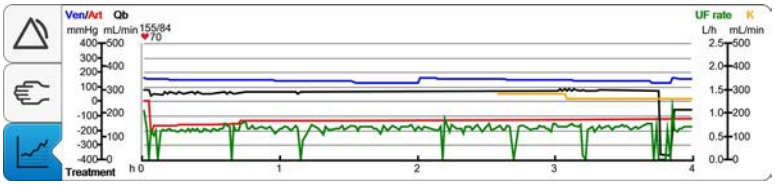
3.4.12 Information tab (17)

The information tab is flashing when an attention or an operator message is generated.

3.4.13 Treatment graph tab (18)

The Treatment graph tab opens the treatment graph. The treatment graph contains information about Venous Pressure, Arterial Pressure, Blood Flow, UF rate and Clearance.

The time scale is based on the treatment settings.



3.4.14 Information field (19)

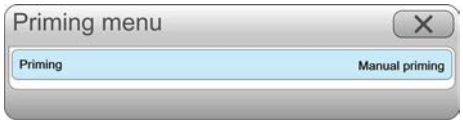
The information field have three tabs; for selecting information alarm, attentions and treatment graph.

3.4.15 Patient page (20)

The `Patient` button opens the patient page. In the patient page, patient information is handled. The available functionality will be dependent on the Clinical Information System (CIS) in use.

3.4.16 Priming button (21)

The `Priming` button opens the `Priming menu`. It continues to be lit until blood is detected.



3.4.17 Rinse back button (22)

The Rinse back button is used to start the rinse-back or to change blood circuit during an ongoing treatment.

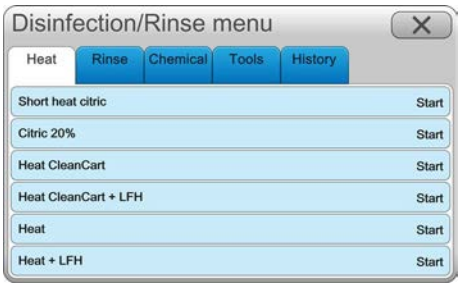
The Rinse back button is only availabe during treatment.

- Rinse back: Start the rinse-back procedure before the treatment has ended. Treatment time shall be set to zero.
- New blood circuit: Select to change to a new blood circuit during an ongoing treatment.

3.4.18 Disinfection button (23)

The Disinfection button is used to select and activate disinfection and rinse programs.

Heat

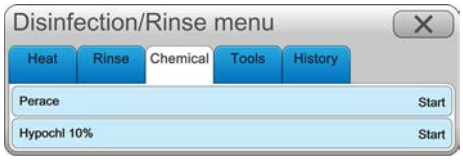


- Short heat citric: Start the short disinfection program with liquid citric acid which is connected at the back of the machine.
- Citric 20%: Start the disinfection program with liquid citric acid which is connected at the back of the machine.
- Heat CleanCart: Start the CleanCart cartridge disinfection program.
- Heat CleanCart + LFH: Start the CleanCart cartridge disinfection program combined with low flow heat; in cases when a WRO 300 H unit is connected.
- Heat: Start the disinfection program with hot water.
- Heat + LFH: Start the disinfection program with hot water combined with low flow heat; in cases when a WRO 300 H unit is connected.

Rinse

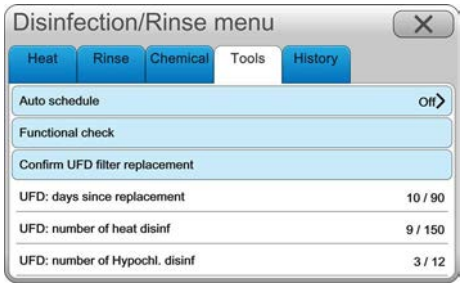
- Rinse: Start the rinse program.
- Drain: Start the drain program.

Chemical



- `Perace`: Start a peracetic acid disinfection program.
- `Hypochl 10%`: Start a hypoclorite disinfection program.

`Tools`



- `Auto schedule`: Schedule rinse and disinfection programs to run at specific times.
- `Functional check`: Start a new functional check.
- `Confirm UFD filter replacement`: Confirm change of the ultrafilter.
- `UFD: days since replacement`: Number of days since last change of the ultrafilter.
- `UFD: number of heat disinf`: Number of heat disinfections since last change of the ultrafilter.
- `UFD: number of Hypochl. disinf`: Number of Hypochlorite disinfections since last change of the ultrafilter.

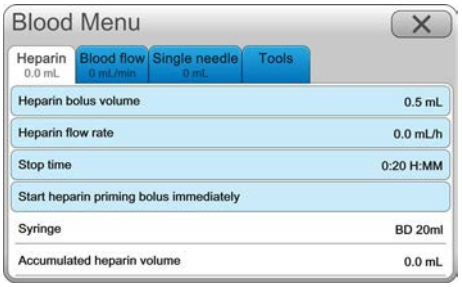
`History`

`History`: Displays a list of the most recently performed disinfection programs (both heat and chemical disinfection programs).

3.4.19 Blood button (24)

The `Blood` button opens the `Blood Menu`, which contain tabs for handling parameters related to the blood path. The `Tools` tab is used to enter the `Service menu`.

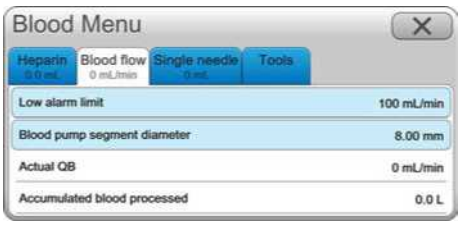
`Heparin`



- `Heparin bolus volume`: Set the heparin solution bolus volume.
- `Heparin flow rate`: Set the heparin solution flow rate.
- `Stop time`: Set the heparin pump to stop before treatment end. The time for this setting is given in minutes.
- `Start heparin priming bolus immediately`: Start an immediate bolus of heparin during priming.

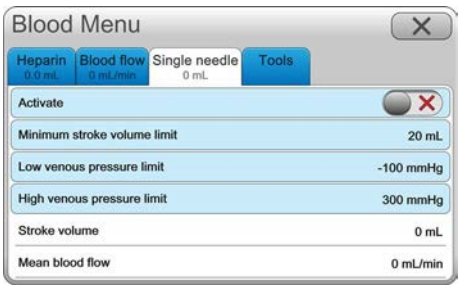
  The button is only available during priming.
- `Syringe`: The preset syringe type.
- `Accumulated heparin volume`: Read out of total administered heparin volume during priming and treatment.

`Blood flow`



- `Low alarm limit`: Set the low alarm limit for the blood flow.
- `Blood pump segment diameter`: Set the blood pump segment size.
- `Actual QB`: Read out of actual blood flow compensated for the arterial pressure.
- `Accumulated blood processed`: Read out of total volume of treated blood that has passed through the dialyzer since start of treatment.

`Single needle`



- `Activate`: Activate the single needle mode for the dialysis machine.
- `Minimum stroke volume limit`: Set the low alarm limit for the stroke volume.
- `Low venous pressure limit`: Set the low alarm limit for the venous pressure. Automatically set when the treatment has been started and the venous pressure limits are centralized.
- `High venous pressure limit`: Set the high alarm limit for the venous pressure. Automatically set when the treatment has been started and the venous pressure limits are centralized.

- `Stroke volume`: Read out of actual stroke volume.
- `Mean blood flow`: Read out of effective blood flow rate during treatment.

`Tools`

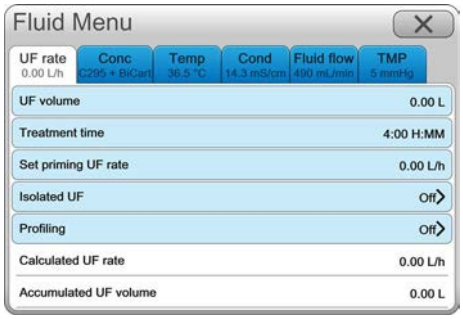
- `Service`: Open the `Service menu`.
- `Clean screen`: Allows the operator to clean the screen when the machine is switched on. It is possible to perform this procedure in any machine status. When the command has been activated the screen is temporarily disabled, allowing the operator to clean it.
- `Night light`: Turns off the operator´s panel. Press the operator´s panel at any time to reactivate it. Any new alarm reactivates the operator´s panel.

3.4.20 Fluid button (25)

The `Fluid` button opens the `Fluid Menu`, which contain tabs for handling parameters related to the fluid path.

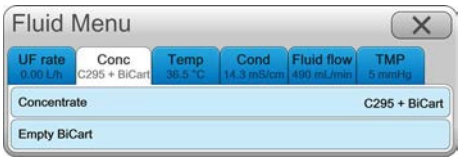
WARNING!
The maximum UF rate must be preset by an authorised technician according to the patient's prescription, when AK 98 dialysis machine is used in home healthcare environment.

`UF rate`



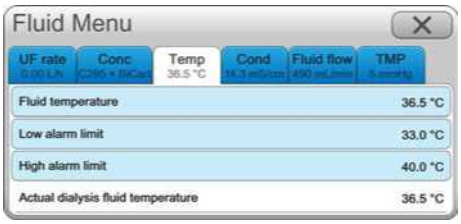
- `UF volume`: Set the ultrafiltration volume (patient weight loss).
- `Treatment time`: Adjust the treatment time. Time menu will display total set treatment time.
- `Set minimum UF rate`: Set the minimum ultrafiltration rate to be applied, as required during the treatment.
- `Isolated UF`: Set the isolated ultrafiltration values, see Section 6 "Isolated ultrafiltration" on page A:113.
- `Profiling`: Set the ultrafiltration profile, see Section 7.1 "General" on page A:118.
- `Calculated UF rate`: Read out of the calculated ultrafiltration rate.
- `Accumulated UF volume`: Read out of accumulated ultrafiltration volume (patient weight loss).

Conc



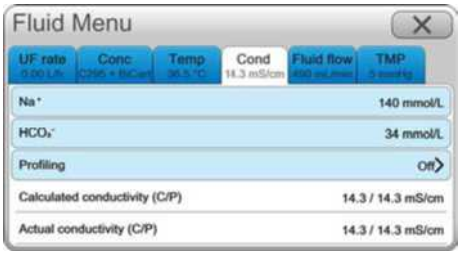
- `Concentrate`: Set the combination of concentrates to be connected.
- `Empty BiCart`: Empty the water from BICART cartridge. This reduces leakage when the cartridge is disconnected. (Not available during treatment).

Temp



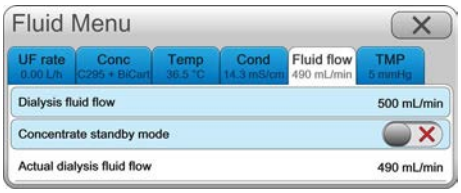
- `Fluid temperature`: Set the dialysis fluid temperature.
- `Low alarm limit`: Set the low alarm limit for the dialysis fluid temperature.
- `High alarm limit`: Set the high alarm limit for the dialysis fluid temperature.
- `Actual dialysis fluid temperature`: Read out of the actual dialysis fluid temperature.

Cond



- `Na` $^{+}$: Set the dialysis fluid sodium value.
- HCO_3^-: Set the dialysis fluid bicarbonate value.
- `Profiling`: Set the ultrafiltration profile, see Section 7.1 “General” on page A:118.
- `Calculated conductivity (C/P)`: Calculated dialysis fluid conductivity (C/P Control/Protective values), based on the settings for sodium and bicarbonate.
- `Actual conductivity (C/P)`: Read out of the actual dialysis fluid conductivity (C/P Control/Protective values).

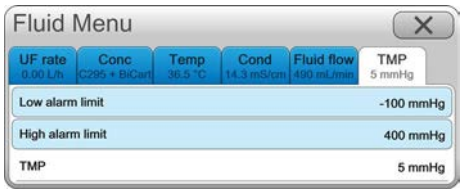
Fluid flow



- `Dialysis fluid flow`: Set the dialysis fluid flow rate. The value can be set during priming, but will not take effect until treatment start.
- `Concentrate standby mode`: Activate standby mode to pause the preparation of dialysis fluid, see Section 3.5 “Concentrate standby mode” on page A:70.

- `Actual dialysis fluid flow`: Read out of actual dialysis fluid flow rate.

`TMP`



- `Low alarm limit`: Adjust the low alarm limit for the transmembrane pressure.
- `High alarm limit`: Adjust the high alarm limit for the transmembrane pressure.
- `TMP`: Read out of the actual transmembrane pressure.

3.4.21 Fluid bypass button (26)

The `Fluid bypass` button is used to manually bypass the dialysis fluid from the dialyzer.

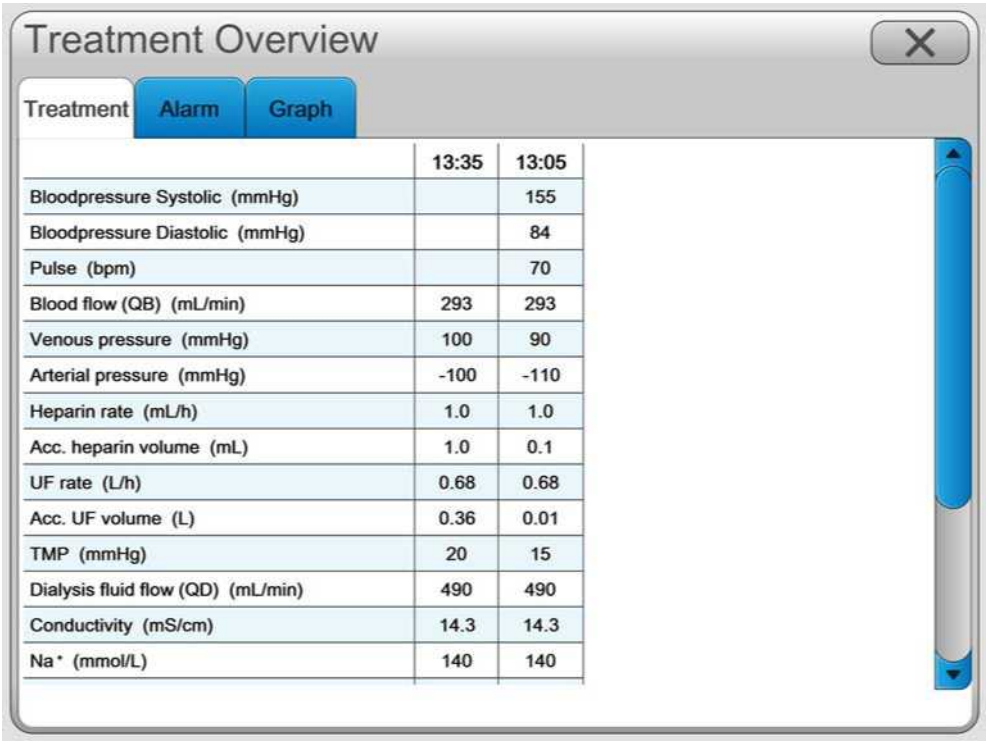
3.4.22 Ultrafiltration button (27)

The `Ultrafiltration` button is used to start or stop the ultrafiltration.

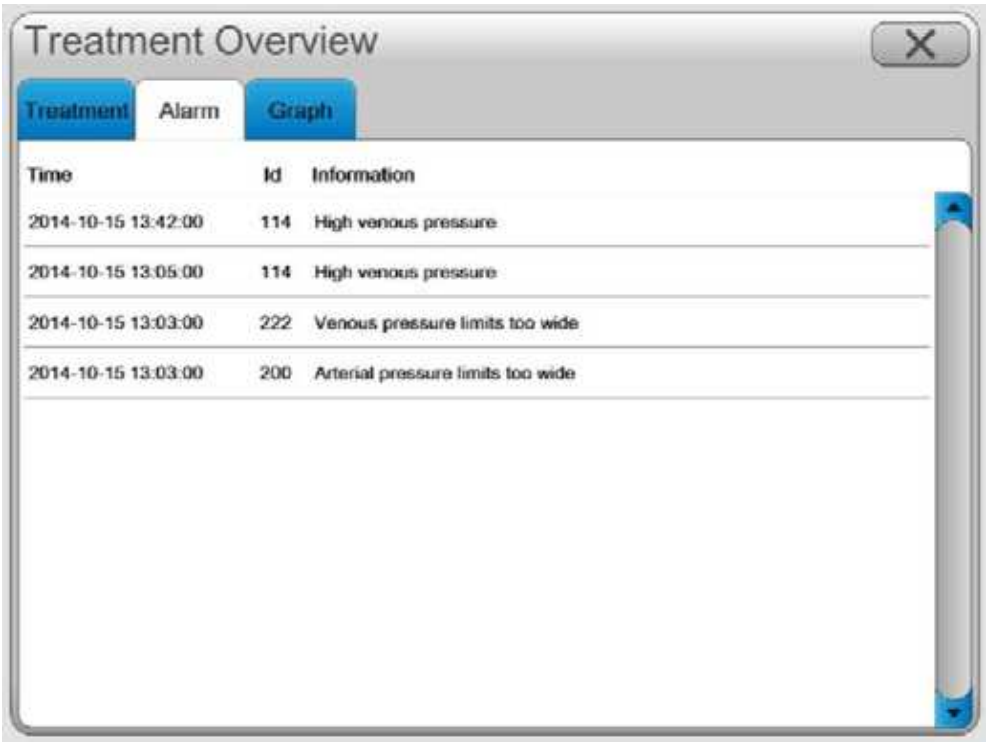
3.4.23 Treatment history page (28)

The `History` button opens the treatment history page, which contain tabs for:

Treatment history log.



Alarm history log for the actual treatment. The last generated alarm is shown at the top of the list.

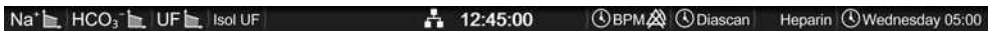


Graph history log with treatment graphs.

3.4.24 Status bar (29)

The status bar indicates when the following function are active:

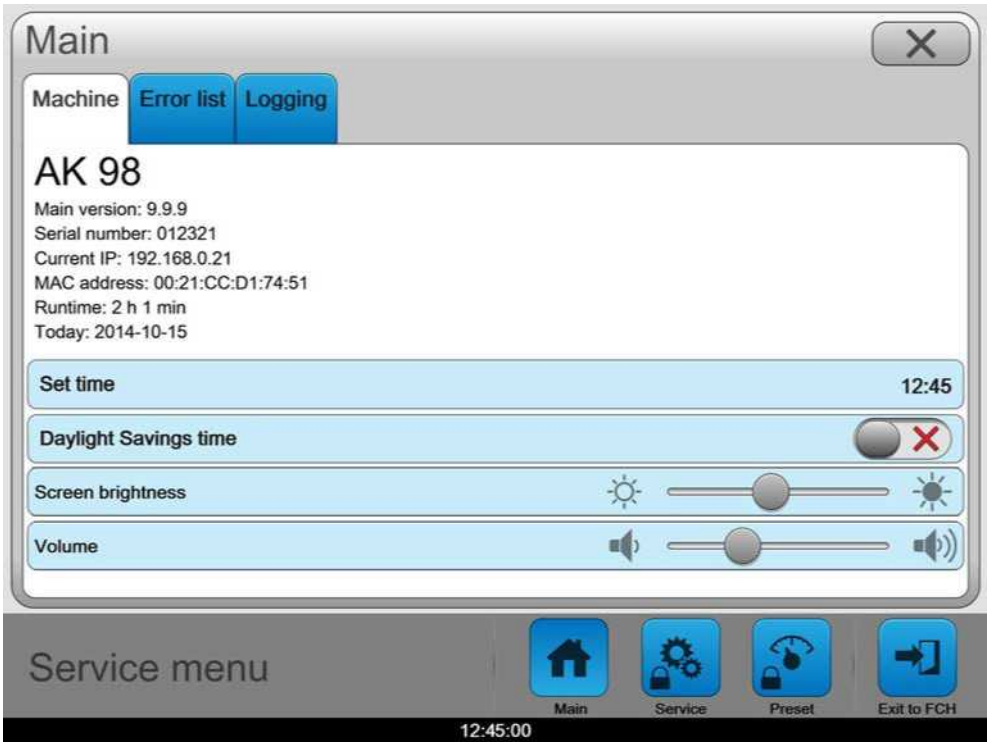
- Sodium profiling
- Bicarbonate profiling
- UF profiling
- Isolated UF
- Network connection
- Actual time
- BPM measurement
- BPM alarm off
- Diascan
- Heparin
- Scheduled disinfection



3.4.25 Service menu

The `Blood` button opens the `Blood Menu`, which is also the entry point to the `Service menu`.

Select the Tools tab and press Service to open the Service menu.



In the Service menu it is possible to observe and adjust some machine settings and to view the Error list.

Machine

- Set time: Press Set time to open the keypad to adjust the system clock.
- Daylight Savings time: Press Activate to activate daylight savings time. When active the clock will be advanced one hour during the summer months. If deactivated the clock will show standard time.
- Screen brightness: Change the position of the slider to adjust the screen brightness.
- Volume: Change the position of the slider to adjust the volume for the speaker.

Error list

- Time: The time when the error appeared.
- Error code: The error code can be used to identify a malfunctioning software or hardware component that caused the error.
- Alarm information: The alarm message shown in the alarm tab.

Logging

Through the Logging tab it is possible to select parameters to be logged. This feature is used by the authorised service technician to check condition and status of hardware or software components.

3.5 Concentrate standby mode

3.5.1 About concentrate standby mode

It is possible to put the machine into concentrate standby mode. In standby mode the consumption of concentrates will be stopped. It is also possible to reduce the water consumption.

Concentrate standby mode can be activated when functional check is done and the flow diagram turns green.

When the concentrate standby mode is active, a message will be displayed in the Information field. The bypass path of the flow diagram will turn to orange.

After 1 hour in concentrate standby mode the dialysis machine will automatically start the dialysis fluid preparation again.

Concentrate standby mode cannot be activated if blood has been detected.

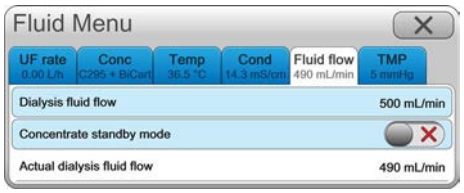
Concentrate standby mode can be activated manually (default function) or preset to be activated automatically . The presets are configured by an authorized service technician.

Concentrate standby mode cannot be performed at the same time as recirculation.

3.5.2 To manually activate concentrate standby mode

Procedure

1) Press the `Fluid` button.



2) Select the `Fluid flow` tab.

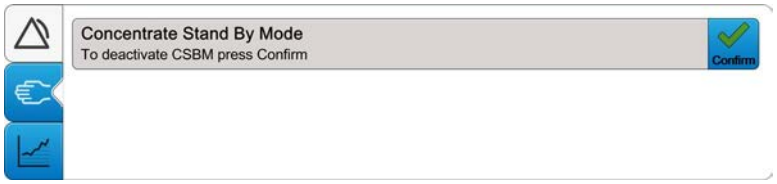
3) Press the activate button to activate concentrate standby mode.

3.5.3 To resume preparation of dialysis fluid

Procedure

1) Select the `Information` tab.

2) Press `Confirm` in the message.



3.5.4 To automatically enter concentrate standby mode

The following conditions can be preset (by an authorised service technician) to pause dialysis fluid preparation:

- When the green fluid path is achieved, or a preset time thereafter.
- When the set priming volume is achieved.

The machine can be preset to activate concentrate stand-by mode, and at the same time shut off the water intake. In this case, the consumption of both water and concentrates are paused.

3.6 Operate the machine during power failure

3.6.1 Power failure with battery back-up

If the dialysis machine loses power, it has a back-up battery that temporarily provides power to the blood unit. All settings and actual values are kept. The blood pump will continue to operate on battery power. Heating of dialysis fluid is not provided.

The back-up battery will only last a limited time, 30 minutes can be expected from a fully loaded battery in good condition.

NOTE!
Consider whether to discontinue treatment if the power failure is expected to last more than a few minutes.

If the dialysis machine loses power and the back-up battery does not work, the dialysis machine shuts down. All settings and actual values are kept, see Section 3.6.3 “Return the blood to the patient manually” on page A:71.

3.6.2 Power failure without battery back-up

If the dialysis machine loses power it shuts down. All settings and actual values are kept.

Continue the treatment after power failure

Press the **On/Off** button to start the machine when the power returns. The machine will recover and continue the treatment from where it was stopped. All settings and actual values are kept. However, all treatment parameters need to be checked by the operator after a recovery.

CAUTION!
After recovery, check treatment parameters to ensure that treatment is continued according to prescription.

3.6.3 Return the blood to the patient manually

WARNING!
During manual procedure to return blood to patient during a power failure, the operator shall take full responsibility for visually monitoring all safety parameters that cannot be monitored by the machine during a power failure (for example air detection).

WARNING!
Check that the arterial blood line is connected to the rinseback solution to prevent patient blood loss.

If the dialysis machine is shut down, you can manually return the blood to the patient.

Pay attention to possible risks when manually returning the blood to the patient, since the dialysis machine is off and cannot trigger alarms.

Procedure

1) Clamp the arterial blood line and patient access clamp.
2) Disconnect the arterial blood line from the patient.
3) Connect the arterial blood line to the rinse-back solution and unclamp the arterial blood line and any clamps on the rinse-back line.
4) Open the blood pump cover.
5) Turn (anticlockwise) the blood pump handle manually to return the blood. During the return of the blood check carefully that no air is entering the patient.
6) When the blood is returned to the patient, clamp the venous blood line and patient access clamp.
7) Disconnect the venous blood line from the patient.

3.7 Change of dialyzer and blood lines during treatment

The blood lines and dialyzer may need to be changed during a treatment, for example if the blood clots. If the new blood circuit procedure is performed, all values and settings are kept in the machine and it will continue on from when treatment was stopped.

Procedure

1) Press the `Rinse back` button.

2) Press `New blood circuit`.
3) Check that the blood pump is stopped.
4) Choose an alternative:
   - To return the blood to the patient first: Press `Rinse back` and follow the normal procedure to return the blood, see Section 4.3.1 “End the treatment” on page A:100.
   - To disconnect the patient immediately: Press `Disconnect Patient`, clamp the blood lines and disconnect them from the patient.
5) Disconnect both of the dialysis fluid tubes and return them to the safety couplings, there is no dialyzer draining during the new blood circuit procedure.
6) Remove the dialyzer and the blood lines.
7) Attach the new dialyzer and blood lines, see Section 4.2.3 “Set up the dialysis machine” on page A:77.
8) Prime and remove the air from the new blood lines, see Section 4.2.7 “Priming the dialysis circuit” on page A:91.

9) Connect the patient and start the treatment again, see Section 4.2.12 “Connect the patient” on page A:97 and Section 4.2.13 “Start the treatment” on page A:99.

3.8 Change of BICART cartridge during Treatment

If the BICART cartridge needs to be replaced by a new one during treatment, close the latches for at least 2 seconds before attaching the new BICART cartridge.

This is necessary in order for the machine to automatically prime the new BICART cartridge.

To attach the BICART cartridge to the BICART cartridge holder, see Section 4.2.3 “Set up the dialysis machine” on page A:77.

3.9 The ultrafiltration control

During treatment the following equation is used when calculating the ultrafiltration rate:

Table 3-1. Formula for calculating UF rate

$$\frac{\text{Ultrafiltration volume}}{\text{Treatment time}} = \text{UF rate}$$

Treatment time and ultrafiltration (UF) volume can be set within certain limits. The machine will automatically calculate and show the ultrafiltration rate in litres/hour. When treatment time or ultrafiltration volume is changed the ultrafiltration rate will also change.

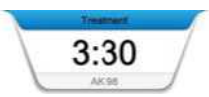
Precise pre- and post-treatment weight is critical for adequate assessment of the ultrafiltration during the treatment. If these measurements are not accurate a discrepancy between the ultrafiltration achieved during the treatment and the changes in body weight will occur. Besides the ultrafiltration, patient weight change during treatment is also affected by other factors. These include factors such as fluid intake, food intake, perspiration, drug administration, infusion priming and rinse-back volumes amongst others.

WARNING!
The maximum UF rate must be preset by an authorised technician according to the patient’s prescription, when AK 98 dialysis machine is used in home healthcare environment.

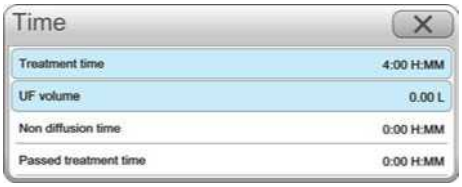
CAUTION!
After recovery, check treatment parameters to ensure that treatment is continued according to prescription.

An example on how a UF setting is to be done is shown as follows:

Procedure



1) Press the `Time` indicator.



2) Press `Treatment time`.

3) Set the desired treatment time.

4) Press `OK`.

5) Press `UF volume`.

6) Calculate the patient's ultrafiltration volume, see Section 4.2.10 "Set ultrafiltration volume" on page A:95.

7) Enter the patient's ultrafiltration volume.

8) Press `OK`.

Results

If the UF rate goes down to zero during treatment, due to alarm conditions, the machine will try to compensate for the time loss within the remaining time. A high UF rate limit is automatically calculated and set as 120% of the calculated UF rate. This limit is the highest UF rate during treatment.

The UF rate will go down to zero if:

- There have been many alarms that have forced the blood pump to stop during treatment.
- The UF rate has been manually stopped during treatment.

CAUTION!
When negative TMP alarm limits are set, the operator will **not** be notified via alarm or attention that backfiltration may occur. However, it is possible for the authorised service technician to preset the machine so that when negative TMP alarm limits have been set, such an attention occurs.

4 Haemodialysis - Double needle treatment

4.1 Basic functionality **A:76**

4.2 Start a double needle treatment **A:76**

4.2.1 Check before treatment A:76
4.2.2 Start functional check A:76
4.2.3 Set up the dialysis machine A:77
4.2.4 Attach the arterial blood line A:79
4.2.5 Attach the venous blood line A:84
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4.3 End a double needle treatment **A:100**

4.3.1 End the treatment A:100
4.3.2 Confirm disconnect patient A:101
4.3.3 Machine aftercare A:101

4.1 Basic functionality

Double needle treatment uses two needles, one connected to the arterial blood line and one connected to the venous blood line.

- The patient's blood leaves the body via the arterial blood line.
- The blood is cleaned in an artificial kidney (dialyzer).
- The blood comes back into the body via the venous blood line.

CAUTION!
Use the correct blood pump rotor. Check that it is adjusted correctly for the occlusion of the blood pump segment being used. This check shall be performed by an authorised service technician.

4.2 Start a double needle treatment

4.2.1 Check before treatment

Procedure

1) The mains cable should be connected to a mains supply with protective earth.
2) The main switch should be on.
3) The water supply should be connected to the inlet water tube, and switched on.
4) The outlet tube (drain) should be properly placed with an air gap between the dialysis machine and the drain/sewer system.
5) The dialysis fluid tubes should be connected to the safety couplings.
6) The WRO 300 H water purification unit should be in standby mode (if it is to be used).
7) All accessories should be ready and available for use, for example A-concentrate, BiCart cartridge, dialyzer, blood lines and priming bag.

4.2.2 Start functional check

Before a treatment can be started the dialysis machine performs a functional check. The machine checks that internal functions, for example safety functions and alarm systems, are working. The machine performs either an extended functional check or a shorter basic functional check. An authorised service technician can preset the machine to perform a basic functional instead of an extended functional check between treatments.

A basic functional check will be performed if these criteria are fulfilled:

- Basic functional check is enabled by an authorised service technician.
- A successful extended functional check has been performed that day (from 00:00).
- A successful extended functional check has been performed after service menu was entered.
- A successful extended functional check has been performed after a technical error was generated.
- A successful extended functional check has been performed after date and/or time were changed.

CAUTION!
During a functional check the blood pump rotor is moving. Do not open the blood pump door until the Blood pump button is flashing.

CAUTION!
During a functional check the blood line clamps are moving. Be careful and protect your fingers by not attempting to attach the blood lines until the Blood pump button is flashing.

Procedure

1) Press the **On/Off** button.

   Check that the alarm indication lights are activated when the machine is switched on. See Section 1.1.1 “Alarm indication” on page B:11 in Alarm handbook.

2) Check that the buttons to the right of the screen light up when the machine is switched on. Contact an authorised service technician if any of the buttons do not light up. Observe that **Blood pump up** button and **Blood pump down** button do not light up.

   The screen will light up when the machine is switched on. Contact an authorised service technician if parts of the screen are dark and not working.

4.2.3 Set up the dialysis machine

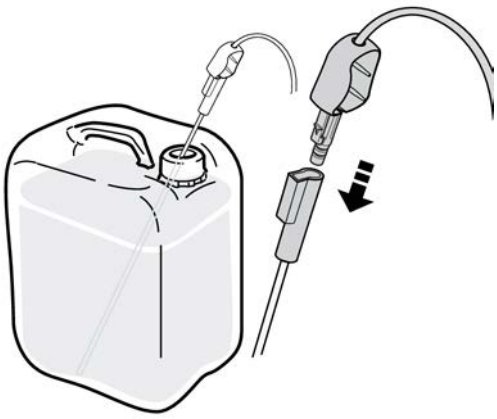
Before you begin

WARNING!
To ensure that the prescription is followed, check that the type of concentrate you have specified in the dialysis machine is the same as you actually use during treatment, and that it is the same as is prescribed for the patient.

WARNING!
Check the content of the concentrate container before connecting the pick-up tube to the concentrate container. If the prescribed concentrate is not used during treatment this may lead to plasma electrolyte imbalance or acid base imbalance. A non-intended content may lead to hemolysis.

Procedure

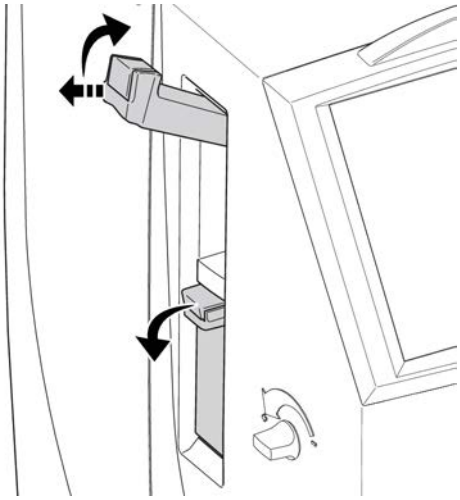
1) Remove the red concentrate connector from the stand-by port.



2) Attach a pick-up tube to the red concentrate connector. Place the pick-up tube in the A-concentrate container.

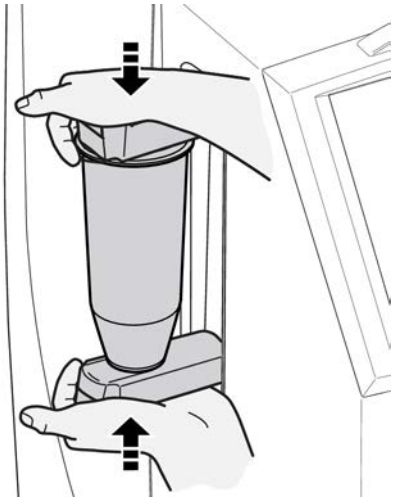
3) Select the concentrate combination to be used from the three preset options on the screen.

4) If SoftPac concentrates are being used, connect the red concentrate connector to the red key-way connector of the SoftPac bag, and then break the frangible pin.

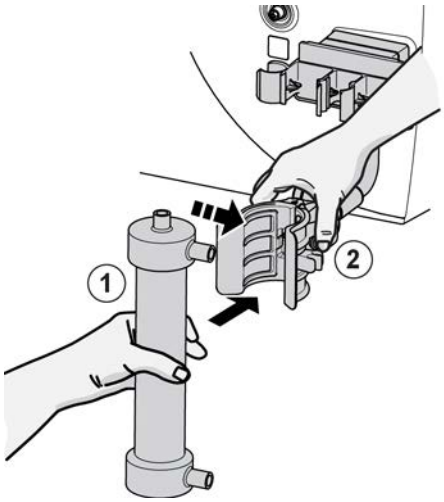


5) Release the latches by pressing the release buttons. Open the BiCart cartridge holder. Fold the upper latch out and up, pull out at the same time. Fold the lower latch out and down.

6) Remove the caps from the BiCart cartridge and attach it bottom down.

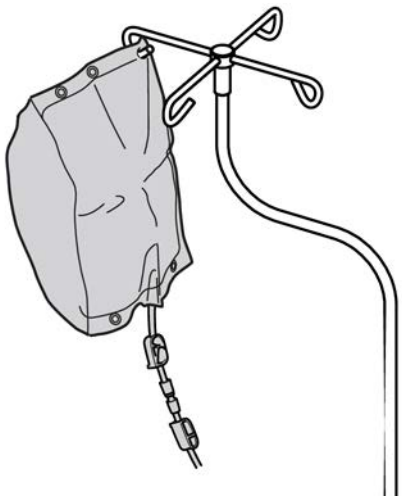


7) Close down the upper latch to secure the cartridge. Hold with one hand underneath the lower latch.



8) Attach the dialyzer (1) in the holder.

If necessary, squeeze the spring-clip (2) to place the dialyzer in the holder.



9) Hang the saline or priming solution bag on the infusion stand.

