INSTRUCTIONS FOR USE

## Platinum Software Version 6.02

# Aquarius System

# Information

This document provides instructions necessary for the proper operation of the Aquarius system. It is not a guide to the administration of the therapies provided.

Safe and effective treatment using the Aquarius system depends primarily upon the medical skills and knowledge of the attending physician and nurses. Consequently, technical competence in operation of the Aquarius system must be supplemented by a thorough understanding of the associated medical procedures.

The operator must use the Aquarius system in accordance with the information detailed in the present Instructions For Use and after adequate training by the manufacturer. Patient treatment must be in accordance with specific procedures prescribed by a qualified physician.

The Aquarius system must be installed by a manufacturer certified technician.

# Table of Contents

# 1 How to use this document (IFU)

The Aquarius system must only be operated in accordance with the procedures contained in this Instructions for Use, by trained and qualified personnel.

The use of operating procedures, maintenance procedures or accessory devices other than those published or recommended by the manufacturer can result in patient injury or death.

## 1.1 Organization

The material in this Instructions for Use is organized in 11 sections.

| Section Title | Content |
|---|---|
| 1-How to use this Instructions for Use | This section describes the organization and content of this document. |
| 2-Intended purpose | This section describes the intended purpose, indications, contraindication, and general warnings of Aquarius system. |
| 3-Getting started with the Aquarius system | This section provides the precautions and instructions needed to set up the Aquarius system. |
| 4-Introducing the Aquarius system | This section describes the Aquarius system. |
| 5-Performing a treatment with the Aquarius system | This section describes the steps necessary to turn on the Aquarius system, prime the system, connect to a patient, perform a treatment and end a treatment. |
| 6-Aquarius system alarms and messages | The alarms and messages generated by the Aquarius system are described. For each alarm, potential causes and corrective actions are listed. |
| 7-Aquarius system technical data | Lists the technical specifications of the Aquarius system. |
| 8-Guidance and manufacturer declaration-Electromagnetic emissions | Describes compliance with EMC norms. |
| 9-Aquarius system cleaning and disinfection | Cleaning and disinfection instructions are listed here for the Aquarius system. |
| 10-Aquarius system warranty and liability | Information related to warranty and liabilities are described in this section. |
| 11-References | References used to generate this document |

## 1.2 Related publications

Aquarius system Service Manual: Information on the configuration of the instrument, testing and calibration of all systems (including safety systems), required periodic maintenance, necessary diagrams and replacement parts are all contained in the Service Manual.

To determine if a more recent version of the Aquarius system Instructions for Use is available, contact your service representative.

## 1.3 Symbols used in this Instructions for Use

When step-by-step instructions are being given, the left column on the page is used for the step number. Otherwise, you may see one of the following symbols.

This symbol indicates that the text to the right is necessary information to fully understand the procedures that follow.

This symbol indicates supplementary information.

This symbol draws attention to a "*Caution*". "*Cautions*" are used to warn the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

This symbol is used to draw your attention to a "*Warning*". "*Warnings*" are used to alert the reader about a situation which, if not avoided, could result in death or serious injury.

This symbol is used in graphics to call your attention to the part of the graphic referred to in the accompanying text. If it includes a number, the number refers to the step or sub-step number in the text.

### Symbols used on/in the Aquarius system

Mute

Reset Air Detector / Return Clamp

Balance On/Off

Blood Pump On/Off

Filtrate Scale (Yellow Dot)

Substitution Scale (Green Dot)

~ Alternating current

Potential equalization conductor

Protective earth conductor

Degree of protection against shock: Type B.

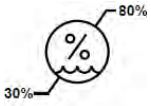
Year of manufacture

Manufacturer

Separate collection for electrical and electronic equipment

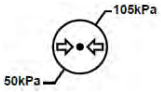
Product conforms to a particular directive of the European Union
(European Medical Device Directive 93/42/EEC)
0123 is the identification number of the Notified Body TUV SUD Product Service

Non-condensing




Humidity range for transportation and storage of product (from 30 to 80%)


Temperature range for transportation and storage (from -5 to 45°C)




Pressure range for transportation and storage (from 50 to 105 kPa)

IPX1

Degree of case waterproofing: protection against vertically falling water drops

Follow instructions for use


Indicates compliance with both Canadian and U.S. requirements with respect to electrical shock, fire and mechanical hazards in accordance with UL 60601-1:2003 and CAN/CSA-C22.2 No. 601.1-M90.

Interference may occur in the vicinity of equipment marked with this symbol

Up (Package labeling)

Fragile (Package labeling)

Keep dry (Package labeling)

Do not remove from pallet

Installation by authorized technician before use


Pollution control symbol (China)

| | |
|---|---|
| Hemofiltration system | Generic device name according Global Medical Device Nomenclature (GMDN) |

## 1.4 Abbreviations and terms used in this Instructions for Use

### 1.4.1 Organizations

| Abbreviation | Definition |
|---|---|
| AAMI | Association for the Advancement of Medical Instrumentation |
| CSA | Canadian Standards Association. This designation indicates that a product conforms to the standards of the Canadian Standards Association. |
| TÜV | Technische Überwachungs-Vereine (Testing laboratories) |
| UL | Underwriters' Laboratories. This designation indicates that a product conforms to the standards set by Underwriters' Laboratories. |

### 1.4.2 Units of measure

| Abbreviation | Definition |
|---|---|
| A | Ampere (unit of electric current) |
| °C | Degrees Celsius |
| cm | Centimeters |
| °F | Degrees Fahrenheit |
| h | Hour |
| Hz | Hertz (unit of frequency) |
| kg | Kilogram |
| l | Liter |
| min | Minute |
| ml/h | Milliliters per hour |
| ml/min | Milliliters per minute |
| mmHg | Millimeter of mercury (unit of pressure) |
| s | Second |
| V | Volt |

### 1.4.3 Other expressions

| Expression | Definition |
|---|---|
| Access | The tubing line supplying blood from the patient. |
| ADU | Automatic Degassing Unit |
| Balance pumps | Pre- and post-dilution pumps, Filtrate pump |
| BLD | Blood Leak Detector |
| CE | Conformité Européenne. This designation indicates that a product conforms to a particular directive of the European Union. |
| CRRT | Continuous renal replacement therapies |
| CVVH | Continuous veno venous hemofiltration |
| CVVHD | Continuous veno venous hemodialysis |
| CVVHDF | Continuous veno venous hemodiafiltration |
| EP | European Pharmacopoeia |
| FFP | Fresh Frozen Plasma |
| Fluid loss total | Amount of fluid removed from the patient |
| Hemofilter | Filter used in hemofiltration for its practical impermeability to albumin. |
| Hemoperfusion (HP) | Blood filtration using adsorption |
| Hypervolemia | Name of the medical state caused by excessive fluid in the blood |
| Hypovolemia | Name of the medical state caused by a decrease in blood plasma |
| Important | Highlights specific actions or steps to be followed in order to avoid defeating equipment functionality or cause product damage |
| IFU | Instructions for Use (this document) |
| I.V. | Intravenous |
| $K_{Uf}$ | Ultrafiltration coefficient |
| Note | Instructs in specific terms where a general statement about an action or a series of actions may be vague or confusing and clarifies other issues needing the reader's attention |
| Operator | Trained medical personnel using Aquarius system |
| PD | Pressure drop |
| Reminder | Specifies that the given information has been previously mentioned |
| Return | The tubing line returning blood to the patient |
| SCUF | Slow continuous ultrafiltration |
| TMP | Transmembrane pressure |
| TPE | Therapeutic plasma exchange |
| Turnover rate | The sum of the programmed Loss rate, the Pre-dilution and the Post-dilution substitution fluid rates. |
| UF | Ultrafiltration |

# 2 Intended purpose

## 2.1 Intended use

The Aquarius system is indicated for continuous renal replacement therapies (CRRT) in patients with acute renal failure or fluid overload.

The Aquarius system may also be used in Therapeutic Plasma Exchange (TPE) and Hemoperfusion therapies.

## 2.2 Area of Application – Indications

The Aquarius system controls and monitors the extracorporeal blood circuit and the fluid balance circuit. The fluid balance circuit is defined as a filtrate/substitution system in hemofiltration, a filtrate/dialysate system in hemodialysis, a filtrate/dialysate-substitution system in hemodiafiltration, a plasma/substitution system in therapeutic plasma exchange, and a filtrate system only in slow continuous ultrafiltration. The fluid balance circuit is inactive in hemoperfusion. The fluid balance is controlled by pumps and scales.

Toxins are removed from the blood and the blood composition is corrected by means of filters and solutions, using filtration and/or adsorption in the extracorporeal circuit. The blood is then returned to the patient.

Details of treatment procedures are described in section 4.2 Proper usage /Treatment procedures of the present Instructions For Use.

All therapies using the Aquarius system must be prescribed by and performed under the responsibility of a physician who is familiar and well informed about the therapies.The prescribed treatment must be performed by trained medical personnel in medical facilities.

The Aquarius system is intended to enable anticoagulation with heparin by using the integrated heparin syringe pump in all treatment procedures. The Aquarius system heparin syringe pump is intended to deliver heparin into the extracorporeal circuit.

The use of the Aquarius system is limited to patients weighing a minimum of 20 kg and the extracorporeal blood volume, including tubing set and filter (in ml), should not exceed 10% of the patient's blood volume.

## 2.3 Contraindications

No contraindications associated specifically to the Aquarius system are currently known when it is used according to Indications.

*General*

All generally applicable side effects and contraindications for extracorporeal therapies must be observed.

An extracorporeal treatment procedure with the Aquarius system should be performed after careful consideration of the risks and benefits by the responsible physician, in patients

- incapable to tolerate an extracorporeal treatment procedure because of their age and their physical development or their clinical condition,
- with known hypersensitivity to the substances used in the extracorporeal circuit,
- with severe anemia,
- with hemorrhagic diathesis (bleeding tendencies),
- with coagulopathy (blood clotting disorders).

*Disposables*

The contraindications for the disposable medical devices / medicinal product used as accessories with the Aquarius system must be considered. It is essential to observe the instructions for use supplied with the medical device / medicinal product, as these contain updated information on areas of use, side effects, and contraindications for the respective disposable product.

## 2.4 Side effects

No side effects associated specifically with the Aquarius system are currently known.
General side effect associated to extracorporal procedures are the following:

*Stress from extracorporeal circuit*

Extracorporeal treatment procedures are always linked to individual stress for each patient, possibly leading to non-specific side effects, such as tiredness, nausea, sweating, dizziness, headache, reduction in blood pressure, change in pulse rate, arrhythmia, shock, chills, fever, or bleeding.

*Vascular access*

Extracorporeal treatment procedures require vascular access mainly created by vein puncture. Therefore, there is a possibility that the vein puncture is performed incorrectly, which may lead to hematoma, thrombosis, nerve injury, vasovegal reaction and/or inflammation of the vascular area.

*Blood loss*

Extracorporeal treatment procedures may result in blood loss caused by circuit leaks or clotting.

*Circulatory complications*

Extracorporeal treatment procedures may result in circulatory complications, such as hypertension and hypotension from temporary fluid displacement within or from the extracorporeal circuit

*Anaphylactic reaction*

Extracorporeal treatment procedures may result in anaphylactic reaction from intolerance to the accessories, exchange fluid, dialysate solution, or anticoagulants

*Heparin anticoagulation*

The heparin administration can lead to side effects. Bleeding, heparin induced thrombocytopenia and other general side effects associate with Heparin must be considered.

## 2.5 Warnings

Read all warnings, precautions and instructions carefully before using the Aquarius system.
This summary does not contain all the safety statements in this Instructions for Use. Other cautions and warnings exist within this Instructions for Use.

The following warnings must be observed in order to avoid possible dangers associated with a high risk of death or severe injury for patients, operators, or third parties.

Installation and connection, moving of the device

The installation of the Aquarius system at the place of operation according to the technical service manual must be performed by trained personnel authorized by the manufacturer.

Connecting additional devices may result in exceeding the permissible leakage currents. If the system is used in parallel operations (according to open heart surgery standards), the equipotential bonding conductor must be connected.

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

When using a device of safety class I, like the Aquarius system, the quality of the protective conductor of the installation is important. It should be noted that it is officially specified by the authorities in many countries.

The Aquarius system may only be operated with connection of the potential equalization to insure electromagnetic immunity.

Release the brake of both wheels before move the device! Move the device carefully over steps or crevice.

No modification of this equipment is allowed.

Do not modify this equipment without authorization of the manufacturer.

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

Treatment environment

Do not operate devices emitting electromagnetic energy near the Aquarius system. E.g. cellular phones.

Do not operate the Aquarius system close to areas where explosive gasses or flammable anesthetics are or have been used.

The Aquarius system must not be operated simultaneously with high frequency surgical systems.

Accessories, disposable products, drugs, and replacement fluids

Solutions of different compositions must not be used simultaneously on the Aquarius system.

All solutions used must be sterile, of appropriate composition and prescribed by a physician. Use of incorrect solutions can result in patient injury or death.

If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

The operator must ensure that the correct substitution solutions and dialysate solutions prescribed by a physician are used appropriately for all therapies.

Only use heparin that complies with the requirements of national drug regulations and observe the information contained in its package insert.

It is recommended that the filters and the Aqualine tubing sets be changed after 24 hours of use.

The Aqualine tubing set (adult) has been tested under the following high end conditions without adverse effect:

Duration = 72 h
Pre-filter pressure = 450-500 mmHg
Post filter pressure = 300-350 mmHg
Blood flow = 450 ml/min
Infusion flow = 10 l/h
Temperature = 37°C

The Aqualine 'S' tubing set (pediatric) has been tested under the following high end conditions without adverse effect:

Duration = 72 h
Pre-filter pressure = 450-500 mmHg
Post filter pressure = 300-350 mmHg
Blood flow = 200 ml/min
Infusion flow = 10 l/h
Temperature = 37°C

Operation and use

Only staff trained by the manufacturer shall operate the Aquarius system.

During the system test, the operator must wait for the visual and audible alarm signals to be generated.

If there are errors during the initial functional system test the Aquarius system must not be used. Refer to onscreen help and repeat. Notify technical support if the system test continues to fail on the same error.

When entering the parameters the operator must compare the entered value with the displayed value.