4.2.4 Attach the arterial blood line

CAUTION!
Do not use the neonatal blood lines: A-5.128-B4, V-5.127-X, A-5.129-B4 or V-5.129-X with AK 98 dialysis machine as these neonatal blood lines are not intended for use with the AK 98 dialysis machine.

The arterial blood line has red connectors.

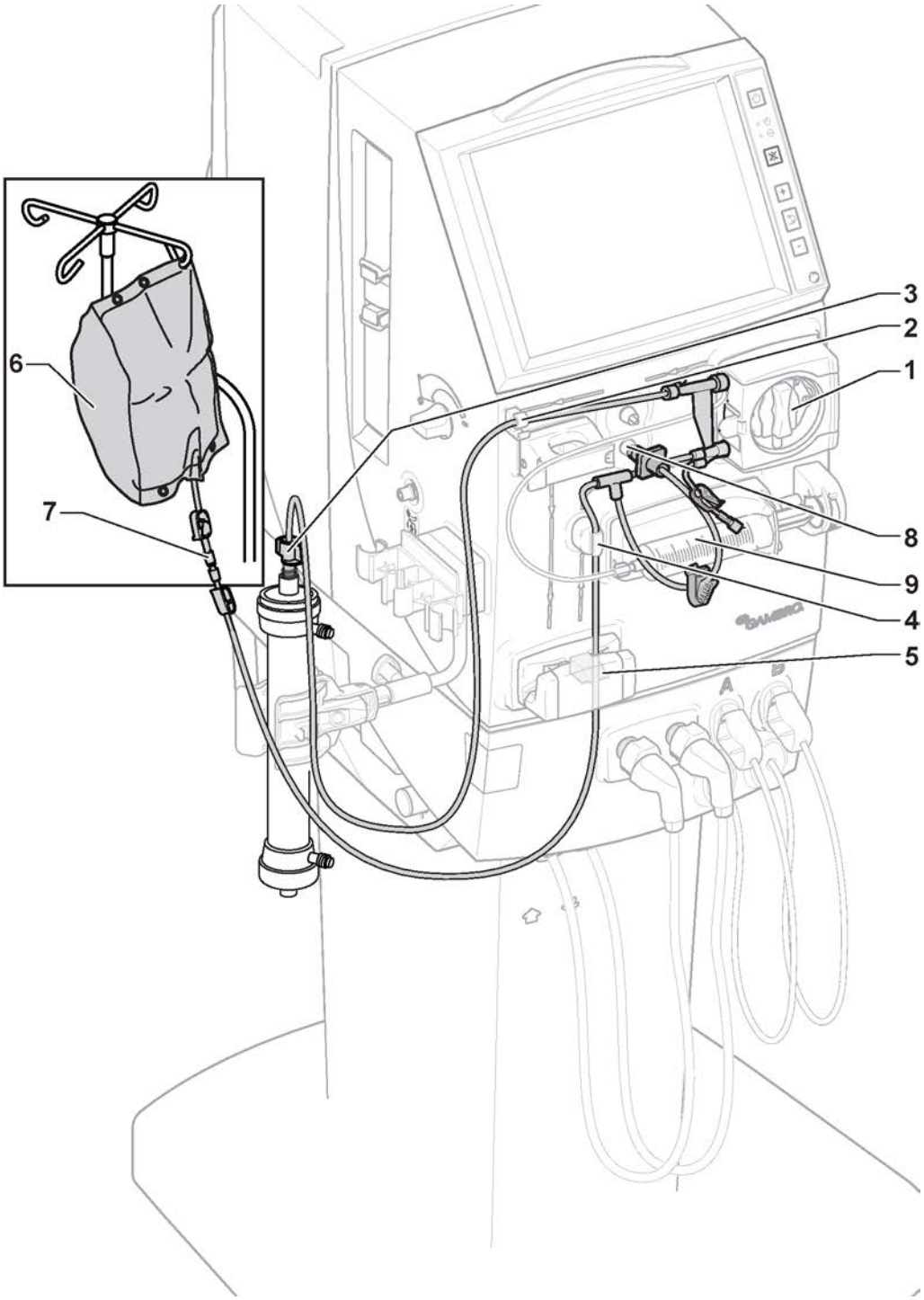
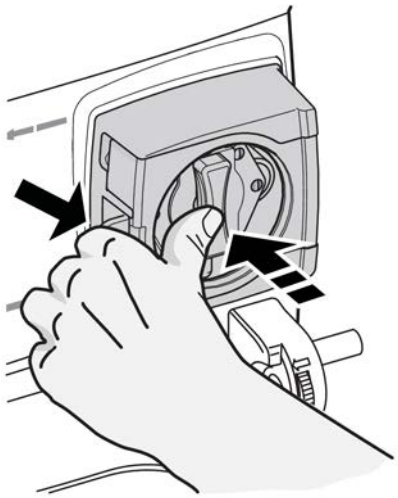


Figure 4-1. The arterial blood line set

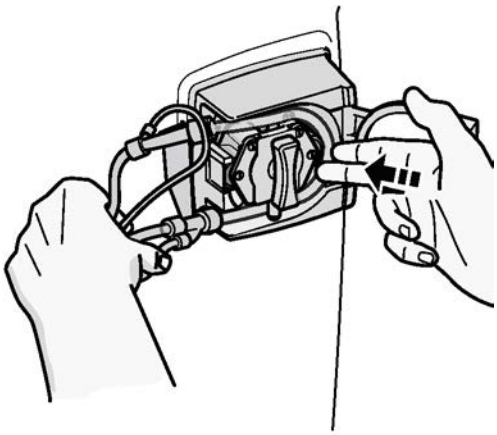
1. Blood pump
2. Blood line guide
3. Dialyzer connection
4. Blood line guide
5. Arterial line clamp
6. Saline or priming bag
7. Arterial patient connector
8. Arterial pressure transducer connector
9. Heparin pump

When the dialysis machine is lined, check that the appropriate clamps are closed.

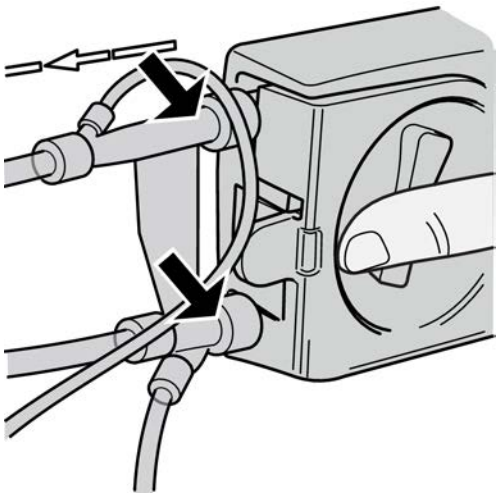
Procedure



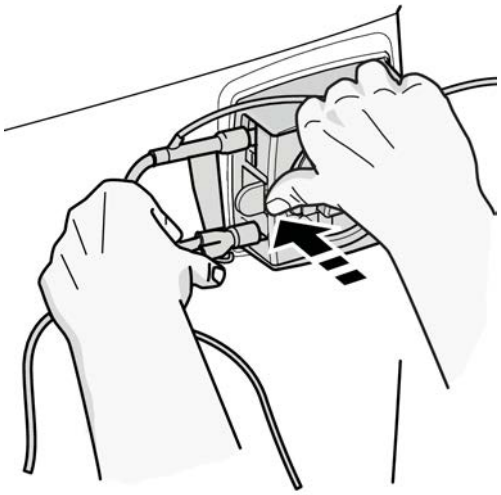
1) Open the blood pump door; press the middle of the cover and pull the tab.



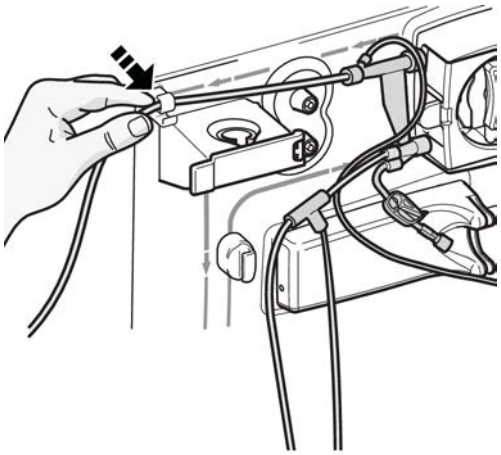
2) Place the blood pump segment over the blood pump rotor.



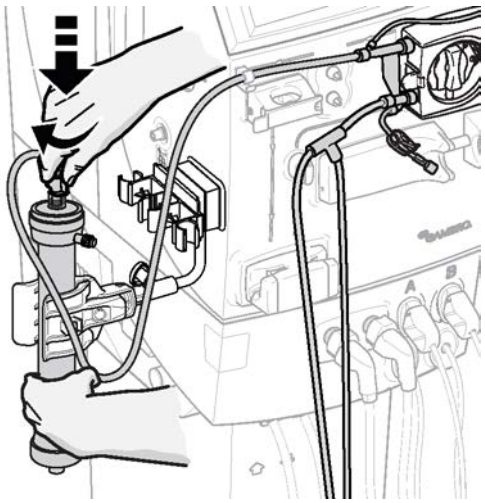
3) Make sure that the blood pump segment collars are outside the pump housing.



4) Hold the segment in place and close the blood pump door.

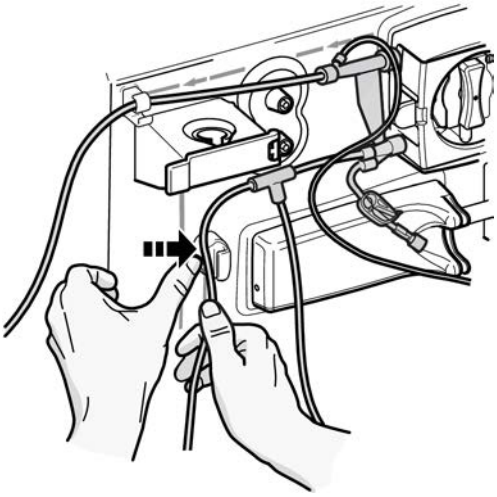


5) Press lightly on the blood line to place it in the upper guide.

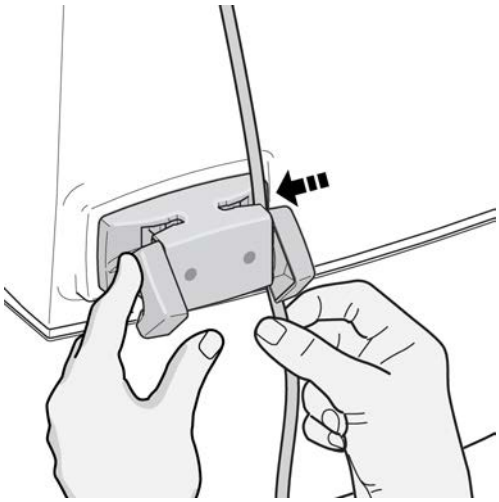


6) Remove protective caps and attach the end of the arterial blood line firmly to the dialyzer; press and turn simultaneously.

WARNING!
Check that the arterial blood line is firmly attached to the dialyzer to prevent patient blood loss.

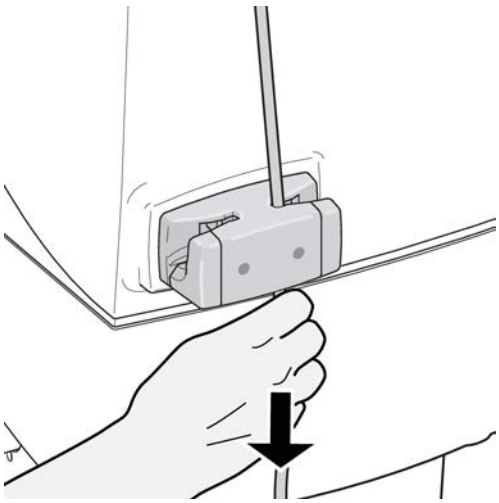


7) Press lightly on the blood line to place it in the guide.



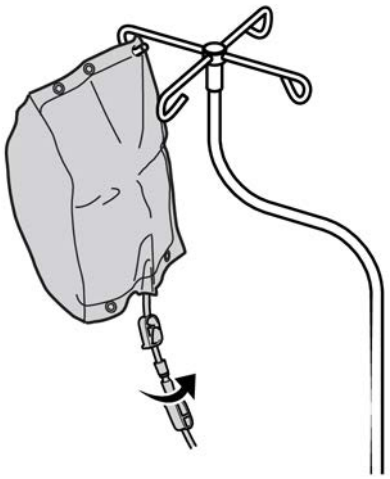
8) Place the blood line in the arterial clamp (marked with a red dot).

CAUTION!
Protect your fingers. Do not put fingers in the clamp.

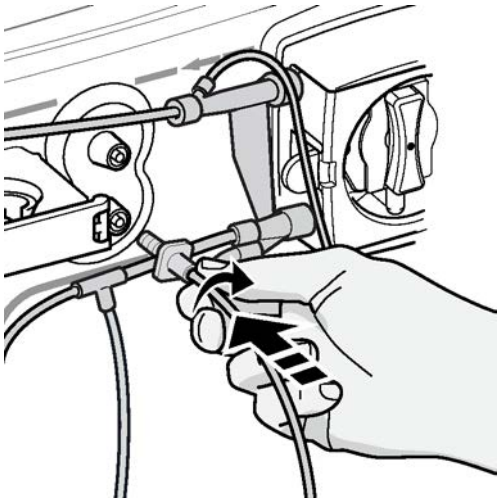


9) Pull the blood line lightly downwards. The line goes into place when it is lightly pressed at the same time.

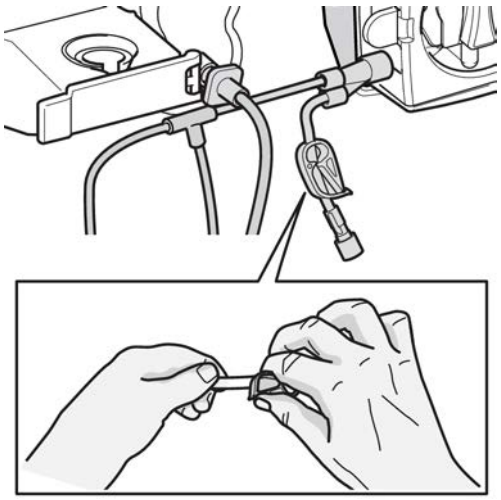
NOTE!
Make sure the blood line between the arterial clamp and blood pump is not too stretched



10) Connect the arterial blood line with the saline or priming solution bag. Check that the connections are tight.



11) Attach the arterial pressure transducer protector of the arterial blood line to the red arterial pressure transducer connector. Press to pierce the membrane and then turn to secure the connection.

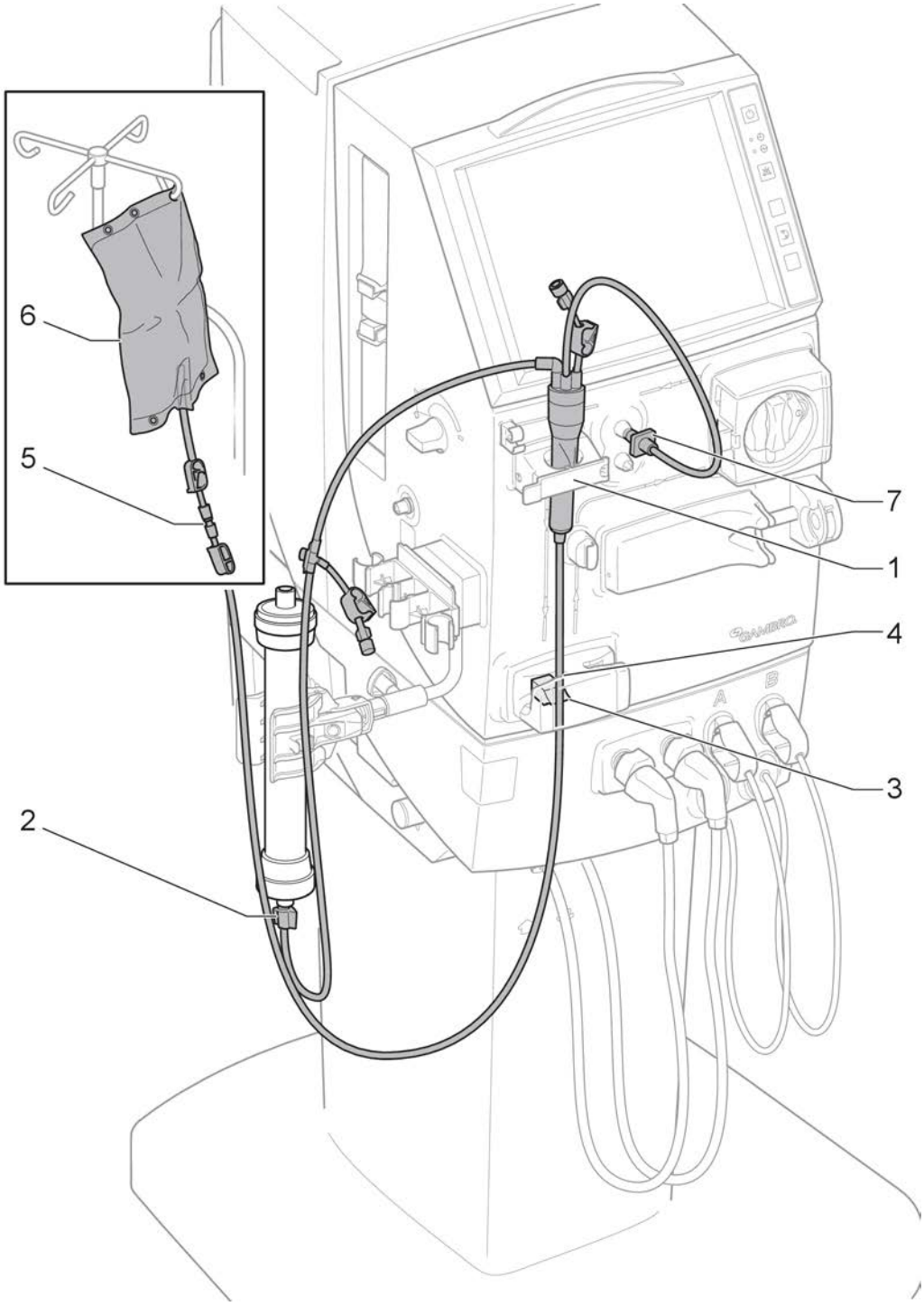


12) Close all relevant clamps.

CAUTION!
Check that all relevant clamps are closed to prevent undetected blood loss.

4.2.5 Attach the venous blood line

The venous blood line has blue connectors.

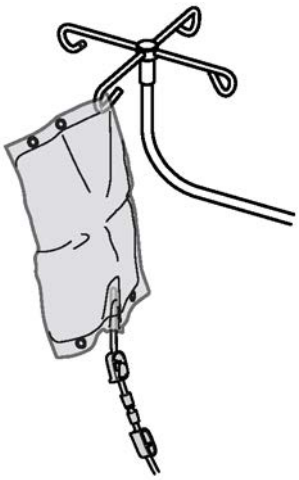


1. Air detector
2. Dialyzer connection
3. Venous line clamp
4. Priming detector
5. Venous patient connector
6. Waste bag
7. Venous pressure transducer connector

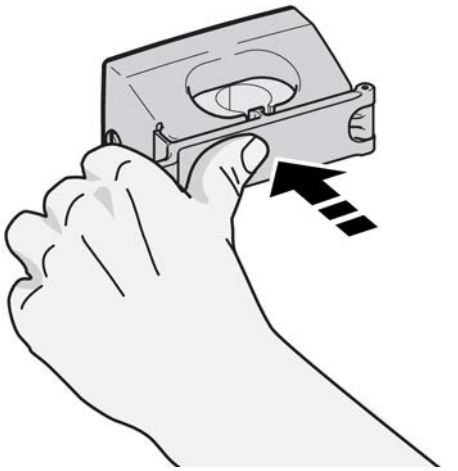
When the dialysis machine is lined, check that the appropriate clamps are closed.

Procedure

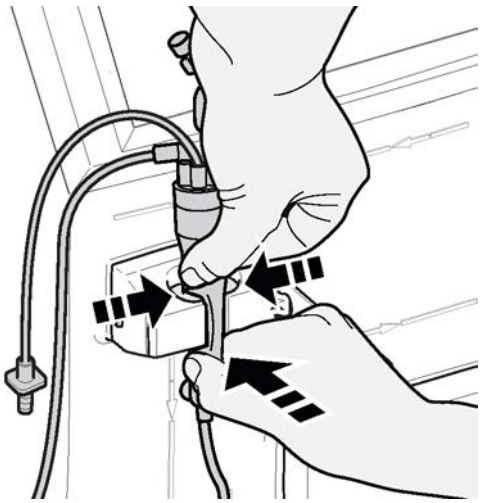
1) Check that the waste bag is securely attached to the end of the venous blood line.



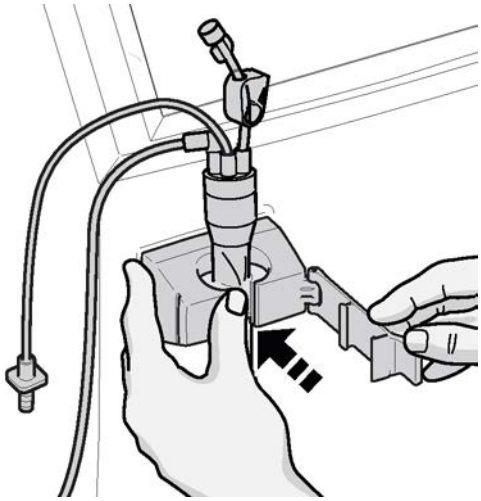
2) Hang the waste bag on the infusion stand.



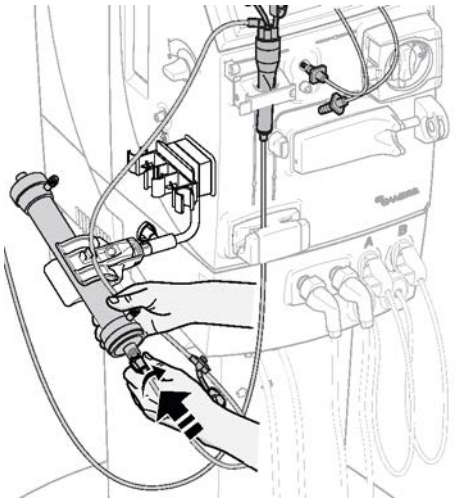
3) To open the air detector cover: pull the opening tab towards you, and at the same time press firmly at the middle of the cover.



4) Pinch the venous drip chamber and place it in the air detector.

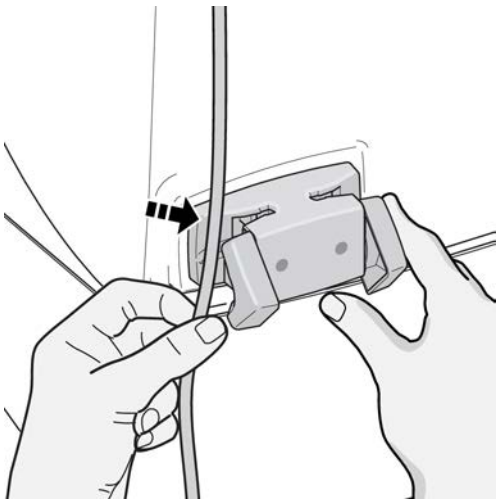


5) Adjust the position of the venous drip chamber to ensure the conical filter is below the air detector, and that there is enough of the chamber above the air detector head. This allows the chamber to be filled with enough blood to prevent unnecessary air detector alarms from being triggered. Always press in the center of the air detector cover when closing to prevent unnecessary stress and potential damage.



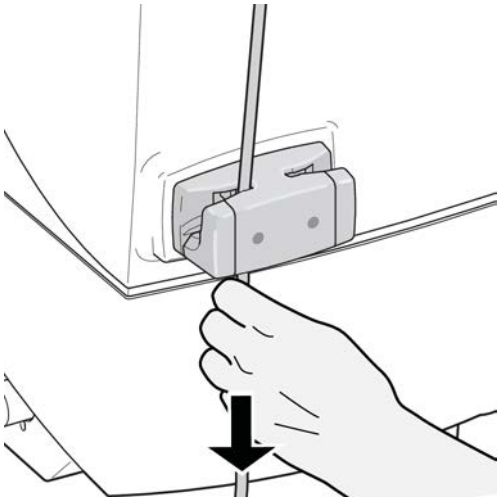
6) Remove the protective caps and attach the end of the venous blood line firmly to the dialyzer; press and turn simultaneously.

WARNING!
Check that the venous blood line is firmly attached to the dialyzer to prevent patient blood loss.



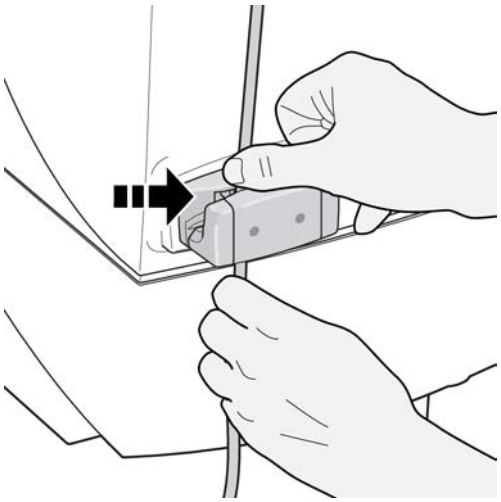
7) Place the blood line in the venous clamp (marked with a blue dot).

CAUTION!
Protect your fingers. Do not put fingers in the clamp.

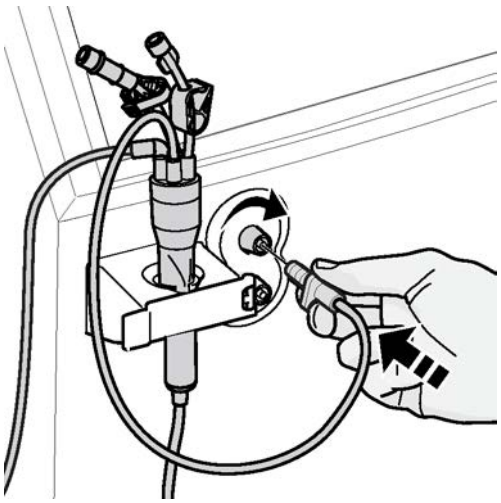


8) Pull the blood line lightly downwards. The line goes into place when it is lightly pressed at the same time.

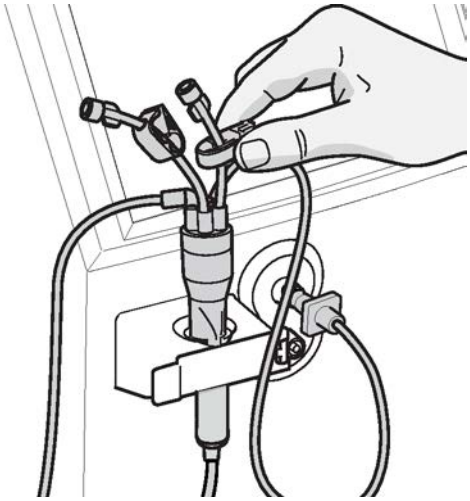
CAUTION!
Check carefully that the venous blood line is correctly placed in the priming detector to make sure that the supervision of alarms is activated.



9) Check carefully that the venous blood line is set correctly in the venous blood line clamp. It is necessary that the venous blood line is correctly placed for the priming detector to be able to detect the blood at treatment start.



10) Attach the venous pressure transducer protector of the venous blood line to the blue venous pressure transducer connector. Press to pierce the membrane and then turn to secure the connection.



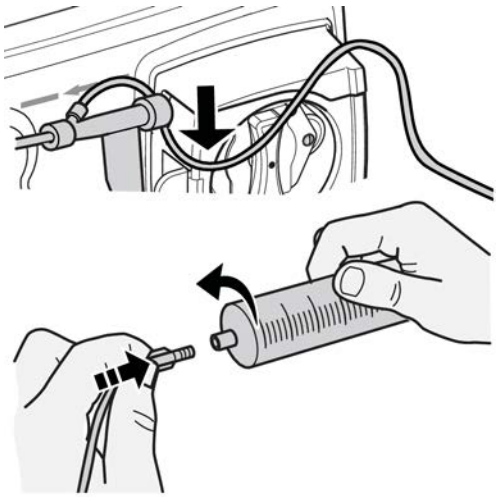
11) Clamp any open lines.

4.2.6 Attach the heparin syringe

Before you begin

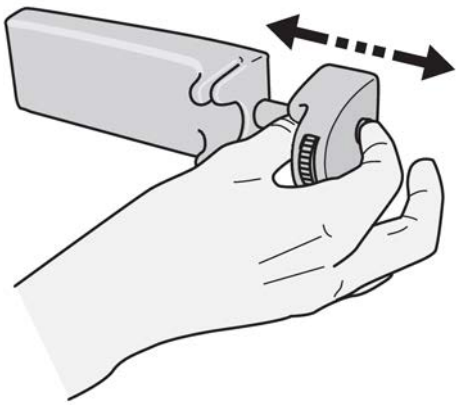
CAUTION!
Check that the syringe size, syringe type and heparin type that you have specified in the dialysis machine are the same as you actually use during treatment. If not, the patient could be either over or under coagulated.

Procedure

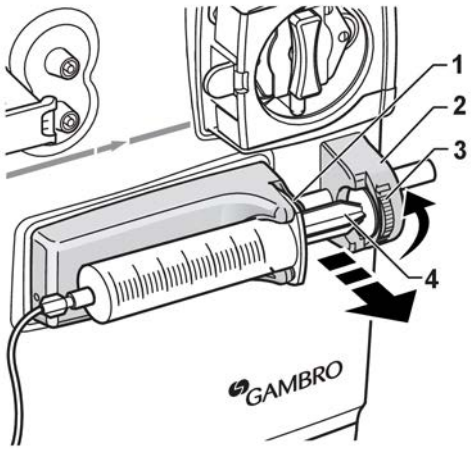


1) Attach the prepared syringe to the heparin line.

2) Prime the line with the solution all the way to where the arterial blood line starts. The luer lock mounting ensures that the syringe is properly connected to the line. Observe that the luer lock must be properly attached.



3) Press the end of the piston on the heparin pump and pull it out as much as possible.



4) Insert the syringe in the pump. The plastic collar at the end of the syringe should fit in the groove of the pump (1).

5) Push back the piston and insert the plastic plate on the plunger in the groove by the locking wheel (2).

6) Turn the locking wheel upwards until you feel resistance (3).

7) Check that the syringe is properly attached by lightly pulling the plunger (4).

WARNING!
To prevent the syringe from loosening from the heparin pump during treatment the syringe plunger has to be thoroughly secured. Check by lightly pulling on the plunger. When doing so, it must be impossible to pull the syringe out of the heparin pump.

WARNING!
If the heparin pump is not used: Tie or clamp the heparin line to prevent patient blood loss.

4.2.7 Priming the dialysis circuit

4.2.7.1 Priming description

The purpose of priming is to get the dialyzer and blood lines ready for a treatment. Priming fluid runs through the blood lines and the dialyzer to rinse them and to remove air. Priming can be performed manually or with assistance from the machine.

In manual priming the operator is in charge of the priming process. In assisted priming the dialysis machine guides you through the priming procedure. For extra priming and recirculation see Section 4.2.8 “Priming options” on page A:94.

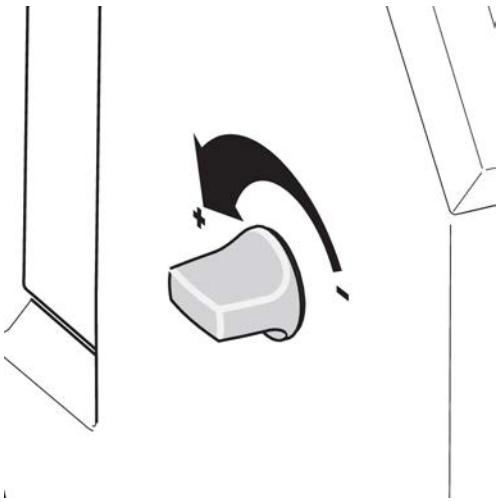
Blood side compartment priming of the dialyzer can be started as soon as the Blood pump button begins to flash.

4.2.7.2 Manual priming

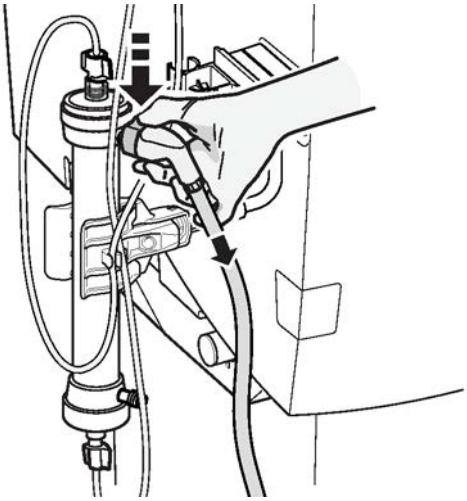
Procedure

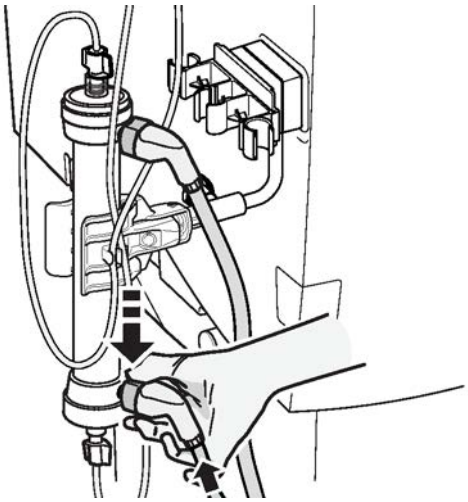
1) Open the clamps on the arterial blood line and saline or priming solution bag.
2) Turn the dialyzer over so that the blue end is up. This helps remove the air from the dialyzer.
3) Check that there are no kinks in the blood lines.

4) Press the flashing **Blood pump** button to start the blood pump and activate the priming.



5) Once a small volume of priming fluid has reached the drain bag, adjust the level of priming fluid in the venous drip chamber with the adjustment knob. The level should be well above the air detector head.
6) When the level in the venous drip chamber is OK, and the dialyzer is free from air, activate the air detector.
7) When the blood pump stops, turn the dialyzer over so that the red end is up.





8) If not already done, attach the dialysis fluid tubes to the dialyzer.

   Connect the red fluid tube from the machine to the same side of the dialyzer as the arterial blood line.

   Connect the blue fluid tube from the machine to the same side of the dialyzer as the venous blood line.

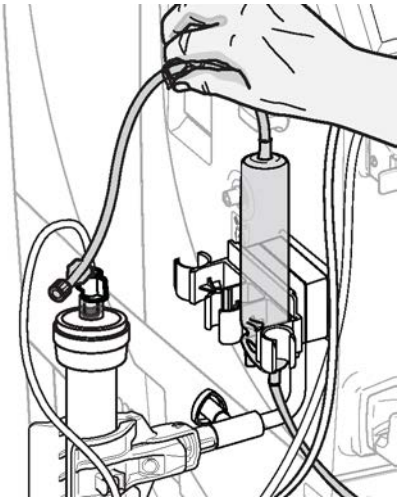
WARNING!
To ensure proper function of the fluid path in the machine, check that the dialysis fluid tubes are properly attached to the dialyzer.

9) Press the `Fluid bypass` button. The dialysis fluid starts to flow into the dialyzer.

10) When the priming volume has been achieved it is possible to perform extra priming or recirculation. See Section 4.2.8 “Priming options” on page A:94.

CAUTION!
Check carefully that the venous blood line is correctly placed in the priming detector to make sure that the supervision of alarms is activated.

11) Press `Connect patient`.

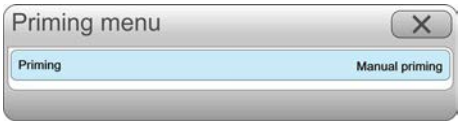


12) **Only for single needle treatment:** The expansion chamber is filled to a suitable level during priming. Close the clamp above the expansion chamber. See Section 5 “Haemodialysis - Single needle treatment” on page A:105 for more information.

4.2.7.3 Assisted priming

Procedure

1) Press the `Priming` button.



2) Press `Priming`.

3) Select `Assisted priming`.

4) Press `OK`.

5) Follow the instructions on the screen.

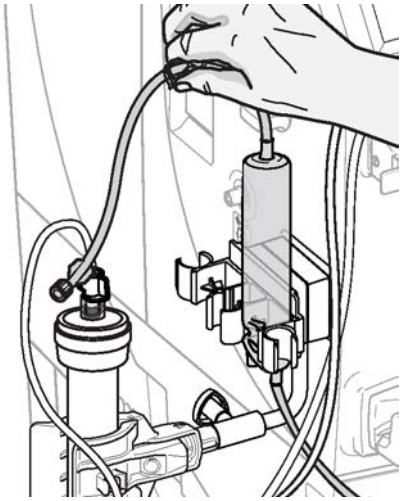
6) When the assisted priming procedure is complete it is possible to perform extra priming or recirculation. See Section 4.2.8 “Priming options” on page A:94.

> **CAUTION!**
> Check carefully that the venous blood line is correctly placed in the priming detector to make sure that the supervision of alarms is activated.

7) When the level in the venous drip chamber is OK, activate the air detector.

8) When the assisted priming procedure is completed, press `Confirm`.

9) Press `Connect patient`.



10) **Only for single needle treatment:** The expansion chamber is filled to a suitable level during priming. Close the clamp above the expansion chamber. See Section 5 “Haemodialysis - Single needle treatment” on page A:105 for more information.

4.2.8 Priming options

4.2.8.1 Extra priming

When the priming is complete an information message will be displayed, containing a selection of possible actions.

Procedure

1) Check that you have enough priming fluid.
2) Press `Extra priming`.
3) Press the flashing **Blood pump** button.

4) **CAUTION!**
Check carefully that the venous blood line is correctly placed in the priming detector to make sure that the supervision of alarms is activated.

   When the extra priming is completed: Press `Connect patient`.

5) Continue starting the treatment. See Section 4.2.9 “Set treatment time” on page A:95.

4.2.8.2 Recirculation

When the priming is complete an information message will be displayed, containing the possible actions to recirculate.

You can set the priming fluid to circulate in the blood lines.

Procedure

1) Press `Recirculation`.
2) Connect the two patient ends of the blood lines to make a closed circuit. Use a sterile disposable blood line connector.

3) Connect the priming fluid via an infusion line. This compensates for the priming fluid that is removed due to ultrafiltration in the dialyzer during recirculation.

4) Check/adjust the level of priming fluid in the venous drip chamber with the adjustment knob. The level should be well above the air detector sensor head.

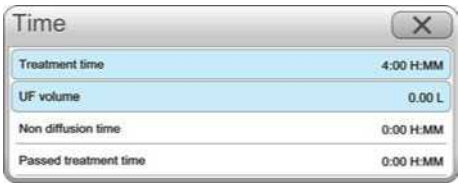
5) When recirculation is finished, close the clamp on the infusion line, then press `Connect patient`.

6) Continue starting the treatment. See Section 4.2.9 “Set treatment time” on page A:95.

4.2.9 Set treatment time

Procedure

1) Press the `Time` indicator.



2) Press `Treatment time`.

3) Set the desired treatment time.

4) Press `OK`.

4.2.10 Set ultrafiltration volume

Ultrafiltration volume (UF volume) is the desired total weight loss for a patient in a treatment.

Calculate UF volume

The patient’s ultrafiltration volume is used to set the desired weight loss for the treatment.

WARNING!
The maximum UF rate must be preset by an authorised technician according to the patient’s prescription, when AK 98 dialysis machine is used in home healthcare environment.

CAUTION!
All parameters and alarm limits must be suitable for the patient’s needs and tolerance.

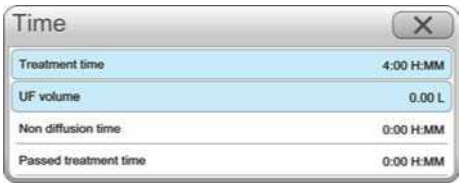
CAUTION!
It is important to set a correct ultrafiltration rate for the patient, to avoid incorrect fluid removal. Set a minimum ultrafiltration rate according to the instructions for the specific dialyzer.

CAUTION!
Once treatment parameters are set, you must verify that all calculated treatment values are as intended.

CAUTION!
Additional measures to supervise the patient weight loss is recommended when treating low weight patients or when performing long treatments. For Ultrafiltration details, refer to Technical data and specifications.

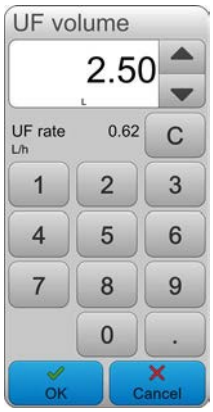
Procedure

1) Press the `Time` indicator.



2) Press `UF volume`.

3) Calculate the patient's ultrafiltration volume, see Section 4.2.10 "Set ultrafiltration volume" on page A:95.



4) Enter the patient's ultrafiltration volume.

5) Press `OK`.

4.2.11 Set heparin values

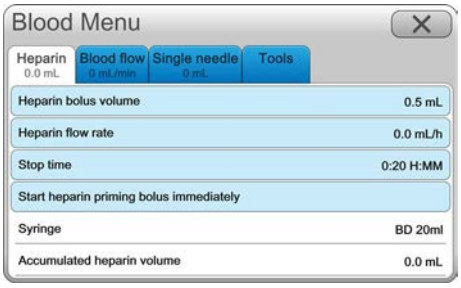
Before you begin

WARNING!
Make sure to set the prescribed heparin values. Incorrect heparin settings may cause blood coagulation or internal bleeding.

Procedure

1) Press the `Blood` button.

2) Select the `Heparin` tab.



3) Press the settings one by one and set the desired treatment parameters.

4) If a bolus dose of heparin solution is to be administered at treatment start, press `Heparin bolus volume` and set a bolus volume in mL suitable for the patient.

4.2.12 Connect the patient

Before you begin

WARNING!
Check that the blood lines and the patient accesses (needles or catheters) are tightly connected. If not, the patient could suffer from blood loss or air embolism.

WARNING!
To minimise the risk of damage to the patient's blood cells, check that there are no kinks in the blood lines and that the needles are of sufficient size.

The machine may not be able to detect all flow and pressure conditions, which in combination with narrowed passages in the blood circuit, may lead to damage of the blood cells.

WARNING!
Using a central venous catheter with potential negative pressure can cause air embolism if the arterial access is disconnected and if infusion is connected before the blood pump.

WARNING!
When using a catheter, keep in mind that a negative pressure may occur from the catheter; check that the arterial line is clamped before connecting any infusion before the blood pump.

WARNING!
The operator must take proper precaution in order to prevent coagulation in the extracorporeal circuit.

Coagulation may lead to:

- inadequate delivery of dialysis.
- risks associated with movement of blood clots to the patient.
- disabling of the air detector function if blood clots aggregate in the drip chamber.

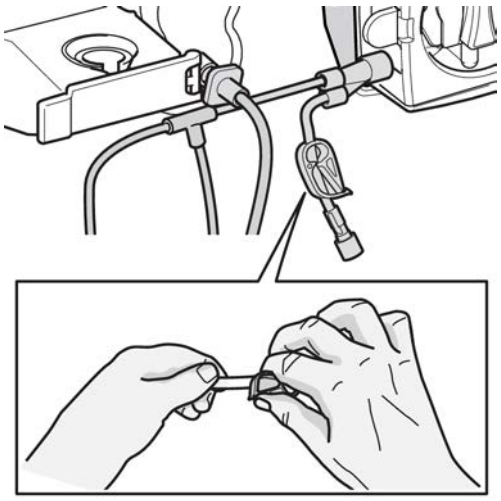
WARNING!
To avoid patient blood loss and blood hemolysis, it is important to follow the manufacturer's instructions for use of the dialyzer and the blood lines. When attaching the blood lines always ensure that all connections are properly secured and that no part of the blood lines have been kinked. If the heparin pump is not to be used, especially ensure that the cap at the end of the thin line used for heparin solution, is properly closed.

CAUTION!
Select `Connect Patient` before connecting the blood lines to the access. This allows the machine to detect blood and to start the treatment.

NOTE!
Your hospital can advise on how to place access needles and how to connect a central venous catheter.

Procedure

1) Check that the venous line is correctly placed in the priming detector.
2) Clamp the priming bag.
3) Disconnect the arterial blood line from the priming bag (or recirculation connector).
4) Connect the arterial blood line to the arterial access (needle or catheter). Make sure the connection is tight and that there is no leakage.
5) Disconnect the venous blood line from the waste bag (or recirculation connector). If a bleed out connection is to be performed, leave the venous blood line attached to the waste bag.
6) Check that there is no air in the venous blood line.
7) If a straight connection is to be performed, connect the venous blood line to the venous access (needle or catheter). Make sure the connection is tight and that there is no leakage.



8) Check that all relevant clamps are closed to prevent blood loss.

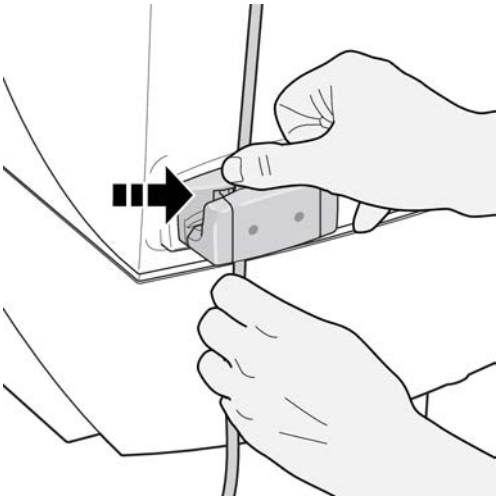
9) Press the flashing **Blood pump** button to start the blood pump. The blood pump will be preset to start at 100 mL/min. Once the blood has passed through the dialyzer and the dialysis machine detects blood at the priming detector, the blood pump will stop automatically.

NOTE!
The blood pump is preset to stop when the priming detector detects blood in the venous blood line and the blood path in the flow diagram lights up.

4.2.13 Start the treatment

Before you begin

CAUTION!
Check that the blood path of the flow diagram lights up. If it does not light up, check that the venous blood line is correctly placed in the priming detector. If the blood path does not light up, the machine considers the patient not connected and as a consequence the UF system is not controlling the patient ultrafiltration. If the air detector has not been activated during priming it will be automatically activated when the priming volume is achieved.



CAUTION!
All parameters and alarm limits must be suitable for the patient's needs and tolerance.

CAUTION!
Additional measures to supervise the patient weight loss is recommended when treating low weight patients or when performing long treatments. For Ultrafiltration details, refer to Technical data and specifications.

Procedure

1) Check that the blood path is lit and that treatment time is counting down. If this is not the case, check that the venous blood line is correctly placed in the priming detector.

2) Press the flashing **Blood pump** button to restart the blood pump.

3) Adjust the blood flow rate using the **Blood pump up** and **Blood pump down** buttons.

4) Press the flashing `Ultrafiltration` button to start ultrafiltration.

5) Press the flashing `Arterial` pressure control to centralise the alarm limits around the actual value.

6) Press the flashing `Venous` pressure control to centralise the alarm limits around the actual value.

7) Check that the venous drip chamber is filled to the correct level, and that the short lines on the top of the chamber are clamped.

4.3 End a double needle treatment

4.3.1 End the treatment

When the treatment is finished and treatment time on the screen has counted down to 0:00, an attention will appear.

```
596 Treatment time expired
To discontinue treatment press Confirm.
```

NOTE!
If the remaining treatment time is not already 0:00, press the `Time` indicator and set `Treatment time` to 0:00, to access the normal end the treatment procedure.

NOTE!
To interrupt the treatment, press the `Time` indicator and decrease the treatment time to 0:0.

Procedure

1) Press the attention to confirm end of treatment.
2) Press the `Rinse back` button that appears in the Information field.
3) Press `Confirm`. The blood pump stops.
4) Disconnect the arterial blood line from the access.

WARNING!
Check that the arterial blood line is connected to the rinseback solution to prevent patient blood loss.

5) Connect the arterial blood line to the rinse back solution. Open the clamp on the rinse back line and/or the arterial bloodline.

CAUTION!
Keep an eye on the venous needle and venous pressure during the rinse back, since there is no automatic supervision at this stage.

6) Press the **Blood pump** button to start the blood pump.

7) When the rinse back is finished and the blood pump stops, disconnect the venous blood line from the access.

4.3.2 Confirm disconnect patient

WARNING!
To avoid air infusion, ensure that the patient is physically disconnected from the arterial and venous bloodlines before confirming `Disconnect patient`. When `Disconnect patient` has been confirmed the air detector is deactivated. The patient must not be reconnected.

Procedure

1) Press `Disconnect patient`.

2) Confirm that the arterial and venous blood lines are disconnected.

3) Remove the venous blood line from the priming detector.

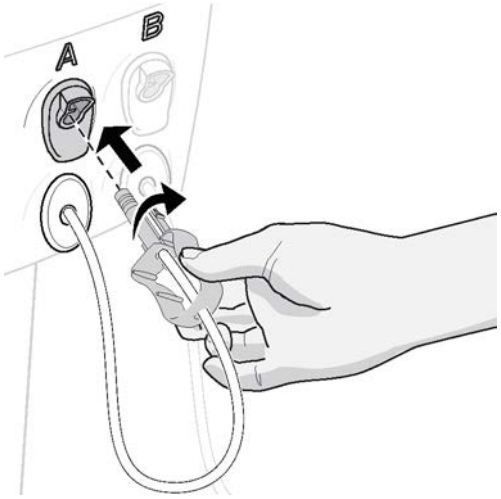
4.3.3 Machine aftercare

Before you begin

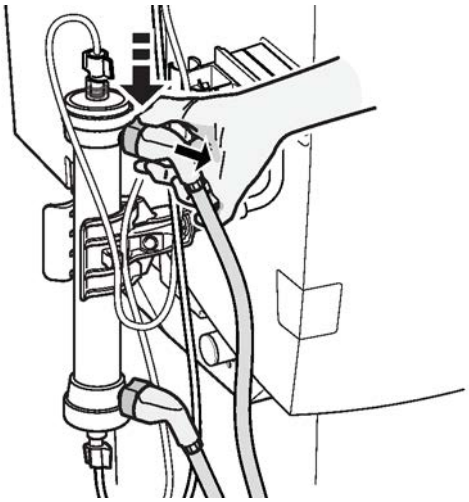
CAUTION!
To ensure that the patient is not connected when doing machine aftercare, check that the arterial and venous blood lines have been completely disconnected from the patient.

Procedure

1) Turn the dialyzer so that the blue connectors are up.



2) Follow instructions on the screen; disconnect the connector from the SoftPac concentrate container or from the pick-up tube and move it to its stand-by port.



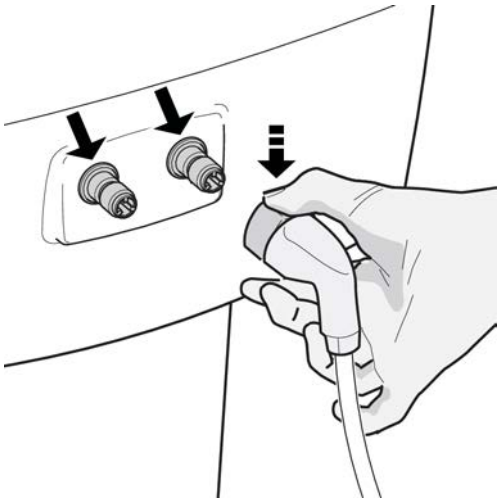
3) Remove the blue (outlet) dialysis fluid tube from the dialyzer and attach it to the blue marked safety coupling. This empties the dialyzer of dialysis fluid.

4) When the dialyzer is empty, remove the red (inlet) dialysis fluid tube from the dialyzer and attach it to the red marked safety coupling.

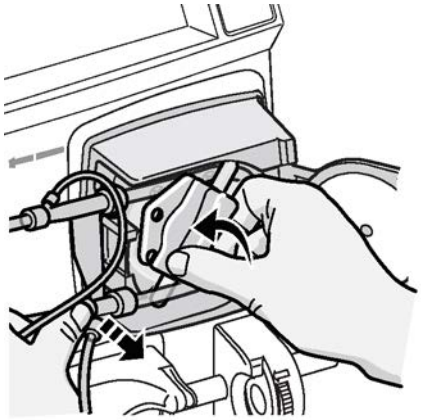
5) Drain the BiCart cartridge by following the instructions on the screen.

6) Remove the BiCart cartridge.

7) Close the BiCart cartridge holder latches.



8) Press the flashing `Disinfection` button to start a disinfection program, see Section 10 “Disinfection and cleaning” on page A:143.



9) Hold the arterial blood line just before the pump segment. Turn the blood pump rotor anticlockwise at the same time as you pull the blood line out.

WARNING!
If any of the pressure transducer protectors on the blood lines contains blood or appears to be damaged, the dialysis machine may be contaminated with blood. An authorised service technician must replace and clean the components in the machine.

10) Open the air detector door. Pinch the venous drip chamber and pull it out.

11) Disconnect and remove the arterial and venous blood lines.

12) **Only for single needle treatment**: Remove the venous expansion chamber together with the blood line set.

This page is intentionally left blank.

5 Haemodialysis - Single needle treatment

5.1 Basic functionality **A:106**

5.2 Preparations **A:106**

5.3 Connect the patient **A:109**

5.4 Start the treatment **A:110**

5.5 End a single needle treatment **A:112**

5.1 Basic functionality

In single needle treatments only one needle is used, but the needle is attached to two blood lines by a Y connector. The patient's blood goes in and out of the body in a cycle with two phases.

1. **The Arterial phase**. The venous blood line is closed. The patient's blood enters the arterial blood line.
2. **The Venous phase**. The arterial blood line is closed. The cleansed blood is returned to the patient via the venous blood line.

Parameters in single needle treatment:

- **Mean blood flow** is the effective mean blood flow rate during the complete arterial and venous cycle.
- **The stroke volume** is the blood volume that passes through the dialyzer during a cycle. A higher stroke volume gives better efficiency.

NOTE!
The volume of the expansion chamber should be as large as possible, and the volume of the saline/blood in the expansion chamber should be as low as possible to allow for a maximised stroke volume.

NOTE!
The stroke volume should be maximised to minimise recirculation.

CAUTION!
Use the correct blood pump rotor. Check that it is adjusted correctly for the occlusion of the blood pump segment being used. This check shall be performed by an authorised service technician.

5.2 Preparations

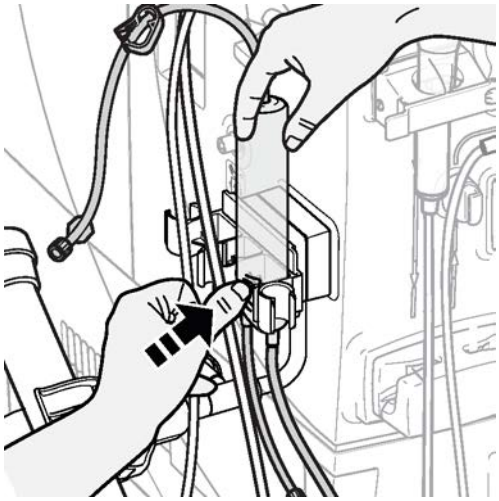
WARNING!
Check that there are no kinks in the blood lines before starting the blood pump to prevent damage to patient blood cells.

When connecting the blood access to the extracorporeal circuit, the operator must ensure that the air detector is activated and the connections between the blood access and blood lines are tightly secured. Check that there is no leakage in the blood lines.

Procedure

1) Perform a check before treatment. Follow the steps in Section 4.2.1 "Check before treatment" on page A:76.
2) Start the functional check. Follow the steps in Section 4.2.2 "Start functional check" on page A:76.
3) Set up the dialysis machine. Follow the steps in Section 4.2.3 "Set up the dialysis machine" on page A:77.
4) Attach the arterial blood line. Follow the steps in Section 4.2.4 "Attach the arterial blood line" on page A:79.

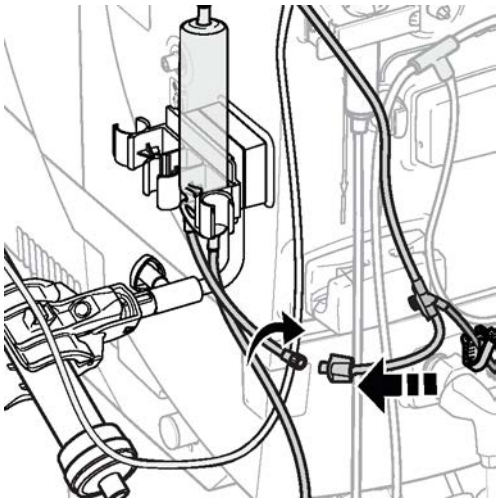
5) Attach the venous blood line. Follow the steps in Section 4.2.5 “Attach the venous blood line” on page A:84, but do not attach the end of the venous blood line to the dialyzer.



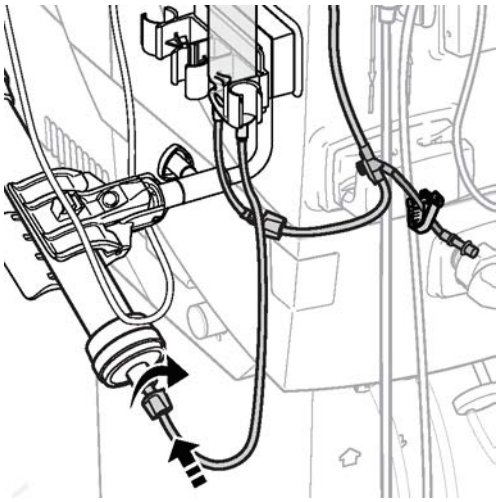
6) Attach the venous expansion chamber.

Place the venous expansion chamber upright in the holder. Make sure that the expansion chamber clicks into its correct position.

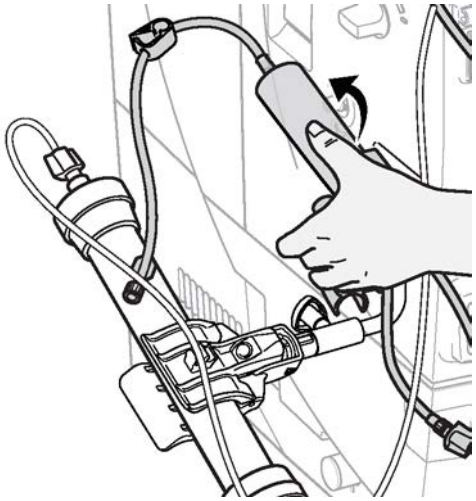
The edge inside the holder should fit into the groove of the expansion chamber.



7) Connect the end of the venous blood line to the expansion chamber blood line.

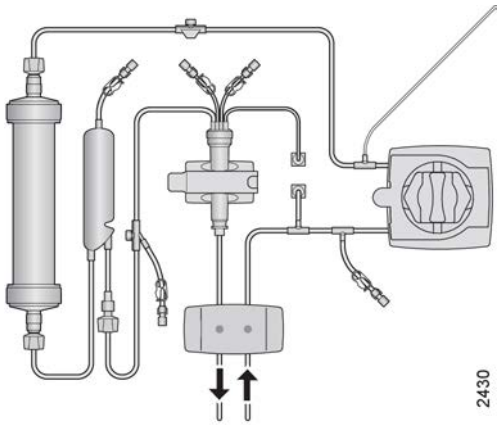


8) Connect the other blood line from the expansion chamber to the dialyzer.

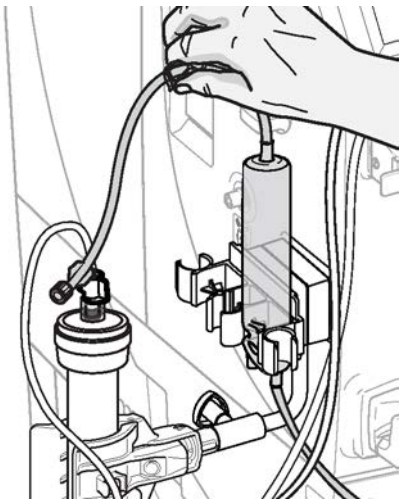


9) Tilt the expansion chamber holder backwards until it clicks into position.

10) Attach the heparin syringe. Follow the steps in Section 4.2.6 “Attach the heparin syringe” on page A:89.



11) Prime the dialysis circuit. Follow the steps in Section 4.2.7 “Priming the dialysis circuit” on page A:91.



12) Check that the venous expansion chamber is filled with priming fluid up to the groove. Close the clamp above the expansion chamber and place the chamber upright again.

13) Set the treatment time. Follow the steps in Section 4.2.9 “Set treatment time” on page A:95.

14) Set the ultrafiltration volume. Follow the steps in Section 4.2.10 “Set ultrafiltration volume” on page A:95.

15) Set the heparin values. Follow the steps in Section 4.2.11 “Set heparin values” on page A:96.

5.3 Connect the patient

WARNING!
Check that the blood lines and the patient access (needle or catheter) are tightly connected. If not, the patient could suffer from blood loss or air embolism.

WARNING!
Check that there are no kinks in the blood lines before starting the blood pump to prevent damage to patient blood cells.

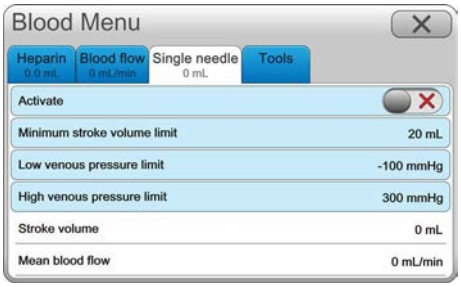
When connecting the blood access to the extracorporeal circuit, the operator must ensure that the air detector is activated and the connections between the blood access and blood lines are tightly secured. Check that there is no leakage in the blood lines.

CAUTION!
Select `Connect Patient` before connecting the blood lines to the access. This allows the machine to detect blood and to start the treatment.

Procedure

1) Check that the expansion chamber is in an upright position.
2) Clamp the priming bag.

3) Press the `Blood` button.



4) Select the `Single needle` tab.
5) Press `Activate`.

6) Press `Confirm`.
7) Connect the blood lines to the access (needle or catheter). Make sure the connection is tight and that there is no leakage.
8) Remove the clamps from the blood lines.

CAUTION!
Check that all relevant clamps are closed to prevent undetected blood loss.

9) Press the flashing **Blood pump** button to start the blood pump. The blood pump will be preset to start at 100 mL/min. Once the blood has passed through the dialyzer and the dialysis machine detects blood at the priming detector, the blood pump will stop automatically.

NOTE!
The blood pump is preset to stop when the priming detector detects blood in the venous blood line and the blood path in the flow diagram lights up.

10) Press the flashing **Blood pump** button to restart the blood pump.

11) Adjust the blood flow rate using the **Blood pump up** and **Blood pump down** buttons.

5.4 Start the treatment

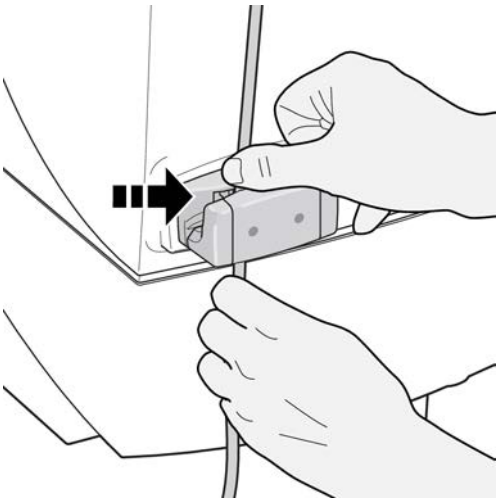
WARNING!
The operator must take proper precaution in order to prevent coagulation in the extracorporeal circuit.

Coagulation may lead to:

- inadequate delivery of dialysis.
- risks associated with movement of blood clots to the patient.
- disabling of the air detector function if blood clots aggregate in the drip chamber.

WARNING!
To avoid patient blood loss and damage to patient blood cells, always follow the manufacturer's instructions for use regarding the dialyzer and blood lines. When attaching the blood lines, ensure that all connections are properly secured and that the blood lines are not kinked. If the heparin pump is not used, make sure that the cap at the end of the thin line used for the heparin solution is closed properly.

CAUTION!
Check that the blood path of the flow diagram lights up. If it does not light up, check that the venous blood line is correctly placed in the priming detector. If the blood path does not light up, the machine considers the patient not connected and as a consequence the UF system is not controlling the patient ultrafiltration. If the air detector has not been activated during priming it will be automatically activated when the priming volume is achieved.



CAUTION!
All parameters and alarm limits must be suitable for the patient's needs and tolerance.

CAUTION!
Additional measures to supervise the patient weight loss is recommended when treating low weight patients or when performing long treatments. For Ultrafiltration details, refer to Technical data and specifications.

CAUTION!
It is important to set a correct ultrafiltration rate for the patient, to avoid incorrect fluid removal. Set a minimum ultrafiltration rate according to the instructions for the specific dialyzer.

NOTE!
The blood flow rate is displayed as `SET QB`. `MEAN QB` is the set blood flow rate when the blood pump is running in the arterial phase.

The achieved stroke volume is determined by the size and position of the venous pressure alarm window and the expansion volume. The wider the window and the bigger expansion volume, the greater the stroke volume. The higher the position of the window, the higher the venous flow. The window is automatically set but can be adjusted in such a way that a proper stroke volume is being achieved. Bear in mind that as the venous pressure alarm limits are used to control the arterial and venous phases the extracorporeal circuit must continuously be monitored by visual inspection. A decreasing stroke volume and/or a decreasing mean blood flow rate may indicate clotting or a kinked venous blood line.

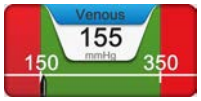
Procedure

1) Check that the blood path on the flow diagram is lit and that the time clock has started to count down.

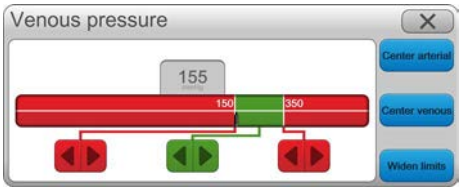
2) Check the blood flow rate. Adjust the blood flow rate using the **Blood pump up** and **Blood pump down** buttons.

3) Press the flashing `Ultrafiltration` button to start ultrafiltration.

4) Press the flashing `Arterial` pressure control to centralise the alarm limits around the actual value.



5) Press the flashing `Venous` pressure control to set the venous pressure alarm limits. Alarm limits for venous pressure are automatically set to +350 mmHg (high limit) and +150 mmHg (low limit).



6) If needed adjust the venous pressure high alarm limit using the arrow buttons to set the desired value.

7) Gradually adjust the venous pressure low alarm limit during the arterial phase, where blood circulates from the patient to the dialysis machine.

8) If necessary, adjust the blood level in the expansion chamber.

5.5 End a single needle treatment

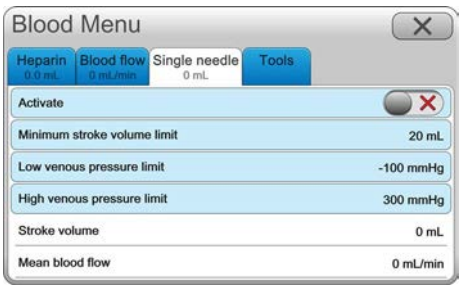
When the treatment is finished and treatment time on the screen has counted down to 0:00, there will be an attention.

```
596 Treatment time expired
To discontinue treatment press Confirm.
```

Procedure

1) Press `Confirm` to confirm treatment time expired.

2) Press the **Blood pump** button to stop the blood pump.



3) Select the `Single needle` tab.

4) Deactivate single needle treatment. Close the menu.

5) End the treatment. Follow the steps in Section 4.3.1 “End the treatment” on page A:100.

6) Remove the dialyzer and the blood lines. Follow the steps in Section 4.3.3 “Machine aftercare” on page A:101.

6 Isolated ultrafiltration

6.1 Basic functionality **A:114**

6.2 Handling isolated ultrafiltration **A:114**

6.2.1 Activate isolated ultrafiltration A:114

6.2.2 How to add a second and subsequent phase of isolated UF A:115

6.2.3 Deactivate isolated ultrafiltration A:115

6.3 Additional information **A:115**

6.3.1 Heparin A:115

6.1 Basic functionality

When performing isolated UF, there is no diffusion. This is because the dialysis fluid in this phase bypasses the dialyzer, and the machine therefore only performs ultrafiltration.

Due to the dialysis fluid bypass during isolated UF, the blood cannot maintain its temperature in the same way as it does during the diffusion phase.

As the UF rate normally is high during the isolated UF phase, high blood flow rate is recommended, within the limits suitable for the patient, to avoid clotting in the dialyzer and the blood lines.

The time and UF volume in isolated UF are added to the diffusion phase and increases the total treatment time and the total ultrafiltration volume .

When the time for the isolated UF phase is finished, the machine will automatically switch to diffusion phase.

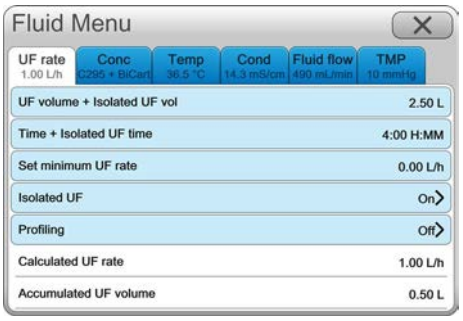
6.2 Handling isolated ultrafiltration

6.2.1 Activate isolated ultrafiltration

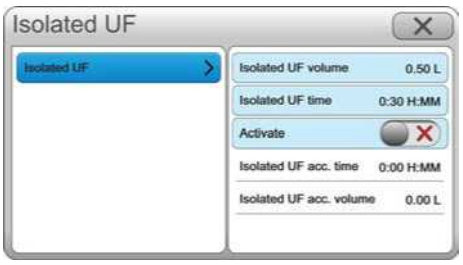
When the settings in Section 4.2.9 “Set treatment time” on page A:95 are being made, set the time and UF volume for the diffusion phase only. Thereafter, make the settings for the isolated UF phase according to the following instructions.

Procedure

1) Press the `Fluid` button.



2) Press `Isolated UF`.



3) Press `Isolated UF volume`. Set the ultrafiltration volume for the isolated UF phase.

4) Press `Isolated UF time`. Set the time for the isolated UF phase.

5) Press `Activate`.

6) Isolated UF will be started when the `Ultrafiltration` button is pressed.

   Follow the instructions in Section 4.2.13 “Start the treatment” on page A:99.

6.2.2 How to add a second and subsequent phase of isolated UF

Second and subsequent phases of isolated UF can be activated at any point during the treatment.

The time and UF volume for the new phase must be added to the previous isolated UF time and UF volume to create a cumulative amount.

Example: If the 1st phase was set to 30 minutes and 0.5L and a second phase is to be set with the same values, the settings need to be 60 minutes and 1.0L which is the total of the two phases together.

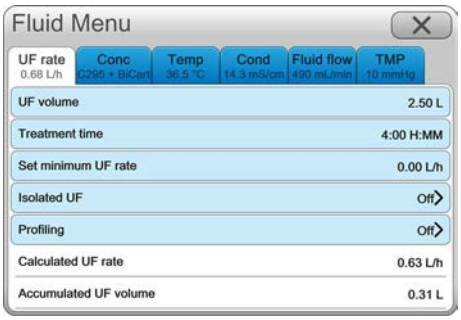
The values set for the second and subsequent phases must always be larger than the accumulated isolated time and UF volume.

6.2.3 Deactivate isolated ultrafiltration

If necessary, isolated UF can be deactivated at any time during the phase.

Procedure

1) Press the `Fluid` button.



2) Press `Isolated UF`.

3) Deactivate Isolated UF.

6.3 Additional information

6.3.1 Heparin

If the heparin pump is used, it will run during the complete isolated UF, unless isolated UF is performed after the diffusion phase. Settings for `Heparin bolus volume`, `Heparin flow rate` and `Stop time` are kept.

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7 Profiling

7.1 General **A:118**

7.2 Profiling of sodium and bicarbonate concentrations **A:118**

7.3 Profiling of ultrafiltration rate **A:119**

7.4 Profiling setting/activation **A:122**

7.5 Profiling without a preset model **A:122**

7.5.1 Profiling ultrafiltration without a preset model A:122

7.5.2 Profiling sodium without a preset model A:123

7.5.3 Profiling bicarbonate without a preset model A:124

7.6 Set and activate profiling with a preset model **A:125**

7.1 General

CAUTION!
The operator has to make sure that the profile chosen is suitable for the patient treated. The profiling parameters have to be checked prior to the treatment.

With profiles it is possible to define patterns for treatment parameters. Predefined profiles can be set-up by an authorised service technician.

The dialysis machine can use profiles for:

- Ultrafiltration rate (UF rate)
- Sodium Na^+ concentration
- Bicarbonate HCO_3^- concentration

Profiles can be activated in a treatment for any combination of these parameters.

7.2 Profiling of sodium and bicarbonate concentrations

Profiles for sodium (Na^+) and bicarbonate ($HCO3^-$) can have either increasing or decreasing concentrations in the dialysis fluid. The concentration adjustment is smooth and constant.

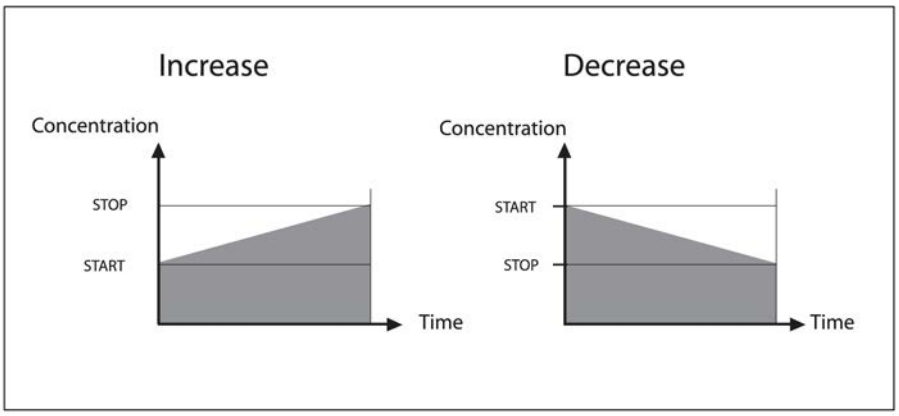


Figure 7-1. Linear graphs for sodium and bicarbonate profiling

NOTE!
If treatment time is changed during sodium and/or bicarbonate profiling the profiling graphs will not change. As a consequence, the set stop values will not be reached if treatment time is decreased.