The patient parameters must be entered and adjusted in accordance with the instructions of the prescribing physician.

Ensure that the patient's blood access (usually a central venous catheter) is secured properly.

Connecting or disconnecting the patient to or from the Aquarius system requires aseptic technique and continuous monitoring to prevent air from entering the system (air infusion) or blood from escaping from the system (blood loss). All system connections must be checked at regular intervals. All blood and fluid paths are sterile and non-pyrogenic.

Always follow hospital policy for standard precautions. Gloves, mask and a face shield should be worn when connecting or disconnecting blood lines from patients and removing lines from the Aquarius system.

In case of negative return pressure, air may enter into the extracorporeal circuit downstream the air detector and not be detected.

The operator must make sure that the heparin syringe used has been configured in service mode by a technician. Use only Luer-lock syringes designed for syringe pumps (ISO 7886-2).

A physician must prescribe the anticoagulation application.

When "*No anticoagulant*" is selected, constantly monitor the TMP and pressure drop values to reduce or avoid the risk of clotting of the extracorporeal circuit (filter and lines).

The operator must make sure that the pressure domes integrated in the tubing sets are clipped on properly to the pressure sensors on the Aquarius system.

Do NOT remove the pressure domes during treatment.

DO NOT move the Aquarius system during treatment: movement of the device while the Balance system is active can cause false balance alarms and may lead to undesired automatic fluid compensation.

The Aquarius system must be placed on a horizontal plane during its normal use. Angle discrepancies from the horizontal plane larger than 10° may cause device instability and inaccurate functioning.

Before removing the Aqualine tubing set or disconnecting domes after ending treatment, make sure that pressure level inside tubes are below 400 mmHg. The end treatment screen displays all four pressures from the system. Use a syringe or Aquasafe bag to decrease the pressure level before removing a dome from a pressure sensor. When domes are removed from pressure sensors in over pressure conditions, there is high risk of burst and leakage of dome membranes.

Negative ultrafiltration: Excessive negative ultrafiltration (a positive balance) may result in patient hazard. The prescribing physician must make this indication.

When pediatric treatment is used, the patient must be physiologically capable to accept the minimum extra-corporeal blood flow of 10 ml/min.

The I.V. pole may only carry a maximum weight of 2.5 kg.

The Aquarius system is not intended to be a substitute for monitoring the patient's condition.

Treatment data sent by the Aquarius system from the optical ports are intended for documentation purpose only. They are NOT intended for diagnostic purposes.

All connecting points on the system must be regularly and carefully checked to protect against blood loss. Particular care should be taken to ensure that the venous access site catheter/needle is secure and does not slip out from the vessel.

Complete monitoring of the extracorporeal system to avoid blood losses is practically impossible with the current state of technology.

The Aquarius system monitors the venous pressure in order to detect disconnections in the extracorporeal system. The system triggers an alarm if it detects a pressure drop of 30 mmHg below the working value measured 1 min after the start of the blood pump or a measured pressure lower than +20 mmHg.

Ensure that the filtrate bags and substitution bags do not touch the cart frame. Ensure that the tubing lines are not supported by and are not resting on the cart frame. Do not touch the filtrate or substitution solution bags while the balance system is active.
Observe this warning to avoid patient fluid balance errors.

Fluid leaks lead to a patient fluid balance error and can harm the patient seriously.
Ensure that all connectors are closed properly to prevent any potential fluid leak.
Ensure that unused tubing lines of the 4 way connectors are properly clamped.

Alarm and system

If for some reason the operator interface is compromised, the machine will normally stop automatically. In rare instances, the machine will continue with a black screen (for example if the back light is broken). In such instances, the machine should be stopped manually and the blood returned to the patient. This is possible by removing the return line from the automatic clamp and manually turning the blood pump with the hand-crank. The hand-crank is located at the back of the scale system. Be careful during manual blood return to patient, as the return line is not automatically clamped if air is present.

When bypassing one or more of the safety controls the operator is responsible for monitoring the patient.

If power is restored after a power outage the operator is responsible for monitoring the patient.

Interference to the Electrocardiograph (ECG) monitor

Electrically isolated peristaltic pumps such as those used on the Aquarius system can produce electrostatic charges in the disposable set that are not hazardous to the patient, but can appear as an artifact on cardiac monitors. When starting treatment, observe the cardiac monitor before and after starting the blood pump to verify that the artifact is not present.

# 3 Getting started with the Aquarius system

## 3.1 Setting up

Personnel authorized by the manufacturer must perform set up and installation of the Aquarius system, according to the requirements.

When setting up the Aquarius system, the room and the necessary power installations must comply with the currently valid standards. Line voltage must conform to the data specified on the data plate of the Aquarius system.

Before putting the Aquarius system into operation carefully read the complete operating manual.

## 3.2 Installation

Before operating the Aquarius system for the first time, ensure that the system is complete and that all parts have been delivered with it. If the Aquarius system is damaged, do not put it into operation. In this case, notify the service technician responsible for this system.

The Aquarius system should only be set up and installed by qualified staff authorized by the manufacturer.

Only authorized staff together with the prescribing physician should do basic modifications of particular settings that do not change the safety concept of the Aquarius system.

## 3.3 Equipment: disposables

The Aquarius system is designed to operate exclusively with the standard disposables intended for the indicated treatments. Follow the instructions for use provided by the manufacturer.

Use only the tubing sets stated below to ensure the proper operation of the Aquarius system.

| Item | Description | Manufacturer |
|---|---|---|
| Tubing set | REF: Aqualine tubing<br>Adult line set<br>Extracorporeal volume (Blood circuit) = 112 ml* | Haemotronic |
| Tubing set | REF: Aqualine 'S' tubing<br>Pediatric line set<br>Extracorporeal volume (Blood circuit)= 65 ml* | Haemotronic |

*These values assume that the drip chamber is full.

The Aquarius system level test was performed with the following disposables:

| Item | Description | Manufacturer |
|---|---|---|
| Tubing set | REF: Aqualine tubing<br>Adult line set<br>Extracorporeal volume (Blood circuit) = 100 ml* | Haemotronic |
| Tubing set | REF: Aqualine 'S' tubing<br>Pediatric line set<br>Extracorporeal volume (Blood circuit) = 61 ml* | Haemotronic |
| Hemofilter | REF: HF03, HF07+, HF12, HF19<br>Aquamax hemofilters | Bellco |
| Plasma filter | REF: MPS05<br>Plasma filter 0.5 $m^2$ | Bellco |
| Solution | Accusol 35<br>Replacement solution for CRRT, 5L | Baxter |
| Disposable | REF: Aquasafe bags<br>For use with Aqualine and Aqualine 'S' tubing sets, prior to their removal from the machine, to decrease internal pressure | Haemotronic |
| Disposable | REF: Aquaspike 2 manifolds<br>Manifolds for connecting up to four solution or waste bags | Haemotronic |
| Disposable | REF: B3052<br>Waste bag | Haemotronic |
| Syringe** | REF: BD Plastipak 50ml<br>Syringe for Heparin pump | Becton Dickinson |
| Syringe** | REF: Fresenius Injektomat Syringe 50ml<br>Syringe for Heparin pump | Fresenius |
| Syringe** | REF: Original Braun Perfusor Syringe 50ml<br>Syringe for Heparin pump | BBraun |

*These values assume that the drip chamber is 2/3 full, which is the normal situation during treatment.
** Important: Use only with max. 50ml, even if the max. volume of the syringe is 60ml

Hemofilters, plasma filters, hemoperfusion cartridges and solutions to be used with the Aquarius system must conform to applicable standards. Use only products with blood port connections compatible with ISO 594 (Part 1+2) female Luer lock connectors, and connections of dialysate, filtrate and plasma ports compatible with male Luer lock connectors.

Use catheters according to the instructions provided by the manufacturer; the catheter connector has to be compatible with male Luer lock connectors.

Use only hemofilters that are CE marked, according to the Medical Device Directive (93/42/EWG) and are registered for the indications CVVH, CVVHD and CVVHDF.
For hemofilters do not exceed a maximum pressure of 400 mmHg to avoid pre-filter pressure alarms. Maximum TMP is 400 mmHg.

Always ensure that the appropriate filter is used for the intended therapy:

- Hemofilter for SCUF, CVVH, CVVHD, CVVHDF
- Plasma filter for TPE
- Hemoperfusion cartridge for Hemoperfusion

The use of an inappropriate filter for a selected therapy can result in a patient injury or death.

Risk of hemolysis. For plasma filters do not exceed the transmembrane pressure indicated in the Instructions For Use of the filter. This alarm limit is preset to 100mmHg in TPE therapy mode.

Replacement solutions and dialysate have to be sterile and must meet European Pharmacopoeia requirements. Use only 4.5 l or 5 l bags with female Luer lock connectors or a sterile adapter to male Luer lock connectors.
The prescribing physician must define concentration and composition requirements.

Never use solutions of different compositions simultaneously with the Aquarius system!

To protect patients from cross-infection, only tubing sets equipped with pressure measurement leads with hydrophobic 0.2 µm filters that exclude bacteria may be used.

3.3.1.1.1

To avoid false “No bag“ alarms, do not use empty bags with a weight less than 80g.

For information on the disposables supplied and recommended for the Aquarius system, please contact your Official Representative or call Customer Service.

## 3.4 Waste management

The Aquarius system and used disposables should be disposed of according to the local provisions. The system must be cleaned before disposal to prevent bio-hazardous risks.

Electronic components of the Aquarius system must be disposed of, according to currently valid regulations for the disposal of electronic components.

For more information on disposal please contact your local Technical Service Representative.

| Part name | Toxic or Hazardous Substances and Elements | | | | | |
|---|---|---|---|---|---|---|
| | Lead (Pb) | Mercury (Hg) | Cadmium (Cd) | Hexavalent Chromium (Cr (VI)) | Polybrominated biphenyls (PBB) | Polybrominated diphenyl ethers (PBDE) |
| Housing | X | ○ | ○ | ○ | ○ | ○ |
| TFT-Display | ○ | X | X | ○ | ○ | ○ |
| Accumulator | X | ○ | ○ | ○ | ○ | ○ |
| Electronics | X | X | X | ○ | ○ | ○ |
| Motors | ○ | ○ | ○ | ○ | ○ | ○ |
| Magnetic Clamp | ○ | ○ | ○ | ○ | ○ | ○ |
| Front Panel | ○ | ○ | ○ | ○ | ○ | ○ |
| Wheels | ○ | ○ | ○ | ○ | ○ | ○ |
| Cabling | ○ | ○ | ○ | ○ | ○ | X |
| Varnishing | ○ | ○ | ○ | ○ | ○ | ○ |

○: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006 ( Standard of the Electronics Industry of the People’s Republic of China)
X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirements in SJ/T11363-2006.

The environmental protection period for the device is specified in the pollution control symbol displayed above. The product should be stored and operated in accordance with the Instructions for Use, with particular regard to the environmental conditions described for use of the device.

## 3.5 Materials used

The patient's blood does not have contact with the components of the Aquarius system, thus there is no danger of infection for patients, operators or other persons dealing with the system and there are no special requirements regarding the biocompatibility of the materials used for manufacturing this system.

All disposables (tubing sets, filters, waste bags, solution bags, accessories) used with the Aquarius system are single use only and must be disposed of after use.

This is also true for the integrated transducers that separate and protect the pressure sensors of the Aquarius system by means of an impermeable membrane.

## 3.6 Transport and storage

To move or transport the Aquarius system it is necessary to release the locking tabs on the wheels. The Aquarius system can then be rotated and freely moved about.

To move the Aquarius system over steps or stairs the locking tabs must be released. The system should be tilted, lifted and carried by at least three people.

Never carry the Aquarius system holding on to the display, the I. V. pole, the scales or the pump doors.

The Aquarius system must not be pushed over uneven floors.

The following environmental conditions are required when storing and transporting the Aquarius system:

| | |
|---|---|
| Relative humidity: | 30% to 80%, non-condensing |
| Ambient temperature: | -5 to +45°C (23 to 113°F) |
| Ambient air pressure: | 50 to 105 kPa |

The Aquarius system must be stored in a room with good ventilation and little temperature variation.

The following environmental conditions are required when operating the Aquarius system:

| | |
|---|---|
| Relative humidity: | 10 to 90%, non-condensing |
| Ambient temperature: | +17 to +35°C (61 to 95°F) |

## 3.7 Packing

At the end of manufacturing the Aquarius system is packed in special packaging including a pallet. If the Aquarius system needs to be transported, special packaging with all relevant safety labels must be used.

## 3.8 Service and maintenance

The Aquarius system is subject to technical safety checks and maintenance at least once a year. Only qualified service staff, authorized by the manufacturer, must carry out this maintenance and any other repair work. Any work done by non-qualified and non-authorized personnel immediately voids all warranties.

Disconnect the power supply cord before servicing the Aquarius system.

More detailed information on the safety check and maintenance can be obtained from Technical Service.

## 3.9 Set time and date

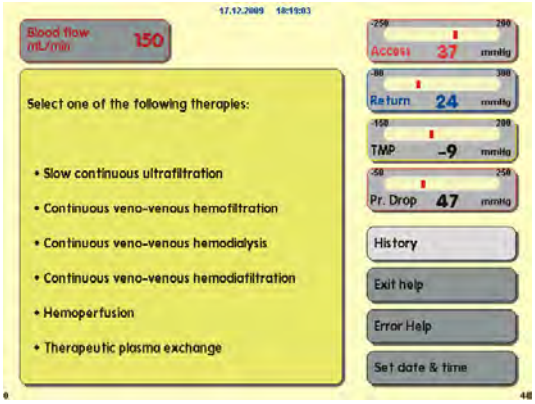



**Figure 1**

When the ***Help*** screen is open, it is possible to set the time and date by selecting the ***Set date and time*** key.

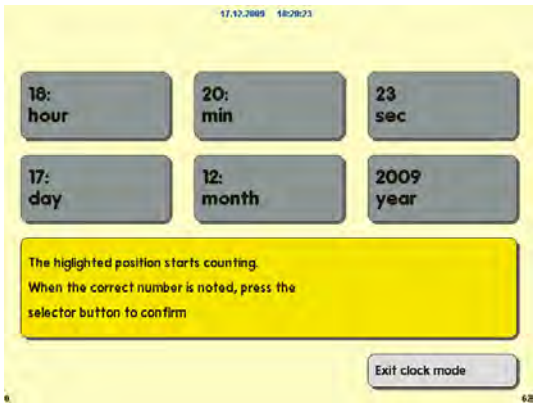



**Figure 2**

Turn the ***Main selector button*** to see set time and date key highlighted.

Press the ***Main selector button*** to validate.

Select the value to be changed by turning the ***Main selector button*** until the value key is highlighted.

Press the ***Main selector button*** to validate.

Press the ***Main selector button*** when the value reaches its target.

Turn the ***Main selector button*** to select another value to be changed if necessary, or select ***Exit clock mode*** key to go back to the ***Help*** screen.

Accessible values for change are:

| For time: | For date: |
|---|---|
| Hour | Day |
| Minute | Month |
| Second | Year |

Note: The Aquarius system does not automatically compensate for Daylight Saving Time (DST). The operator will need to adjust the time manually, as described above. Patient treatment is based on an elapsed-time system and will not be affected by this manual adjustment.

# 4 Introducing the Aquarius system

## 4.1 General machine description

The Aquarius system is an Automated Fluid Balance Monitor, designed to be used with various extracorporeal treatments in the field of renal replacement therapies or plasma therapies. All therapies must be prescribed by a physician.

The Aquarius system is divided into three circuits: the extracorporeal (blood) circuit, the substitution/dialysate circuit and the filtrate circuit.

Toxic substances are removed by filters and clean blood is returned to the patient.

The Aquarius system uses two scales to accurately measure and precisely balance filtration and substitution volumes.

The Aquarius system has four peristaltic pumps.

The Aquarius system has an integrated heater system which may be used to warm the substitution fluid before it is given to the patient.

Heparin (anticoagulant) may be supplied to the extracorporeal circuit via an integrated heparin anticoagulant pump. The prescribing physician may select continuous or intermittent options.

A blood leak detector and an air detector are provided to ensure patient safety.

The Aquarius system's protective system is designed as a 2-channel system to protect the patient from foreseeable danger.

At the back of the scale system, a removable hand-crank is mounted. This can be used to manually turn the blood pump.

The Aquarius system has two optical ports at the rear, which can be used for data transfer from the machine.

The Aquarius system is portable. It has a wheeled base connected with a handle to move or carry the Aquarius system.

A transparent protective cover adequately guards against inadvertent contact with the pump's powered roller assemblies.

The Aquarius system contains a filter holder system designed to allow correct positioning of the filter and to facilitate handling and installation of the line set.

The Aquarius design allows the patient to be positioned left or right of the instrument.

The operator is expected to stand in front of the machine when interacting with the Aquarius system.

Aquarius system
Front view

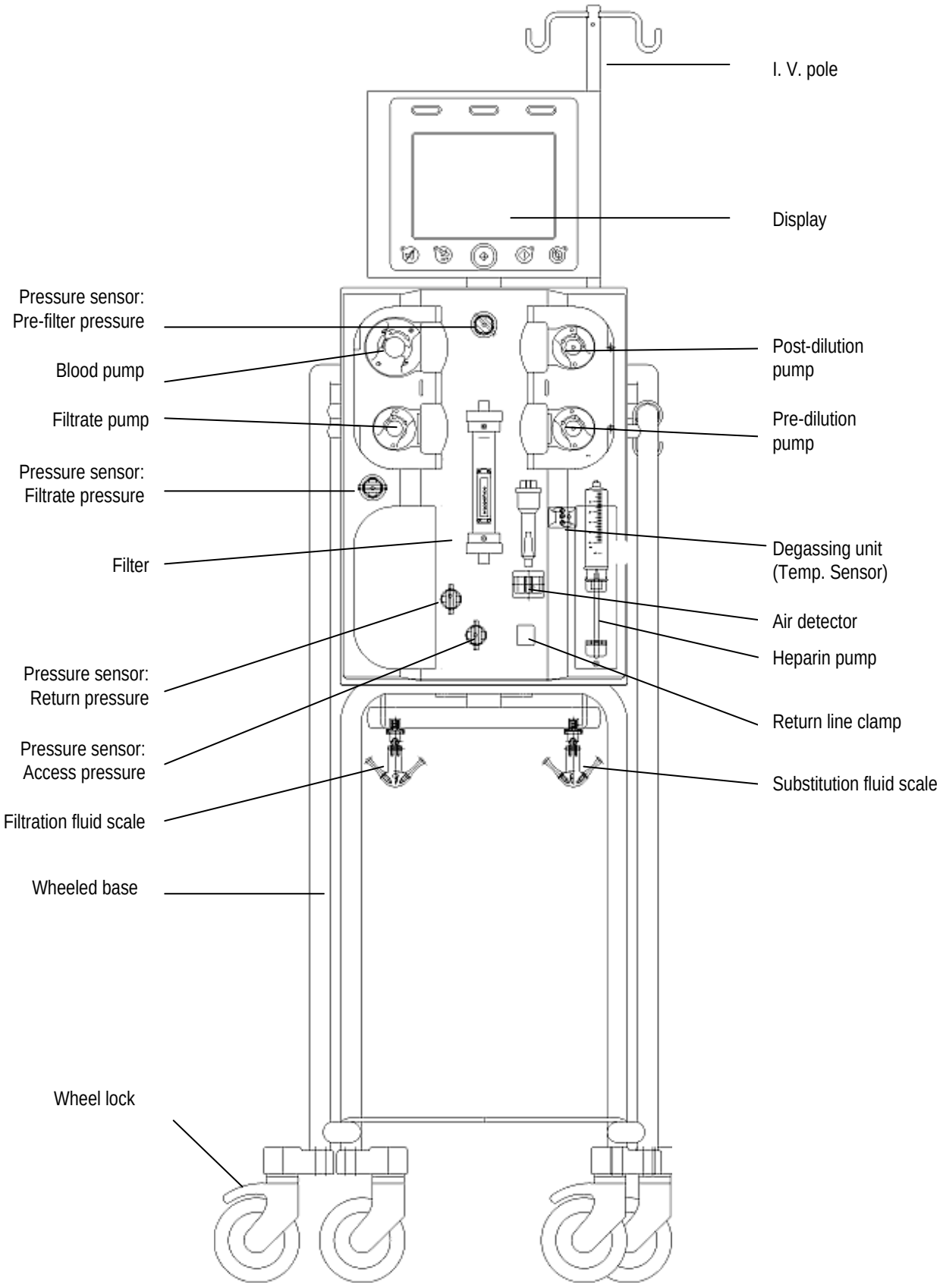



**Figure 3**

Aquarius system

Side View (Left)

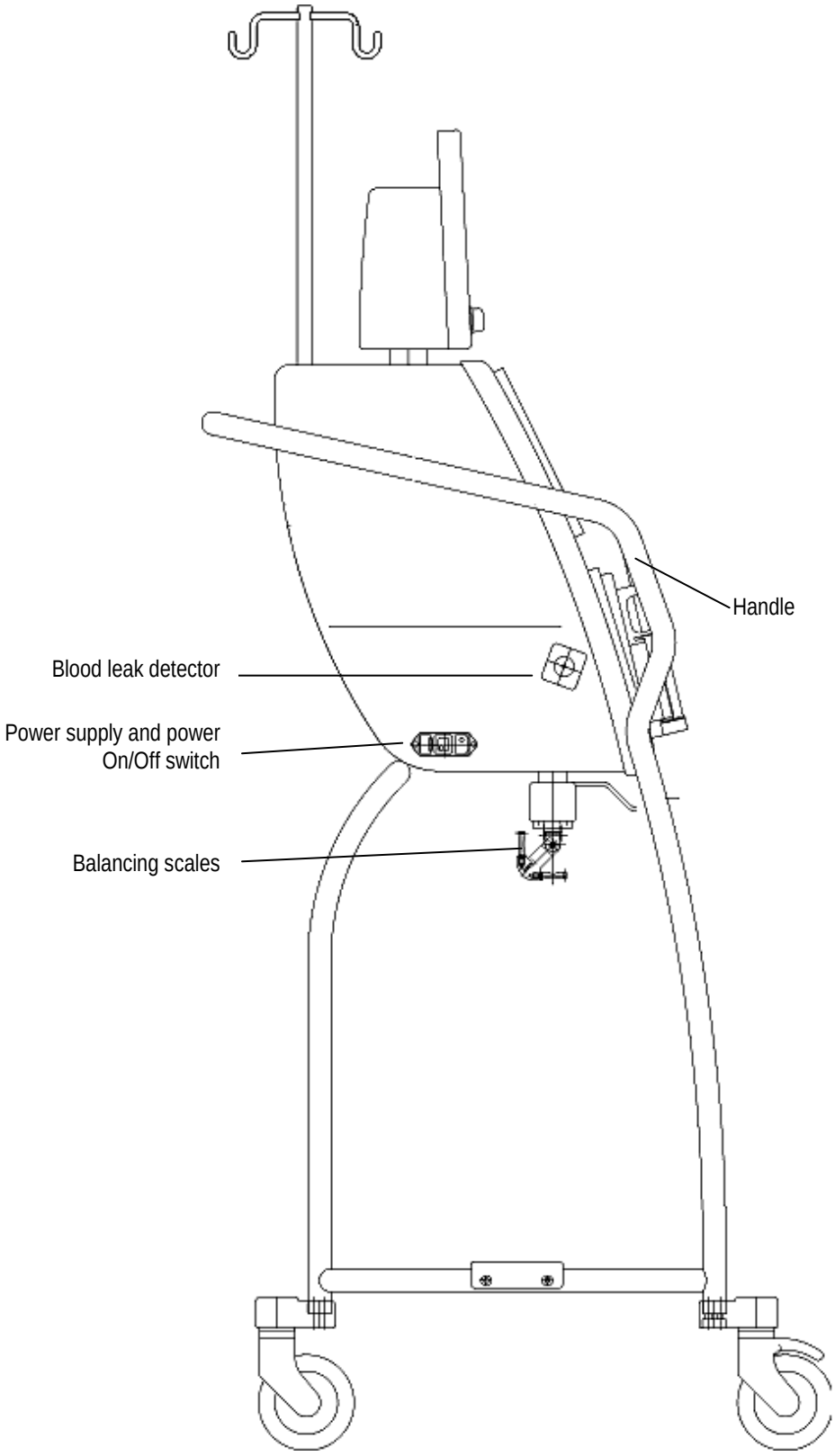



**Figure 4**

Aquarius system

Side View (Right)

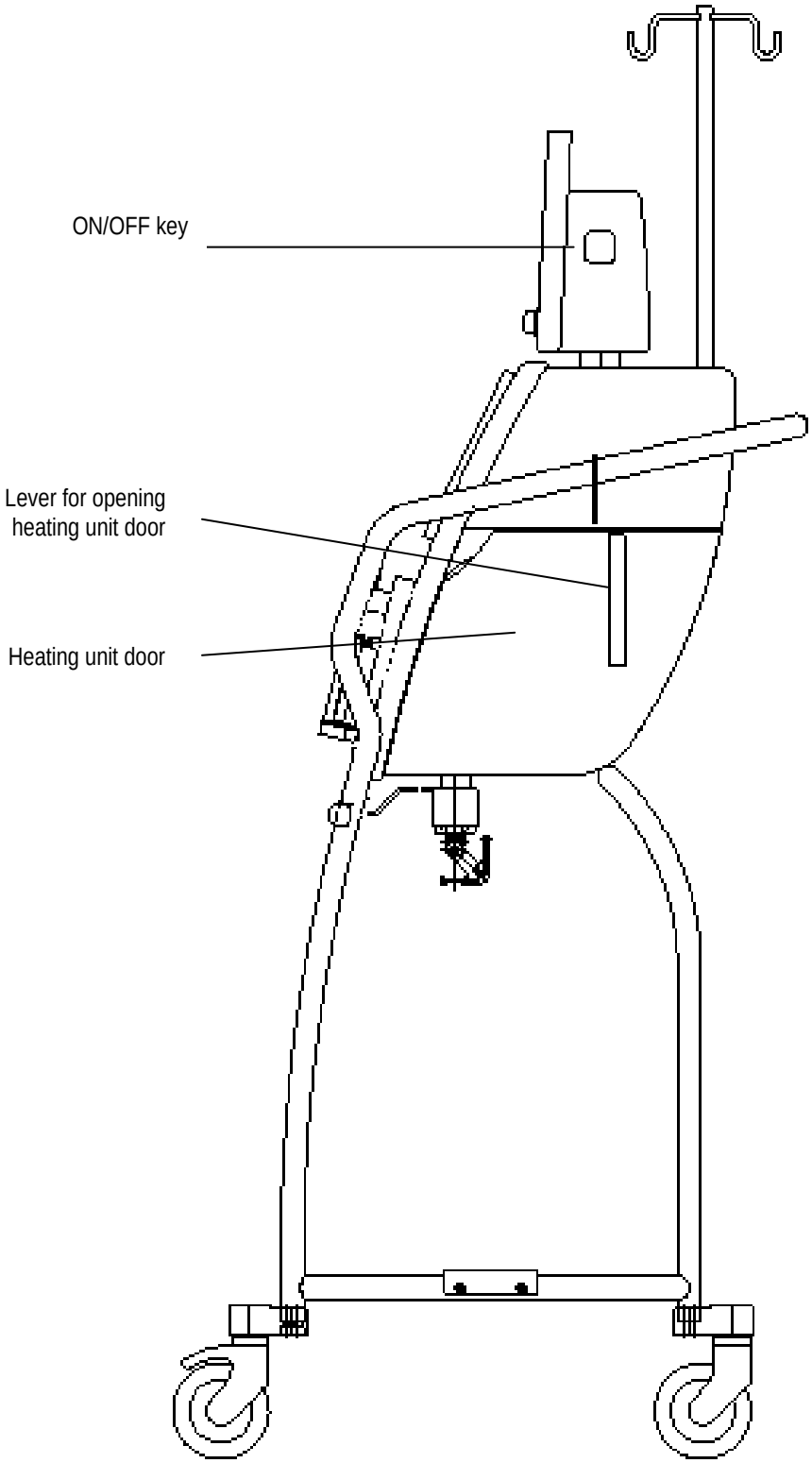



**Figure 5**

## 4.2 Proper usage / Treatment procedures

The Aquarius system is an Automated Fluid Balance Monitor. It is only designed for the treatments described below. It may only be operated within the given specifications and limits detailed in this Instructions for Use.