NOTE!
If sodium and/or bicarbonate profiling is deactivated during treatment, the machine will continue running on the values from the point at which it was stopped. If profiling is reactivated without changed profiling parameters, the machine will continue running from the point where profiling was deactivated.

7.3 Profiling of ultrafiltration rate

There are three available profiles for adjusting the ultrafiltration rate.

- Linear mode
- Step mode
- Interval mode

Changes in the ultrafiltration rate are determined by:

- total UF volume.
- treatment time.
- starting value for the `UF rate`.
- in `Step` mode: `No of steps`.
- in `Interval` mode: `No of intervals`.

Based on these parameters, the machine will perform an adjustment of the `UF rate` during the treatment time when profiling has been activated.

Before activating a profile for ultrafiltration rate, set the patient's ultrafiltration volume and treatment time.

Always check the ultrafiltration profile settings after changing ultrafiltration volume or treatment time when a profile is active, since such changes affect the ultrafiltration rate.

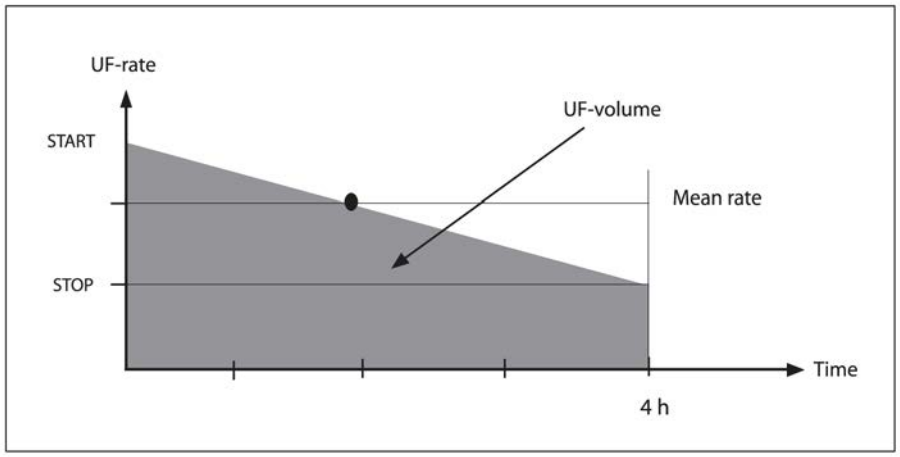


Figure 7-2. Decreasing linear mode for UF rate profiling

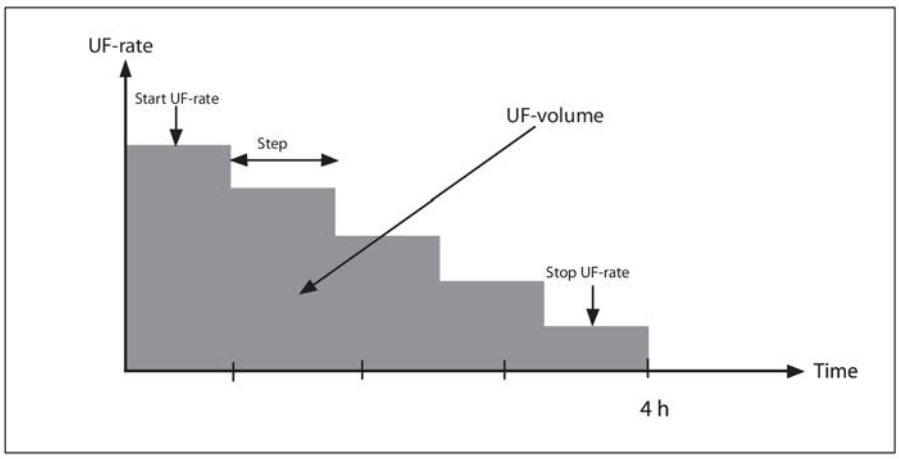


Figure 7-3. Decreasing step mode for UF rate profiling

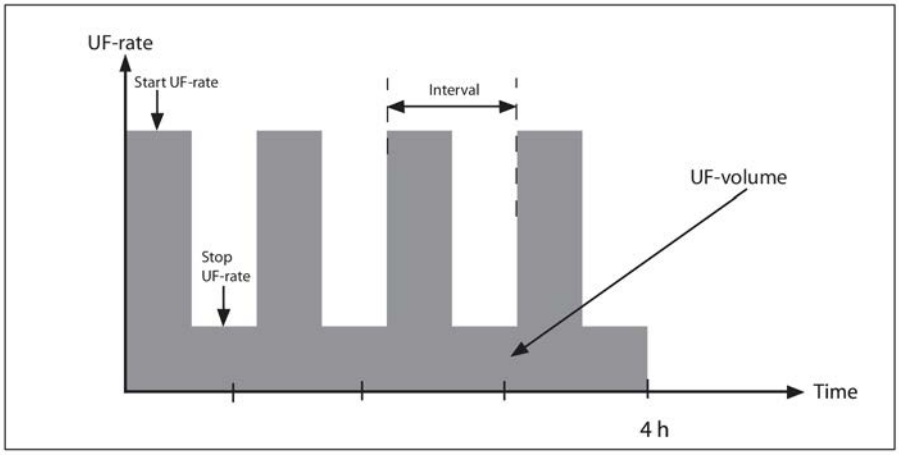


Figure 7-4. Interval mode for UF rate profiling

Below are examples of the ultrafiltration rate in linear mode where treatment time (see Figure 7-6 “UF rate in linear mode when treatment time is changed” on page A:121) or UF volume (see Figure 7-5 “UF rate in linear mode when UF volume is changed” on page A:121) has been changed. Changed rate is shown in grey and original rate in black. When the treatment time is changed and the new stop value reaches the minimum UF rate, the slope will change.

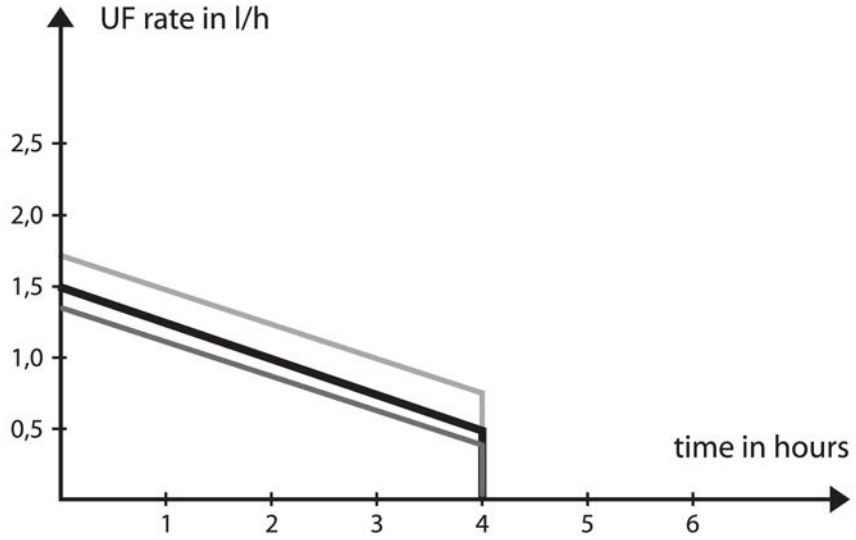


Figure 7-5. UF rate in linear mode when UF volume is changed

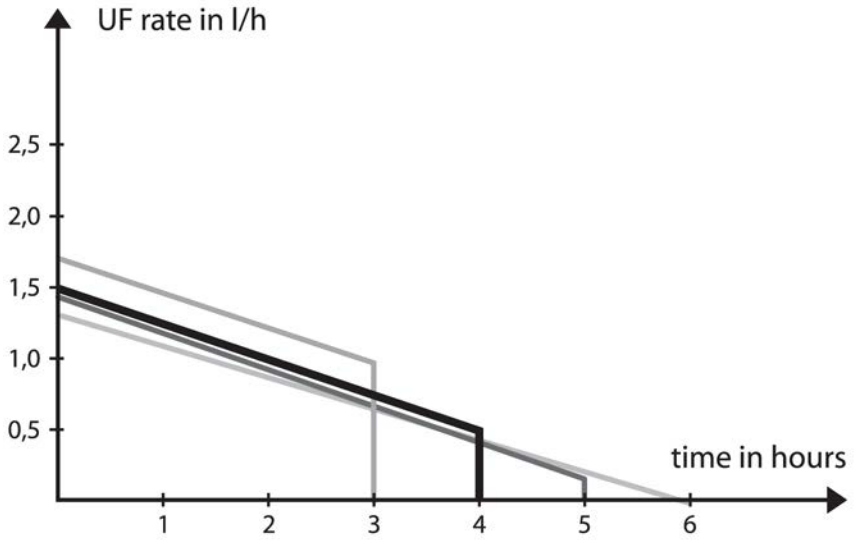


Figure 7-6. UF rate in linear mode when treatment time is changed

NOTE!
If UF volume or treatment time is changed, during activated UF profiling, the profile parameters will automatically change as well. Always check the UF profile settings if UF volume or treatment time is changed when a UF profile is activated, see Section 7.3 “Profiling of ultrafiltration rate” on page A:119

NOTE!
If UF profiling is deactivated during treatment, the machine will recalculate the UF rate according to remaining UF volume and treatment time. If UF profiling is reactivated, without changed profiling parameters, the UF profiling graph will automatically change according to remaining UF volume and treatment time. Always check the UF profile settings after deactivating and reactivating a UF profile.

7.4 Profiling setting/activation

Ultrafiltration profiling can be started at treatment start or at any time during treatment. The model that is to be used can be manually set or be preset by an authorised technician.

Step-by step instructions for the two alternatives are described in Section 7.5.1 “Profiling ultrafiltration without a preset model” on page A:122 and Section 7.6 “Set and activate profiling with a preset model” on page A:125.

Profiling settings

Profiling settings can be done as soon as the machine has been switched on and `Functional check` is shown in the Machine state indicator field. It is possible to manually set a model or just select a preset model. Profiles for sodium (Na^+), bicarbonate (HCO_3^-) and ultrafiltration rate (`UF rate`) can be set/adjusted for each model. The ultrafiltration volume for the treatment must be set before ultrafiltration profiling (`UF volume`) is to be used.

To reach the profiling function for all three profiling parameters: Press the `Fluid` button, select the `UF rate` or the `Cond` tab, and then press `Profiling`.

Activation

The profiling function can be activated at the same time as all of the other patient prescription parameters are being set before the treatment, or at any other time desired during treatment. When UF profiling has been activated it is possible to change the UF profiling settings without first deactivating profiling. However, changing sodium (Na^+) and/or bicarbonate profiling settings cannot be done without first deactivating profiling. The UF profiling function starts to be active when blood has been detected in the venous line and the `Ultrafiltration` button has been pressed.

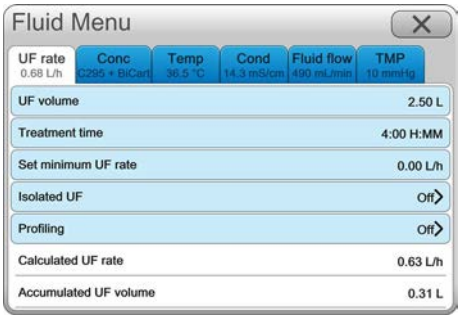
NOTE!
If isolated UF is to be used, when profiling has been activated, the profiling will be paused during the isolated UF phase. `Profiling` will still be displayed on the screen. When the isolated UF phase is complete, the profiling will automatically be reactivated starting where it was interrupted.

7.5 Profiling without a preset model

7.5.1 Profiling ultrafiltration without a preset model

Procedure

1) Press the `Fluid` button.



2) Select the UF rate tab.

3) Press Profiling.

4) Press UF rate.

5) Press Mode.

6) Select graph method, Linear, Step, or Interval.

7) Press Confirm.

8) If the **profile** is Step or Interval:

Select No of steps or No of intervals, whichever is applicable and adjust according to the prescribed treatment.

9) Set the Start value for UF rate. The Stop value for UF rate will be automatically adjusted in relation to the Start value. This is to keep the previously set UF volume for the following treatment.

10) Press Activate.

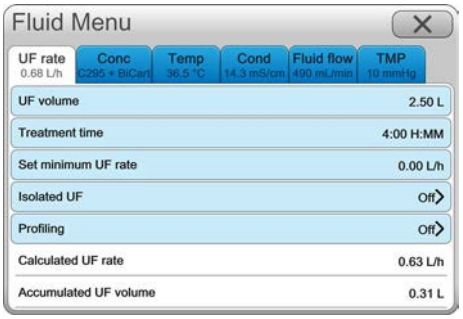
11) Change Na^+ (if applicable). See Section 7.5.2 "Profiling sodium without a preset model" on page A:123.

12) Change HCO_3^- (if applicable). See Section 7.5.3 "Profiling bicarbonate without a preset model" on page A:124.

7.5.2 Profiling sodium without a preset model

Procedure

1) Press the Fluid button.



2) Select the UF rate tab or Cond tab.

3) Press Profiling.

4) Press Na^+.

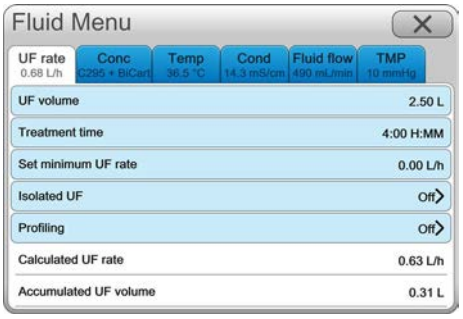
5) Set the Start and/or Stop values.

6) Press Activate.

7.5.3 Profiling bicarbonate without a preset model

Procedure

1) Press the Fluid button.



2) Select the UF rate tab or Cond tab.

3) Press Profiling.

4) Press HCO_3^-.

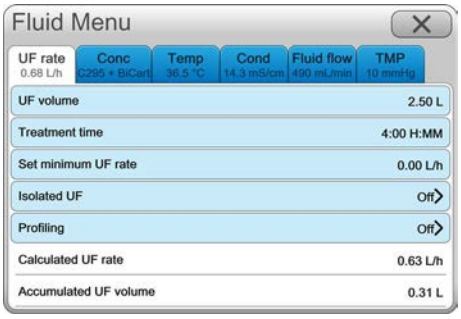
5) Set Start and Stop values.

6) Press Activate.

7.6 Set and activate profiling with a preset model

Procedure

1) Press the `Fluid` button.



2) Select the `UF rate` tab.

3) Press `Profiling`.

4) Press a preset model, `Model 1`, `Model 2` or `Model 3`.

5) Check that the preset values in the model are correct.

6) Activate the profiling model. If desired, it is possible to activate the profiling function at any time during priming or treatment.

   The parameter settings of the complete model will be activated simultaneously. It is possible to adjust the preset values of the parameters when the profiling model is deactivated, refer to Section 7.5.1 “Profiling ultrafiltration without a preset model” on page A:122.

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8 Measuring blood pressure

8.1 Blood pressure monitor (BPM) **A:128**

8.2 Blood pressure cuff **A:128**

8.3 Direct blood pressure measuring **A:130**

8.4 Interval blood pressure measuring **A:130**

8.5 Measurement history **A:131**

8.6 Set alarm limits **A:131**

8.7 Patient care during blood pressure measuring **A:132**

8.7.1 All patients A:132

8.7.2 Patients with high blood pressure A:133

8.7.3 Patients with arrhythmia A:134

8.1 Blood pressure monitor (BPM)

CAUTION!
The manufacturer advises the user that the information originating from the Blood Pressure Monitor cannot be used alone as a unique source of information to induce any therapeutic or pharmacological actions.

CAUTION!
Check that the blood circulation in the arm is not affected due to blood pressure measurement checks.

CAUTION!
The Blood Pressure Monitor shall be used only for adult patients or for children with a paediatric cuff as other patient groups are not proven for use intended for this Blood Pressure Monitor.

CAUTION!
The Blood Pressure Monitor shall not be used for infant or neonatal patients as the Blood Pressure Monitor is not proven for use with this patient group.

CAUTION!
The Blood Pressure Monitor is not proven for use with pregnant or pre-eclamptic patients.

CAUTION!
A blood pressure reading can be affected by the conditions of the measurement site.

CAUTION!
The performance of the blood pressure monitor can be affected by extremes of temperature, humidity or altitude.

NOTE!
The blood pressure monitoring feature is not available on all product configurations of the AK 98 dialysis machine.

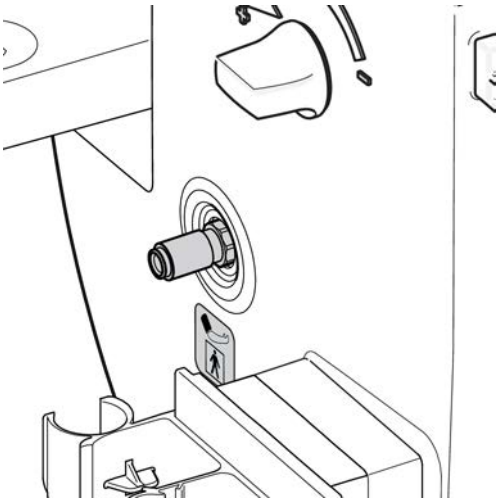
The Blood Pressure Monitor (BPM) measures blood pressure and pulse rate. The BPM is used to monitor the blood pressure of the patient in order to warn about hypotension or hypertension.

To start measuring, go to the instruction you need:

- Section 8.3 “Direct blood pressure measuring” on page A:130
- Section 8.4 “Interval blood pressure measuring” on page A:130
- Section 8.6 “Set alarm limits” on page A:131

8.2 Blood pressure cuff

The cuff for measuring blood pressure is attached to the side of the dialysis machine.



Use a cuff that is the right size for the patient. Wrap the cuff tight on the arm of the patient. One finger should fit between the cuff and the arm.

The middle of the cuff should be at the same level as the heart of the patient.

For more information about how to apply the cuff and how to connect it to the dialysis machine, see the package insert leaflet supplied with the cuff.

Do not apply the cuff on:

- a limb with an access, for example a fistula or a graft.
- a limb with intravascular access, therapy, or arterio-venous (A-V) shunt.
- a limb that is monitored with a pulse oximetry sensor.
- a limb with restricted blood flow.
- a limb with an intravenous line in place.
- a wound.
- an arm on the same side as a mastectomy.

CAUTION!
Do not touch the BPM cuff or cuff hose if a defibrillator is being discharged, as doing so may cause electric shock.

CAUTION!
In the event of accidental wetting of the BPM cuff or cuff hose connections, wipe immediately to prevent moisture from entering the machine.

CAUTION!
No protective means against burns to the patient are provided when the BPM is used together with high frequency (HF) surgical equipment.

CAUTION!
Substitution of a replaceable component may result in measurement error. Always use the replacement components recommended by the manufacturer.

CAUTION!
Pressurisation of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.

CAUTION!
To ensure proper measurement avoid compression or restriction of the connection tubing.

CAUTION!
If the patient has other monitoring devices on the same arm as the cuff, these devices may not work as they should while the blood pressure is measured.

CAUTION!
Do not apply a cuff to a limb that has restricted blood flow as this may affect the blood pressure measuring.

CAUTION!
Do not apply a cuff to a limb with an access, for example a fistula or a graft as this may have a negative effect of the fistula or graft.

8.3 Direct blood pressure measuring

Procedure

1) Press the BPM readout field.

   The measurement starts. The heart in the read out field starts flashing and BPM is flashing in the status bar.

   NOTE!
   First inflation pressure is 180 mmHg.

Results

The measured value appears in the BPM read out field.

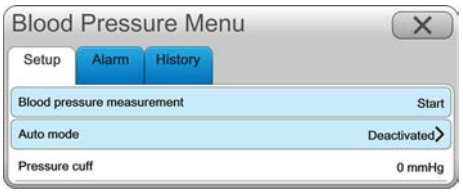
To stop measuring: Press the BPM read out field to stop an ongoing measurement.

8.4 Interval blood pressure measuring

Procedure

1) Press the BPM button.

2) Select the Setup tab.



3) Press Auto mode.

4) Press Interval time.

5) Set how often the blood pressure monitor should measure blood pressure, a value between 5 and 60 minutes.

6) Press OK.

7) Press Activate to activate interval blood pressure measurement.

Results

The latest measured value is available in the BPM read out field.

The dialysis machine measures blood pressure at the set intervals, starting when the first interval has passed. For example, if you set to measure with 20 minutes intervals, the first measuring will start after 20 minutes.

It is possible to start a single measurement at any time between the intervals if necessary. The next measurement will then be delayed and start 20 min after the single measurement (if 20 min intervals is set).

When a single measurement is running or auto mode is activated no BPM alarms will be generated if the BPM alarm off symbol is lit in the status bar.

To stop an ongoing measurement: press the `BPM` button to open `Blood Pressure Menu` and press `Blood pressure measurement` or press the readout field on main screen.

When treatment has ended, and the cuff has been removed from the patient:

- The blood pressure measurement will continue as set, when automatic blood pressure measuring has been activated.
- When the next functional check is started, the machine will return to displaying default values.

8.5 Measurement history

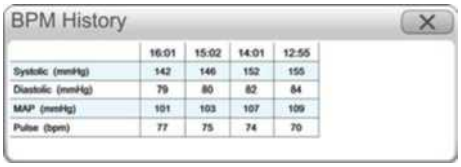
The blood pressure measurments are logged and saved during the treatment. The measurement data is viewed in the `History` tab.

Procedure

1) Press the `BPM` button.

2) Select the `History` tab.

3) Press `History`.



8.6 Set alarm limits

It is possible to set high and low alarm limits for systolic, diastolic and mean blood pressure as well as pulse rate.

An alarm will occur if a value is outside the set alarm limits.

Procedure

1) Press the BPM button.

2) Select the Alarm tab.

3) Press Set limits.

4) Select the alarm limits you want to set. Enter the alarm limit value.

5) Press OK.

6) Repeat step 4 and 5 for all of the alarm limits you want to set. Close the Set Limits menu.

7) Press the activate button for alarm limits to activate the new settings.

8.7 Patient care during blood pressure measuring

8.7.1 All patients

CAUTION!
Check the material used in cuff before use to avoid allergic symptoms. Allergic symptoms caused by the fabric material of the cuff could lead to exanthema and urticaria with swollen skin and intense itching in the cuff area.

CAUTION!
Check the material used in cuff before use to avoid allergic symptoms. Multiple or few petechia (small purple spots containing blood) on the forearm following the application of the cuff which may lead to decrease of thrombocytes in the blood. Inflammation of a vein (phlebitis) may be observed.

CAUTION!
Continuous cuff pressure due to kinks in the connection tubing may result in blood flow interference and cause harmful injury to the patient.

CAUTION!
Too frequent blood pressure measurements may cause injury to the patient due to blood flow interference.

CAUTION!
Do not apply a blood pressure cuff over a wound, as this can cause further injury to the patient.

CAUTION!
Do not apply a blood pressure cuff to any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present. Doing so may result in temporary interference to blood flow and can cause injury to the patient.

CAUTION!
Do not apply a blood pressure cuff on the arm on the side of a mastectomy as this may affect the blood pressure measuring.

CAUTION!
A blood pressure reading can be affected by the position of the patient (standing, sitting, lying down) or recent exercise.

CAUTION!
A blood pressure reading can be affected by the patient's physiological condition.

CAUTION!
Environmental or operational factors can affect the performance of the Blood Pressure Monitor and/or its blood pressure reading, for example arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, shivering, common arrhythmias (such as atrial or ventricular premature beats, or atrial fibrillation).

The patient should preferably not move or talk during measuring, since it may affect the result. The patient should be comfortably seated or lying down.

Check that the blood circulation in the patient’s arm is not affected.

Blood pressure can be affected by the patient's physiological condition, for example arterial sclerosis, poor blood circulation, diabetes, age or renal diseases.

Risk factors:

- After measuring blood pressure some patients get small purple spots containing blood on the forearm. It could lead to fewer thrombocytes in the blood, or inflammation of a vein.
- Check that the connection tube to the cuff is not twisted or knotted, since the cuff may then continue to put pressure on the patient’s arm. This is harmful to the patient and affects the blood flow.
- Measuring a patient’s blood pressure too often can be harmful and affects the blood flow.

8.7.2 Patients with high blood pressure

CAUTION!
During hypertension the operator shall always continuously monitor the blood pressure reading and have the patient under direct observation.

CAUTION!
To obtain accurate resting blood pressure measurements for patients with the condition hypertension, the patient shall be comfortably seated, with legs uncrossed and feet flat on the floor. The patients back and arm shall be supported. The middle of the cuff should be at the same level as the right atrium of the heart. It is recommended that the patient relax and refrain from talking during the measurement procedure.

CAUTION!
To obtain accurate resting blood pressure measurements for patients with the condition hypertension, the patient should rest for five minutes before the first reading is taken.

Patients should rest for five minutes before the measuring. During the measuring they should be relaxed, comfortably seated, legs uncrossed and feet flat on the floor. Back and arm should be supported.

8.7.3 Patients with arrhythmia

Do not use the AK 98 blood pressure measurement device for patients with arrhythmia.

9 DIASCAN

9.1 How DIASCAN function works A:136

9.2 What DIASCAN function checks A:136

9.3 Check K and Kt A:136

9.4 Check Kt/V A:137

9.5 Measurement history A:138

9.6 Set a Kt/V target value A:139

9.7 Set an alarm for low K or Kt/V A:140

9.8 Factors that affect measuring A:140

9.1 How DIASCAN function works

NOTE!
The DIASCAN feature is not available on all product configurations of the AK 98 dialysis machine.

The DIASCAN function measures clearance.

The DIASCAN function can be used to:

- review the current dialysis efficiency for the ongoing treatment
- check that the prescribed dialysis dose is being maintained which provides quality assurance for the treatments
- constantly calculate if the desired and minimum values for Kt/V, set by the operator for each individual patient, can be reached at treatment end.

The conductivity of the dialysis fluid is measured before and after the dialyzer. Based on these measurements the clearance for sodium is calculated, which gives a representative clearance value for small molecules. Each waste substance in the blood has its own specific clearance that depends on the properties of the waste substance and the characteristics of the dialyzer.

Clearance data generated by the machine has been validated with clearance data which is based on blood urea data collected during dialysis.

Reference: Relationship Between Effective Ionic Dialysance and In Vivo Urea Clearance During Hemodialysis. Robert M Lindsay, Bernard Bene, Nicholas Goux, A. Paul Heidenheim, Christina Landgren and Jan Sternby American Journal of Kidney Diseases, vol.38, No.3 (September), 2001: pp 565-574.

9.2 What DIASCAN function checks

When the treatment has started, the dialysis machine can measure and calculate these parameters:

- **clearance (K)** — how much blood is cleaned per time unit (mL/min), this is related to the dialyzer used and the blood flow rates.
- **clearance multiplied by treatment time (Kt)** — the volume of blood that has been cleaned so far in the treatment.
- **clearance multiplied by treatment time and divided with patients fluid distribution volume (Kt/V)** — the patient's dialysis dose. When Kt/V is 1.0, all of the patient's fluid distribution volume has been cleaned once.

To start checking clearance, go to the instruction you need:

- Section 9.3 "Check K and Kt" on page A:136
- Section 9.4 "Check Kt/V" on page A:137

9.3 Check K and Kt

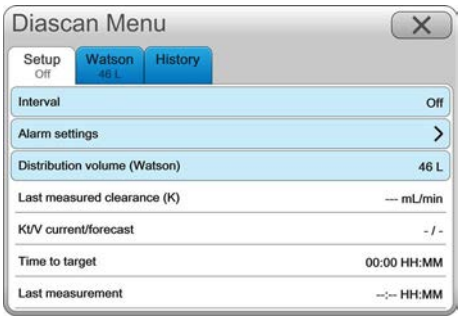
The dialysis machine can measure clearance (K) and calculate Kt as a single measurement or at intervals.

NOTE!
The dialysis machine needs a certain amount of time to measure. Do not start single measutement if there is less than 30 minutes left of the treatment time.

Procedure

1) Press the `Diascan` button.

2) Select the `Setup` tab.



3) Press `Interval`.

4) Select `60 minutes`, `30 minutes` or `Single`.

5) Press `OK` to start the measurement.

Results

The result of the measuring is displayed in the clearance measurement readout field.

The clearance measurement readout field shows:

- latest measured clearance value.
- time of latest measuring.
- current/estimated end of treatment Kt.
- the `Diascan` button (opens the Diascan menu).

9.4 Check Kt/V

The dialysis machine can calculate Kt/V as a single measurement or at intervals.

If Kt/V measurement is required, distribution volume has to be set before the measurement check takes place. The distribution volume is patient-related (based on the patient's dry weight) and has to be properly estimated and set by the operator in order to obtain a correct Kt/V value.

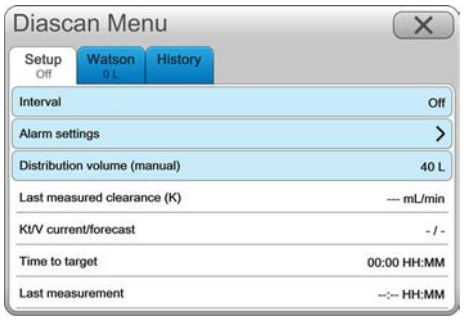
Distribution volume is the urea distribution volume in litres (water in the body), estimated for the individual patient, and based on the patient’s dry weight. The estimation is based on certain formulae used for this purpose, chosen by the prescribing physician responsible for the patient. The distribution volume has to be set by the machine operator in order for a correct Kt/V value to be obtained.

! **NOTE!**
To get a reliable Kt/V value, it is very important that the dialysis machine calculates with an accurate distribution volume for the patient. Therefore fill in the patient information with care in Distribution volume.

NOTE!
The dialysis machine needs a certain amount of time to measure. Do not start single measutement if there is less than 30 minutes left of the treatment time.

Procedure

1) Press the `Diascan` button.



2)
- If **the patient's distribution volume is known**, press `Distribution volume (manual)`, in the `Setup` tab, and set the volume.
- If you want to **calculate the patient's distribution volume**, select the `Watson` tab and then press `Enter parameters`.

3) Enter information about the patient in the settings shown on the screen.

4) Select the `Setup` tab.

5) Press `Interval`.

6) Select `60 minutes`, `30 minutes` or `Single`.

7) Press `OK` to start the measurement.

Results

The result of the measuring is displayed in the clearance measurement readout field.

The clearance measurement readout field shows:

- last measured clearance value.
- time of latest measurement.
- current/estimated end of treatment Kt/V.

The `Diascan` button (opens the Diascan menu).

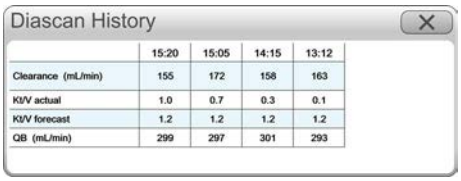
9.5 Measurement history

Procedure

1) Press the `Diascan` button.

2) Select the History tab.

3) Press History. The view in Diascan History will be different if distribution volume has not been added.



9.6 Set a Kt/V target value

It is possible to set the desired Kt/V target for the patient to have achieved at the end of the treatment. This value is called **Kt/V target**.

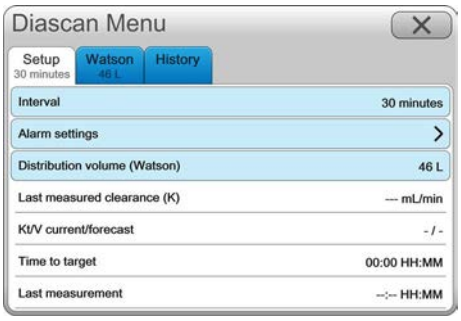
NOTE!
Before setting a Kt/V target, the dialysis machine needs to know the patient's distribution volume. See Section 9.4 "Check Kt/V" on page A:137.

Procedure

1) Press the Diascan button.

2) Select the Setup tab.

3) Press Alarm settings.



4) Press Kt/V target.

5) Enter a target value for Kt/V.

6) Press OK.

7) Press Activate and close the menu.

Results

The dialysis machine estimates how much treatment time is left before it can reach the target value. You can see this `Time to target` in the Diascan menu.

9.7 Set an alarm for low K or Kt/V

The dialysis machine can alarm if the K value drops below a certain limit, and/or if the Kt/V is estimated to end at a limit lower than the set Kt/V limit.

NOTE!
Before setting a Kt/V target, the dialysis machine needs to know the patient's distribution volume. See Section 9.4 "Check Kt/V" on page A:137.

Procedure

1) Press the `Diascan` button.

2) Select the `Setup` tab.

3) Press `Alarm settings`.

4) Press `K limit` and/or `Kt/V limit`.

5) Enter a value to act as limit and trigger for the alarm.

6) Press `OK`.

7) Press `Activate` and close the menu.

9.8 Factors that affect measuring

CAUTION!
Medical decisions must not only be based on information from the DIASCAN function, as there are many other factors which should be taken into account.

The factors below affect the measuring.

Double or single needle treatment: The measuring results are more reliable in double needle treatments.

Profiling: The clearance measurement can be affected if profiling of sodium and bicarbonate is active.

Ultrafiltration (UF): It is not possible to measure clearance when isolated ultrafiltration or ultrafiltration in steps or intervals is active.

Handling that affect the clearance measurement:

- Changing the blood flow rate
- Pressing the **Blood pump** button
- Pressing the `Ultrafiltration` button
- Pressing the `Fluid bypass` button
- Changing the sodium or bicarbonate values in the dialysis fluid
- Changing the temperature of the dialysis fluid
- Changing the flow rate of the dialysis fluid
- Changing the UF volume
- Changing the linear UF profiling settings
- Activating or deactivating linear UF profiling
- Activating or deactivating sodium or bicarbonate profiling
- Activating isolated UF
- An alarm sending dialysis fluid to bypass the dialyzer
- An alarm stopping the blood pump

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10 Disinfection and cleaning

10.1 Disinfection and cleaning – general **A:144**

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10.1 Disinfection and cleaning – general

In order to maintain a high microbiological quality of the dialysis fluid, it is important that you tend to the hygiene and maintenance of the machine.

Clean and disinfect the dialysis machine only according to the recommendations in this operator's manual.

It is recommended that you choose integrated heat disinfection when possible, since this program also disinfects the inlet water tubing. See Section 10.3.7.1 "Integrated heat disinfection" on page A:147 and Section 11.2 "Integrated heat disinfection with a WRO 300 H unit" on page A:160.

WARNING!
To ensure proper functionality of the dialysis machine, preventive maintenance shall be performed according to instructions in Section 1.2.1 "General precautions before use" on page A:15.

CAUTION!
No further cleaning and disinfection other than that described in this chapter shall be performed by the operator/user of the machine. The casing must only be opened by an authorised service technician, refer to the AK 98 Service manual.

There are different programs for cleaning and disinfecting the dialysis machine:

- Heat and cleaning programs
  - Heat disinfection
  - Cleaning
  - Decalcification
- Chemical disinfection
- Rinse

Failure to clean and disinfect the machine according to recommendation may lead to patient reactions due to endotoxins.

10.2 Check before you start

CAUTION!
Before starting a chemical disinfection program, check that there is enough disinfectant in the container for the program. If not, the machine will not be properly disinfected.

Check this before you start any kind of cleaning or disinfecting activity:

- The dialysis fluid tubes are connected to the safety couplings.
- The latches for the BICART cartridge holder are closed to avoid fluid leakage from the machine.
- The concentrate connectors are placed in their corresponding stand-by ports.
- The arrangement of the drain connection from the machine, i.e. there must be a sufficient air gap between the drain tube of the machine and the drainage system to avoid back contamination from the drainage system.

NOTE!
For best results when cleaning (CLEANCART A cartridge or sodium hypochlorite), perform a decalcification first.

NOTE!
The pick-up tubes must be rinsed/disinfected separately. See Section 13.5 "Pick-up tubes" on page A:173 for instructions.

When disinfection is completed

- An operator message appears when the disinfection program is complete. To start a new treatment: Press `Confirm` to reset previous values and start the functional check.

! **NOTE!**
You can stop a disinfection program at any time. The machine will interrupt the procedure and finish off with a rinse and drain phase.

Stopping a disinfection program

- To stop a disinfection program: Press the `Disinfection` button.

- Select the tab with the actual disinfection program.
- Press `Stop` for the actual disinfection program.

Set the machine to switch off after completed program

Press the **On/Off** button for three seconds while a program is running to set the dialysis machine to switch off after the program is completed.

- The machine can also be preset by an authorised service technician to automatically switch off after a complete program.

10.3 Heat disinfection

10.3.1 Description of heat disinfection

During the heat disinfection program the inlet water is heated up and flushed through the fluid monitor. The AK 98 dialysis machine fluid path is constructed in a way that prevents possible contaminants in the post-dialyzer fluid path from reaching the patient.

Heat disinfection reduces the number of viable microorganisms. The program can be combined with cleaning and decalcification.