### 4.2.1 SCUF (Slow Continuous Ultra-filtration):

During Slow Continuous Ultra-filtration blood is driven through a hemofilter via an extracorporeal circuit.
SCUF is used primarily to manage fluid overload. The underlying principle of water removal is Ultrafiltration. The underlying principle of clearance is convection.

Fluid removal is controlled and balanced by the filtrate pump and the scales.
The filtrate is not replaced by substitution solution.

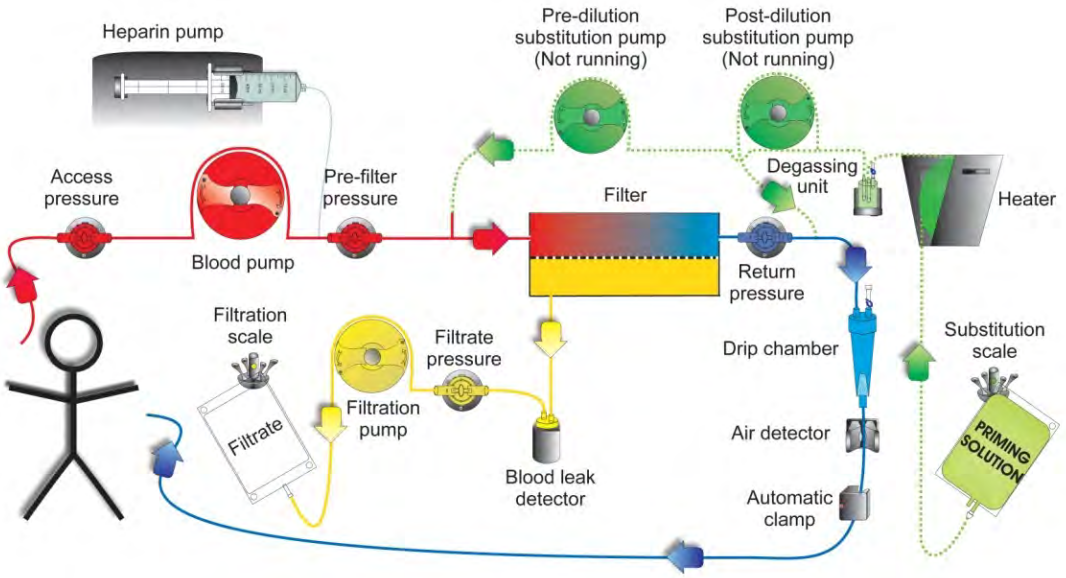



**Figure 6**

### 4.2.2 CVVH (Continuous Veno-Venous Hemofiltration):

During Continuous Veno-Venous Hemofiltration, blood is driven through a hemofilter via an extracorporeal circuit.

Sterile, physiological substitution solution is infused into the blood circuit before (pre-dilution) and/or after the filter (post-dilution). Filtrate is removed simultaneously at an equal or greater rate.

CVVH is used to achieve solute removal (small, medium and large sized molecules) and fluid balance. The principle of clearance is convection.

The substitution solution and filtrate are controlled and balanced by the substitution pumps, the filtrate pump and the scales.

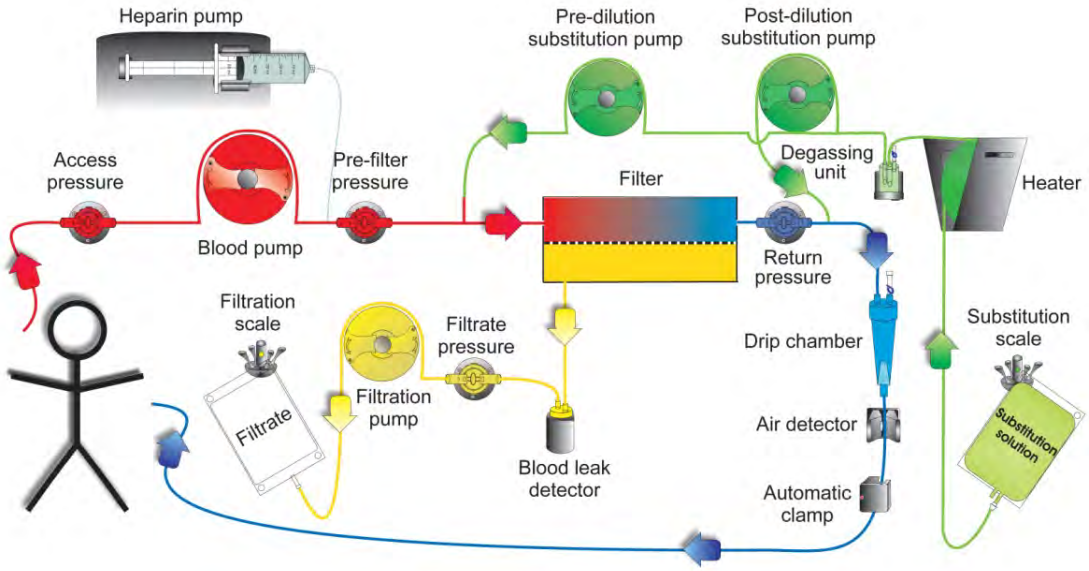



**Figure 7**

All substitution solutions used must be labeled for intravenous injection, of appropriate composition and prescribed by a physician.
Use of incorrect or outdated solutions can result in a patient hazard.

### 4.2.3 CVVHD (Continuous Veno-Venous Hemodialysis):

During Continuous Veno-Venous Hemodialysis, blood is driven through a hemofilter/dialyzer via an extracorporeal circuit. Dialysate solution flows through the dialysate compartment of the hemofilter/dialyzer, counter-current to the blood flow.

CVVHD is used to achieve solute removal (small and medium sized molecules) and fluid balance. Filtrate should correspond to the desired net weight loss. No substitution solution is used. The principle of clearance is diffusion.

The dialysate solution and filtrate are controlled by the dialysate pumps (otherwise known as the pre-dilution pump), the filtrate pump and the scales.

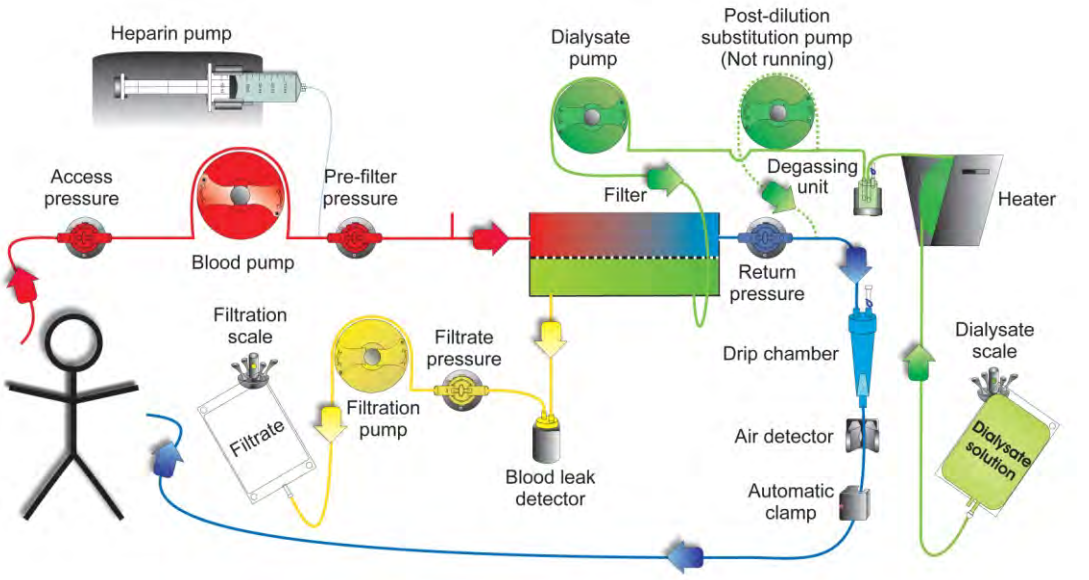



**Figure 8**

## 4.2.4 CVVHDF (Continuous Veno-Venous Hemodiafiltration):

During Continuous Veno-Venous Hemodiafiltration, blood is driven through a hemofilter via an extracorporeal blood circuit.
Sterile, physiological substitution solution is infused into the blood circuit after the filter. Filtrate is removed simultaneously at an equal or greater rate.
Dialysate solution flows through the dialysate compartment of the filter, counter-current to the blood flow.
CVVHDF is used to achieve solute removal (small, medium and large sized molecules) and fluid balance.
The principles of clearance are convection and diffusion.
The substitution solution, dialysate solution and filtrate are controlled and balanced by the substitution pumps (the dialysate pump is the pre-dilution pump), the filtrate pump and the scales.

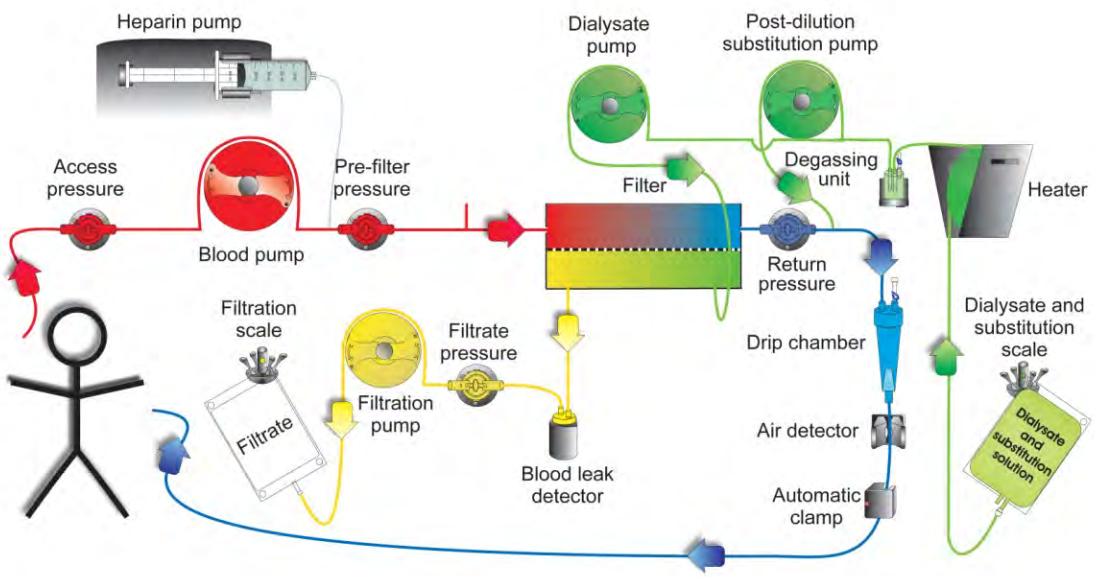



**Figure 9**

All substitution solutions used must be labeled for intravenous injection, of appropriate composition and prescribed by a physician.
Use of incorrect or outdated solutions can result in a patient hazard.

## 4.2.5 TPE (Therapeutic Plasma Exchange):

During TPE, blood is driven through a plasma filter via an extracorporeal blood circuit.
Plasma is separated from the rest of the blood components and replaced by a plasma replacement fluid, typically albumins or Fresh Frozen Plasma (FFP).

TPE is used to achieve the removal of toxic substances (large molecules). Fluid balance usually remains unchanged.
Plasma exchange is controlled and balanced by the substitution pump, the filtrate pump and the scales.

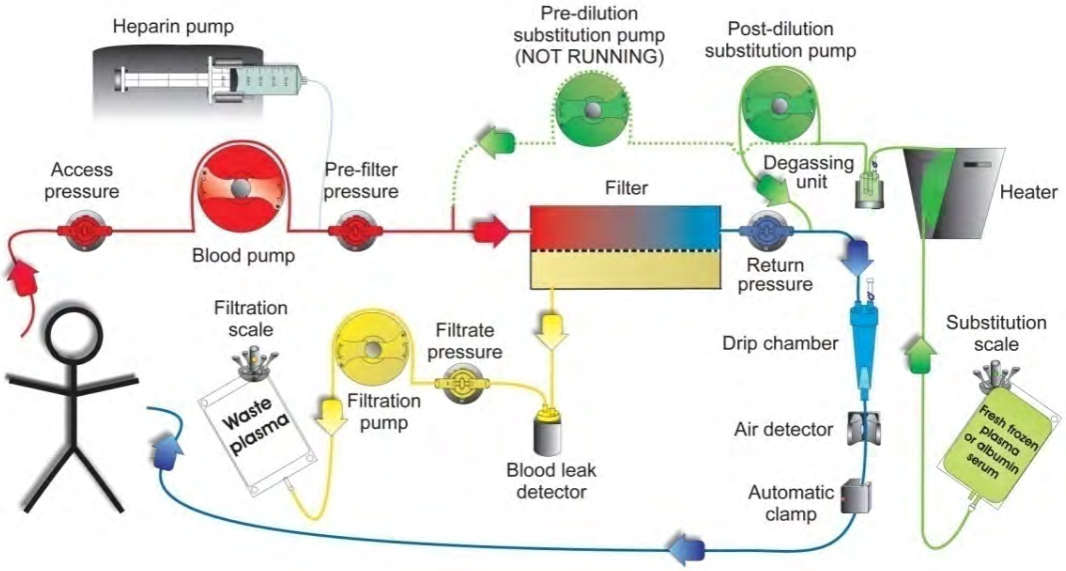



**Figure 10**

## 4.2.6 Hemoperfusion (Blood Detoxification):

During hemoperfusion blood is driven through a hemoperfusion cartridge via an extracorporeal circuit. Hemoperfusion is intended to remove toxic substances from the blood using a hemoperfusion cartridge. The principle of clearance is adsorption. Substitution solutions are not used in this therapy and no filtrate is produced.