A heat disinfection begins with a rinse in order to rinse out possible residues from concentrates used in the last treatment, followed by the circulation phase. The circulation phase consists of a number of cycles, during each cycle heated water is passed through all parts of the fluid path.

10.3.2 Cleaning and decalcification

Cleaning and decalcification are always done with a heat disinfection program. Cleaning or decalcification solution is mixed with water, heated and flushed through the fluid path during the heat disinfection program. A decalcification (CLEANCART C cartridge or liquid citric acid) program cannot be replaced by a chemical disinfection program.

The cleaning solution can be a CLEANCART A cartridge cleaning solution or sodium hypochlorite. These alternatives remove fat, protein and organic material.

The decalcification solution can be a CLEANCART C cartridge solution or liquid citric acid. These alternatives remove calcium-carbonate deposits.

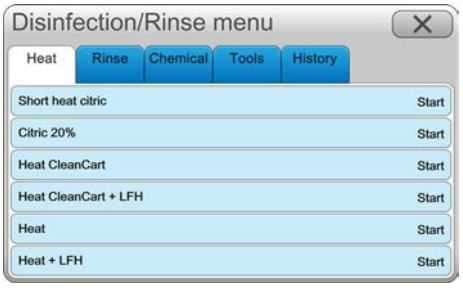
NOTE!
For the best cleaning results, start with a decalcification.

10.3.3 Start a heat disinfection

Procedure

1) Press the `Disinfection` button.

2) Select the `Heat` tab.



3) Press `Heat`.

4) Press `Confirm`.

10.3.4 Start a heat disinfection with a CLEANCART cartridge

Procedure

1) Press the `Disinfection` button.

2) Select the `Heat` tab.

3) Press `Heat CleanCart`.

4) Press `Confirm`.

5) When you are prompted by an attention:

   Attach the CleanCart cartridge to the holder.

10.3.5 Start a heat disinfection with liquid citric acid

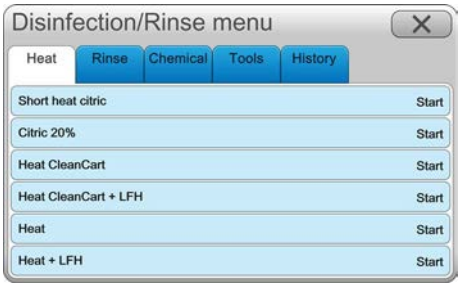
Procedure

1) Press the `Disinfection` button.

2) Select the `Heat` tab.

3) Press `Citric 20%`.

4) Make sure that the disinfectant inlet tube is placed in the disinfectant solution.



NOTE!
Only liquid citric acid shall be used from the back of the machine. Liquid citric acid shall never be used from the front of the machine.

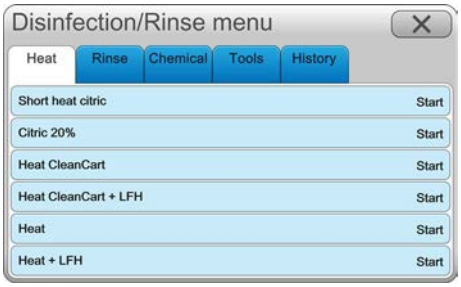
5) Press `Confirm`.

10.3.6 Start a short heat disinfection with liquid citric acid

Procedure

1) Press the `Disinfection` button.

2) Select the `Heat` tab.



3) Press `Short heat citric`.

4) Make sure that the disinfectant inlet tube is placed in the disinfectant solution.

NOTE!
Only liquid citric acid shall be used from the back of the machine. Liquid citric acid shall never be used from the front of the machine.

5) Press `Confirm`.

10.3.7 Integrated heat disinfection

10.3.7.1 Integrated heat disinfection

The dialysis machine can be scheduled to perform a heat disinfection that is integrated to the central water system.

During a heat disinfection program the machine receives hot water from the central water system. It is recommended that the program is scheduled to start automatically, during the heating of the central water supply system. The program can also be started manually.

The advantage with heat disinfection with hot water from the central water system is that both the inlet water tube and the machine are disinfected.

10.3.7.2 To schedule a heat disinfection program

It is possible to schedule the dialysis machine to run a heat disinfection any day of the week.

Set the time for when the disinfection shall finish.

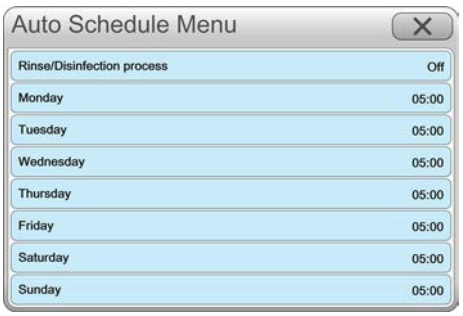
Procedure

1) Press the `Disinfection` button.

2) Select the `Tools` tab.

3) Press `Auto schedule`.

4) Press `Rinse/Disinfection process`.



5) Select `Heat`.

6) Press `OK`.

7) Select day.

8) Set the time when the program should finish.

9) Press `OK`.

10) To schedule more days in the week: repeat steps 7-9.

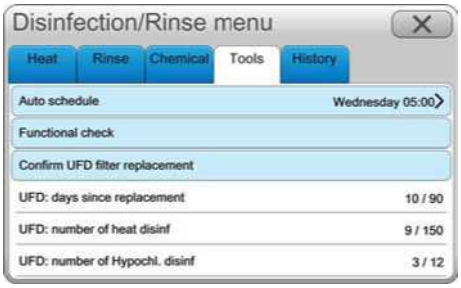
11) To perform a heat disinfection with CleanCart cartridge: Place a CleanCart cartridge into the cartridge holder before the disinfection starts.

10.3.7.3 To turn off a scheduled program

Procedure

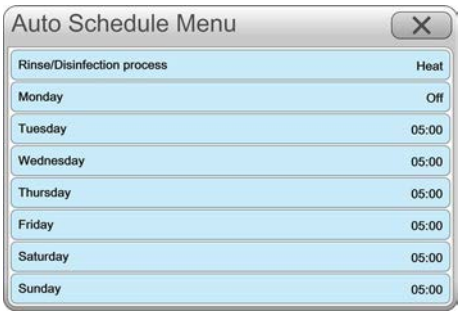
1) Press the `Disinfection` button.

2) Select the `Tools` tab.



3) Press `Auto schedule`.

4) Select day.



5) Press `Off`.

6) Press `OK`.

10.3.8 Integrated heat disinfection with a WRO 300 H unit

10.3.8.1 Integrated heat disinfection with a WRO 300 H unit

An integrated heat disinfection program has an extra phase compared to normal heat disinfection. In this phase hot water from the water purification unit WRO 300 H slowly flows through the dialysis machine. This means that also the inlet water tube is disinfected. Therefore, choose integrated heat disinfection if possible. For more information, see Section 11 “Disinfection with the AK 98 dialysis machine and WRO system” on page A:159

10.4 Chemical disinfection

10.4.1 About chemical disinfection

During the chemical disinfection program the machine is filled with a concentrated disinfectant . Concentrated disinfectant is mixed with water to the correct concentration in the machine. The diluted solution fills all parts of the fluid path. After a certain time (dwell time) the fluid path is rinsed and drained.

Heat disinfection can be replaced by chemical disinfection. But note that decalcification (CLEANCART C cartridge or liquid citric acid) cannot be replaced by chemical disinfection.

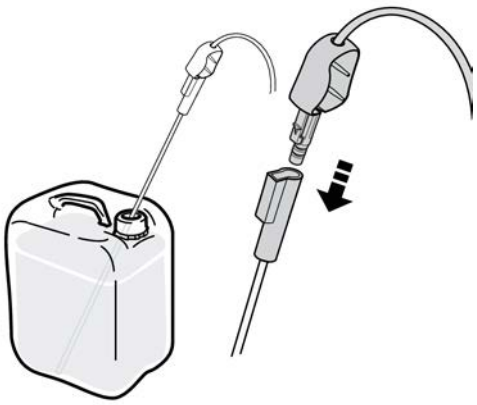
10.4.2 Start a chemical disinfection

Procedure

1) Press the `Disinfection` button.

2) Select the `Chemical` tab.

3) Select disinfectant.



4) Connect the disinfectant. From the **front** of the machine: connect the **blue** concentrate connector to the **yellow** pick-up tube.

5) Place the pick-up tube in the disinfectant solution.

6) Follow instructions on the screen.

WARNING!
After a chemical disinfection program, a test for residues shall be performed prior to connecting a patient to the dialysis machine to make sure that no residues exist in the dialysis machine.

10.4.3 Start a central chemical disinfection

In a central chemical disinfection the disinfectant comes from the central water supply system.

This function has to be preset by an authorised service technician.

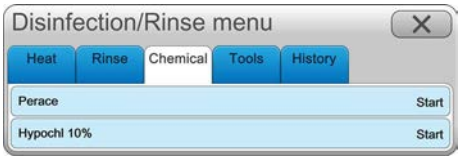
Procedure

1) Press the `Disinfection` button.

2) Select the `Chemical` tab.

3) Select the disinfectant that is set for central administration.

4) When you get an attention that the dwell time is over, and you have confirmed that no disinfectant is circulated in the central water system the machine starts a rinse program.



WARNING!
After a chemical disinfection program, a test for residues shall be performed prior to connecting a patient to the dialysis machine to make sure that no residues exist in the dialysis machine.

10.4.4 Chemical disinfection program with a WRO unit

The dialysis machine and a WRO water purification unit can work together and do an integrated chemical disinfection. Both the dialysis machine and the WRO unit must be preset by an authorised service technician. For more information, see Section 11 “Disinfection with the AK 98 dialysis machine and WRO system” on page A:159.

10.4.5 Test for disinfectant residues

After a chemical disinfection the dialysis machine shall be tested for disinfectant residues. The fluid path must not contain chemical disinfectant residues, which can cause harm to a patient.

Use an appropriate test method, either with proven sensitivity for the chemical or recommended by the manufacturer of the chemical disinfectant. Limit values for levels of disinfectant residues are specified by the clinic or by national standards.

Procedure

1) Press the **On/Off** button to start the dialysis machine.

   When functional check is completed with the proper concentrates attached, and the green fluid path lights up:

2) Press the `Fluid bypass` button.

3) Collect a test sample of the dialysis fluid from the fluid outlet tube going to the dialyzer.

4) If the test shows disinfectant residues:

   Remove and discard the BiCart cartridge and disconnect the Liquid A concentrate.

5) Press the `Disinfection` button.

6) Select the `Rinse` tab.

7) Press `Rinse`.

8) Press `Confirm`.

9) When the program is completed:

   Restart the machine, attach Bicart cartridge and Liquid A concentrate and repeat the test for disinfectant residues.

Results

If the machine is found to repeatedly contain disinfectant residues, contact an authorised service technician.

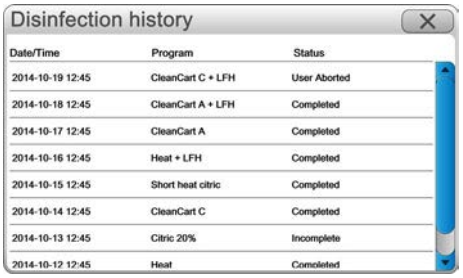
10.4.6 Disinfection history

Procedure

1) Press the `Disinfection` button.

2) Select the `History` tab.

3) Press `History`.



4) The following information is shown in the `Disinfection history` menu.

- `Date/Time`: shows which day the disinfection program was performed and what time the disinfection program finished.
- `Program`: type of disinfection program.
- `Status`: shows if the disinfection program was completed.

10.4.7 About chemical disinfectants

CAUTION!
Chemical disinfectants may be toxic to humans and also harmful to the fluid path, if not used properly. Chemical disinfectants can foam and be difficult to rinse from the dialysis machine and shall only be used in accordance with this manual.

CAUTION!
Be aware of the precautions for a certain chemical disinfectant before you use it. Follow the manufacturer's instructions and recommendations, as well as local regulations for how to use it.

CAUTION!
Remaining spillage of disinfectants may negatively affect the surface of the machine. Wipe up any disinfectant spilled on the dialysis machine. Use a damp cloth.

CAUTION!
Store chemical disinfectants according to the manufacturer's recommendations.

Using the right disinfectant

The dialysis machine tolerates disinfectants based on peracetic acid (such as the DIALOX and DIALOX HP disinfectants) and sodium hypochlorite, provided you use them as intended. For information about different disinfectants, for example dwell times, concentrations, consumption and mixing instructions, see Section 14.1.10

“Disinfection and cleaning – chemical disinfection” on page A:180. For information about efficiency, see Section 10.7.1 “Disinfection, Decalcification and Cleaning Agents - Characteristics” on page A:156.

10.5 Rinse and Drain

10.5.1 Start rinse or drain

Procedure

1) Press the `Disinfection` button.

2) Select the `Rinse` tab.

3) Press `Rinse` or `Drain`.

4) Press `Confirm`.

Results

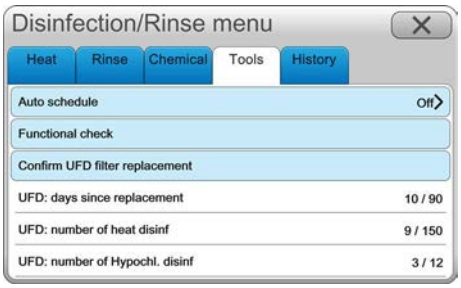
The `Rinse` program ends with a `Drain` phase.

10.5.2 To schedule a rinse program

Procedure

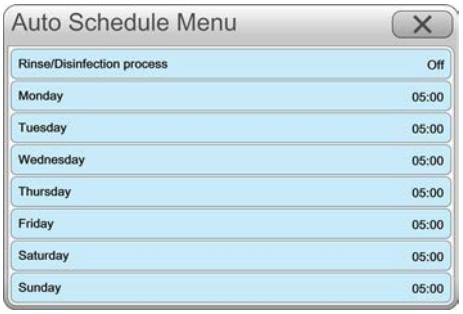
1) Press the `Disinfection` button.

2) Select the `Tools` tab.



3) Press `Auto schedule`.

4) Press `Rinse/Disinfection process`.



5) Select `Rinse`.

6) Press `OK`.

7) Select day.

8) Set the time when the program should finish.

9) Press `OK`.

10) To schedule more days in the week: repeat steps 7-9.

10.5.3 To turn off rinse program for a certain day

Procedure

1) Press the `Disinfection` button.

2) Select the `Tools` tab.

3) Press `Auto schedule`.

4) Select day.

5) Press `Off`.

6) Press `OK`.

10.6 Machine storage with chemical disinfectant

10.6.1 Fill the dialysis machine with chemical disinfectant

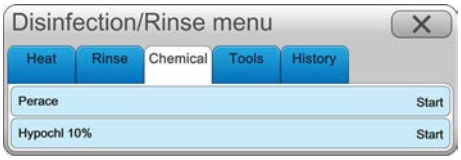
If the dialysis machine is not to be used for more than 7 days it is recommended to fill it with a chemical disinfectant before storage. It is recommended to use peracetic acid as disinfectant during storage.

This function has to be preset by an authorised service technician.

Procedure

1) Press the `Disinfection` button.

2) Select the `Chemical` tab.



3) Select disinfectant.

4) Connect the disinfectant. From the **front** of the machine: connect the **blue** concentrate connector to the **yellow** pick-up tube.

5) Place the pick-up tube in the disinfectant solution.

WARNING!
After a chemical disinfection program, a test for residues shall be performed prior to connecting a patient to the dialysis machine to make sure that no residues exist in the dialysis machine.

6) Press the **On/Off** button to schedule the dialysis machine to stop after the disinfection fill-up is completed.

7) When the disinfection fill-up phase is completed there is an attention (or the machine stops).

8) Remove the pick-up tube from the disinfectant solution and return the blue concentrate connector to its stand-by port.

10.6.2 Start using a dialysis machine filled with chemical disinfectant

WARNING!
After a chemical disinfection program, a test for residues shall be performed prior to connecting a patient to the dialysis machine to make sure that no residues exist in the dialysis machine.

A dialysis machine that has been stored with chemical disinfectant must be disinfected and rinsed before use.

Procedure

1) Press the **On/Off** button.

2) The dialysis machine automatically starts a disinfection and rinse program.

   An operator message appears when the disinfection program is ready.

3) To start a **new treatment**: Press `Confirm` to reset previous values and start the functional check (extended).

To **switch off** the machine: press the **On/Off** button for 3 seconds.

10.7 Reference

10.7.1 Disinfection, Decalcification and Cleaning Agents - Characteristics

The Table 10-1 “Disinfection, decalcification and cleaning” on page A:156 summarises the characteristics of some generic substances used for internal disinfection, decalcification and cleaning of the AK 98 dialysis machine. For more specific information about a certain commercial product, see manufacturer's information. A recommended schedule for cleaning and disinfection is found in Section 10.7.2 “Cleaning and disinfection schedule” on page A:156

Table 10-1. Disinfection, decalcification and cleaning

	Efficiency on inorganic precipitates		**Efficiency on organic precipitates fats, proteins**	**Efficiency of disinfection**
	Calcium	**Iron oxide**		
CLEANCART C cartridge and heat	High	Low	Medium	High
CLEANCART A cartridge and heat	None	None	High	High
Peracetic acid 0.01 to 0.15 %	Low[a]	None	None	High
Citric acid liquid 2 % and heat	High	Low	Medium	High
Sodium hypochlorite 0.5 %	None	None	High	High

[a] Peracetic acid is not reliable when used alone. Use CLEANCART C cartridge, citric acid or acetic acid regularly.

The test procedure by which the effectiveness of cleaning and disinfection has been verified is available on request from the local Baxter representative.

10.7.2 Cleaning and disinfection schedule

The schedule in Table 10-2 “Cleaning and disinfection schedule” on page A:157 is recommended for use by the operator/user of the AK 98 dialysis machine. This recommendation is to keep a high level of performance of the machine. It is a guideline for maintaining the hygiene of the fluid path and the exterior of the machine to ensure the safety of the patient.

WARNING!
To avoid cross patient infection it is recommended that you wipe the outside of the machine with disinfectant after each treatment.

Table 10-2. Cleaning and disinfection schedule

Frequency	Activity	Result
After each treatment	1. Run a heat disinfection program (with or without citric acid), or a short heat citric program. 2. Wipe the outside of the dialysis machine with 70% ethanol or 60% isopropanol. 3. Rinse the outside and flush the inside of the pick-up tubes with water. Let them dry naturally.	Disinfection
At least after every 3rd treatment	1. Run a heat disinfection program together with CleanCart C cartridge.	Cleaning Decalcification Disinfection
At least once every 7th treatment day	1. Run a chemical disinfection program with sodium hypochlorite. A heat disinfection program together with CleanCart C cartridge shall be performed before a sodium hypochlorite program. **or** 1. Run a heat disinfection program together with CleanCart C cartridge. 2. Run a heat disinfection program together with CleanCart A cartridge 3. Wipe the outside and flush the inside of the pick-up tubes with 70% ethanol. Let them dry naturally.	Cleaning Decalcification Disinfection
When more than 7 days passed since last disinfection	1. Run a heat disinfection program before treatment.	Disinfection
Every 1-3 months if UFD is installed	1. Change the ultrafilter. 2. Run a heat disinfection program.	Disinfection

Additional constraints if ultrafilter U9000 is used:

- Disinfection using sodium carbonate, e.g. CLEANCART A cartridge, shall not be performed before periods when the machine is inactive, e.g. storage over weekend.
- The recommended process of heat disinfection using CLEANCART A cartridge shall be followed by heat disinfection using CLEANCART C cartridge the same (working) day and shall preferably be performed in the middle of the working week.

10.7.3 Flow path

During treatments, the flow path can be soiled by **calcium-carbonate** from the dialysis fluid, or **fat**, **protein**, and **organic material** from the patient. The dialysis machine has decalcification and cleaning programs to take care of this, see Section 10.3 “Heat disinfection” on page A:145.

The number of treatments and the setting of parameters will influence the amount of deposits downstream of the dialyzer.

An increased level of cleaning may be necessary, depending on the conditions described above. To see a general schedule for cleaning, go to Section 10.7.2 “Cleaning and disinfection schedule” on page A:156.

NOTE!
If you need to both decalcify and clean the flow path, start with the decalcification and then do the cleaning.

NOTE!
If ultrafiltration values are not correct, you may need to clean the UF cell. Clean the UF cell once a week using heat disinfection program with CLEANCART A cartridge.

11 Disinfection with the AK 98 dialysis machine and WRO system

11.1 General description **A:160**

11.2 Integrated heat disinfection with a WRO 300 H unit **A:160**

11.2.1 Description of integrated heat disinfection with a WRO 300 H unit A:160

11.2.2 Schedule an integrated heat disinfection A:160

11.2.3 Start an integrated heat disinfection manually A:160

11.3 Central chemical disinfection program with a WRO unit **A:161**

11.3.1 Description of central chemical disinfection program with a WRO unit A:161

11.3.2 Start a central chemical disinfection with a WRO unit A:161

11.4 Settings for rinse **A:163**

11.4.1 Rinse settings A:163

11.1 General description

The AK 98 dialysis machine and the WRO water purification unit is a system that can perform integrated heat disinfection and central chemical disinfection. An interface cable is used to connect the AK 98 dialysis machine with the WRO unit. The cable is ordered separately.

11.2 Integrated heat disinfection with a WRO 300 H unit

11.2.1 Description of integrated heat disinfection with a WRO 300 H unit

The AK 98 dialysis machine and a WRO water purification unit can be preset to perform an integrated heat disinfection program. Both the dialysis machine and the WRO unit must be preset by an authorised service technician.

The integrated heat disinfection procedure includes the following phases:

- Heat disinfection of the AK 98 dialysis machine.
- “Low Flow Heat” (LFH), where all wet parts between the AK 98 dialysis machine and the WRO unit are exposed to hot water at a low flow rate.
- Heat disinfection of the WRO 300 H unit, if this has been selected as preset on the WRO unit.

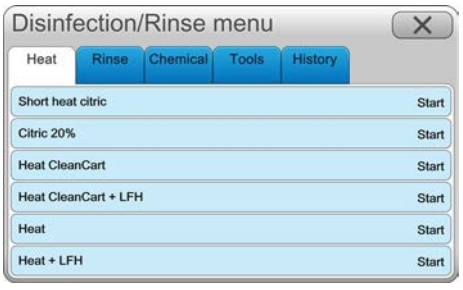
The dialysis machine can be set to start a scheduled integrated heat disinfection.

11.2.2 Schedule an integrated heat disinfection

Procedure

1) Check that the WRO 300 H unit is switched on.
2) Press the `Disinfection` button.

3) Select the `Heat` tab.
4) Press `Heat` or `Heat + LFH`.



11.2.3 Start an integrated heat disinfection manually

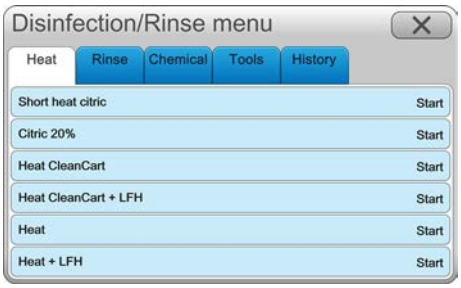
Procedure

1) Check that the WRO 300 H unit is switched on.

   The following steps are made in the AK 98 dialysis machine.

2) Press the `Disinfection` button.

3) Select the `Heat` tab.



4) Select the preferred disinfection program.

5) Press `Confirm`.

6) If an automatic switch off is required, press the **On/Off** button for three seconds.

7) An operator message will be displayed when the disinfection is completed.

8) Press the **On/Off** button for three seconds to switch off the machine.

11.3 Central chemical disinfection program with a WRO unit

11.3.1 Description of central chemical disinfection program with a WRO unit

The dialysis machine and a WRO water purification unit (WRO 300 H, WRO 300) can be preset to perform a central chemical disinfection program. Both the dialysis machine and the WRO unit must be preset by an authorised service technician.

11.3.2 Start a central chemical disinfection with a WRO unit

WARNING!
After a chemical disinfection program, a test for residues shall be performed prior to connecting a patient to the dialysis machine to make sure that no residues exist in the dialysis machine.

The following steps are made in the AK 98 dialysis machine.

Procedure

1) Press the `Disinfection` button.

2) Select the `Chemical` tab.

3) Select the preferred central disinfection program.

The following steps are made in the WRO unit.

4) Check that the WRO 300 unit is switched on.

5) As soon as the LED test sequence is completed: Press the `CHEM DISINF` button on the WRO unit.

6) Select the central chemical disinfection program.

7) Press the `CHEM DISINF` button on the WRO unit until the light goes on.

   When the central chemical disinfection program has started the remaining disinfection time is shown in the time indicator on the screen of the dialysis machine.

8) Immediately insert the wand connector into the chemical intake port of the WRO unit, press firmly and turn the connector to lock. Check that the connector is securely in place.

9) `CHEM SELECT` is now shown in the display of the WRO unit.

10) The `Disinfection` button starts to flash. Press `CENTR_CH_98`.

11) Initiate the disinfectant intake by pressing the Disinfection button until it lights up (steady light).

    A few low inlet water alarms may occur on the dialysis machine, these should be disregarded.

12) Press the **On/Off** button **on the dialysis machine** for three seconds to activate the automatic switch off.

    When the intake phase is completed (10-20 minutes depending on program) the buzzer will sound.

    The `Mute` button will flash and 401 REMOVE WAND will be displayed on the WRO unit.

13) Press the `Mute` button on the WRO unit to silence the buzzer.

14) Leave the wand in the disinfectant container and disconnect the wand connector from the WRO unit. Let the disinfectant from the line and wand flow back into the container and then clamp the line.

15) Remove the wand from the container and flush it with water.

16) The chemical disinfection procedure of the WRO unit will now continue with Dwell period followed by Rinse. The WRO unit then goes to standby.

17) Rinse of the dialysis machine.

- Auto rinse, if selected, will take place at the preset time.
- If the dialysis machine is to be manually rinsed this can now be initiated at any time on the dialysis machine.

18) Perform a test for residual chemicals. See Section 10.4.5 “Test for disinfectant residues” on page A:151.

11.4 Settings for rinse

11.4.1 Rinse settings

The rinse in the integrated chemical disinfection program can either be performed manually or automatically at a pre-defined time (Auto rinse). Auto rinse requires a communication cable between the units. For Auto rinse, the desired ready time (day, hour, minute) must be set in the program. Auto rinse must be activated before the dialysis machine is switched off.

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12 IT Connectivity

12.1 Basic functionality **A:166**

12.2 Confirmed Patient ID and retrieval of patient prescription when the Patient ID is confirmed **A:166**

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12.4 Clearing Patient ID and patient prescription **A:168**

12.5 Setting treatment parameters manually **A:169**

12.6 Setting Station ID **A:169**

12.7 Unconfirmed patient with data transfer only **A:170**

12.1 Basic functionality

The AK 98 dialysis machine can be configured to communicate with the CIS, Clinical Information System. If configured, the AK 98 dialysis machine will send treatment data regularly to the CIS. Depending on the CIS, three levels of support can be configured:

1. Confirmed Patient ID and retrieval of patient prescription when the Patient ID is confirmed.
2. Confirmation of the patient's ID from CIS.
3. Unconfirmed patient with data transfer only.

12.2 Confirmed Patient ID and retrieval of patient prescription when the Patient ID is confirmed

To be able to retrieve patient information and prescription, the AK 98 dialysis machine needs to be correctly configured and connected to the CIS, Clinical Information System.

CAUTION!
When retrieving patients from the CIS make sure that the retrieved patient is identical to the patient to be treated.

CAUTION!
To avoid outdated information in the Patient Comments field add the date of when entering the information to the CIS.

Patient ID can be retrieved during the whole treatment session.

A patient prescription can be retrieved until treatment is started or until the prescription is confirmed.

Procedure

1) Press the `Patient` button.

2) The Patient menu window is shown.

Press the `Patient ID` button.

3) The Patient ID dialog is shown.

Enter the patient's ID and press `OK`

Figure 12-1. A list of patients is retrieved from CIS.

Figure 12-2. One patient is retrieved from CIS.

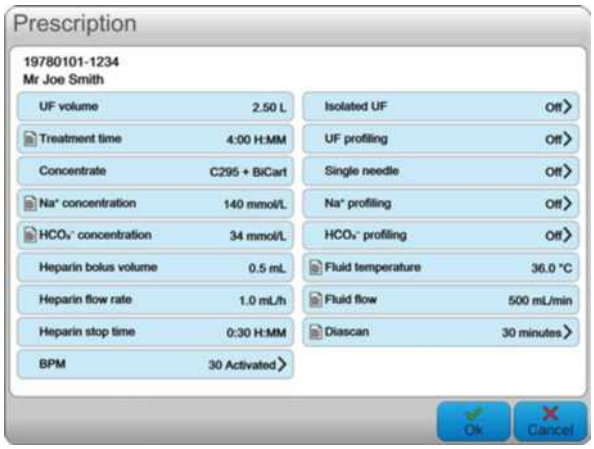
4) A patient identification dialog is shown. CIS can retrieve up to five patient in return.

Select the correct patient in the list, see Figure 12-1 "A list of patients is retrieved from CIS." on page A:167.

In case only one patient is retrieved it is selected by default, see Figure 12-2 "One patient is retrieved from CIS." on page A:167

CAUTION!
Before pressing `Confirm`, make sure that the Patient ID is correct.

5) Press `Confirm` to accept that correct patient data has been retrieved.

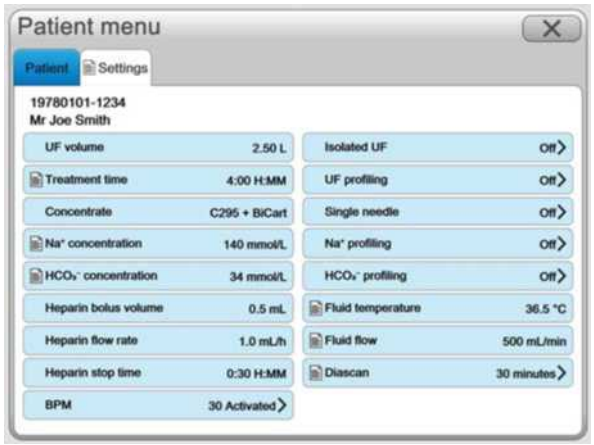


6) The Prescription dialog is shown.

The prescription icon indicates the treatment parameters retrieved from CIS. Treatment parameters without the prescription icon have the default settings.

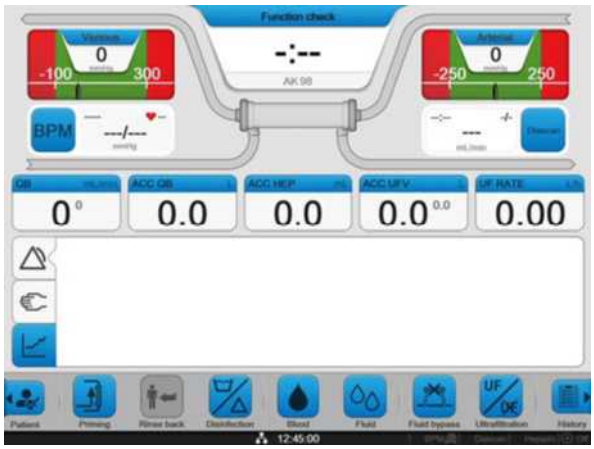
If the prescription icon looks like this the treatment parameters has been changed.

Verify that all required treatment settings have been made correctly and then Press `OK` to set the treatment parameters in the machine.



7) The prescription icon will be shown at the Setting tab and in front of the patient name in the Patient menu.

In the main window the icon in the patient button will be filled black completed with a checkmark.



12.3 Cancel prescription retrieval

If `Cancel` is pressed the identified patient and the patient prescription will be discarded and all set parameters will revert to default.

To retrieve the prescription again repeat the steps in Section 12.2 “Confirmed Patient ID and retrieval of patient prescription when the Patient ID is confirmed” on page A:166.

A prescription can be retrieved until treatment is started or until the prescription is confirmed.

12.4 Clearing Patient ID and patient prescription

The treatment parameters will revert to default/startup values if the `Clear` button is pressed before the treatment starts. If the `Clear` button is pressed when the AK 98 dialysis machine is in treatment mode, only the patient's ID will be cleared. Parameter settings will remain unchanged.

Procedure

1) Press the `Clear` button to remove the patient's ID and prescription data.

   If the machine is in treatment mode only the patient's ID is cleared.

2) Press `Confirm`.

12.5 Setting treatment parameters manually

In the Patient menu under the Settings tab the treatment parameters can be entered manually.

The treatment parameters can also be set in the Blood menu and the Fluid menu, see Section 3.4.19 “Blood button (24)” on page A:62 and Section 3.4.20 “Fluid button (25)” on page A:64.

12.6 Setting Station ID

It is possible to set a Station ID that indicates where the AK 98 dialysis machine is located at the clinic.

The Station ID is saved togheter with the patient treatment data.

Procedure

1) Press the `Station ID` button.

2) A Station ID dialog is shown.

   Enter a Station ID in the dialog and press `OK`.

12.7 Unconfirmed patient with data transfer only

If the AK 98 dialysis machine is configured to not handle patients it is still possible to label the information sent to the CIS, Clinic Information System by entering a patient ID.

Procedure

1) Press the `Patient` button.

2) The Patient menu window is shown.

Press the `Patient ID` button.

A dialog is shown where a Patient ID can be entered.

3) Enter the patient´s ID number and press `OK`.

No confirmation from CIS is shown.

13 Maintenance handling

13.1 Maintenance **A:172**

13.2 Blood Pump Rotor **A:172**

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13.1 Maintenance

The contents of this chapter concerns the maintenance of the AK 98 dialysis machine that can be carried out by the operator of the machine.

Maintain the dialysis machine according to recommendations in AK 98 Operator's manual.

CAUTION!
To ensure proper functionality of the dialysis machine, only perform maintenance activities that are described in AK 98 Operator's manual.

CAUTION!
To ensure proper functionality of the dialysis machine, only an authorised service technician should open the casing and do repairs and modifications.

CAUTION!
Do not use the dialysis machine if it is damaged in any way, or does not work as described in this operator's manual.

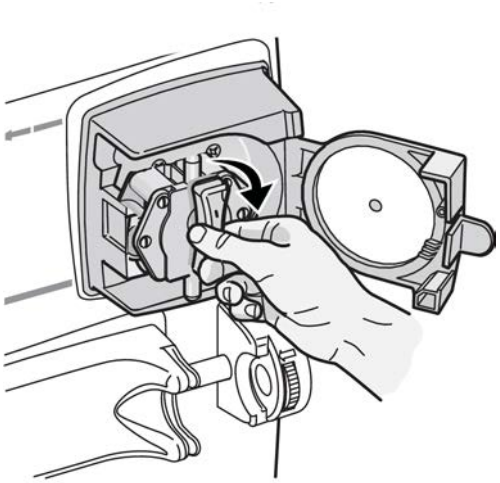
13.2 Blood Pump Rotor

13.2.1 Maintenence of the blood pump rotor

Clean the blood pump rotor when it is dirty.

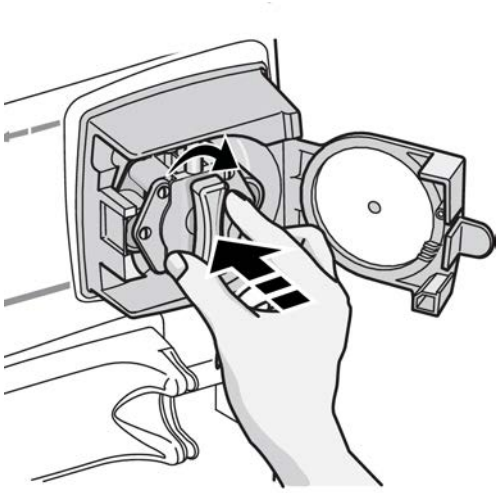
13.2.2 Clean the blood pump rotor

Procedure



1) To open the pump cover: pull the opening tab towards you, and at the same time press firmly at the middle of the cover.
2) Turn the handle clockwise until the blood pump rotor loosens.

   Wipe the rotor and the interior of the pump housing with a lint-free cloth, moistened with ethanol (70 %) or isopropanol (60 %).

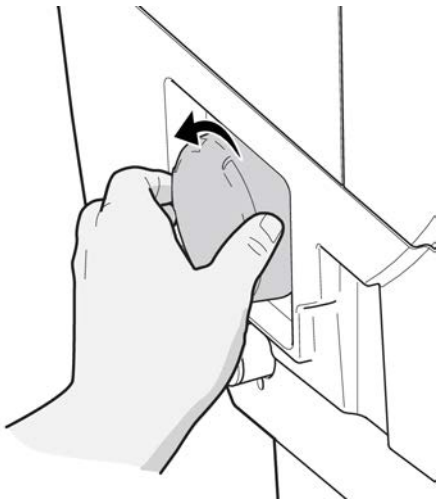


3) Hold the handle and place the rotor on the pump shaft.
4) Grip the rotor and slowly turn it clockwise at the same time as you push slightly.
5) Continue turning until the blood pump handle clicks in.

13.3 Clean the blood leak detector

The detector easily becomes contaminated when the cover is open. The blood leak detector should only be cleaned, after a blood leakage alarm that is suspected to be false.