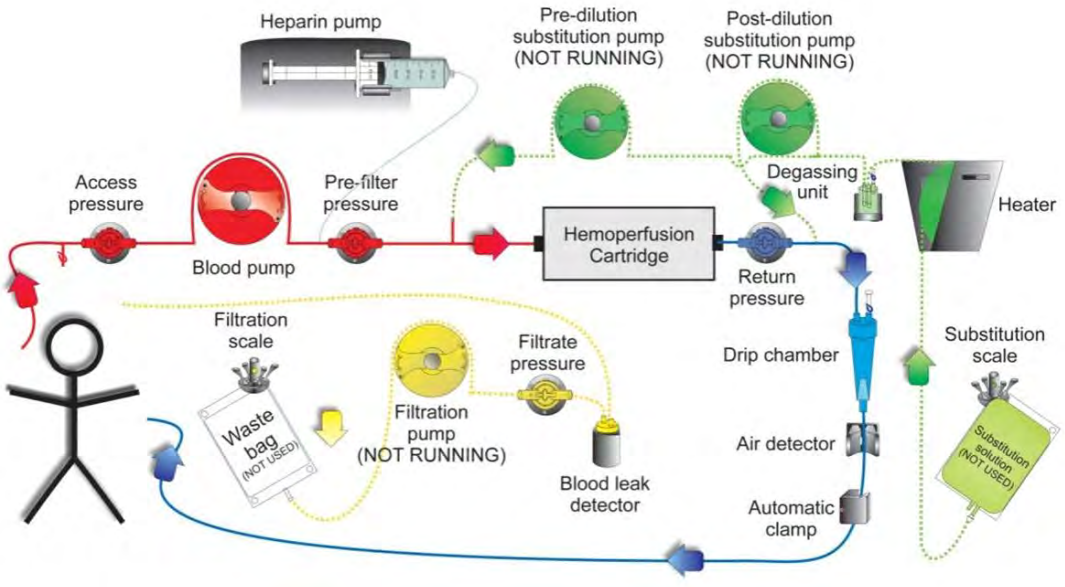



**Figure 11**

Always use a hemoperfusion cartridge when performing a hemoperfusion therapy. For all disposables used (e.g. hemoperfusion cartridge and tubing sets), please follow the instructions for use from the relevant manufacturer.

## 4.3 Labeling

The following labels are on the Aquarius system:

### 4.3.1 Data Plate

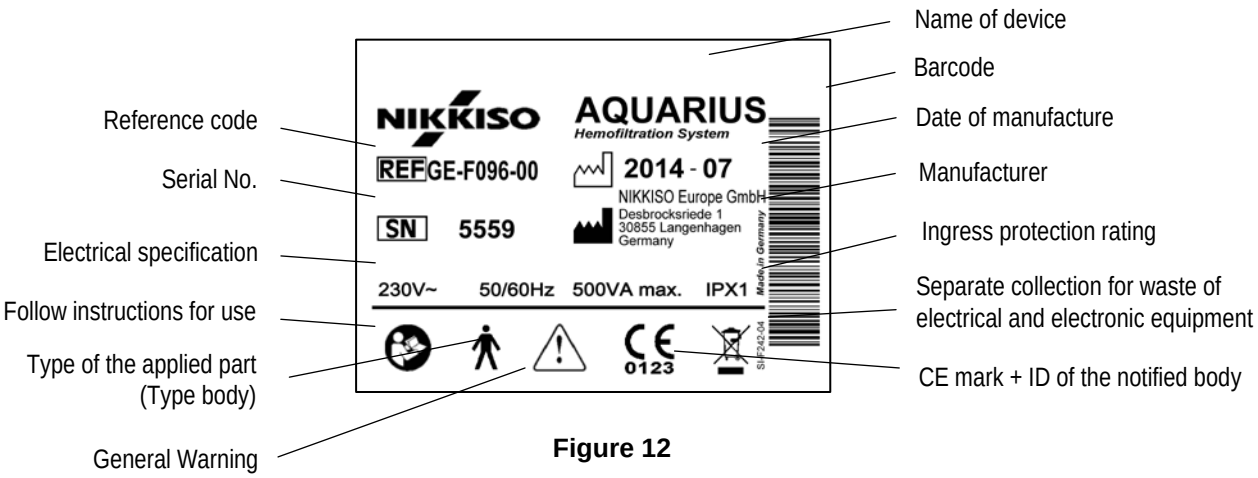



**Figure 12**

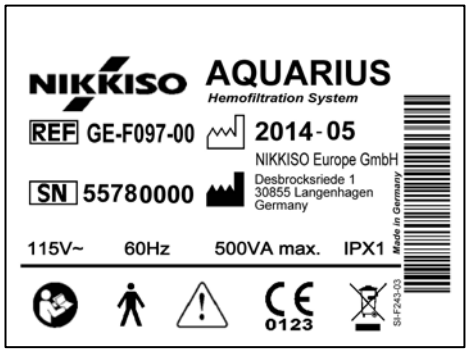
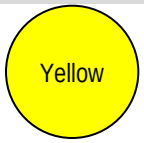



**Figure 13**

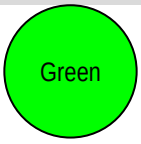
### 4.3.2 Filtrate scale

The filtrate scale is marked yellow.

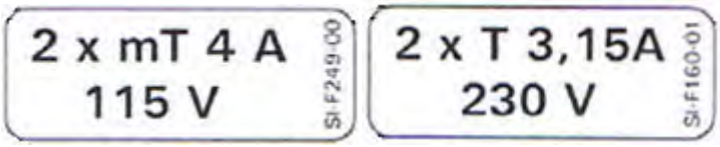



### 4.3.3 Substitution fluid scale

The dialysate/substitution fluid scale is marked green.



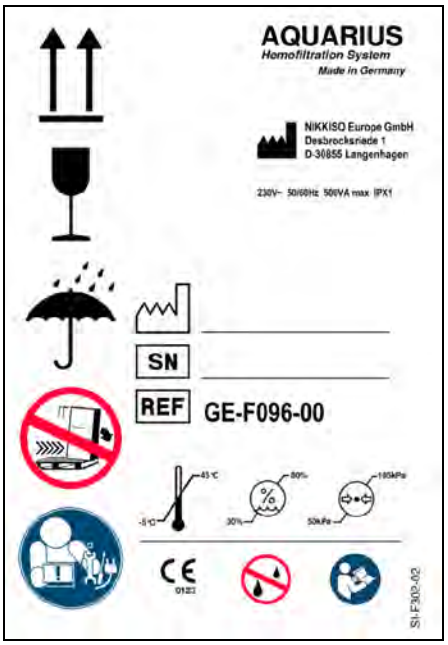
### 4.3.4 Fuses

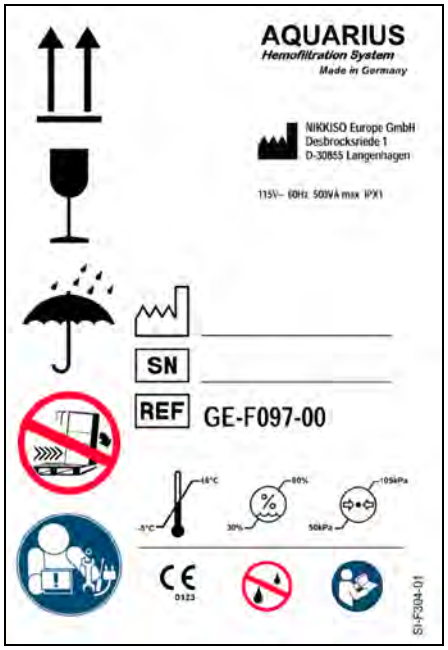



### 4.3.5 Potential equalization conductor

### 4.3.6 Protective earth conductor

### 4.3.7 Package labeling



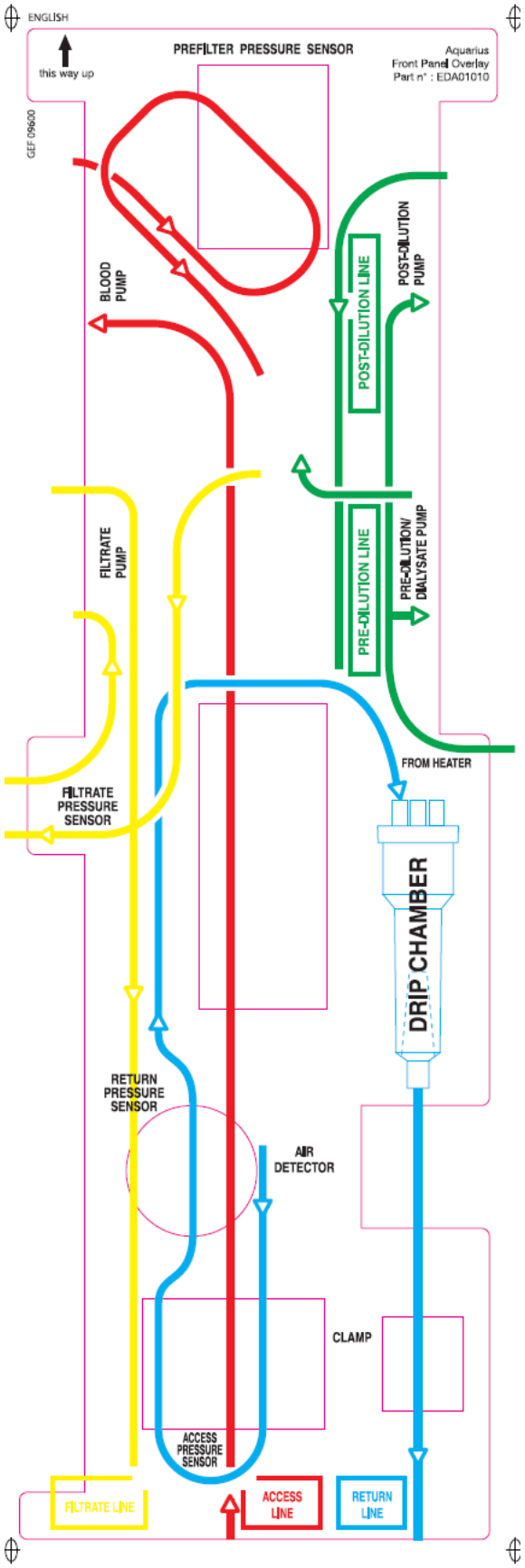




### 4.3.8 Aqualine tubing set color code

Access line = Red
Return line = Blue
Filtrate line = Yellow
Substitution line = Green

The Aqualine tubing set is color coded. A corresponding color coded overlay is available to help the operator correctly install the Aqualine tubing set.

## 4.3.9 Front overlay panel




A color coded front panel overlay is available for the Aquarius system, to help the operator correctly install the Aqualine tubing set.

**Figure 14**

## 4.4 Operational sequence (modes)

The operational sequence for the Aquarius system is fixed. It is impossible for the operator to accidentally change the sequence.

### 4.4.1 System test

When the power is switched on, the Aquarius system is initialized. A system test is performed to verify the system´s main functions. The system test must be performed before the tubing set is attached to the machine. The current software version is displayed during the test.

### 4.4.2 System test failed

The system test must be repeated if it fails. The onscreen *Help* function will provide further information to assist with troubleshooting any failure. Follow all suggested corrective actions and retry system test. If alarm messages continue, inform technical service. The device can be used only if the system test passes

### 4.4.3 Preparation

One of the following therapies can be selected in the *Preparation mode*:

- SCUF
- CVVH
- CVVHD
- CVVHDF
- TPE
- Hemoperfusion

Selection of the tubing set to be used (Aqualine tubing set for adult and Aqualine 'S' tubing set for pediatric) is made during *Preparation mode*.

The Aquarius system must be prepared for priming.

- Refer to section 5.1 for detailed instructions.

The tubing set selected has to be installed on the Aquarius system before for priming.

### 4.4.4 Priming

A test compares the tubing set selected (adult or pediatric) and the tubing set in-situ at the beginning of priming.

In the *Priming mode* the blood and fluid circuit sections are rinsed and filled.

At the end of the priming procedure the operator can select *Reprime* or *Next* to proceed.

- Refer to section 5.2 and 5.3 for detailed instructions.

### 4.4.5 Clamp and Pressure Test

During this test phase, the return clamp occlusion function, the access pressure function, the return pressure function, the pre filter pressure function and the filtrate pressure function are tested. This test is only possible if, after priming, the air detector has determined that the extracorporeal circuit is free from air which will be indicated by a steady green light in the *Clamp* key  . The access pressure, return pressure and transmembrane pressure are displayed during the test.

After a successful test the system goes to *Start Connection* mode. The operator may select from the following options: *Go to programming*, *Go to recirculation*, *Single connection* or *Double connection*

- Refer to section 5.4 for detailed instructions.

### 4.4.6 Recirculation

During *Recirculation mode* the extracorporeal circuit is flushed until the operator is ready to connect the patient to the Aquarius system. This mode is started and stopped manually by the operator. The patient parameters may be entered during recirculation by selecting the *Go to programming* option. If the patient parameters are not entered during *Recirculation mode* they MUST be entered before starting treatment. Patient parameters must be entered according to the prescription of the responsible physician.

To leave *Recirculation mode* select the *Go to connection* key to connect the patient to the Aquarius system or the *End treatment remove tube* system key to switch off the device.

- Refer to section 5.5 for detailed instructions.

### 4.4.7 Connecting the Patient

Parameters must be programmed before going to connection mode.

During *Single connection* mode, the operator is asked to connect the Aqualine access line (red) to the access port (red) of the patient's catheter. After pressing the *Start blood pump* key, the Aqualine tubing set is filled with blood up to the air detector. The blood pump automatically stops when the air detector detects blood. Treatment can then commence.

During *Double connection* mode, the operator is asked to connect the Aqualine access (red) and return (blue) lines to the access (red) and return (blue) ports of the patient's catheter at the same time. After pressing the *Start blood pump* key, the Aqualine tubing set is filled with blood. Once blood is detected by the air detector system, the Aquarius system automatically switches into *Treatment mode*. Treatment can then commence.

- Refer to section 5.6 and 5.7 for detailed instruction.

### 4.4.8 Treatment

If *Single connection* has been selected, during the *Start treatment* mode the operator is asked to connect the return segment of the Aqualine tubing set to the return port (blue) of the patient's catheter.

Start treatment:

If the operator has not already programmed the patient parameters, it must be done before starting treatment.

Treatment begins after selecting the *Start treatment* key  (blood pump must run to start treatment). The patient parameters are displayed on the screen and may be modified during treatment. The operator may stop the filtrate / substitution solution circulation to exchange empty or full bags.

When *Therapy target achieved by time* or *Therapy target achieved by fluid loss* are displayed on the screen, the time target or the fluid loss target respectively have been achieved. The operator may now reprogram to continue treatment or may move into Disconnection phase.

- Refer to section 5.8 for detailed instructions.

### 4.4.9 Disconnecting the Patient

During *Disconnection* mode the operator is asked to disconnect the patient's blood access and to connect it to a saline solution bag. The system re-infuses the blood contained in the system to the patient. The blood pump stops when the air detector unit detects saline solution. By selecting the *Next* key the operator moves to the *Treatment end* mode.

- Refer to section 5.9 for detailed instructions.

### 4.4.10 Terminating the Treatment

During the *Treatment end* mode the operator is requested to remove all tubing from the machine. The operator has to select the *Aquarius Off* key to switch off the Aquarius system.

- Refer to section 5.10 for detailed instructions.

## 4.5 Operating concept

Only trained and qualified personnel should operate the Aquarius system.

During *Preparation mode* a *Zoom graphic* key allows a step by step guide to the complete installation of the device with visual assistance.

Instructions displayed on the screen provide the operating staff with information about subsequent treatment steps. *Help* function will provide further information on screen at all stages. Alarms and messages are color coded and displayed in separate windows on the screen. Alarms, messages and the end of the respective mode are also indicated to the operating staff by an audible signal.

Selected screen pages close 5 min after last key press and lead back to the main menu page.

The *Main selector button* is a rotary switch, located below the display screen. It is used to select and confirm different functions and to modify treatment parameters.

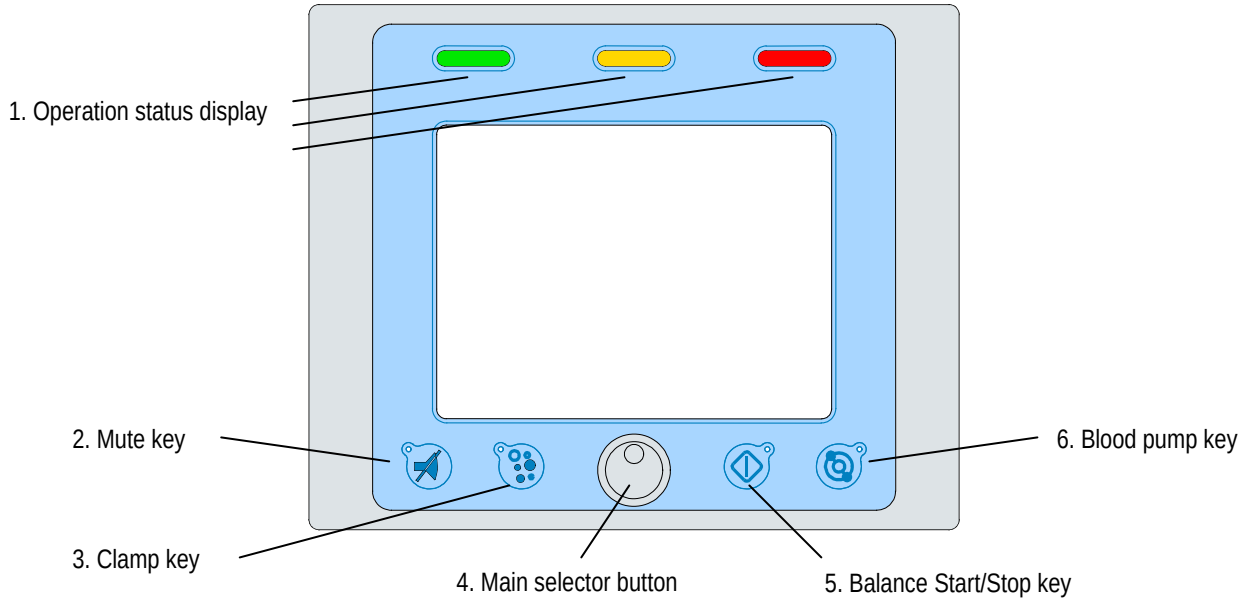



**Figure 15**

The individual function keys and their displayed functions are explained below.

### 4.5.1 Operation status display

Three status lights indicate the different operation modes. They are visible from the front and the back of the machine.

a) An illuminated **red** status light indicates:
Warning! Alarm or system error

b) An illuminated **green** status light and flashing **yellow** status light indicates
Caution! Heater self test is running. Priming mode is not accessible.

c) Illuminated **green** and **yellow** status lights indicate:
Caution! Treatment time has run down or Treatment was stopped
Caution! Bag change required
Caution! Anticoagulant syringe is empty
Caution! Aquarius system is in *Preparation* or *Recirculation* or *Connection* mode

d) An illuminated **green** status light indicates:
Treatment is running. No alarms are active

e) An illuminated **yellow** status light indicates:
Caution during Preparation mode
Caution during Recirculation mode
Caution during Patient connection mode

f) All three status lights illuminating one after the other indicates:
Machine is performing system test

### 4.5.2 *Mute* function key

Pressing the *Mute* key enables the operator to silence the alarm signal for a period of 2 min. The LED integrated into the key changes from flashing to ON. If the cause of the alarm cannot be removed within the given period, the audible alarm is reactivated. If another alarm occurs during this period, the audible alarm is generated at once.

### 4.5.3 *Clamp* function key

Pressing the *Clamp* key opens the return line clamp during an air detected alarm to allow removal of air bubbles from within the tubing set. The LED integrated into the key flashes. The return line clamp is automatically reactivated after 1 min. When the air is removed, treatment may be resumed by pressing the *Blood pump* key.

The red indicator of the return line clamp is illuminated when the clamp is closed and extinguished when the clamp is open.

### 4.5.4 Main Selector button

The *Main selector button* is a multi-function rotary button. These functions include:

a) Selecting function windows by turning the *Main selector button*

b) Confirming selected functions by pressing the *Main selector button*

c) Selecting input parameters by turning the *Main selector button* and having the corresponding parameter highlighted

d) Opening the input window for the selected parameter by pressing the *Main selector button*

e) Raising the parameter input for the selected parameter by turning the *Main selector button* to the right

f) Lowering the parameter input for the selected parameter by turning the *Main selector button* to the left

g) Confirming the entered parameter by pressing the *Main selector button*. The modified parameter is displayed on the screen

### 4.5.5 *Balance Start/Stop* function key

Pressing the *Balance Start/Stop* key starts the selected treatment whilst maintaining the selected parameters as programmed by the operator.

Pressing the *Balance Start/Stop* key stops the filtrate and substitution pumps. This can be used to temporarily stop treatment, for example, to exchange bags.

If an alarm occurs in the filtrate and/or the substitution circuits, the pumps stop and the LED integrated into the key starts flashing. After correcting the cause of the alarm the pumps may be restarted by pressing the *Balance Start/Stop* key. The treatment restarts with the parameters previously programmed by the operator.
*Balance Start/Stop* key is also called *Start treatment* key.

When therapy is running and no filtrate or substitution alarm is active, the *Balance Start/Stop* key's indicator is green.

During pre and post-treatment, the *Balance Start/Stop* key's indicator is extinguished.

### 4.5.6 *Blood pump* function key

Pressing the *Blood pump* key starts or stops the flow of blood through the blood circuit. If the pumps are running, pressing the *Blood pump* key stops all pumps and the *Blood pump* indicator flashes. If an alarm occurs in the blood circuit, all pumps stop and the LED integrated in the *Blood pump* key starts flashing. After correcting the cause of the alarm the alarm is cleared by pressing the *Blood pump* key. The system is restarted by pressing the *Blood pump* key again. The filtrate, pre-dilution and post-dilution pumps start after the blood pump.

The *Blood pump* key is also used to immediately stop all pumps in case of an unpredictable occurrence.

## 4.6 Safety concept

The Aquarius system has a safety concept based on three independent processors, which are the control system, the protective system and the display system. Figure 16 shows the basic principle.

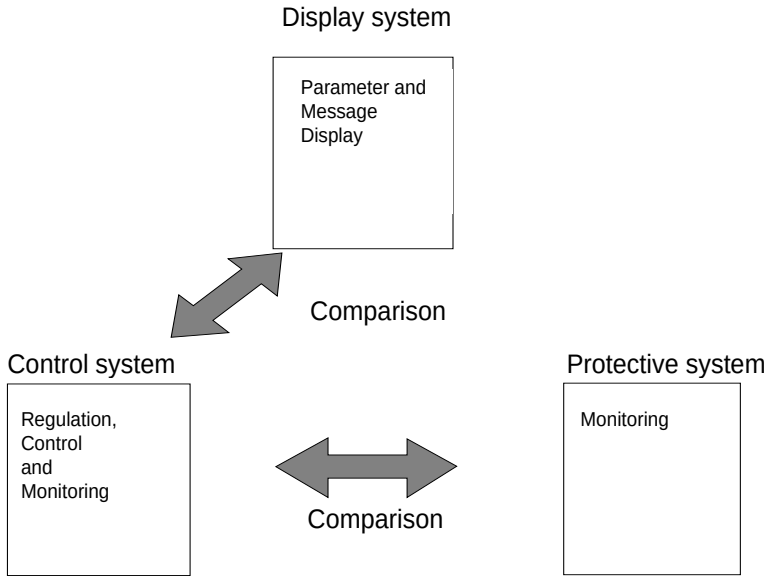



**Figure 16**

The safety mode is determined by the nature of the occurring alarm:

| Alarm type | Aquarius system safety mode |
|---|---|
| Alarms in blood circuit | • Visual and audible signals will be generated.<br>• All pumps will stop.<br>• The return line clamp will close if air or micro-foam is detected or the return pressure drops below the lower alarm limit. |
| Alarms in filtrate / dialysate circuit | • Visual and audible signals will be generated.<br>• The filtrate, pre-dilution and post-dilution pumps will stop. |
| System error | • Visual and audible signals will be generated.<br>• All pumps will stop.<br>• The return line clamp will close if air or micro-foam is detected or the return pressure drops below the lower alarm limit. |

The control system regulates, controls and monitors the operation of the Aquarius system. If an out-of-range condition occurs, either a system error or an alarm is generated and the Aquarius system switches to safety mode.

The protective system monitors all control system processes. If the protective system detects an alarm or a system error, this alarm or system error will be generated independently of the control system and the Aquarius system switches to safety mode.

The display system is responsible for communication between the protective system, the control system and the operator. The information coming from the protective system and the control system is displayed on the screen and the operator's input is communicated to both systems.

# 5 Performing a treatment with the Aquarius system

## 5.1 Preparing the Aquarius system

### 5.1.1 Switch ON


**Figure 17**

Plug the power cable into the socket and turn socket on.

Ensure the switch on the power input module is set to the I position. This is located on the left side of the Aquarius system.

Before proceeding, ensure no tubing set or bags are installed on the Aquarius system.

Press the *On/Off* key located on the right side of the display screen.

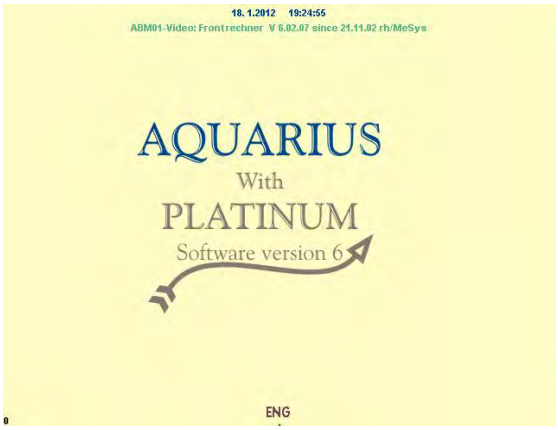



**Figure 18**

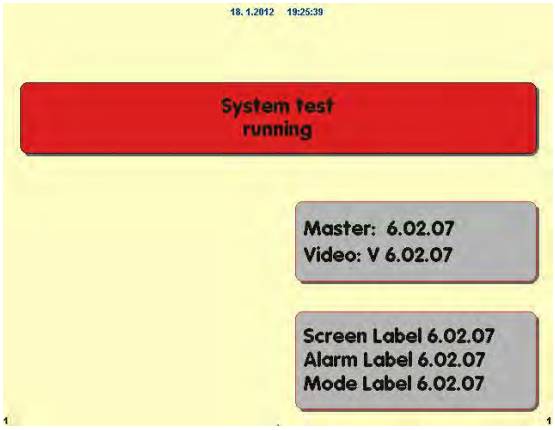



**Figure 19**

The system turns on and performs a system test, which checks the main system functions as well as safety control functions. During this process, the three status lights of the operation status display, located above the screen, illuminate one after the other until the system test is finished. The screen displays ***System test running***. The operator must wait until the system test is completed.

NOTE: The software version number displayed by the Aquarius system may change in revision.

When the system test is finished, an audible alarm is generated and the green and yellow status lights are illuminated. The pumps stop in the correct position for the tubing set to be installed. The operator can now proceed to select a therapy.

The Aquarius system system test must be performed before tubing, bags, pressure sensors and solutions are placed on the machine. The pump doors must be closed.

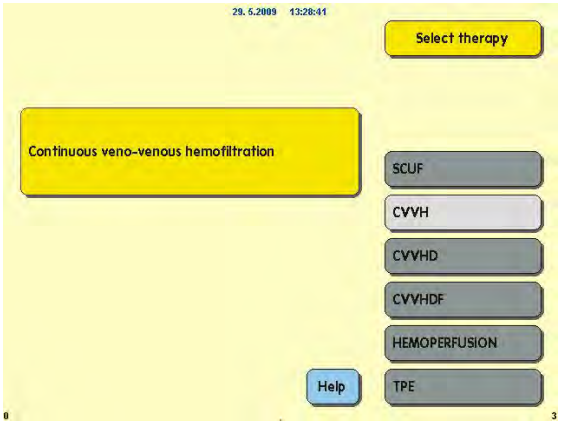



**Figure 20**

If the yellow status light is still flashing after the system test is finished, the heater self test is still running. Entering the priming process before the heater self test is finished is not possible. The yellow light stops flashing when the heater self test is finished.