Procedure



1) Make sure the dialysis machine is turned off.
2) Open the cover.
3) Clean the lenses with a soft lint-free cloth, moistened with disinfectant solution.
4) Make sure the sealing ring on the inside of the cover is in place.
5) Close the cover.

13.4 Water inlet tube

The tube between the water supply system, and the tube into the dialysis machine, are not automatically disinfected by the local disinfection program. It requires either an integrated disinfection together with the water delivery system (see Section 10.3.8.1 “Integrated heat disinfection with a WRO 300 H unit” on page A:149) or a manual disinfection procedure performed by an authorised service technician.

13.5 Pick-up tubes

The pick-up tubes can be soiled by **salts** and **concentrates**. After each treatment, flush the pick-up tube with water. Let them dry naturally – do not wipe them.

Every week, disinfect the pick-up tubes by wiping the outside with 70% ethanol and flushing the inside with 70% ethanol. Let them dry naturally – do not wipe them.

13.6 Surface

After each treatment, you need to clean and disinfect the exterior surface and the top tray of the dialysis machine. Wipe them with a cloth moistened with ethanol (70 %) or isopropanol (60 %).

CAUTION!
In order to protect the internal parts of the AK 98 dialysis machine against spillage, the top tray shall always be placed on top of the machine, except during technical service.

CAUTION!
The leakage detector sensor and leakage detector tray shall on a regular basis be cleaned and inspected for cracks.

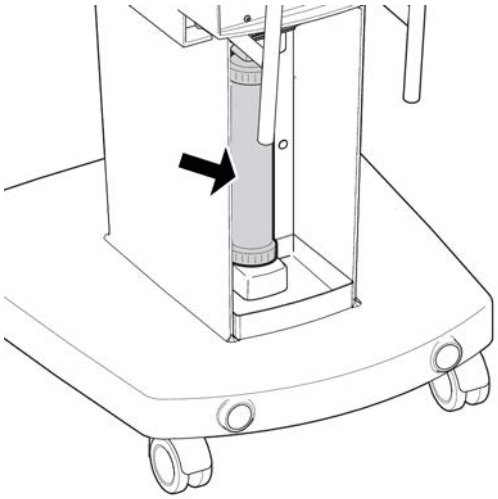
NOTE!
Do not use disinfectants containing tensides or iodine-based disinfectants. Such disinfectants may discolour and cause cracks on the surface of the dialysis machine cabinet.

13.7 Change ultrafilter

WARNING!
Check carefully that there is no leakage from the ultrafilter after changing it.

WARNING!
Before a new treatment can be performed after changing the ultrafilter, the machine must go through a disinfection to ensure the quality of the dialysis fluid.

NOTE!
The ultrafilter is not available on all product configurations of the AK 98 dialysis machine.



Replace the ultrafilter regularly, to maintain high hygienic quality.

NOTE!
Make sure that the ultrafilter is handled in an aseptic way according to the corresponding package insert.

Procedure

1) Pull the handle of the lower latch to open the locking mechanism and press the lower latch downwards.

2) Pull the ultrafilter gently downwards and remove it.

3) Label the new ultrafilter with the actual date.

4) Lubricate the ultrafilter connections with RO-water.

5) Insert the new ultrafilter into the holder and push it gently upwards.

6) Make sure the ultrafilter is pushed all the way upwards.

7) Close the lower latch by pushing it gently upwards until the locking mechanism becomes locked. A distinct "klick" shall be generated.

8) Make sure the lower latch is locked into position by pushing the lower latch upwards without using the handle.

9) Press the `Disinfection` button.

10) Select the `Tools` tab.

11) Press `Confirm UFD filter replacement`.

12) Press `Confirm`.

13) Perform a disinfection of the dialysis machine before a new treatment.

14) Check carefully during and/or after disinfection that there is no leakage from the ultrafilter.

15) Check Fluid leakage detector tray for leakage, and wipe dry if needed.

13.8 Storage

If the dialysis machine is not used for seven days or longer, you have two alternatives:

- Heat disinfect the dialysis machine at least every seventh day. Heat disinfect the dialysis machine just before the first treatment after the storage period.
- Fill the dialysis machine with chemical disinfectant before storage. See Section 10.6.1 “Fill the dialysis machine with chemical disinfectant” on page A:154.

13.9 Service

An authorised service technician should regularly inspect the dialysis machine according to the instructions in the service manual.

An authorised service technician should carry out preventive maintenance at least every other year. How often depends on the environment the dialysis machine is in.

An authorised service technician should carry out general maintenance at least once every second year.

13.10 Disposal

The dialysis machine should be separately collected and not disposed with general waste. For more information, check with your local Baxter representative and national regulations.

14 Technical data and specifications

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14.1 Performance and specification - Control System

14.1.1 Blood flow control

For pump segments with an inner diameter of 3.9 mm to 8.0 mm.

Table 14-1. Double Needle

The blood flow is compensated for arterial pressure when the arterial blood line is connected.	
Flow rate 8 mm pump segment	User settable between 20 to 500 mL/min
Flow rate 3.9 mm pump segment	User settable between 20 to 225 mL/min
Accuracy	For pre-pump pressure range from -200 mmHg to +100 mmHg: ±10 mL/min or ±10 % of the set point value, whichever is the largest

Table 14-2. Single Needle

Flow rate 8 mm pump segment	User settable between 20 to 500 mL/min
Accuracy	For pre-pump pressure range from -200 mmHg to +100 mmHg: ±10 mL/min or ±10 % of the calculated mean value, whichever is the largest
Pressure control	10 to 500 mmHg, venous pressure control

14.1.2 Heparin pump

Table 14-3. Heparin pump specifications

Heparin pump flow rate	User settable 0 - 10 mL/h in step of 0.1 mL
Accuracy	±1 mL/5h or ±5 %, whichever is the largest
Bolus volume	User settable 0 to 10 mL
Accuracy	±0.2 mL or ±5%, whichever is the largest
Syringes size	10-30 mL Syringes shall be compliant to ISO 7886-2 and have a luer lock.

14.1.3 Blood pressure

Table 14-4. Venous Pressure

Alarm limits	User settable between 10 to 500 mmHg in treatment mode User settable between -100 to 500 mmHg in priming mode
Accuracy	±10 % within range -700 to -500 mmHg ±5 mmHg or ±3 %, whichever is largest within range -500 to 500 mmHg ±10 % within range 500 to 750 mmHg

14.1.4 Blood pressure monitor (BPM)

Blood pressure monitoring is only available if the blood pressure monitor is installed.

Rated range for cuff pressure during normal use	0 - 280 mmHg

The alarm limits below can be preset. The value put in brackets and in italics is the default value.

Systolic pressure range	40 - 260 mmHg
Low alarm limit	40 - 260 mmHg *(100 mmHg)*
High alarm limit	40 - 260 mmHg *(180 mmHg)*
Diastolic pressure range	20 - 200 mmHg
Low alarm limit	20 - 200 mmHg *(40 mmHg)*
High alarm limit	20 - 200 mmHg *(110 mmHg)*
Mean pressure range	26 - 220 mmHg
Low alarm limit	26 - 220 mmHg *(45 mmHg)*
High alarm limit	26 - 220 mmHg *(220 mmHg)*
Pulse rate range	30 - 220 bpm (±3 bpm or ±2 % of reading)
Low alarm limit	30 - 220 bpm *(40 bpm)*
High alarm limit	30 - 220 bpm *(130 bpm)*

14.1.5 Dialysis fluid preparation

Table 14-5. Temperature

Temperature	User settable 33 to 40°C
Accuracy	+0.5/-1.5°C (+1.0/-2.5°C with UFD) at the dialysis fluid outlet from the machine, under the condition that dialysis fluid temperature is higher or equal to ambient temperature.
Alarm limits	User settable 32.5 to 40°C

Table 14-6. Flow rate

Dialysis Fluid Flow Rate	User settable 300 to 700 mL/min
Accuracy	±10 % or 50 mL/min whichever is largest

Table 14-7. Degassing

Dialysis fluid	Contain less than 5 mg O_2/L

Table 14-8. Proportioning of concentrates

The proportioning of concentrate is regulated by using the equipments conductivity control functionality. If central concentrate system is used, the output pressure from this system cannot exceed 50 kPa.	
Bicarbonate based dialysis fluid	User settable Na^+, 130 to 150 mmol/L User settable HCO_3^-, 20 to 40 mmol/L
Conductivity measuring range	9 to 16 mS/cm
Accuracy	±0.2 mS/cm
Alarm limits	±5 % of the calculated conductivity set value

14.1.6 Ultrafiltration control

UF volume	User settable to maximum 10.00 L
Accuracy	±50 mL or ±50 mL/h x passed treatment time (h) or ±2.5 % of the accumulated UF volume, whichever is largest.
Dialyzer UF coefficient	Maximum 85 mL/h/mmHg
UF-rate	0.0 to 4.0 L/h, given by the user settable UF volume and treatment time.
Treatment Time	User settable to maximum 9:59 h
Accuracy	±2 minutes or ±1 %, whichever is the largest.

14.1.7 Ultrafiltration protective

Table 14-9.

Accuracy of measured volume	±85 mL or ±85 mL/h x passed treatment time (h), whichever is largest.

14.1.8 Profiling

Table 14-10.

UF-rate	User settable to maximum 4.0 L/h
Na^+, Bicarbonate mode	User settable between 130 to 150 mmol/L
HCO_3^-, Bicarbonate mode	User settable between 20 to 40 mmol/L

14.1.9 DIASCAN function

Clearance measurement is only available if the DIASCAN clearance sensor is installed. During UF step and interval profiling, DIASCAN measurement is not available. The specification is based on in vitro measurements with saline.

Clearance K typical precision	±8% (±1SD). Precision has been validated in HD double needle, for blood flows 200 to 400 mL/min and fluid flows 500 to 700 mL/min.
Dialysis dose Kt/V target	Dialysis dose Kt/V target User settable alarm limit maximum 3
Measurement interval	User settable measurement interval 30 or 60 minutes

14.1.10 Disinfection and cleaning – chemical disinfection

Total time for disinfection programs is estimated and may vary.

Table 14-11. Peracetic Acid Program (presettable)

Concentration of disinfectant	3.5 % peracetic acid
Concentration in machine	0.1 %; i.e. diluted 1 + 34 (1:35)
Volume	Approximate volume disinfectant used during disinfection program, 100 ml (with UFD approximately 125 ml)
Contact time between treatments	10 minutes

Contact time overnight or when not in use (recommended with UFD)	If stored overnight a minimum of 3 hours dwell time is recommended.
Total time for disinfection program	30 minutes (230 V and 115 V) 59 minutes (230 V) with UFD 65 minutes (115 V) with UFD Time includes 10 min contact time

Table 14-12. Hypochlorite Program (presettable)

Concentration of disinfectant	10 % available chlorine
Concentration in machine	0.5 %; i.e. diluted 1 + 19 (1:20)
Volume	Approximate volume disinfectant used during disinfection program, 155 ml (with UFD approximately 163 ml)
Contact time between treatments	10 minutes
Contact time	Maximum 20 min, not intended for overnight disinfection!
Total time for disinfection program	29 minutes 50 minutes with UFD Time includes 10 min contact time

14.1.11 Disinfection and cleaning - heat disinfection

Temperature:	93 °C (measured after heating rod) ≥80 °C (measured in the outlet before the heat exchanger)

NOTE!
The temperatures are verified at nominal values for the mains voltage and at 20 °C ambient temperature.

Total time for disinfection programs is estimated and may vary.

One of four alternatives for heat disinfection can be selected. The second and third alternatives are presettable for a combined heating program and the fourth is a CLEANCART cartridge disinfection / heating program alternative.

The default settings are as follows:

AK 98	Disinfection programs	Total Time	
		230 V	115 V
Approximate time with UFD	Heat	34	40
	Heat Citric acid 20 %	50	54
	Short Heat Citric acid 20 %	25	27
	Heat and CleanCart cartridge	47	51
Aproximate time without UFD	Heat	31	36
	Heat Citric acid 20 %	46	51
	Short Heat Citric acid 20 %	25	27
	Heat and CleanCart cartridge	43	48

14.1.12 Auto heat disinfection

Auto heat disinfection is used with or without CLEANCART agents. When auto heat disinfection is performed with a CLEANCART cartridge agent, the cartridge shall be installed before start of the auto heat program.

Total time for disinfection programs is estimated and may vary.

AK 98	Disinfection programs	Total Time (min)	
		230 V	115 V
Aproximate time with UFD	Heat	29	35
	Heat and CLEANCART cartridge	42	46
Aproximate time without UFD	Heat	29	34
	Heat and CLEANCART cartridge	41	46

14.1.13 Heat disinfection program including WRO 300 H

Table 14-13. Heat disinfection program including WRO 300 H

Entity	UFD not installed	UFD installed
Temperature	93 °C	93 °C
Fill up phase	10	13
Circulation phase	15	15
Low flow heat phase	20	20
Drain phase	4	4
Total time	49	52

Drain phase follows after low flow heat phase. WRO 300 H will start heat disinfection simultaneously (if preset, see WRO 300 H service manual).

14.1.14 Disinfection and cleaning – rinse/drain

Total time for disinfection programs is estimated and may vary.

Aproximate time Rinse/Drain	10 minutes
Aproximate time Drain	4 minutes

14.1.15 Disinfection and cleaning – exterior cleaning

All outside parts of the machine can be cleaned with ethanol (70 %) or isopropanol (60 %).

14.1.16 Water supply

WARNING!
To ensure the quality of the dialysis fluid, inlet water quality shall comply with appropriate regulations and as a minimum requirement according to ISO 13959.

The table below is presenting the requirements for the water supply required for the AK 98 dialysis machine.

AK 98 dialysis machine water consumption	During treatment: maximum 770 mL/min During disinfection: 800 mL/min with peaks of 1100 mL/min not exceeding 40 seconds.
Minimum inlet pressure	0.12 MPa (1.2 bar)
Maximum inlet pressure	0.6 MPa (6 bar)
Inlet temperature	Treatment: +5 to +30 ºC Disinfection: +5 to +90 ºC
Connector in/outlet	Diameter 8 mm
Quality	Inlet water quality shall comply with appropriate regulations and as a minimum requirement according to ISO 13959. Level for conductivity shall not exceed 0.1mS/cm. It is possible to use water with higher conductivity if it consists mainly of sodium salts. This may however affect the accuracy of the fluid composition. **NOTE!** Local regulations may require the use of separation devices in the supply and special measures to protect against the possibility of back-syphonage from dialysis equipment into the water supply.
Drain	The drain tube outlet shall be placed between floor level and maximum 1.2 m above the outlet connection from the fluid monitor. An air gap to atmospheric pressure must always be arranged at the tube outlet.
Length of drain tube	≤10 m

14.1.17 Power supply

Mains voltage	115 V AC, 50 Hz 115 V AC, 60 Hz
	230 V AC, 50 Hz 230 V AC, 60 Hz
Protection class	Machine: Class 1 type B BPM: Type BF

Power consumption	Max. 2025 W at 230 V Max. 1575 W at 115 V
Cable	3 conductor cable, Length max. 3.5 m Ratings: 230 - 250 V AC 10 A or 110 - 125 V AC 15 A
External fuses	For 115 V AC, 2 x T15AH for heater For 230 V AC, 2 x T10AH for heater
Mains plug	Earthed plug, 250 V AC / 10 A Earthed plug, 125 V AC / 15 A Hospital grade
Earth leakage current	max 500 µA
Patient leakage current	max 100 µA AC max 10 µA DC

All leakage currents specified are without external equipment connected to the AK 98 dialysis machine.

14.1.18 Network connection

Cable	Network cable shall be of type Cat5e shielded cable. Shielding shall be F/UTP, S/UTP or SF/UTP

14.1.19 Connection of external equipment

External connector	To communicate via the external connector 25 pin D-Sub as USB, a virtual COM port driver (VCD) needs to be installed on your PC.

External equipment

Additional equipment connected to medical electrical equipment shall comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment).

Furthermore all configurations shall comply with the requirements for medical electrical systems (see clause 16 of IEC 60601-1).

Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local **Baxter Service representative** or the technical service department.

Table 14-14. External alarm

Max voltage	24 V AC or DC
Max current	100 mA AC or DC
Max delay time	100 ms

USB type	USB 2.0 mass storage device

Table 14-15. RS-232C

Max input voltage	± 15 V DC
High level min output voltage	5.0 V DC
Low level max output voltage	- 5.0 V DC
Max output current	± 5 mA DC

14.1.20 Battery back-up

Table 14-16.

Battery type	Sealed Lead Acid
Running time	>30 minutes

14.2 Performance and specification - Supervisory system

14.2.1 Blood pressure supervision

Table 14-17. Venous pressure

Measuring range	-700 to +750 mmHg
Alarm limits, in treatment mode	Maximum rage 10 to 500 mmHg
Alarm limits, in priming mode	Maximum rage -100 to 500 mmHg
Accuracy	±10 % within range -700 to -500 mmHg ±5 mmHg or ±3 %, whichever is largest within range -500 to 500 mmHg ±10 % within range 500 to 750 mmHg

Table 14-18. Arterial pressure

Measuring range	-700 to +750 mmHg
Alarm limits	Maximun range -250 to + 250 mmHg
Accuracy	±10 % within range -700 to -500 mmHg ±5 mmHg or ±3 %, whichever is largest within range -500 to 500 mmHg ±10 % within range 500 to 750 mmHg

Table 14-19. Extracorporeal blood loss to the environment

Detection method	Venous pressure supervision

14.2.2 Air detection

Detection method	Ultrasonic detector placed at the venous drip chamber. The detector has a two-channel structure and the function of the detector is tested at the function test made by the microcomputers.
Drip chamber on blood tubing set, size	Diameter 22 mm
Sensitivity	The air infusion detector prevents the following from reaching the patient: ● A continuous air flow ≥ 0.03 mL/kg/min ● An infusion of an air bolus > 0.1 mL/kg

14.2.3 Extracorporeal blood loss due to coagulation

Detection method	Supervision of the stop time of the blood pump. The default alarm limit is 60 seconds.
Alarm	The alarm

```
107 Blood pump is stopped for too long
```

14.2.4 Dialysis fluid preparation

Table 14-20. Temperature

High temperature alarm (fixed)	40 °C (±0.5 °C)
Low temperature alarm (fixed)	32.5 °C (±0.5 °C)

Table 14-21. Conductivity

Alarm limits	Error in the preparation of the dialysis fluid may lead to conductivity alarms. The maximum possible deviation of each ion before a conductivity alarm is issued, is ±5 % for sodium ion and ±25 % for bicarbonate ion.
Accuracy	0.2 mS/cm

14.2.5 TMP

TMP	TMP is defined as the difference, $P_{b\ out}$ - $P_{d\ out}$, where $P_{b\ out}$ is the venous pressure and $P_{d\ out}$ is the pressure measured in the dialysis fluid, where it enters the machine after the dialyzer. The displayed TMP value is compensated for vertical difference between the measure points.
Alarm limits	User settable between -200 to 500 mmHg
Accuracy	±10 mmHg or ±6 %, whichever is largest (within range ±500 mmHg)

14.2.6 Blood leakage detection

Detection method	Infrared light detector.
Sensitivity	Alarm will be given if ≥0.35 mL/min blood with hematocrit at 32 % is entered into the dialysis fluid flow.

14.3 Alarm sound pressure

14.3.1 Alarm sound pressure

The alarm sound pressure is presetable to minimum 55 dB (A) and maximum 85 dB (A). The default preset is 65 dB (A).

14.4 Physical data

14.4.1 Dimensions and weight

Width; machine	Approx. 345 mm
Width; stand	Approx. 585 mm

Depth; machine	Approx. 600 mm
Depth; stand	Approx. 620 mm
Height	Approx. 1305 mm (without infusion stand).
Weight	Approx. 70 kg (without options).

14.4.2 Infusion stand

Table 14-22.

Maximum total load	3 kg

14.5 Materials in contact with dialysis fluid, concentrates, and water

14.5.1 Polymers

Silicon rubber
Nitrile (Nitrile butadiene rubber)
EPDM (Ethylene propylene diene)
PA (Polyamide)
PVC (Polyvinyl chloride)
PEEK (Polyetherketone)
PEX (Polyethylene)
PP (Polypropylene)
PPSU (Polyphenylsulfone)
PSU (Polysulphone)
PVDF (Polyvinylidene fluoride)
PTFE (Polytetrafluoro ethylene)
PPE (Polyphenyl ether)

14.5.2 Metals

Stainless steel EN 1.4435
Stainless steel EN 1.4436
Stainless steel EN 1.4539
Titanium
Platinum
HASTELLOY C-22

14.5.3 Other materials

Carbon
Ceramic, Aluminium oxide (Al2O3)
Glass

14.6 Environmental data

14.6.1 Operation

If condensation occur when moving the equipment between locations with different temperatures and high relative humidity (e.g. outdoor and indoor locations), the inside of the equipment shall be allowed to dry before switching on the equipment.

Table 14-23.

Ambient Temperature range	+18 to +35 °C
Relative Humidity range	15 to 85 % RH
Air Pressure range (atm. pressure)	700 to 1060 hPa

14.6.2 Transportation and storage

It is recommended that the equipment is kept in its original packing during transportation and storage.

Ambient Temperature range	-20 to +70 °C
Relative Humidity range	10 to 93 % RH non-condensing condition.

14.6.3 Electromagnetic environment

The AK 98 dialysis machine is intended for use in the electromagnetic environment associated with a Professional healthcare facility environment or a Home healthcare environment as specified below. The customer or the user of the AK 98 dialysis machine should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The AK 98 dialysis machine uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AK 98 dialysis machine is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A (Not applicable for 115 V version)	-
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies (Not applicable for 115 V version)	-

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment-guidance
Electrostatic discharge (ESD), IEC 61000-4-2	±6 kV contact ±8 kV Air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for Input/Output lines	±4 kV for power supply lines ±1 kV for Input/Output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV for differential mode ±2kV for common mode	±1kV for differential mode ±2kV for common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T(>95 % dip in U_T) for 0,5 cycle 40 % U_T(60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T(>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T)for 5 cycles 70 % U_T (30 % dip in U_T)for 25 cycles <5 % U_T(>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AK 98 dialysis machine requires continued operation during power mains interruptions, it is recommended that the AK 98 dialysis machine be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE!
U_T is the a.c. mains voltage prior to application of the test level.

NOTE!
Extremes of temperature, supply voltage, shock, vibration, loading, physical forces, etc. can reduce Electromagnetic immunity by degrading the shield. Ageing can also degrade Electromagnetic immunity and can be caused by condensation, liquid spillages, dust and cleaning etc.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment-guidance
-	-	-	Portable and mobile RF communications equipment should be used no closer to any part of the AK 98 dialysis machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
-	-	-	**Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	$d = \left[\frac{3,5}{10}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m 80 MHz to 2,7 GHz	$d = \left[\frac{3,5}{10}\right]\sqrt{P}$ 80 MHz to 800 $d = \left[\frac{7}{10}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Immunity to RF wireless communications equipment	N/A	27 V/m 380 MHz to 390 MHz 28 V/m 430 MHz to 470 MHz 9 V/m 704 MHz to 787MHz 28 V/m 800 MHz to 960 MHz 28 V/m 1700 MHz to 1990 MHz 28 V/m 2400 MHz to 2570 MHz 9 V/m 5100 MHz to 5800 MHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AK 98 dialysis machine is used exceeds the applicable RF compliance level above, the AK 98 dialysis machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AK 98 dialysis machine.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

NOTE!
At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE!
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and the AK 98 dialysis machine			
The AK 98 dialysis machine is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AK 98 dialysis machine can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AK 98 dialysis machine as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter(m)**		
	150kHz - 80MHz $d = \left[\frac{3,5}{10}\right]\sqrt{P}$	**80MHz - 800MHz** $d = \left[\frac{3,5}{10}\right]\sqrt{P}$	**800MHz - 2500MHz** $d = \left[\frac{7}{10}\right]\sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.12	0.12	0.23
1	0.35	0.35	0.7
10	1.2	1.2	2.3
100	3.5	3.5	7.0
Rated maximum output power of mobile phone	-	-	$d=\left[\frac{7}{28}\right]\sqrt{2W}$
Bluetooth/GSM/CDMA /LTE/RFID/WLAN	-	-	0.35
For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

NOTE!
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE!
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

14.6.4 Expected service life

Table 14-24. Expected service life

AK 98 dialysis machine	10 years
BPM cuff	2 years

Valid under conditions that preventive maintenance and repair have been performed at least every other year by an authorized technician.

14.6.5 Energy and water consumption

Typical energy consumption and energy delivery to environment and drain at inlet water temperature of approximately 23 °C given the conditions stated in Table 14-27 “Consumption conditions” on page A:192.

Table 14-25. Energy consumption

Energy consumption	2.2 kWh
Energy delivery to the environment	1.3 kWh
Energy delivery to the drain	0.9 kWh

Table 14-26. Consumption of water and dialysis fluid concentrates

Water	140 L
A concentrate	2.9 L
B concentrate, liquid	5.0 L
B concentrate, dry powder	0.4 kg

Data in Table 14-25 “Energy consumption” on page A:192 and Table 14-26 “Consumption of water and dialysis fluid concentrates” on page A:192 have been obtained given the conditions stated in this table.

Table 14-27. Consumption conditions

Dialysing time	4h plus preparation time and post treatment operation
Dialysis fluid flow	500 mL/min
Blood flow	300 mL/min
Ultrafiltration flow	0,5 L/h
Dialysis fluid temperature	37 °C
Type of disinfection	Heat disinfection with CLEANCART C cartridge

14.7 Standards

The machine complies with the following standards:

IEC 60601-1:2005/AMD1:2012/COR1:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-6:2010/AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (+ Amendment 1).

IEC 60601-1-8:2006 + AM1:2012 Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for

medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-2-16:2012 Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment.

IEC 80601-2-30:2009 + Cor1:2010 + AMD1:2013 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers (+ Amendment 1 and Corrigendum 1). The SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.

CAN/CSA C22.2 No. 60601-1:14 (Harmonized with Ed. 3.1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations).

IEC 62304:2006/AMD1:2015 Medical device software - Software life cycle processes (+ Amendment 1).

IEC 62353:2014 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment.

YY 0054-2010 Haemodialysis Equipment (Medical industry standard in the People's Republic of China).

GB9706.1-2007 Medical Electrical Equipment - Part 1: General Requirements for Safety. (National standard in the People's Republic of China).

GB9706.2-2003 Medical Electrical Equipment - Part 2-16: Particular requirements for safety of haemodialysis, haemodiafiltration and haemofiltration equipment. (National standard in the People's Republic of China).

YY 0709-2009 Medical electrical equipment-Part 1-8: General requirements for safety-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. (Medical industry standard in the People's Republic of China).

YY 0505-2012 Medical Electrical Equipment - Part 1-2: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests. (Medical industry standard in the People's Republic of China).

YY 0667-2008 Medical Electrical Equipment - Part 2-30: Particular requirements for the safety including essential performance of automatic cycling non-invasive blood pressure monitoring equipment. (Medical industry standard in the People's Republic of China).

GB/T 26125-2011 Testing Methods for Hazardous Substances in Electronic Information Products.

GB/T 26572-2011 Requirements of Concentration Limits for Certain Restricted Substances in Electrical and Electronic Products. (National standard in the People's Republic of China).

SJ/T11364-2014 Marking for the restriction of the use of hazardous substances in electronic and electrical product.

EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices.

No 6 Provisions for IFU and labeling of Medical device.

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15 Local regulatory registration (if applicable)

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1 Alarms

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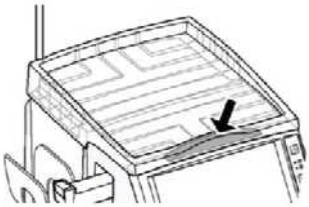
1.1 General about alarms

1.1.1 Alarm indication

There are two alarm levels, equal to high priority alarm and medium priority alarm. When an alarm is generated, the machine indicates an alarm as follows:

The **Alarm** tab is flashing.

The **Alarm** tab turns **red** and the alarm message is displayed. If a menu is open an alarm banner is displayed (flashing) above the open menu.



The indication light above the screen flashes.

- A flashing **red** light (frequency 2.5 Hz) indicates a high priority alarm. The light stops flashing when the cause of the alarm is corrected.
- A flashing **yellow** light (frequency 0.5 Hz) indicates a medium priority alarm. The light stops flashing when the cause of the alarm is corrected.

The buzzer sounds.

- - -- - (1 sec) - - -- - (3.5 sec)... For high priority alarms the alarm is a recurring sound of two groups of five tones that are repeated. There is a 1 second intermission after the first five tones and a 3.5 second intermission after the second five tones.

- - - (5 sec) - - - (5 sec)... For medium priority alarms the alarm is a recurring sound of three tones that are repeated with a 5 second intermission.

The **Mute** button is flashing.

The light stops flashing when the alarm is confirmed and/or the cause of the alarm is corrected.

Medium priority alarms have priority over attentions and high priority alarms have priority over both medium priority alarms and attentions. The generated sound and light always indicates the highest priority of the currently active alarms.

NOTE!
The minimum alarm sound pressure is preset by an authorised service technician.

1.1.2 General alarm handling

CAUTION!
There is a potential hazard that the AK 98 dialysis machine alarms are not heard or evaluated correctly, if any equipment with a different alarm system or different alarm preset values is placed in the same location and distracts the operator.

When an alarm is triggered the alarm message is displayed and the alarm tab is flashing. If a menu is open an alarm banner is shown. If any text is visible in the information field the **Alarm** tab must be pressed to show the alarm.

When the alarm tab is pressed the **Mute** button lights up and the buzzer is muted for 2 minutes.

1.1.3 External alarm

The AK 98 dialysis machine can be connected to an external alarm unit for alarm signals. When an alarm is generated, the external alarm unit is activated. The external alarm is controlled by the indication light on the AK 98 dialysis machine. When the alarm situation ceases, the external alarm is deactivated.

Each remote visual / acoustic indicator (external alarm unit) shall be connected to only one AK 98 dialysis machine to ascertain the correct location of the source of the remote alarm.

WARNING!
The clinical staff are responsible for ensuring that an alarm refers to only one AK 98 dialysis machine.

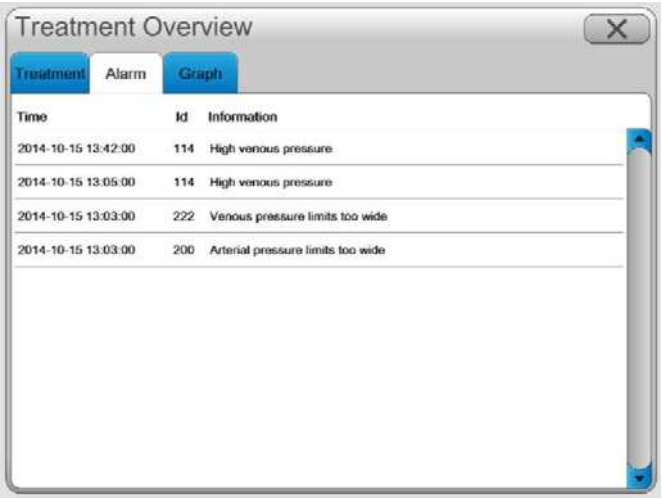
WARNING!
Do not rely exclusively on a remote alarm device to monitor alarm signals.

1.1.4 Alarm history

A list with the most recently generated alarms is shown in the alarm tab in treatment history.

To reach the alarm list:

1. Press the `History` button.
2. Select the `Alarm` tab.



The time for when the alarm was generated is shown in the alarm list.

The alarm list is cleared when the machine is shut down.

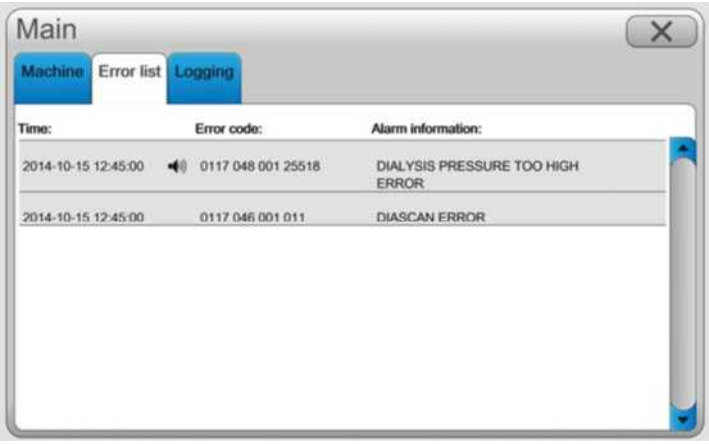
The alarm list is maintained during a power failure as long as the battery backup allows.

The last generated alarm is shown at the top of the list.

1.1.5 Error list

To reach the error list:

1. Press the `Blood` button.
2. Select the `Tools` tab.
3. Press `Service`.
4. Select the `Error list` tab.



The time for when the error was generated is shown in the error list.

The last 100 errors are shown in a rolling replacement schedule with the latest at the top.

The list is maintained when the machine is shut down and during a power failure.

1.1.6 How to find the alarm in the alarm handbook

The alarm descriptions in this chapter are arranged in numerical order. Each alarm description has the following sections:

Appears	Describes what conditions must be present for an alarm to appear; what triggers/generates the alarm.
Machine actions	Describes which actions that will automatically be taken by the machine due to the alarm.
Operator action	Describes the actions that are expected from the operator when an alarm appears.

When {0} is displayed in the descriptive text in an alarm, it is replaced with a live integer value.

1.2 High priority alarms

100 Air in venous drip chamber

```
100 Air in venous drip chamber
To start blood pump for {0} sec. to raise drip
chamber level, press Timer button.
```

Appears:
When air has come into the venous drip chamber.

Machine actions:

- The blood pump stops.
- The venous and arterial blood line clamps close.
- Ultrafiltration rate is set to zero.
- The dialysis fluid bypasses the dialyzer.

Operator action:

1. Check that the blood line connections are properly connected to the arterial needle and to the dialyzer.
2. Check that the arterial needle is in proper position.
3. Start the blood pump to resolve the alarm situation, by pressing the Timer button in the alarm message.

4. Simultaneously, raise the blood level in the drip chamber with the level adjustment knob by turning the knob anticlockwise.
5. When the blood level is correct and the alarm text has changed, check that there is no air in the venous and arterial line.
6. Check that there is no air in the infusion line.
7. Start the blood pump by pressing `Confirm` in the alarm message.
8. Adjust the blood flow rate.

101 Blood detected in fluid path

```
101 Blood detected in fluid path
To start blood pump for {0} sec. to rinse
detector, press Timer button.
```

Appears:
When blood has entered the fluid path of the machine downstream the dialyzer.

Machine actions:

- The blood pump stops.
- The venous and the arterial blood line clamps close.
- Ultrafiltration rate is set to zero.
- The dialysis fluid bypasses the dialyzer (when blood is detected).
- Part of the fluid flow path on the screen flashes.

Operator action:

1. Check the inlet fluid tube (the tube from the dialyzer to the machine) for blood. Follow your local routines[1]and consider the amount of blood that has leaked and the status of the patient.
2. Check that the dialyzer connectors are properly attached to the dialyzer.
3. The alarm actions may be overridden (bypassed) by pressing `Confirm`. The blood pump will start up at 50 mL/min blood flow rate, adjust if necessary. The blood leak detector will automatically be rinsed with dialysis fluid during the override period. If the cause of the alarm has not been corrected within the override time of 2 minutes, the machine alarm actions will automatically recur. If necessary, repeat the override procedure. The blood flow rate will remain at 50 mL/min after the override period. Adjust the blood flow rate manually.

[1] Measures can vary between immediately stopping the treatment without returning the blood to the patient, to continuing the treatment without any action.

4. Clean the blood leak detector. See Section 13.3 “Clean the blood leak detector” on page A:173 in Operators handbook.
5. When the blood leak alarm disappears, the alarm text will change. Press `Confirm` to reset the alarm function.

WARNING!
When entering override, the operator is responsible for monitoring the treatment since this is not done by the dialysis machine during the override time.

102 Blood is detected during functional check

```
102 Blood is detected during functional check
Blood in priming detector. Functional check is
stopped.
```

Appears:
When the priming detector detects blood during functional check.

Machine actions:

- The blood pump stops.
- The venous blood line clamp closes.

Operator action:

1. Make sure that the patient is not connected to the blood lines.
2. Clean the priming detector lens.

If previous steps do not help, call an authorised technician.

103 Blood is detected in assisted priming

```
103 Blood is detected in assisted priming
Blood in priming detector. Blood pump is
stopped.
```

Appears:
When the priming detector detects blood during assisted priming procedure.

Machine actions:
The blood pump stops.

Operator action:

1. Make sure that the patient is not connected to the blood lines.
2. Clean the priming detector lens.

If previous steps do not help, call an authorised technician.

104 Blood is not detected

```
104 Blood is not detected
Check cause and press Confirm.
```

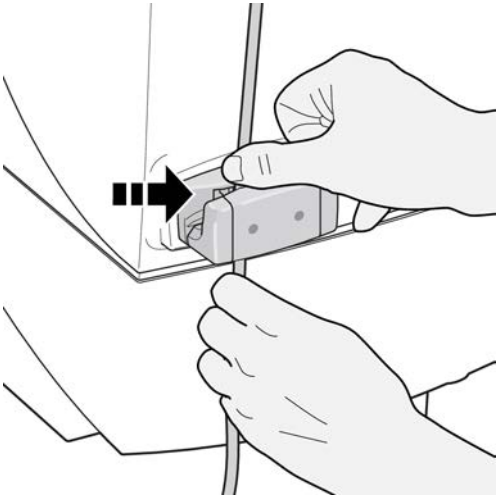
Appears:
When the connect patient procedure has been started, the connect patient volume is achieved and no blood has been detected in the venous blood line.