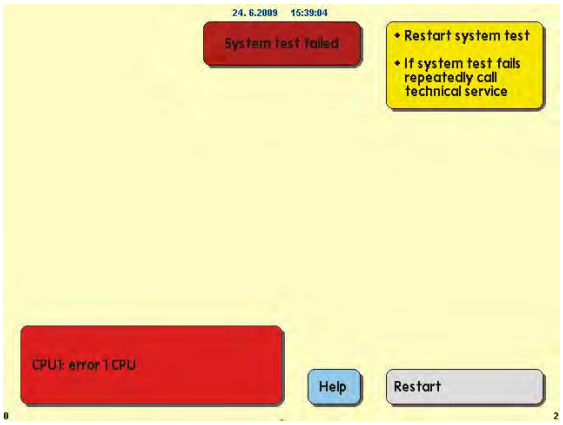



**Figure 21**

If the system test fails it is important to read the onscreen *Help* to understand what has failed and follow the suggested corrective action. Select and confirm the *Help* function and further select and confirm the *Error Help* function.

If the system test fails select *Restart* to run the system test again. If the system test continues to fail, please contact technical services.

## 5.1.2 Selecting a therapy

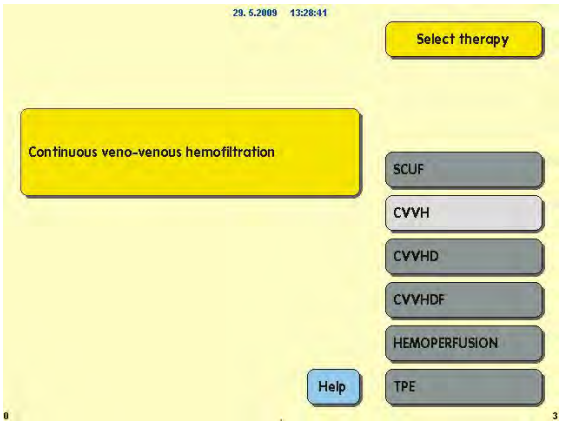



**Figure 22**

Select the desired therapy by turning the *Main selector button* until the chosen therapy is highlighted.

Confirm the selected therapy by pressing the *Main selector button* .

The system switches to the *Preparation Mode*. If a different therapy is desired select and confirm the *Previous* function to return to the previous screen.

Note: When displayed, the *Previous* function simply takes the operator back one screen.

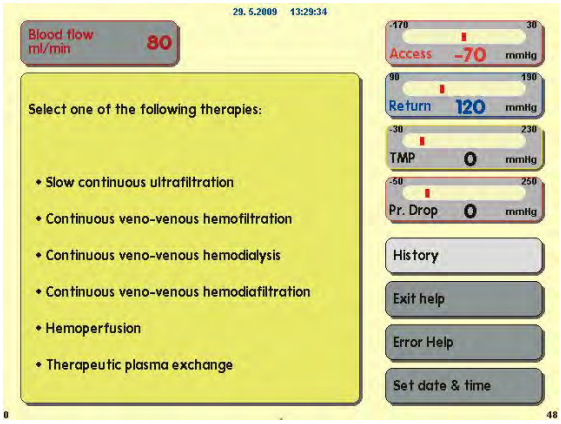



**Figure 23**

***Help*** function will provide further onscreen information.

## 5.1.3 *Preparation Mode* - Selecting the tubing set

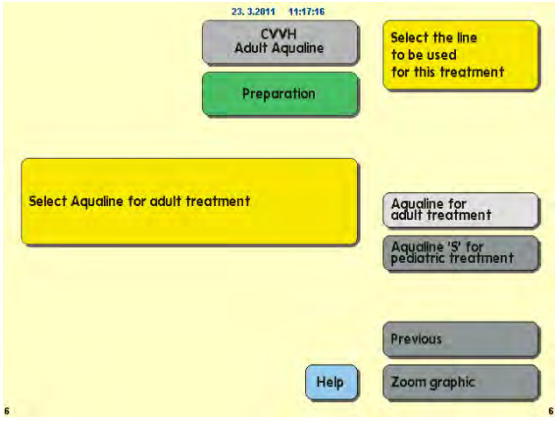



**Figure 24**

Select the tubing set by turning the *Main selector button* until the chosen tubing set is highlighted.

Aqualine tubing set for adult treatment.

- Blood flow rates from 30-450 ml/min
- Extracorporeal volume 100 ml

Aqualine 'S' tubing set for pediatric treatment

- Blood flow rates from 10-200 ml/min
- Extracorporeal volume 61 ml

**Figure 25 Aqualine tubing set**

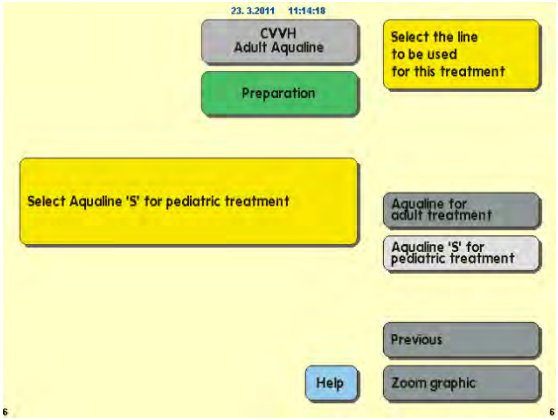



**Figure 26**

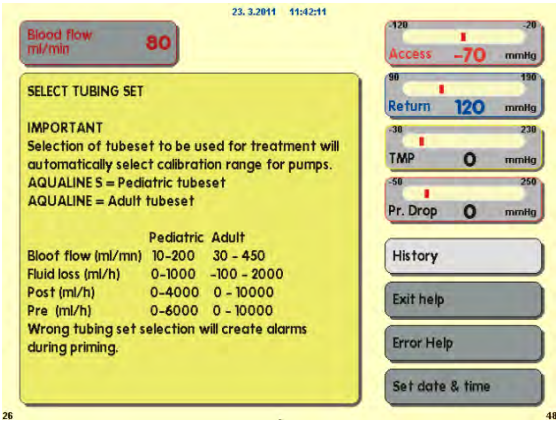



**Figure 27**

*Help* function will provide further onscreen information.

A *Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions. Select and confirm *Yes* to confirm the tubing set selection OR select and confirm *No* to return to the previous step (tubing set selection screen).

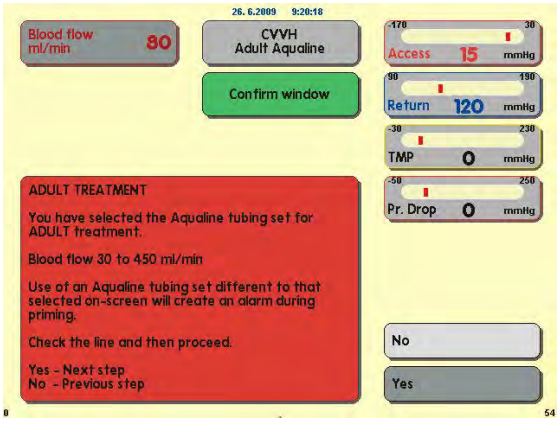



**Figure 28**

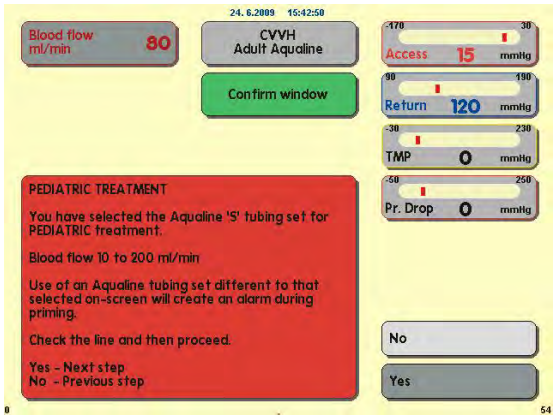



**Figure 29**

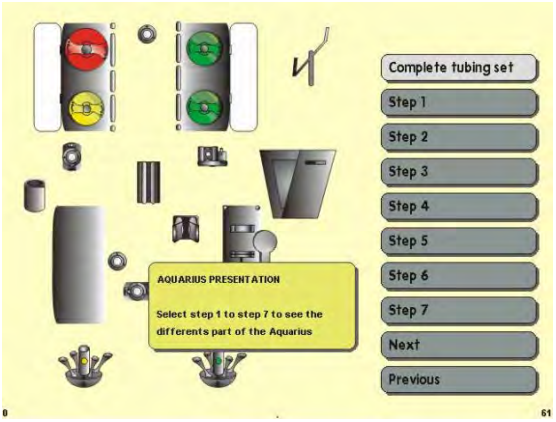



**Figure 30**

*Zoom graphic* key will provide step-by-step visual help with graphics.

## 5.1.4 *Preparation Mode* - Installing the tubing set and empty bags

NEVER use any type of fluid or gel on the tubing or the air detector sensor. Any foreign substance applied to the air detector sensor could result in patient injury or death.

Use only bloodlines approved for use with Aquarius system.

To prevent fingers from getting pinched in the pump chamber, keep fingers out of the pump chamber while rotating the pump heads.

The pump rotors are placed in the load position at the end of system test (horizontal) to enable correct installation of the tubing. Always ensure the rotors are in the load position before starting to wrap the pump segments into the pumps.

Step 1. Open both pump doors.

Step 2. Install the ***blood*** pump segment by pressing the tubing, located near the red marker, into the bottom of the ***blood*** pump housing and ***carefully*** wrap the segment around the pump by turning the rotor clockwise. Then press the tubing into the holder at the pump outlet.

The operator must make sure that the tubing set is not pinched between the rotor and the housing or twisted in the pump chamber.

If the tubing is not installed in the pump chamber correctly, the pump segment may leak or rupture.

If the tubing is pinched or twisted during installation of the pump segments, discard the tubing and do not use it for treatment.

The blood pump inlet and outlet tube holders are shown below on the left.
The picture on the right shows a properly inserted tubing segment that is seated all the way in the chamber.

**Figure 31**

**Figure 32**

Step 3. Install the ***filtrate*** pump segment by pressing the tubing, located near the yellow marker, into the bottom of the ***filtrate*** pump housing and ***carefully*** wrap the segment around the pump by turning the rotor clockwise. Then press the tubing into the holder at the pump outlet.

Step 4. Install the *post-dilution* pump segment (top segment with green marker) by pressing the tubing into the inlet (bottom) of the *post-dilution* pump housing and *carefully* wrap the segment around the pump by turning the rotor counter-clockwise. Then press the tubing into the holder at the pump outlet (top).

Step 5. Install the *pre-dilution* pump segment (lower segment with green marker) by pressing the tubing into the inlet (bottom) of the *pre-dilution* pump housing and *carefully* wrap the segment around the pump by turning the rotor counter-clockwise. Then press the tubing into the holder at the pump outlet (top). Close both pump doors.

If the pump doors do not close easily, open the doors and re-check the pump segments for proper positioning. The doors should close easily when the tubing is properly inserted.

The operator must make sure that all pressure domes are properly in place.

Step 6. Attach the *pre-filter* pressure dome to the *pre-filter* pressure sensor and close the dome clamp.

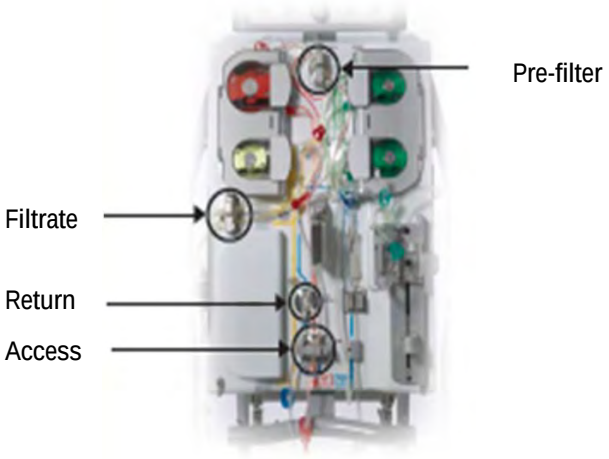



**Figure 33**

The tubing from the top of the blood pump should project outward and form a loop to prevent kinking of the tubing.

Step 7. Attach the *filtrate* pressure dome to the *filtrate* pressure sensor and close the dome clamp.

Step 8. Attach the *return* pressure dome to the *return* pressure sensor.

Step 9. Attach the *access* pressure dome to the *access* pressure sensor and close the dome clamp.

Step 10. Place the blood leak detector chamber in the holder on the left side of the cabinet.

**Figure 34**

Step 11. Insert the tubing coil into the heater, close the door.

**Figure 35**

Place the degassing chamber in the automatic degassing unit holder, see section 5.2 Automatic degassing unit priming and use.

Step 12. Install the *return* line in the air detector tube holder, press the unit together and push back to hold the *return* line in place. Ensure the return tubing is located securely within the groove of the air detector unit before attempting to press together and push back.

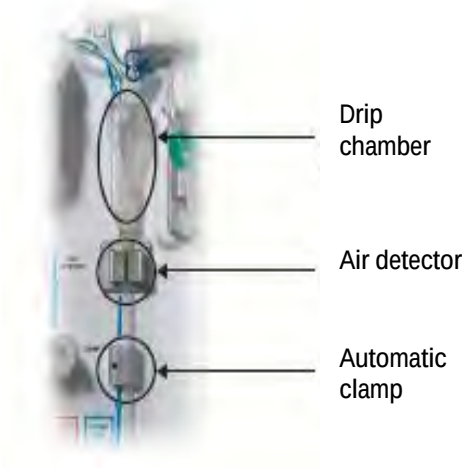



**Figure 36**

Step 13. Install the *return* line in the *return* line clamp.

Step 14. Connect the empty collection bag for priming to the access line and hang it on the I.V. pole.

The operator must make sure that the tubing in the pump segments are not dislodged or twisted by installation of the filter.
Any time the tubing has been manipulated, visually verify that the pump segment is properly inserted into the pump chamber.

Step 15. Select and confirm *Next* to see the following screen.