Machine actions:

- The blood pump stops.
- The venous blood line clamp closes.

Operator action:

1. Check that the venous blood line is properly inserted into the priming detector.



2. When the priming detector detects blood, the blood path on the screen lights up red and treatment time starts to count down.
3. Press `Confirm`.
4. Select `Continue connect patient` and press `Confirm`.

105 Blood pump door is not closed

```
105 Blood pump door is not closed
Close blood pump door.
```

Appears:
When the blood pump door is not properly closed during treatment or priming.

Machine actions:
The blood pump stops.

Operator action:

1. Check that the blood pump segment is positioned correctly.
2. Check that the blood pump rotor is positioned correctly.
3. Close the blood pump door.

106 Blood pump is overloaded

```
106 Blood pump is overloaded
Check pump segment and arterial blood line for
obstruction.
```

Appears:
When the blood pump cannot run.

Machine actions:
The blood pump stops.

Operator action:

1. Check that the blood pump segment is positioned correctly.
2. Check that the blood pump rotor is positioned correctly.
3. Press the **Blood pump** button to start the blood pump.

If the alarm appears again, call an authorised technician.

107 Blood pump is stopped for too long

```
107 Blood pump is stopped for too long
```

Appears:
When the blood pump has been stopped for a configurable time.

Machine actions:
None.

Operator action:
Press the **Blood pump** button to start the blood pump when the patient is connected and the dialysis machine detects blood. Make sure that the cause of the alarm has been corrected.

108 Fluid path obstruction

```
108 Fluid path obstruction
Too high blood circuit pressure. Check
circuit, start blood pump.
```

Appears:
When the fluid path is blocked.

Machine actions:
The blood pump stops.

Operator action:

1. Press the `Fluid bypass` button.

   If the alarm disappears, the obstruction is external, for example located in the blood lines, the dialysis fluid tubes or the dialyzer.
2. Check for obstructions in the blood lines, the dialysis fluid tubes or the dialyzer and remove them if you find any.
3. Press the `Fluid bypass` button.

If the alarm does not disappear, the obstruction is internal. Call an authorised technician.

109 High arterial pressure

```
109 High arterial pressure
```

Appears:

When the patient's arterial pressure reaches the set high alarm limit. The arterial pressure is the pressure in the blood line from a patient.

Machine actions:

- The blood pump stops.
- The venous blood line clamp closes.
- Ultrafiltration rate is set to zero.

Operator action:

1. Stop the blood pump. The arterial and venous pressure alarm limits are automatically widened.
2. Check that the arterial needle is in proper position.
3. Check that there is no air in the arterial blood line between the needle and the blood pump.

This can happen, for example, when you connect an infusion to the arterial blood line prior to the blood pump.

4. Restart the blood pump and adjust the blood flow.
5. Check the arterial and venous pressures and press the flashing pressure control to re-centralise the alarm limits.

When the arterial pressure is within the set alarm limits again, the blood pump starts automatically and the venous blood line clamp opens.

110 High diastolic blood pressure

```
110 High diastolic blood pressure
To clear the alarm press Confirm.
```

Appears:
When the patient's diastolic blood pressure is outside the set high alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the BPM button.
   - Select the History tab.
   - Press History.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually (see Section 8.3 “Direct blood pressure measuring” on page A:130 in Operators handbook).
4. If possible, adjust the alarm limits to the patient’s status:
   - Press the BPM button.
   - Select the Alarm tab.
   - Press Set limits.
   - Press Diastolic High and adjust the alarm limit.
5. Press OK.

111 High mean blood pressure

```
111 High mean blood pressure
To clear the alarm press Confirm.
```

Appears:
When the patient's mean blood pressure is outside the set high alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the `BPM` button.
   - Select the `History` tab.
   - Press `History`.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually (see Section 8.3 "Direct blood pressure measuring" on page A:130 in Operators handbook).
4. If possible, adjust the alarm limits to the patient's status:
   - Press the `BPM` button.
   - Select the `Alarm` tab.
   - Press `Set limits`.
   - Press `MAP High` and adjust the alarm limit.
5. Press `OK`.

112 High pulse rate

```
112 High pulse rate
To clear the alarm press Confirm.
```

Appears:
When the patient's pulse rate reaches the set high alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the BPM button.
   - Select the History tab.
   - Press History.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually, see Section 8.3 “Direct blood pressure measuring” on page A:130 in Operators handbook.
4. If possible, adjust the alarm limits to the patient’s status:
   - Press the BPM button.
   - Select the Alarm tab.
   - Press Set limits.
   - Press Pulse High and adjust the alarm limit.
5. Press OK.

113 High systolic blood pressure

```
113 High systolic blood pressure
To clear the alarm press Confirm.
```

Appears:
When the patient's systolic blood pressure reaches the set high alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the `BPM` button.
   - Select the `History` tab.
   - Press `History`.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually, see Section 8.3 “Direct blood pressure measuring” on page A:130 in Operators handbook.
4. If possible, adjust the alarm limits to the patient’s status:
   - Press the `BPM` button.
   - Select the `Alarm` tab.
   - Press `Set limits`.
   - Press `Systolic High` and adjust the alarm limit.
5. Press `OK`.

114 High venous pressure

```
114 High venous pressure
```

Appears:
When the patient's venous pressure reaches the set high alarm limit. The venous pressure is the resistance of the blood returning to a patient.

Machine actions:

- The blood pump stops.
- Ultrafiltration rate is set to zero.
- The arterial blood line clamp closes in single needle mode.

During single needle treatment the alarm is delayed for 3 seconds, to avoid false alarms since the venous pressure limits are used for single needle phase shift.

Operator action:

1. Stop the blood pump. The arterial and venous pressure alarm limits are automatically widened.
2. Check that there are no kinks or clamps on the venous blood line between the needle and the drip chamber.
3. Check the position of the venous needle.
4. Check that there are no clots in the venous blood line, the drip chamber or the needle.
5. Adjust the blood flow and restart the blood pump.
6. Check the arterial and venous pressures and press the flashing pressure control to re-centralise the alarm limits.

When the venous pressure is within the set alarm limits again, the blood pump starts automatically.

115 Low arterial pressure

```
115 Low arterial pressure
```

Appears:
When the patient's arterial pressure reaches the set low alarm limit. The arterial pressure is the pressure in the blood line from a patient.

Machine actions:

- The blood pump stops.
- The venous blood line clamp closes.
- Ultrafiltration rate is set to zero.

Operator action:

1. Stop the blood pump. The arterial and venous pressure alarm limits are automatically widened.
2. Check that the patient´s blood flow rate is the same as the blood flow rate set in the dialysis machine.
3. Check the patient´s blood pressure.
4. Check the position of the arterial needle.
5. Check that there are no kinks or clots in the arterial blood line between the needle and the point where the blood pressure is measured.
6. Adjust the blood flow and restart the blood pump.
7. Check the arterial and venous pressures and press the flashing pressure control to re-centralise the alarm limits.

When the arterial pressure is within the set alarm limits again, the blood pump starts automatically and the venous blood line clamp opens.

116 Low diastolic blood pressure

```
116 Low diastolic blood pressure
To clear the alarm press Confirm.
```

Appears:
When the patient's diastolic blood pressure is outside the set low alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the BPM button.
   - Select the History tab.
   - Press History.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually (see Section 8.3 “Direct blood pressure measuring” on page A:130 in Operators handbook).
4. If possible, adjust the alarm limits to the patient’s status:
   - Press the BPM button.
   - Select the Alarm tab.
   - Press Set limits.
   - Press Diastolic Low and adjust the alarm limit.
5. Press OK.

117 Low mean blood pressure

```
117 Low mean blood pressure
To clear the alarm press Confirm.
```

Appears:
When the patient's mean blood pressure is outside the set low alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the `BPM` button.
   - Select the `History` tab.
   - Press `History`.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually (see Section 8.3 "Direct blood pressure measuring" on page A:130 in Operators handbook).
4. If possible, adjust the alarm limits to the patient's status:
   - Press the `BPM` button.
   - Select the `Alarm` tab.
   - Press `Set limits`.
   - Press `MAP Low` and adjust the alarm limit.
5. Press `OK`.

118 Low pulse rate

```
118 Low pulse rate
To clear the alarm press Confirm.
```

Appears:
When the patient's pulse rate reaches the set low alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the BPM button.
   - Select the History tab.
   - Press History.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually, see Section 8.3 “Direct blood pressure measuring” on page A:130 in Operators handbook.
4. If possible, adjust the alarm limits to the patient’s status:
   - Press the BPM button.
   - Select the Alarm tab.
   - Press Set limits.
   - Press Pulse Low and adjust the alarm limit.
5. Press OK.

119 Low systolic blood pressure

```
119 Low systolic blood pressure
To clear the alarm press Confirm.
```

Appears:
When the patient's systolic blood pressure reaches the set low alarm limit.

Machine actions:
None.

Operator action:

1. Check the blood pressure history:
   - Press the `BPM` button.
   - Select the `History` tab.
   - Press `History`.
   - Observe the measurement results from the treatment.
2. Do standard patient checks and take measures for patients with circulatory disturbances.
3. If desired, measure the blood pressure manually, see Section 8.3 “Direct blood pressure measuring” on page A:130 in Operators handbook.
4. If possible, adjust the alarm limits to the patient’s status:
   - Press the `BPM` button.
   - Select the `Alarm` tab.
   - Press `Set limits`.
   - Press `Systolic Low` and adjust the alarm limit.
5. Press `OK`.

120 Low venous pressure

```
120 Low venous pressure
```

Appears:
When the patient's venous pressure reaches the set low alarm limit. The venous pressure is the resistance of the blood returning to a patient.

Machine actions:

- The blood pump stops.
- The venous blood line clamp closes.
- Ultrafiltration rate is set to zero.

During single needle treatment the alarm is delayed for 3 seconds, to avoid false alarms since the venous pressure limits are used for single needle phase shift.

Operator action:

1. Stop the blood pump. The arterial and venous pressure alarm limits are automatically widened.
2. Check that the venous blood line is properly attached to the dialyzer.
3. Check that the venous needle is in proper position.
4. Check that there are no clots before or in the dialyzer.
5. Adjust the blood flow and restart the blood pump.
6. Check the arterial and venous pressures and press the flashing pressure control to re-centralise the alarm limits.

When the venous pressure is within the set alarm limits again, the blood pump starts automatically.

121 No change in SN venous blood pressure

```
121 No change in SN venous blood pressure
Check bloodlines and venous pressure
transducer protector.
```

Appears:
When the venous blood pressure is not varying as expected during the arterial and venous phases in a single needle treatment.

Machine actions:
The blood pump stops.

Operator action:
1. Check the venous blood line for kinks or clamps.
2. Check for blood in the pressure transducer protector.
3. Check the arterial blood flow rate.

122 Restarted after power failure

```
122 Restarted after power failure
To continue press Confirm.
```

Appears:
When the machine has recovered from power failure.

Machine actions:
None.

Operator action:
1. Press `Confirm`.
2. Check power supply, mains cable and backup battery.

123 Technical error

```
123 Technical error
The machine has been automatically restarted.
To continue press Confirm.
```

Appears:
When there is a technical fault in the machine.

Machine actions:
A number of automatic restart attempts will be made. If this is unsuccessful an unconditional or conditional technical alarm will appear.

Operator action:

1. Press `Confirm`.
2. Open the `Error list`:
   a) Press the `Blood` button.
   b) Select the `Tools` tab.
   c) Press `Service`.
   d) Select the `Error list` tab.

   Read and note the error code text on the screen. If more than one technical error have been generated, the most recent is displayed at the top of the list.
3. Technical error during functional check; restart the machine using the **On/Off** button and the machine will perform a new functional check.

If the technical error reoccurs, call an authorised technician.

124 Technical error

```
124 Technical error
Contact technical service.
```

Appears:
When there is a technical fault in the machine that affects the patient safety.

Machine actions:
The actions depend on the kind of technical error. The machine sometimes automatically enters a state which makes it impossible to continue the treatment.

Operator action:

1. Press `Confirm`.
2. Open the `Error list`:
   a) Press the `Blood` button.
   b) Select the `Tools` tab.
   c) Press `Service`.
   d) Select the `Error list` tab.

   Read and note the error code text on the screen. If more than one technical error have been generated, the most recent is displayed at the top of the list.
3. Technical error during treatment: call an authorised technician. If necessary during treatment, manually return the blood to the patient. See Section 3.6.3 “Return the blood to the patient manually” on page A:71 in Operators handbook.

WARNING!
A restart attempt after technical error during treatment may create a potential hazard for the patient.

223 No BPM values

```
223 No BPM values
BPM measurement failed. Check BPM cuff and
restart measurement. To clear the alarm press
Confirm.
```

Appears:
When it was not possible to measure the patient's blood pressure. The patient may have moved during the measuring.

Machine actions:
The buzzer sounds.

Mute time: 2 minutes.

Operator action:

1. To clear the alarm press Confirm.

   If the cause of the alarm has not been corrected within the override time of 2 minutes, the machine alarm actions will automatically recur.
2. Make sure that the BPM cuff is correctly wrapped around the patient’s arm.
3. Restart measurement.

1.3 Medium priority alarms

200 Arterial pressure limits too wide

```
200 Arterial pressure limits too wide
Centralize limits.
```

Appears:
When the arterial pressure alarm window is wider than the preset value.

Machine actions:

- Alarm sound is delayed for 2 minutes.
- The arterial pressure control is activated.

Operator action:

1. Check that correct blood flow rate is set.
2. Press the arterial pressure control.
3. Press `Center arterial`.
4. Check that the arterial pressure limits are correct.

201 Blood flow is too low

```
201 Blood flow is too low
```

Appears:
When the set blood flow rate has been lower than, or equal to, 100 mL/min for more than 5 minutes.

Machine actions:
None.

Operator action:

1. Check for a cause, for example: recurring problems with the needle, previous alarms that took a long time to solve and technical alarms.
2. Press the **Blood pump** button to start the blood pump when the cause of the alarm has been corrected.
3. If possible, increase the blood flow rate to the intended value.
4. If necessary, adjust the low alarm limit.

   - Press the `Blood` button.

   - Select the `Blood flow` tab.

   Press `Low alarm limit` and set a suitable alarm limit for low blood flow.

202 Fluid tubes in safety couplings

```
202 Fluid tubes in safety couplings
Connect the fluid tubes to the dialyzer.
```

Appears:

- When blood is detected by the priming detector when connecting the patient.
- When the dialysis fluid tubes are connected to the safety couplings during treatment.

Machine actions:

None.

Operator action:

Move the dialysis fluid tubes from the safety couplings to the dialyzer.

203 Heparin pump is overloaded

```
203 Heparin pump is overloaded
Check heparin line for obstruction.
```

Appears:
When the pressure in the syringe is too high.

Machine actions:
The heparin pump stops.

Operator action:

1. Check that the heparin syringe is installed.
2. Check that the heparin syringe is filled.
3. Check for kinks and clamps on the heparin line.

When the pressure in the syringe is within limits again the heparin pump starts automatically.

205 High dialysis fluid temperature

```
205 High dialysis fluid temperature
```

Appears:
When the dialysis fluid temperature has reached the set temperature high alarm limit.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. Press the `Fluid` button.
2. Select the `Temp` tab to reach the temperature settings.
3. Check the inlet water supply and the power supply. Take appropriate actions when you find an issue.
4. Wait until the dialysis fluid temperature is correct. Then the dialysis fluid automatically enters the dialyzer and the alarm disappears.
5. If necessary, call for an authorised technician or end the treatment.

206 Incorrect acidic concentrate

```
206 Incorrect acidic concentrate
Check set value and connected concentrate.
```

Appears:
When the selected concentrate does not match the concentrate connected to the machine.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. Check that the concentrate container is filled.
2. Check that there is no air in the concentrate tube.
3. Check what concentrate is set in the dialysis machine.
   a) Press the `Fluid` button.
   b) Select the `Conc` tab.
4. Check that the concentrate that is set is the same as the concentrate connected.
5. Check that the proper concentrate has been connected correctly.

207 Incorrect bicarbonate concentrate

```
207 Incorrect bicarbonate concentrate
Check set value and connected concentrate.
```

Appears:
When the selected concentrate does not match the concentrate connected to the machine.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. Check that the concentrate container is filled.
2. Check what concentrate is set in the dialysis machine.
   a) Press the `Fluid` button.
   b) Select the `Conc` tab.
3. Check that the concentrate that is set is the same as the concentrate connected.
4. Check that the proper concentrate has been connected correctly.
5. Check that there is no air in the concentrate tube.

208 Incorrect dialysis fluid composition

```
208 Incorrect dialysis fluid composition
Check set values and connected concentrates.
```

Appears:
When the dialysis fluid composition deviation (the relation between the acidic and the bicarbonate concentrate) is too high.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. Check that the concentrate container is filled.
2. Check what concentrate is set in the dialysis machine.
   a) Press the `Fluid` button.
   b) Select the `Conc` tab.
3. Check that the concentrate that is set is the same as the concentrate connected.
4. Check that the proper concentrate has been connected correctly.
5. Check that there is no air in the concentrate tube.

209 Insufficient inlet water pressure

```
209 Insufficient inlet water pressure
Check water supply.
```

Appears:
When the water supply pressure is too low.

Machine actions:
The fluid flow to and from the dialyzer is bypassed.

Operator action:

1. Check that the water supply works as intended. If not, take appropriate actions depending on the cause.
2. Check that the external water supply valve is open.
3. Check that the water supply tube is not blocked.

210 Low battery power

```
210 Low battery power
The machine will turn off within one minute.
```

Appears:
During power failure when the battery power is too low.

Machine actions:

- The machine will automatically be switched off.
- Power failure sound will appear.

Operator action:
Consider to end the treatment manually.

The battery may need to be replaced.

211 Conductivity out of limits

```
211 Conductivity out of limits
```

Appears:
When the dialysis fluid conductivity is outside the set alarm limits.

Machine actions:

- The alarm sound is delayed for 30 seconds.
- When conductivity is too low the dialysis fluid is bypassed to and from the dialyzer.
- When conductivity is too high the dialysis fluid is bypassed to the dialyzer.
- If the dialysis fluid conductivity is below 9 mS/cm, the UF rate will automatically be set to zero.
- The flow path on the screen turns yellow.

Operator action:

1. Check that the concentrate container/BiCart cartridge is filled.
2. Check that there is no air in the concentrate tube.
3. Press the lit `Fluid` button and select the `Cond` tab to reach the conductivity settings.
4. Check what concentrate is set in the dialysis machine.
   a) Press the `Fluid` button.
   b) Select the `Conc` tab.
5. Check that the concentrate that is set is the same as the concentrate connected.
6. Check that the proper concentrate has been connected correctly.
7. Check that the BiCart cartridge is properly attached. See Section 4.2.3 “Set up the dialysis machine” on page A:77 in Operators handbook.
8. Check connectors and tubes and make sure there is no leakage.

9. Check that the concentrate tube is not kinked or occluded.
10. Check that the filter integrated on the concentrate tubes is not clogged.

Wait for correct dialysis fluid conductivity to be resumed. If necessary, call for an authorised technician or discontinue treatment.

When the dialysis fluid conductivity is within the set alarm limits again, the dialysis fluid automatically enters the dialyzer.

212 Low dialysis fluid temperature

```
212 Low dialysis fluid temperature
```

Appears:
When the dialysis fluid temperature has reached the set temperature low alarm limit.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. Press the `Fluid` button.
2. Select the `Temp` tab to reach the temperature settings.
3. Check that the machine is connected to the power socket.
4. Check the inlet water supply and the power supply. Take appropriate actions when you find an issue.
5. Wait until the dialysis fluid temperature is correct. Then the dialysis fluid automatically enters the dialyzer.

If necessary, call for an authorised technician or end the treatment.

213 Power failure

```
213 Power failure
Battery operated for {0} minutes.
```

Appears:
Immediately at power failure when battery back-up is operating. The displayed minutes indicate how long the power failure has lasted.

Machine actions:
Only the blood unit will run during a power failure.

Operator action:
Check power supply and mains cable.

214 Pv and Qd settings in conflict

```
214 Pv and Qd settings in conflict
Increase Qd to 500 mL/min.
```

Appears:
When the dialysis machine cannot achieve the set UF rate since there is a conflict between the patient's venous pressure and the set dialysis fluid flow rate.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. If possible, increase dialysis fluid flow rate to at least 500 ml/min:
   - Press the `Fluid` button.
   - Select the `Fluid flow` tab.
   - Press `Dialysis fluid flow` and adjust the flow rate.
2. If you cannot increase the dialysis fluid flow rate, decrease the venous pressure and wait, maximum 5 minutes, until the dialysis fluid enters the dialyzer again.
3. If the alarm goes off again, consider ending the treatment.

215 Single needle stroke volume is too low

```
215 Single needle stroke volume is too low
```

Appears:
When the measured stroke volume is lower than the set stroke volume in single needle treatment.

The performance of the patient's blood access may be decreased.

The single needle treatment may not be optimised.

Machine actions:
None.

Operator action:

1. Check the level in the expansion chamber. It should be as low as possible but air should not pass into the blood lines at the end of the venous phase.
2. If possible, adjust the venous pressure alarm window. The wider the window, the greater the stroke volume. The higher the position of the window (i.e. how high in the mmHg scale the window is placed), the higher the venous flow.
3. If previous steps do not help, adjust the stroke volume in the dialysis machine:
   - Press the `Blood` button.
   - Select the `Single needle` tab.
   - Press `Minimum stroke volume limit`.
   - Adjust the limit value.

For more information, see Section 5 “Haemodialysis - Single needle treatment” on page A:105 in Operators handbook.

216 Heparin pump technical error

```
216 Heparin pump technical error
Heparin pump failure. To confirm not using
heparin pump, set heparin values to zero.
```

Appears:
When there is a technical fault with the heparin pump.

Machine actions:
The machine actions differ depending on the kind of technical error.

Operator action:
1. Set the heparin values to zero to confirm that the heparin pump is not going to be used:
   - Press the `Blood` button.
   - Select the `Heparin` tab.
   - Set the heparin values to zero.

217 TMP is too high

```
217 TMP is too high
```

Appears:
When the transmembrane pressure (TMP) has reached the set high alarm limit.

Machine actions:
None.

Operator action:
1. Press the `Fluid` button.
2. Select the `TMP` tab.
3. Check for a cause: unexpected patient weight loss or issues with the needle, extracorporeal circuit or dialyzer (clogged dialyzer), and take appropriate actions.
4. Do standard patient checks, for example measure blood pressure.
5. If possible, increase the treatment time, decrease the set UF volume or increase the blood flow rate.
6. If possible, adjust the high TMP alarm limit.
7. Confirm that the actual TMP value and alarm limits are in accordance with the actual UF rate and UF coefficient.
8. If necessary, end the treatment and call an authorised technician.

218 TMP is too low

```
218 TMP is too low
```

Appears:
When the transmembrane pressure (TMP) has reached the set low alarm limit.

Machine actions:
None.

Operator action:
1. Press the `Fluid` button.
2. Select the `TMP` tab.
3. Check for a cause: unexpected patient weight loss or issues with the needle, extracorporeal circuit or dialyzer (clogged dialyzer), extracorporeal circuit kink or clamp on the venous blood line, and take appropriate actions.
4. Do standard patient checks, for example measure blood pressure.
5. If possible, decrease the set treatment time, increase the set UF volume or decrease the blood flow rate.
6. If possible, adjust the low TMP alarm limit.
7. Check that the blood line between the dialyzer and the venous drip chamber is not clamped.
8. Confirm that the actual TMP value and alarm limits are in accordance with the actual UF rate and UF coefficient.
9. If necessary, end the treatment and call an authorised technician.

219 UF rate stopped due to high venous pressure

```
219 UF rate stopped due to high venous
pressure
Check blood access, blood lines and venous
pressure transducer protector for
obstruction.
```

Appears:
When the dialysis machine cannot achieve the set UF rate since the patient's venous pressure is too high.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. Check the patient's blood access, the venous pressure transducer and check for clots in the dialyzer. Take appropriate actions when you find an issue.
2. Make sure that the venous pressure is decreased by at least 50 mmHg. The alarm will automatically disappear when the actual venous pressure has been decreased.
3. If it is not possible to decrease the actual venous pressure, wait (maximum 5 minutes) until the dialysis fluid enters the dialyzer again.
4. If the alarm reappears, consider ending the treatment.

220 UF volume deviation

```
220 UF volume deviation
Actual UF may differ from set UF with {0} mL.
Check patient weight loss. If not accepted
discontinue treatment and call technical
service, to continue treatment press Confirm.
```

Appears:
When the ultrafiltration volume measurements are not within the specification of the dialysis machine.

This can happen when:

- the UF control is not calibrated or incorrectly calibrated.
- the UF control does not work correctly.
- the protective UF sensor does not work correctly.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:

1. Check patient weight loss. If patient weight loss is not acceptable, end the treatment and call an authorised technician.
2. If patient weight loss is acceptable it is possible to continue treatment. Press `Confirm` to continue treatment.

If the alarm occurs a second time, always end the treatment.

221 UF volume deviation

```
221 UF volume deviation
Second UF volume deviation {0} mL. Check
patient weight loss. Discontinue treatment and
call service.
```

Appears:
When the ultrafiltration volume measurements, for the second time, are not within the specification of the dialysis machine.

This can happen when:

- the UF control is not calibrated or incorrectly calibrated.
- the UF control does not work correctly.
- the protective UF sensor does not work correctly.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:
End the treatment and call an authorised service technician.

222 Venous pressure limits too wide

```
222 Venous pressure limits too wide
Centralize limits.
```

Appears:
When the venous pressure alarm window is wider than the preset value.

Machine actions:

- Alarm sound is delayed for 2 minutes.
- The venous pressure control is activated.

Operator action:

1. Check that correct blood flow rate is set.
2. Press the venous pressure control.
3. Press `Center venous`.
4. Check that the venous pressure limits are correct.

224 Second internal fluid leakage detected

```
224 Second internal fluid leakage detected
Check patient weight loss. Discontinue
treatment and call service technician.
```

Appears:
When the machine has detected a second fluid leakage during treatment.

Machine actions:

- Close valves to stop leakage to the environment.

Operator action:

1. Check patient weight loss.
2. Discontinue treatment. Check patient and call service technician
3. Call technical service.

225 Internal fluid leakage detected

```
225 Internal fluid leakage detected
Check patient weight loss. To continue, wipe
fluid detector container dry.
```

Appears:
When the machine has detected a fluid leakage during treatment.

Machine actions:

- Close valves to stop leakage to the environment.

Operator action:

1. Check patient weight loss.
2. Wipe the fluid detector tray dry.
3. Continue treatment.

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2 Attentions

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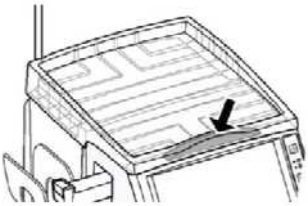
2.1 Attention indication

When an attention is generated, the machine indicates an attention as follows:



The **Information** tab is flashing.

The **Information** tab turns **blue** and the attention message is displayed.

The indication light above the screen shows a flashing **blue** light (frequency 1 Hz).

- - - (5 sec) - - - (5 sec)...

For most attentions the buzzer sounds. The buzzer sound for attentions is called notification sound. The notification sound is a recurring sound of three tones that are repeated with a 5 second intermission.

The **Mute** button is flashing.

The light stops flashing when the attention is confirmed and/or the cause of the attention is corrected.

2.2 General attention handling

Press the **Information** tab.

The attention message is displayed. The **Mute** button lights up and the buzzer is muted (the mute time varies depending on the attention).

2.3 How to find the attention

The attention descriptions in this chapter are arranged in numerical order. Each attention description has the following sections:

Appears	Describes what conditions must be present for an attention to appear; what triggers/generates the attention.
Machine actions	Describes which actions that will automatically be taken by the machine due to the attention.
Operator action	Describes the actions that are expected from the operator when an attention appears.
Mute time	When the mute button is pressed, the buzzer sound will be muted during the specified period of time

When {0} is displayed in the descriptive text in an attention, it is replaced with a live integer value.

2.4 List of attentions

500 Air detector not activated

```
500 Air detector not activated
Activate air detector.
```

Appears:
During priming, 15 seconds after the venous drip chamber has been filled upon another attention request.

Machine actions:
None.

Operator action:
Press the **Air detector** button to activate the air detector alarm function.

Mute time:
2 minutes.

501 Air leakage in fluid path

```
501 Air leakage in fluid path
Check fluid tube connectors to dialyzer.
```

Appears:
When the dialysis fluid tubes are not properly connected to the dialyzer.

Machine actions:
None.

Operator action:
Check the dialysis fluid tubes connections. See Section 4.2.7 “Priming the dialysis circuit” on page A:91 in Operators handbook.

Mute time:
2 minutes.

WARNING!
If no action is taken for this attention, the patient may get incorrect weight loss during the treatment.

502 Arterial clamp test failed

```
502 Arterial clamp test failed
Check arterial line and press Confirm.
```

Appears:
When the arterial clamp test fails.

Machine actions:
The machine stops the arterial clamp test until the attention is confirmed.

Operator action:
Press `Confirm`.

Mute time:
2 minutes.

503 Battery failure

```
503 Battery failure
Blood pump will not be able to run in case of
power failure. To continue, change battery or
press Confirm.
```

Appears:

- When the backup battery does not pass functional check.
- After treatment if the backup battery test fails.

If the functional check fails, the alarm sound will be delayed for 1 minute.

Machine actions:

None.

Operator action:

Press `Confirm`.

Mute time:

Permanent.

504 Battery power is low

```
504 Battery power is low
The machine will turn off within one minute.
```

Appears:
During power failure when the battery power is too low during priming or disinfection.

Machine actions:
The dialysis machine stops.

Operator action:
None.

Mute time:
Permanent.

505 BiCart holder is not closed

```
505 BiCart holder is not closed
Close BiCart cartridge holder.
```

Appears:
When the BICART cartridge holder is not properly closed.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:
Close the BICART cartridge holder.

Mute time:
2 minutes.

506 BiCart is not attached to holder

```
506 BiCart is not attached to holder
Attach BiCart cartridge.
```

Appears:
When the BICART cartridge is not properly attached to the holder.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:
Attach or check BICART cartridge. See Section 4.2.3 “Set up the dialysis machine” on page A:77 in Operators handbook.

Mute time:
Permanent.

507 Blood leak detector failure

```
507 Blood leak detector failure
Clean detector and press Confirm.
```

Appears:
During functional check if the blood leak detector is dirty or out of function.

Machine actions:
None.

Operator action:

1. Clean the blood leak detector, see Section 13.3 “Clean the blood leak detector” on page A:173 in Operators handbook.
2. Press `Confirm` to continue.

If the attention appears again, contact an authorised technician.

Mute time:
Permanent.

508 Blood pump door is not closed

```
508 Blood pump door is not closed
Close blood pump door and if not possible,
check the mounting of the pump rotor.
```

Appears:
When the blood pump door has not been properly closed.

Machine actions:
- The blood pump stops.
- After 2 minutes there is a buzzer sound.

Operator action:
Close the blood pump door.

Mute time:
2 minutes.

509 Blood pump is overloaded

```
509 Blood pump is overloaded
Check blood lines for obstruction. Start blood
pump.
```

Appears:
When the blood pump is overloaded and can hardly run in priming.

Machine actions:
The blood pump stops.

Operator action:

1. Check that the blood pump segment is correctly placed, see Section 4.2.4 “Attach the arterial blood line” on page A:79 in Operators handbook.
2. Press `Confirm` to continue.

If the attention appears again, contact an authorised technician.

Mute time:
2 minutes.

510 Blood pump overloaded

```
510 Blood pump overloaded
Check blood pump for obstruction. To continue
press Confirm.
```

Appears:
When the blood pump is overloaded and can hardly run in functional check.

Machine actions:
The blood pump stops.

Operator action:

1. Check that the blood pump segment is correctly placed, see Section 4.2.4 “Attach the arterial blood line” on page A:79 in Operators handbook.
2. Press `Confirm` to continue.

If the attention appears again, contact an authorised technician.

Mute time:
Permanent.

511 Blood pump test failed

```
511 Blood pump test failed
Check pump segment and arterial bloodline for
obstruction. To continue press Confirm.
```

Appears:
When the blood pump rotation test fails.

Machine actions:
The machine stops the blood pump test until the attention is confirmed.

Operator action:
Check the blood line and confirm the attention.

Mute time:
2 minutes.

512 BPM failure

```
512 BPM failure
To turn off BPM press Confirm.
```

Appears:
When an error is detected by the BPM.

Machine actions:
None.

Operator action:
Press `Confirm` to confirm that the BPM will not be used.

If the attention appears again, contact an authorised technician.

Mute time:
Permanent.

513 Buzzer failure

```
513 Buzzer failure
No audible alarm will be issued.
```

Appears:
When the loudspeaker fails to produce sounds in a alarm or attention situation.

Machine actions:
None.

Operator action:
Continue treatment and pay attention to visual alarm indications.

Mute time:
-

514 Central chemical disinfection dwell is complete

```
514 Central chemical disinfection dwell is
complete
To continue press Confirm.
```

Appears:
When the dwell time in central disinfection has passed.

The dwell time can be preset.

Machine actions:
None.

Operator action:
Press `Confirm` to continue.

Mute time:
Permanent.

515 Check rotor/tube distance

```
515 Check rotor/tube distance
To continue press Confirm.
```

Appears:
When the blood pump segment has been changed.

Machine actions:
None.

Operator action:
See Section 4.2.4 “Attach the arterial blood line” on page A:79 in Operators handbook and press `Confirm` to clear the attention.

Mute time:
2 minutes.

516 Chemical fillup volume is too low

```
516 Chemical fillup volume is too low
Check pickup tube and disinfectant container.
```

Appears:
In the fill-up phase during a chemical disinfection program.

Machine actions:
The disinfection program stops.

Operator action:
1. Check the pick-up tube and the disinfectant container.
2. Press `Confirm` to start the fill-up phase again.

Mute time:
Permanent.

517 CleanCart fill is completed

```
517 CleanCart fill is completed
Open upper latch, press Confirm and wait for
CleanCart cartridge to drain.
```

Appears:
During heat disinfection program with CLEANCART cartridge.

The appearance of the attention can be preset.

Machine actions:
None.

Operator action:

1. Open the upper latch of the BiCart cartridge holder.
2. Press `Confirm`.

See Section 10.3.4 “Start a heat disinfection with a CLEANCART cartridge” on page A:146 in Operators handbook.

Mute time:
Permanent.

518 CleanCart is not attached

```
518 CleanCart is not attached
Attach CleanCart cartridge.
```

Appears:
When the CleanCart cartridge is not properly attached to the BiCart cartridge holder during a heat disinfection program.

Machine actions:
After 1 minute there is a buzzer sound. The delay is only valid at first occurrence.

Operator action:

1. Attach the CleanCart cartridge to the BiCart cartridge holder.
2. If it is already attached, make sure it is properly located.

See Section 10.3.4 “Start a heat disinfection with a CLEANCART cartridge” on page A:146 in Operators handbook.

Mute time:
Permanent.

519 Cleaning is required

```
519 Cleaning is required
{0} hours since last cleaning. To clear
attention press Confirm.
```

Appears:
When a cleaning program is needed.

The period of time between the last performed cleaning and the appearance of the attention can be preset.

Machine actions:
None.

Operator action:
If possible, run a cleaning program, for example a heat disinfection program with CLEANCART A cartridge or a chemical disinfection program with sodium hypochlorite.

If the time or situation is not suitable for a cleaning program, press `Confirm` to clear the attention. Clean the dialysis machine after the treatment, or the attention will appear again during the next treatment.

Mute time:
Permanent.

520 Concentrate tube A is out of position

```
520 Concentrate tube A is out of position
Check the position.
```

Appears:
When the red concentrate connector is not in the correct position.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:
Check the placement of the red concentrate connector.

Mute time:
5 minutes.

521 Concentrate tube B is out of position

```
521 Concentrate tube B is out of position
Check the position.
```

Appears:
When the blue concentrate connector is not in the correct position.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:
Check the placement of the blue concentrate connector.

Mute time:
5 minutes.

522 Decalcification required

```
522 Decalcification required
{0} treatments since last decalcification. To
clear attention press Confirm.
```

Appears:
When a decalcification program is needed. Too many treatments performed since last decalcification.

The number of treatments between the last performed decalcification and the appearance of the attention can be preset.

Machine actions:
None.

Operator action:
If possible, run a decalcification program, for example a heat disinfection program with CLEANCART C cartridge or liquid citric acid. (A Short heat Citric program cannot be used).

If the time or situation is not suitable for a decalcification program, press `Confirm` to clear the alarm. Disinfect the dialysis machine after the treatment, or the attention will appear again during the next treatment.

Mute time:
Permanent.

523 Dialysis fluid flow is too low

```
523 Dialysis fluid flow is too low
```

Appears:
When the flow rate of the dialysis fluid is below the set low alarm limit. This is because the flow rate is manually set below the alarm limit or there is an obstruction in the dialysis fluid flow path.

Machine actions:
None.

Operator action:
If possible, increase the dialysis fluid flow rate. If this is not possible, contact an authorised technician.

If the attention is not solved, it will appear again in the next treatment.

Mute time:
Permanent.

524 Dialysis fluid is bypassed

```
524 Dialysis fluid is bypassed
Check fluid tube connections to the dialyzer.
Deactivate fluid bypass.
```

Appears:
When fluid is bypassed by the operator during recirculation and extra recirculation.

Machine actions:
During bypass the remaining recirculation time is not updated.

Operator action:
Press the `Fluid bypass` button.

Mute time:
Permanent.

525 Dialysis fluid not ready for treatment

```
525 Dialysis fluid not ready for treatment
Fluid is ready in {0} s.
```

Appears:
When ultrafilter flush is started.

Machine actions:
None.

Operator action:

1. Wait until the attention disappears and the bypass path on the screen lights up green.
2. Disconnect the dialysis fluid tubes.

Mute time:
-

526 Diascan clearance is too low

```
526 Diascan clearance is too low
Check treatment settings and check/adjust
clearance limit. To continue press Confirm.
```

Appears:
When the measured clearance value is below the set alarm limit.

Machine actions:
None.

Operator action:
1. Check for a cause.
2. Adjust treatment parameters to increase clearance or adjust the alarm limit for clearance.

Mute time:
Permanent.

527 Diascan clearance measurement failed

```
527 Diascan clearance measurement failed
To continue press Confirm.
```

Appears:
When the dialysis machine cannot perform the measurement check.

Machine actions:

- If a single clearance measurement check is activated it will automatically be deactivated. The clearance measurement function is turned off.
- If continuous clearance measurement is activated, the actual clearance measurement check will automatically be deactivated. The following measurement checks will continue as set.

Operator action:
Press `Confirm` to confirm the machine actions. If desired, reactivate the single clearance measurement check.

Mute time:
-

528 Diascan clearance measurement is not restarted

```
528 Diascan clearance measurement is not
restarted
Check Diascan set values and reactivate
Diascan.
```

Appears:
When the clearance measurement function has been automatically deactivated.

Machine actions:
None.

Operator action:
1. Press the `Diascan` button.
2. Check that the set clearance measurement parameter values are the correct ones, adjust if necessary.
3. Press `Confirm` to restart the clearance measurement function.

Mute time:
2 minutes.

529 Diascan clearance measurements paused during isolated UF

```
529 Diascan clearance measurements paused
during isolated UF
Clearance measurement restarts when isolated
UF is complete.
```

Appears:
During an attempt to activate the clearance measurement function or a clearance measurement check (single or continuous) during ongoing isolated UF phase.

Machine actions:
The clearance measurement will automatically be paused during the Isolated UF phase. The clearance measurement starts automatically when the isolated UF phase is complete.

Operator action:
The attention disappears after 30 seconds.

Mute time:
Permanent.

530 Diascan not possible during UF profiling

```
530 Diascan not possible during UF profiling
Clearance measurement is not possible during
step/interval UF profiling.
```

Appears:
During an attempt to have the clearance measurement function and UF profiling in steps or intervals active at the same time.

Machine actions:
The clearance measurement function will automatically be deactivated.

Operator action:
The attention disappears after 30 seconds.

Mute time:
Permanent.

531 Diascan sodium limit is reached

```
531 Diascan sodium limit is reached
Clearance measurement is stopped due to sodium
limit is reached. To continue press Confirm.
```

Appears:
When too many clearance measurement steps have been done during that particular treatment. Further measuring may cause the patient an imbalance in the sodium level.

Machine actions:
Clearance measurement is deactivated.

Operator action:
1. Press `Confirm` to clear the attention.
2. Contact an authorised technician.

If this attention appears frequently, discuss preset limits with an authorised technician.

Mute time:
Permanent.

533 Disinfection required

```
533 Disinfection required
{0} days since last disinfection. To clear
attention press Confirm.
```

Appears:
When a disinfection program is needed.

The period of time between the last performed disinfection and the appearance of the attention can be preset.

Machine actions:
None.

Operator action:
If possible, run a heat disinfection program.

If the time or situation is not suitable for a heat disinfection program, press `Confirm` to clear the attention. Disinfect the dialysis machine after the treatment, or the attention will appear again during the next treatment.

Mute time:
Permanent.

534 Fluid in bypass for too long

```
534 Fluid in bypass for too long
Fluid has been in bypass for more than 5 min.
```

Appears:
5 minutes after the dialysis fluid has been bypassed (the `Fluid bypass` button has been pressed).

Machine actions:
None.

Operator action:
Press the `Fluid bypass` button.

Mute time:
2 minutes.

535 Fluid path leakage test enabled

```
535 Fluid path leakage test enabled
Do not connect concentrate or BiCart
cartridge.
```

Appears:
During functional check when the extended fluid path leakage test is enabled.

Machine actions:
Ongoing extended fluid path test.

Operator action:
Wait until the test is finished. It is possible to connect the concentrates when the attention text has disappeared.

Mute time:
-

536 Fluid path obstruction

```
536 Fluid path obstruction
Too high blood circuit pressure. Check
circuit, start blood pump.
```

Appears:
When the machine detects an obstruction in the extracorporeal circuit (blood lines and dialyzer) or in the fluid path.

Machine actions:
The blood pump stops.

Operator action:
Check for obstructions in the extracorporeal circuit, for example kinked blood lines or clotted dialyzer and/or blood lines. Restart the blood pump when the obstruction is corrected.

Mute time:
2 minutes.

537 Fluid path obstruction during disinfection

```
537 Fluid path obstruction during
disinfection
Disinfection is stopped due to obstructed
fluid path.
```

Appears:
When an obstruction has been detected in the fluid path during disinfection.

Machine actions:

- The disinfection program stops.
- The dialysis fluid pumps stop.

Drain is automatically performed when the pressure has decreased.

Operator action:

1. Wait until the drain is finished.
2. Check if the obstruction is external, for example if the fluid tubes are clamped.
3. Check the ultrafilter (if a ultrafilter is installed)
4. Restart the disinfection.

If the attention appears again, contact an authorised technician.

Mute time:
5 minutes.

538 Fluid tube sensor test

```
538 Fluid tube sensor test
Attach fluid tubes to safety couplings. To
interrupt test press Confirm.
```

Appears:
When the dialysis machine cannot detect that the dialysis fluid tubes are attached to the safety couplings. The corresponding machine test cannot be made.

Machine actions:
The ongoing disinfection or rinse program stops.

Operator action:
To continue the disinfection or rinse program:

1. Check that the dialysis fluid tubes are properly attached to the safety couplings.
2. Press `Confirm`. The disinfection or rinse program continues.

As an alternative, consult an authorised technician.

Mute time:
2 minutes.

539 Fluid tube sensor test

```
539 Fluid tube sensor test
Attach fluid tubes to safety couplings. To
start disinfection press Confirm.
```

Appears:
When the dialysis machine cannot detect that the dialysis fluid tubes are attached to the safety couplings. The corresponding machine test cannot be made.

Machine actions:
The ongoing disinfection or rinse program is paused.

Operator action:
To continue the disinfection or rinse program:

1. Check that the dialysis fluid tubes are properly attached to the safety couplings.
2. Press `Confirm` to continue the disinfection or rinse program.

   As an alternative, consult an authorised technician.

Mute time:
2 minutes.

540 Fluid tube sensor test

```
540 Fluid tube sensor test
Attach fluid tubes to safety couplings.
```

Appears:
When a dialysis fluid tube sensor test is stopped during a disinfection or rinse program.

Machine actions:
None.

Operator action:
Remove and attach the dialysis fluid tubes from the safety couplings to restart the test.

Mute time:
2 minutes.

541 Fluid tube sensor test

```
541 Fluid tube sensor test
Fluid tube sensor test failed. To continue
press Confirm.
```

Appears:
When the machine cannot restart the dialysis fluid tube sensor test.

Machine actions:
None.

Operator action:
1. Check that the dialysis fluid tubes are properly attached to the safety couplings.
2. Press `Confirm` to bypass the dialysis fluid tube sensor test and continue the activated disinfection or rinse program.

As an alternative, contact an authorised technician.

Mute time:
2 minutes.

542 Fluid tube sensor test

```
542 Fluid tube sensor test
To start fluid tube sensor test, remove fluid
tubes from safety couplings.
```

Appears:
When a dialysis fluid tube sensor test is stopped during a disinfection or rinse program.

Machine actions:
None.

Operator action:
Remove and attach the dialysis fluid tubes from the safety couplings to restart the test.

Mute time:
2 minutes.

543 Fluid tube sensor test

```
543 Fluid tube sensor test
Remove tubes from safety coupling. To
interrupt test press Confirm.
```

Appears:
When the dialysis machine cannot restart the dialysis fluid tube sensor test.

Machine actions:
None.

Operator action:
To continue the activated disinfection or rinse program:

1. Check that the dialysis fluid tubes are properly attached to the safety couplings.
2. Press `Confirm`. The dialysis fluid tube sensor test is bypassed.

As an alternative, consult an authorised technician.

Mute time:
2 minutes.

544 Fluid tubes in safety couplings

```
544 Fluid tubes in safety couplings
Connect fluid tubes to dialyzer.
```

Appears:
This attention can appear:

1. If the dialysis fluid tubes are still connected to the safety couplings and blood is detected by the priming detector.
2. If the dialysis fluid tubes are reconnected to the safety couplings during treatment.

Machine actions:
None.

Operator action:
Move the dialysis fluid tubes from the safety couplings to the dialyzer.

Mute time:
Permanent.

545 Fluid tubes not in safety couplings

```
545 Fluid tubes not in safety couplings
Connect fluid tubes to safety couplings.
```

Appears:
When the dialysis fluid tubes have been removed from the safety couplings during a functional check or a disinfection program.

Machine actions:
The functional check stops.

Operator action:
Connect the dialysis fluid tubes to the safety couplings. Make sure they are properly connected.

Mute time:
2 minutes during a functional check or disinfection.

546 Functional check is on hold

```
546 Functional check is on hold
Water temperature is too high.
```

Appears:
When the inlet water temperature is too high during functional check.

Machine actions:
The functional check stops. The functional check will automatically continue when the inlet water temperature has decreased.

Operator action:
Check possible cause:

- The inlet water temperature has not decreased below 45 °C within 5 minutes after the high temperature test is started.
- The inlet water temperature has not decreased below 39 °C within 5 minutes after the high temperature test is finished.

If the attention does not disappear, contact an authorised technician.

Mute time:
Permanent.

547 Functional check is prolonged due to power failure

```
547 Functional check is prolonged due to power
failure
```

Appears:
During power failure.

Machine actions:
The functional check is delayed until power returns.

Operator action:
Please wait.

Mute time:
-

548 Functional check is stopped

```
548 Functional check is stopped
To continue, disconnect venous pressure
transducer connector.
```

Appears:
When the venous pressure transducer of the venous blood line has been attached too early in functional check. See Section 4.2.5 “Attach the venous blood line” on page A:84 in Operators handbook.

Machine actions:
None.

Operator action:
Disconnect the venous pressure transducer. If the attention appears again, contact an authorised technician.

Mute time:
5 minutes.

549 Functional check is stopped

```
549 Functional check is stopped
To continue, disconnect arterial pressure
transducer connector.
```

Appears:
When the arterial pressure transducer of the arterial blood line has been attached too early in functional check. See Section 4.2.4 “Attach the arterial blood line” on page A:79 in Operators handbook.

Machine actions:
None.

Operator action:
Disconnect the arterial pressure transducer. If the attention appears again, contact an authorised technician.

Mute time:
5 minutes.

550 Functional check is stopped

```
550 Functional check is stopped
To continue functional check, connect
concentrate connectors to stand by port.
```

Appears:
During functional check if a chemical disinfection program has previously been performed and the concentrate connectors (or disinfectant connector) are not properly connected to the machine.

Machine actions:
The functional check stops.

Operator action:
- Check that the concentrate connectors are properly connected to the stand-by ports.

- Check that the disinfectant connector is properly connected to the parking port.

It is not possible to connect the concentrates yet.

Mute time:
2 minutes.

551 Functional check is stopped

```
551 Functional check is stopped
To continue functional check, close BiCart
latches.
```

Appears:
When the latches of the BICART cartridge holder are open during a functional check.

Machine actions:
The functional check stops.

Operator action:
Close the latches of the BICART cartridge holder.

It is not possible to connect the BICART cartridge yet.

Mute time:
2 minutes.

552 Functional check prolonged due to WRO

```
552 Functional check prolonged due to WRO
Water purification unit is not ready.
```

Appears:
When WRO is not accessible during a functional check.

Machine actions:
None.

Operator action:
Please wait.

Mute time:
-

553 Functional check restarted

```
553 Functional check restarted
To continue press Confirm.
```

Appears:
When the functional check is prolonged due to internal tests.

Machine actions:
The functional check restarts and is therefore prolonged.

Operator action:
None.

Mute time:
-

554 Profiling is not restarted

```
554 Profiling is not restarted
Check HCO3- setting and press Confirm.
```

Appears:
When the dialyzer and the blood lines are changed during treatment, and the treatment is resumed.

Machine actions:
The machine reactivates the previously set bicarbonate profiling setting.

Operator action:
Check actual profile settings.

1. Press the `Fluid` button.
2. Select the `Cond` tab.
3. Press `Profiling`.
4. Check that the start and stop values for HCO_3^- are the correct ones.

   If not, select HCO_3^- and deactivate profiling.
5. Change the values and reactivate profiling as usual procedure. See Section 7 “Profiling” on page A:117 in Operators handbook.

Mute time:
-

555 Heat disinfection temperature is too low

```
555 Heat disinfection temperature is too low
To clear attention press Confirm.
```

Appears:
When the dialysis machine cannot reach the right temperature during a heat disinfection program.

Machine actions:
None.

Operator action:
Press `Confirm`. Let the machine pass the ongoing program and then start a new heat disinfection program.

If the attention appears again, contact an authorised technician.

Mute time:
-

556 Heparin flow rate set to 0.0 mL/h

```
556 Heparin flow rate set to 0.0 mL/h
To accept press Confirm.
```

Appears:
When the heparin solution flow rate is set to zero.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:
Press `Confirm` to confirm that the heparin pump is not going to be used for the treatment.

Mute time:
2 minutes.

557 Heparin functional check failed

```
557 Heparin functional check failed
Heparin pump is disabled. To continue without
heparin pump press Confirm.
```

Appears:
When the functional check of the heparin pump fails.

Machine actions:
None.

Operator action:
Press `Confirm` to continue.

Mute time:
-

558 Heparin infusion is completed

```
558 Heparin infusion is completed
To continue press Confirm.
```

Appears:
This attention appears:

- when heparin bolus is completed during priming.
- when heparin bolus is completed during treatment and the heparin solution flow rate is set to zero.
- at heparin pump stop time.

The appearance of the attention can be preset.

Machine actions:
The heparin pump stops.

Operator action:
Press `Confirm` to continue.

Mute time:
Permanent.

559 Heparin pump is overloaded

```
559 Heparin pump is overloaded
Check heparin line for obstruction.
```

Appears:
When the pressure in the syringe is too high during priming.

Machine actions:
The heparin pump stops.

Operator action:
Check the syringe. Check for kinks on the thin line connected to the syringe. See Section 4.2.6 “Attach the heparin syringe” on page A:89 in Operators handbook.

Mute time:
2 minutes.

560 High inlet water conductivity

```
560 High inlet water conductivity
Too high inlet water conductivity {0:0.0}
mS/cm. Check inlet water.
```

Appears:
When the inlet water conductivity is too high (higher than 2.5 mS/cm) during a functional check.

Machine actions:
A technical alarm is generated.

Operator action:
Contact an authorised technician.

Mute time:
Permanent.

561 High inlet water conductivity

```
561 High inlet water conductivity
K+, Ca+ and Mg concentrations may be lower
than expected. To accept and continue press
Confirm.
```

Appears:
When the inlet water conductivity is between 0.5 and 2.5 mS/cm during a functional check.

Machine actions:
Depending on the inlet water conductivity, minor electrolytes concentration (potassium, calcium, magnesium) will be reduced by 4-20% in the dialysis fluid.

Operator action:
Consult the attending physician before confirming the attention and continuing the treatment.

It will not be possible to start a treatment until the attention is confirmed.

Mute time:
2 minutes.

562 Improper auto start setting

```
562 Improper auto start setting
Ready time is too close to actual time. Adjust
ready time.
```

Appears:
When the machine is switched off and the time for when the heat disinfection program or rinse program is set to be finished is too close to present time.

Machine actions:
The machine does not switch off until the time setting has been changed.

Operator action:
Change the finish time for the rinse program or heat disinfection program.

Mute time:
2 minutes.

563 Improper time and/or UF volume settings

```
563 Improper time and/or UF volume settings
Adjust time and/or UF volume.
```

Appears:
When a too high UF volume has been set in combination with the set treatment time.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:
Adjust Time (`Isolated UF time`), or UF volume (`UF volume`), until the calculated UF rate is lower than the high limit for UF rate.

Mute time:
2 minutes.

564 Incorrect acidic concentrate

```
564 Incorrect acidic concentrate
Check set value and connected concentrate.
```

Appears:
Before treatment when the selected concentrate does not match the concentrate connected to the machine.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:
Check what concentrate is set and what is connected. Make sure they are the same. See Section 4.2.3 “Set up the dialysis machine” on page A:77 in Operators handbook.

Mute time:
2 minutes.

565 Incorrect bicarbonate concentrate

```
565 Incorrect bicarbonate concentrate
Check set value and connected concentrate.
```

Appears:
Before treatment when the selected concentrate does not match the concentrate connected to the machine.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:
Check what concentrate is set and what is connected. Make sure they are the same. See Section 4.2.3 “Set up the dialysis machine” on page A:77 in Operators handbook.

Mute time:
2 minutes.

566 Incorrect conductivity

```
566 Incorrect conductivity
Check set values and concentrate/connectors
and press Confirm.
```

Appears:
When the conductivity is not correct during a functional check.

Machine actions:
None.

Operator action:
1. Check that the red concentrate connector is properly connected to the pick-up tube and the concentrate container, see Section 4.2.3 “Set up the dialysis machine” on page A:77 in Operators handbook.
2. Check that the correct concentrate is connected.
3. Check that the SoftPac container pin is broken.
4. Press `Confirm`.

Mute time:
5 minutes.

567 Incorrect dialysis fluid composition

```
567 Incorrect dialysis fluid composition
Check selection of concentrate.
```

Appears:
When the dialysis fluid composition deviation (the relation between the acidic and the bicarbonate concentrate) is too high.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Operator action:
Check what concentrate is set and what is connected. Make sure they are the same. See Section 4.2.3 “Set up the dialysis machine” on page A:77 in Operators handbook.

Mute time:
2 minutes.

568 Inlet water pressure is too low

```
568 Inlet water pressure is too low
Check water supply.
```

Appears:
When the water supply pressure is too low.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:
Check the water supply.

Mute time:
2 minutes.

569 Kt/V target reached

```
569 Kt/V target reached
To continue press Confirm.
```

Appears:
When the set target value for Kt/V is reached.

Machine actions:
None.

Operator action:
Press `Confirm` to confirm the attention.

It is possible to increase the Kt/V target value. The machine will recalculate time to target.

Mute time:
-

570 Kt/V target will not be reached

```
570 Kt/V target will not be reached
Check treatment settings and check/adjust Kt/V
alarm limit. To continue press Confirm.
```

Appears:
Kt/V forecast value is below the set alarm limit for Kt/V.

Machine actions:
None.

Operator action:
Check for a cause, adjust treatment parameters or adjust the alarm limit for Kt/V.

Mute time:
Permanent.

571 Leakage test failed

```
571 Leakage test failed
Check fluid tubes. To continue press Confirm.
```

Appears:
When the fluid tubes are not properly attached to the safety couplings.

Machine actions:
The leakage test is repeated until it is approved, or until the function check is stopped.

Operator action:
Check the fluid tubes and confirm the attention.

Mute time:
2 minutes.

573 Low flow heat is stopped

```
573 Low flow heat is stopped
To continue to drain phase press Confirm.
```

Appears:
When the WRO 300 H cannot deliver hot water during integrated heat disinfection program with WRO 300 H. The low flow heat phase (where the machine receives hot water from the WRO 300 H) will not start.

This attention can appear if you manually choose to start a low flow heat phase but do not confirm it within 5 minutes.

Machine actions:
The low flow heat phase does not start.

Operator action:
1. Press `Confirm` to confirm the attention. The machine now enters drain phase.
2. Contact an authorised technician.

Mute time:
Permanent.

574 Monitor temperature is too high

```
574 Monitor temperature is too high
Switch off the machine.
```

Appears:
When the temperature inside the monitor is more than 58 °C.

Machine actions:
None.

Operator action:
Consult an authorised technician. The air filter may be filled with dust.

Mute time:
Permanent.

575 Profiling is not restarted

```
575 Profiling is not restarted
Check Na+ setting and press Confirm.
```

Appears:
When the dialyzer and the blood lines are changed during treatment, and the treatment is resumed.

Machine actions:
The machine reactivates the previously set sodium profiling setting.

Operator action:
Check actual profile settings.

1. Press the `Fluid` button.
2. Select the `Cond` tab.
3. Press `Profiling`.
4. Check that the start and stop values for `Na+` are the correct ones.

   If not, select `Na+` and deactivate profiling.
5. Change the values and reactivate profiling as usual procedure. See Section 7 “Profiling” on page A:117 in Operators handbook.

Mute time:
-

576 Negative UF rate

```
576 Negative UF rate
Check patient for weight gain. Check for
obstructions.
```

Appears:
When there is a backfiltration of 500 mL to the patient or a backfiltration rate >50 mL/min for 5 minutes.

Machine actions:
None.

Operator action:

1. Check if there are obstructions in the outlet tube (the tube where the used dialysis fluid flows out from the dialysis machine).
2. Remove any obstructions and press `Confirm`.
3. Check that the UF rate is correct. If not, contact an authorised technician.

Mute time:
2 minutes.

WARNING!
If no action is taken for this attention, the patient may get incorrect weight loss during the treatment.

577 New Ultrafilter required

```
577 New Ultrafilter required
{0} days since last change.
```

Appears:
When the ultrafilter needs to be replaced. Too many days passed since last change.

The period of time between the last change and the appearance of the attention can be preset.

Machine actions:
None.

Operator action:
Replace the ultrafilter and confirm that the ultrafilter has been replaced.

Mute time:
Permanent.

578 New Ultrafilter required

```
578 New Ultrafilter required
{0} disinfections since last change.
```

Appears:
When the ultrafilter needs to be replaced. Too many disinfections performed since last change.

The number of disinfections between the last change and the appearance of the attention can be preset.

Machine actions:
None.

Operator action:
Replace the ultrafilter and confirm that the ultrafilter has been replaced.

Mute time:
Permanent.

579 New Ultrafilter required

```
579 New Ultrafilter required
{0} hypochlorite disinfections since last
change.
```

Appears:
When the ultrafilter needs to be replaced. Too many hypochlorite disinfections performed since last change.

The number of hypochlorite disinfections between the last change and the appearance of the attention can be preset.

Machine actions:
None.

Operator action:
Replace the ultrafilter and confirm that the ultrafilter has been replaced.

Mute time:
Permanent.

580 No backfiltration warning

```
580 No backfiltration warning
TMP alarm limit/s below 0 mmHg. To accept and
continue treatment press Confirm.
```

Appears:
When the low TMP alarm limit is set below zero.

The appearance of the attention can be preset.

Machine actions:
None.

Operator action:
Since the TMP alarm limits have been set below zero there may be backfiltration to the patient without TMP alarm.

Mute time:
-

581 No BPM cuff is attached

```
581 No BPM cuff is attached
Check BPM connectors. To clear attention press
Confirm.
```

Appears:
When the blood pressure monitor detects that the cuff is not attached to the machine.

Machine actions:
After 2 minutes there is a buzzer sound.

Operator action:

- Check for kinks or leakage from the cuff and the cuff hose.
- Check that the cuff hose is properly connected to the machine.

Mute time:
Permanent.

584 Priming volume limit is achieved

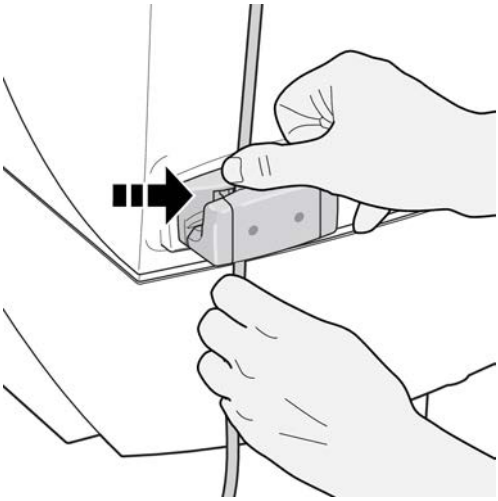
```
584 Priming volume limit is achieved
To continue press Confirm.
```

Appears:
When the extra priming volume limit has been reached.

The extra priming volume limit can be preset.

Machine actions:
None.

Operator action:
If this attention appears during initiation of the treatment, check that the venous blood line is properly inserted into the priming detector.



Press `Confirm`.

Mute time:
2 minutes.

585 Profiling is not restarted

```
585 Profiling is not restarted
Check profiling and UF, Na+ and HCO3+ set
values and reactivate profiling.
```

Appears:
When treatment is resumed after the dialyzer and the blood lines have been changed during treatment.

Machine actions:
The machine runs with the conductivity and/or the UF rate settings present when `New blood circuit` was selected and discontinuing mode was activated.

Operator action:
Check actual set profiling values and reactivate profiles.

1. Press the `Fluid` button.
2. Check that the start and stop values for one or both of the following profiling type are correct.
   - Select the `UF rate` tab and then press `Profiling`.
   - Select the `Cond` tab and then press `Profiling`.
3. Reactivate the profiling function, see Section 7 “Profiling” on page A:117 in Operators handbook.

Mute time:
2 minutes.

586 Restarted after power failure

```
586 Restarted after power failure
To continue press Confirm.
```

Appears:
When the machine has recovered from power failure during priming or disinfection.

Machine actions:
None.

Operator action:
1. Press `Confirm`.
2. Check power supply and mains cable.

Mute time:
2 minutes.

588 Set fluid flow is not reached

```
588 Set fluid flow is not reached
Adjust dialysis fluid flow or call technical
service.
```

Appears:
The actual dialysis fluid flow rate is not the same as the set value. The dialysis machine cannot set the required dialysis fluid flow rate.

Machine actions:
None.

Operator action:
If the treatment can continue with a lower flow, adjust the set value to the actual value.

If this is not possible, contact an authorised technician.

Mute time:
Permanent.

589 Start air detector test

```
589 Start air detector test
Fill venous drip chamber.
```

Appears:
In the beginning of the priming phase when the venous drip chamber has not yet been filled.

Machine actions:
None.

Operator action:
When the blood pump is running, fill the venous drip chamber using the level adjustment knob. The level of priming fluid should be well above the air detector head.

When the venous drip chamber is filled, the machine will finish the functional check.

Mute time:
-

590 Heat disinfection

```
590 Heat disinfection
Start heat disinfection on WRO. To clear
attention press Confirm.
```

Appears:
When it is time to manually start the heat program in the WRO.

Machine actions:
None.

Operator action:
Press `Confirm`.

Mute time:
Permanent.

591 Low flow heat disinfection

```
591 Low flow heat disinfection
Start Low flow heat disinfection on WRO. To
clear attention press Confirm.
```

Appears:
When it is time to manually start the low flow heat program in the WRO.

Machine actions:
None.

Operator action:
Press `Confirm` to continue.

Mute time:
Permanent.

593 Time to prepare for treatment

```
593 Time to prepare for treatment
Connect concentrates.
```

Appears:
When concentrates are not connected to the machine during a functional check.

Machine actions:
The functional check stops. The functional check will automatically continue when the concentrates have been connected.

Operator action:
Connect the selected concentrate to the machine, see Section 4.2.3 “Set up the dialysis machine” on page A:77 in Operators handbook.

Mute time:
Permanent.

594 Too high TMP required

```
594 Too high TMP required
Increase time or decrease UFV.
```

Appears:
When the machine cannot maintain the required UF rate.

Machine actions:
Alarm sound is delayed for 2 minutes.

Operator action:

- Check if the dialyzer is too small or is clotted, act in accordance.
- If possible, adjust treatment time and/or UF volume until TMP decreases.

Mute time:
2 minutes.

595 Total set UF volume

```
595 Total set UF volume
To obtain total UF volume start isolated UF.
```

Appears:
When there are 2 minutes left of a diffusion phase.

Machine actions:
None.

Operator action:
The dialysis machine calculates not to reach the intended UF volume within the remaining treatment time. Do one of the following things:

- Start `Isolated UF`.
- Adjust `Isolated UF time`.
- Adjust `Treatment time`.

Mute time:
Permanent.

596 Treatment time expired

```
596 Treatment time expired
To discontinue treatment press Confirm.
```

Appears:
When treatment is finished.

Machine actions:
None.

Operator action:
Press `Confirm` to confirm end of treatment. See Section 4.3.1 “End the treatment” on page A:100 in Operators handbook for instructions how to discontinue treatment.

Mute time:
Permanent.

597 UF has been stopped for too long

```
597 UF has been stopped for too long
UF stopped for {0} min.
```

Appears:
5 minutes after UF has manually been stopped.

Machine actions:
None.

Operator action:
Press the `Ultrafiltration` button.

Mute time:
5 minutes.

598 UF rate limit is reached

```
598 UF rate limit is reached
To calculate a new limit adjust time or UF
volume. Check the resulting UF rate.
```

Appears:
When the actual UF rate differs more than 20 % from the initially calculated UF rate.

Machine actions:
Alarm sound is delayed for 2 minutes.

Operator action:
Adjust treatment time and/or UF volume to allow the machine to calculate a new UF rate.

Mute time:
2 minutes.

599 UF rate lower than minimum set

```
599 UF rate lower than minimum set
Calculated UF rate lower than set min UF rate.
Adjust time and/or UF volume or min UF rate.
```

Appears:
When the machine needs to decrease the UF rate below the set minimum UF rate in order to obtain the set UF volume at the end of treatment.

Machine actions:
Alarm sound is delayed for 2 minutes.

Operator action:
Change one or several of these settings:

- Decrease the set minimum UF rate
- Decrease treatment time to increase the UF rate
- Increase UF volume

Mute time:
2 minutes.

600 Profiling is not restarted

```
600 Profiling is not restarted
Check UF rate settings and press Confirm.
```

Appears:
When treatment is resumed after the dialyzer and the blood lines have been changed during treatment.

Machine actions:
None.

Operator action:

1. Press the `Fluid` button.
2. Select the `UF rate` tab.
3. Press `Profiling`.
4. Check that the start and stop values for UF rate are the correct ones and then press `Confirm`. If they are not correct, deactivate profiling.

   Change the values and reactivate profiling. See Section 7 “Profiling” on page A:117 in Operators handbook.

Mute time:
-

601 Actual UF may differ from set UF

```
601 Actual UF may differ from set UF
Continuously observe patient weight loss and
status.
```

Appears:
As a reminder after the first UF deviation alarm has been reset. The attention is visible throughout the treatment as a reminder that the UF regulation might be wrong.

Machine actions:
None.

Operator action:
None.

Mute time:
-

602 UF volume is achieved too early

```
602 UF volume is achieved too early
Check and adjust min UF rate set value. To
continue press Confirm.
```

Appears:
When the set UF volume has been achieved and the remaining treatment time is more than 20 minutes.

Machine actions:
Alarm sound is delayed for 2 minutes. The machine automatically sets the actual UF rate to minimum UF rate.

Operator action:

1. Press the `Fluid` button.
2. Select the `UF rate` tab.
3. Check that the minimum UF rate is suitable the patient. If not, adjust the value. If necessary, consider adjusting treatment time or UF volume within the limits for the patient´s needs and tolerance.

Mute time:
2 minutes.

603 UF volume is set to 0.0 L

```
603 UF volume is set to 0.0 L
To accept press Confirm.
```

Appears:
When the priming detector detects blood and the set UF volume is zero.

Machine actions:
Alarm sound is delayed for 2 minutes.

Operator action:
Press `Confirm` to confirm no ultrafiltration during treatment.

Mute time:
2 minutes.

604 Venous clamp test failed

```
604 Venous clamp test failed
Check venous line placement in venous clamp.
To continue press Confirm.
```

Appears:
When the venous clamp test fails.

Machine actions:
The machine stops the venous clamp test until the attention is confirmed.

Operator action:
Check that the blood lines are correctly inserted into the venous clamp and confirm the attention.

Mute time:
2 minutes.

605 WRO communication failure

```
605 WRO communication failure
Check WRO and cables.
```

Appears:
When the dialysis machine and the WRO unit cannot communicate.

Machine actions:
None.

Operator action:
Contact an authorised technician.

Mute time:
Permanent.

606 WRO not ready

```
606 WRO not ready
Check WRO status and wait for WRO to get
ready.
```

Appears:
When the WRO unit is not accessible.

Machine actions:
None.

Operator action:
Check information on WRO unit.

Mute time:
Permanent.

607 Wrong disinfectant

```
607 Wrong disinfectant
Check disinfectant. To continue press
Confirm.
```

Appears:
When the dialysis machine detects a too high or too low disinfectant concentration.

The appearance of the attention can be preset.

Machine actions:
None.

Operator action:
1. Check that the disinfectant set in the dialysis machine is the same as the actual disinfectant connected to the machine.
2. Press `Confirm` to repeat the fill-up phase.

Mute time:
Permanent.

608 Disinfection fill-up phase completed

```
608 Disinfection fill-up phase completed
Move concentrate tube B to standby position.
```

Appears:
When chemical disinfection fill-up phase is completed.

Machine actions:
None.

Operator action:
Move concentrate tube B to standby position.

Mute time:
5 min.

609 Start air detector test

```
609 Start air detector test
Fill venous drip chamber.
```

Appears:
At the end of the priming phase when the venous drip chamber has not yet been filled.

Machine actions:
None.

Operator action:
When the blood pump is running, fill the venous drip chamber using the level adjustment knob. The level of priming fluid should be well above the air detector head.

When the venous drip chamber is filled, the machine will finish the functional check.

Mute time:
Permanent.

612 No patient ID is confirmed

```
612 No patient ID is confirmed
Confirm a patient ID. To continue without a
patient ID, press Confirm.
```

Appears:
When the machine is in pre-treatment mode or when `Connect patient` is selected, and the patient´s ID is not defined.

Machine actions:
None

Operator action:

1. Enter the patient´s id and press `Confirm`.

When it is not required to enter a patient ID:

1. Press the `Confirm` button.

Mute time:
Permanent

613 Treatment history was not transferred to the server

```
613 Treatment history was not transferred to
the server
Document treatment history manually. To close
this message, press Confirm.
```

Appears:
If the machine has a permanent failures sending treatment data to the Clinical Information System.

Appears when the operator presses the `Disinfection` button and unsent messages remain or permanent failures have occurred.

Machine actions:
None

Operator action:
Treatment data in the Clinical Information System is not complete. Treatment information is available in the History tab.

Manual documentation on paper, etc. is needed.

1. Press `Confirm` to continue.

Mute time:
Permanent

614 Leakage detected

```
614 Leakage detected
Internal fluid leakage detected. To continue,
wipe fluid detector container dry.
```

Appears:
When the machine has detected a fluid leakage.

Appears in:

- Function check
- Blood line preparation
- Pre treatment
- Post treatment

Machine actions:

- Close valves to stop leakage to the environment.

Operator action:

1. Wipe the fluid leakage detector tray dry.
2. Continue treatment.

Mute time:
2 min

615 Internal fluid leakage detector functional check failed

```
615 Internal fluid leakage detector functional
check failed
To continue without leakage detector, press
Confirm.
```

Appears:

- When the internal leakage detector did not pass the functional check.
- Is repeated after treatment to remind the operator of a failed function check.

Machine actions:

None

Operator action:

1. Press `Confirm` to continue treatment with the internal leakage detector disabled.
2. Contact an authorised technician if the error remains.

Green fluid path will not occur until `Confirm` is pressed.

Mute time:

Permanent

616 Network connection failed

```
616 Network connection failed
Check network cable. Treatment history saved
on the machine. To close this message press
Confirm.
```

Appears:
When it is not possible to connect to the Clinical Information System.

Machine actions:
The machine will save treatment data until restarted. If a network connection is established before a restart, the saved data will be sent to the Clinical Information System.

Operator action:
1. Check the network cable.
2. Press `Confirm` to continue.

Mute time:
N/A

617 Leakage detected during disinfection

```
617 Leakage detected during disinfection
Internal fluid leakage detected. Disinfection
is aborted. Not possible to continue
disinfection.
```

Appears:
When the machine has detected a fluid leakage during disinfection.

Machine actions:

- Close valves to stop leakage to the environment.
- Disinfection is stopped.

Operator action:

1. Empty the fluid leakage detector.
2. Contact an authorised technician.

It is not possible to continue disinfection.

Mute time:
2 min

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