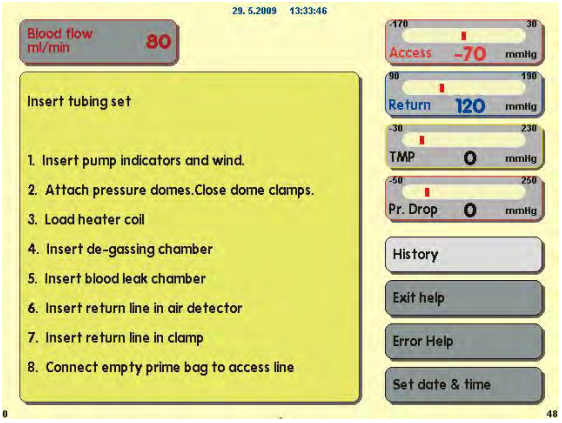



**Figure 37**

*Help* function will provide further onscreen information.

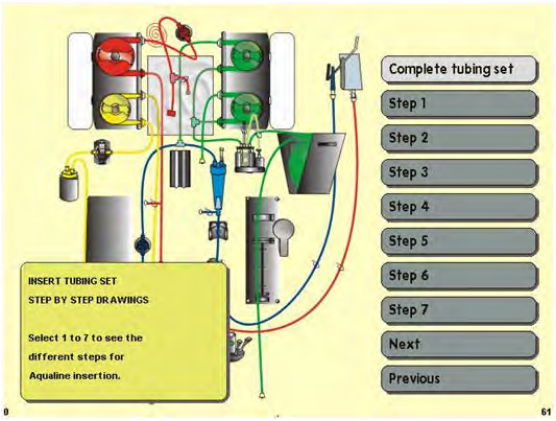



**Figure 38**

*Zoom graphic* key will provide step-by-step visual help with graphics.

## 5.1.5 *Preparation Mode* - Installing the filter and bags, and connecting the lines

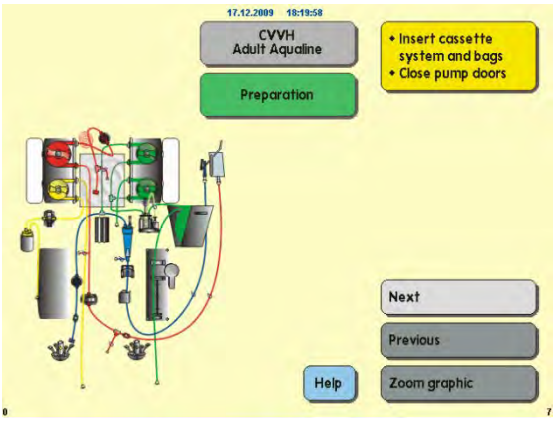



**Figure 39**

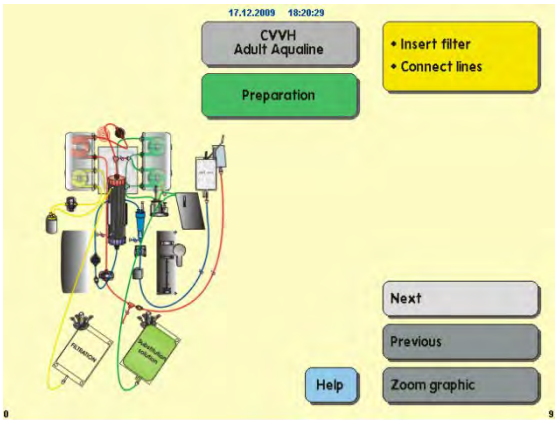



**Figure 40**

Step 1. Place the prescribed hemofilter in the filter holder. Attach the red connector of the tubing set to the red connector of the filter. Attach the blue connector of the tubing set to the blue connector of the filter.

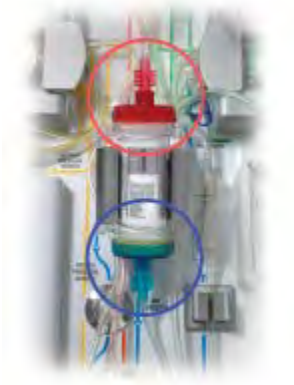


**Figure 41**

Step 2. Attach the filtrate line (short line from the blood leak detector) to the clear luer lock filtrate port at the top of the filter.

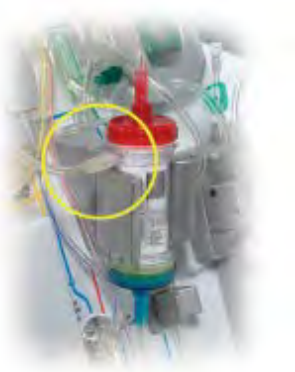


**Figure 42**

For hemoperfusion treatments, the filtrate tubing line is not used and should not be connected to the blood circuit.

Step 3. Attach the free line depending on the treatment required.

The “free line” is the colorless line exiting the pre-dilution pump (bottom green pump). The free line can be connected to the access line prior to the filter (SCUF, CVVH, TPE and Hemoperfusion) or to the dialysate port at the bottom of the filter (CVVHD and CVVHDF).


**Figure 43**

SCUF, CVVH, TPE , Hemoperfusion
Attach the free line to the access line prior to the filter.

CVVHD or CVVHDF
Attach the free line to the dialysate port at the bottom of the filter.

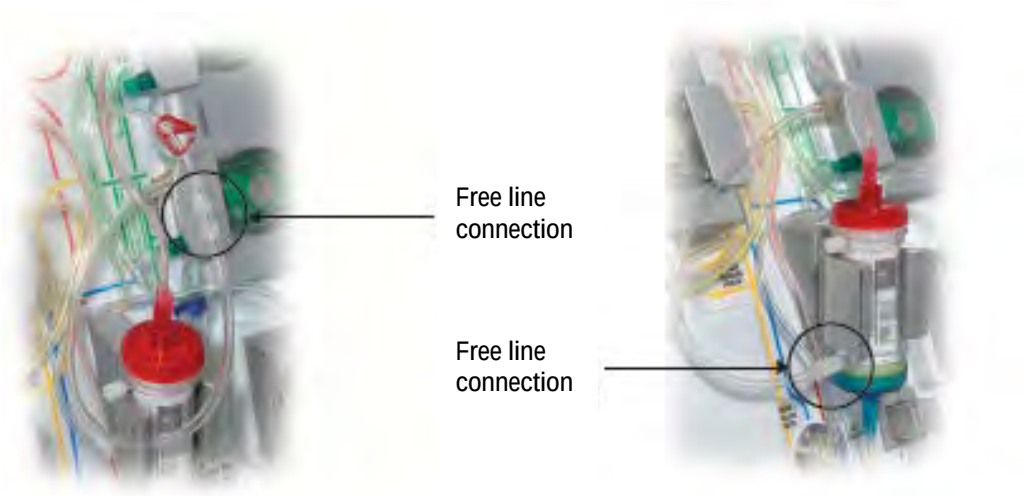
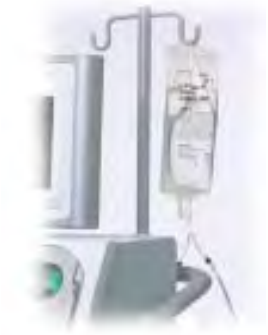



**Figure 44**

Step 4. Hang the empty collection bag for priming on the I.V. pole and connect the red end of the Aqualine tubing set (access line) to the bag.

**Figure 45**



Step 5. Hang a 1 l bag of priming solution (usually heparinized saline) on the I.V. pole.

Step 6. Insert the spiked Y-connector provided with the Aqualine tubing set into the priming solution bag. Remove the blue capped spiked end from the Aqualine tubing set (return line) and connect the blue luer-lock end to the Y-connector.

**Figure 46**

The I.V. pole may only carry a maximum weight of 2.5 kg.

**Figure 47**

Step 7. Connect the empty, 5 l collection bag(s) to the filtrate tubing and hang it on the filtrate scale. Be sure to open all clamps on the bags and manifold set.

Step 8. Hang the substitution solution bag(s) on the substitution scale and connect it to the heater tubing. Be sure to open all clamps on the bags and manifold set.

If using 2.5 l substitution or dialysate bags, in order to detect empty bags properly, enter the number to be used and use the appropriate number of 5 l filtrate bags. One 5 l filtrate bag will be needed for two 2.5 l fluid bags.

To prevent overfilling or rupturing of the filtrate bags, please ensure that an equal number of bags of the same size are used on the substitution and filtrate scales. At the start of treatment, if three 5 l substitution bags are placed on the substitution scale, then three empty 5 l filtrate bags must be placed on the filtrate scale.

Do not hang anything except soft plastic fluid bags on the balancing scale hooks located at the base of the Aquarius system. Foreign objects on the scale hooks can significantly alter fluid balance, resulting in patient injury or death.

Ensure that the filtrate bags and substitution bags do not touch the cart frame. Ensure that the tubing lines are not supported by and are not resting on the cart frame. Do not touch the filtrate or substitution solution bags while the balance system is active. Observe this warning to avoid patient fluid balance errors.

When using a manifold with multiple bags, all applicable clamps must be opened to allow the fluid to move freely.
If a substitution bag is kinked or remains clamped, air may be pumped into the substitution lines and balance alarms may occur due to the unbalanced load hanging on the scale.

To prevent misdirection of substitution solution or extracorporeal blood loss, be sure that all lines are properly installed and correctly connected.

Step 9. At this time it is good to connect the ADU hydrophobic sensor to prevent a positive pressure within the tubing. See chapter 5.2 for how to proceed.

Step 10. Verify that the output of the dialysate/pre-dilution pump (lower green pump) is connected to the bottom of the filter for CVVHD and CVVHDF therapies.

The output of the pre-dilution pump (lower green pump) should be connected to the pre-dilution luer connector of the pre-filter blood line leading to the top of the hemofilter, for all other therapies.

Step 11. Verify that all tubing clamps are open for the access, return, filtrate and substitution/dialysate tubing lines. If the substitution line is connected to the pre-dilution luer connector, open the pre-dilution line clamp.

Step 12. Select and confirm *Next* to prepare the heparin syringe.

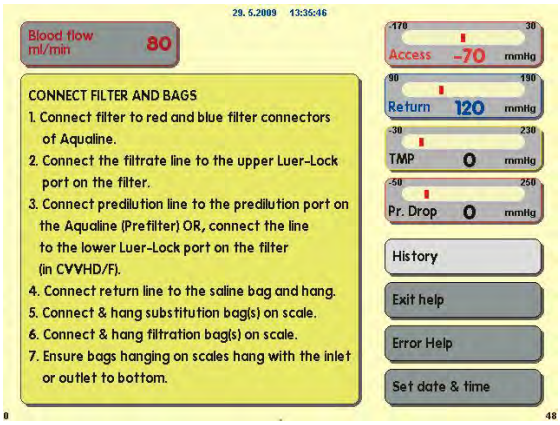



**Figure 48**

*Help* function will provide further onscreen information.

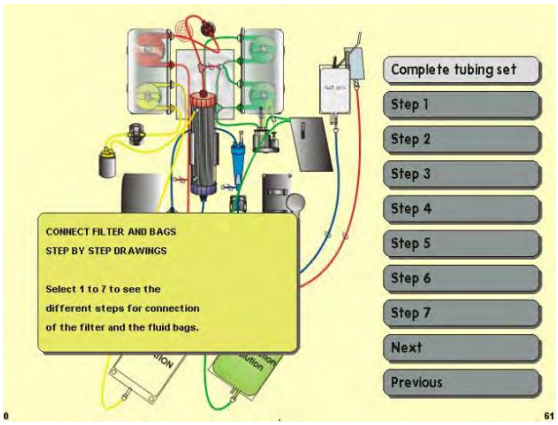



**Figure 49**

*Zoom graphic* key will provide step-by-step visual help with graphics.

## 5.1.6 *Preparation Mode* - Preparing the anticoagulant

Only use the heparin syringe type that the Aquarius system has been calibrated to use (See also 3.3. Equipment disposables).
The Aquarius system must be calibrated for the particular type of syringe you are using by a certified technician. The syringe size is shown at the right of the *Prepare syringe* screen.

Use only Luer-lock syringes and ensure that the heparin line is not clamped prior to the start of heparin infusion.
Use of non-Luer lock syringes or failing to unclamp the heparin line can result in patient blood loss due to coagulation.

When no anticoagulant is used, there is a risk of blood clotting in the extracorporeal circuit. Clotting may result in blood loss.

When no heparin is used the heparin line should be clamped.

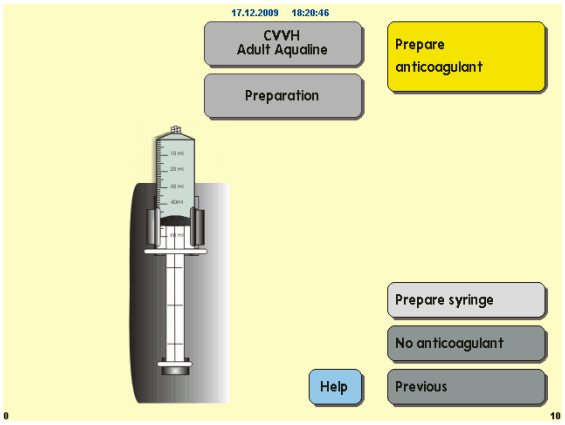



**Figure 50**

If heparin is to be infused select and confirm *Prepare Syringe*

OR

If no heparin is to be infused select and confirm *No Anticoagulant*

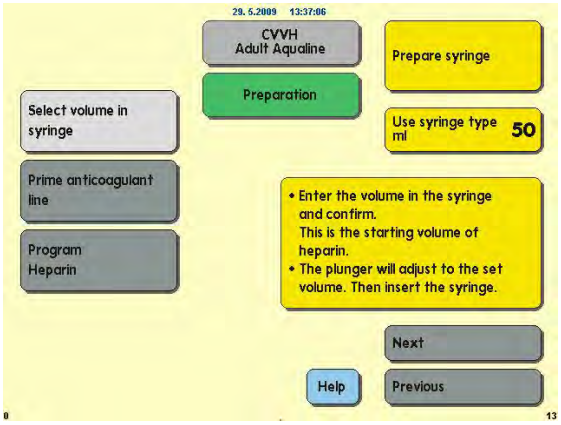



**Figure 51**

If *Prepare syringe* has been selected:

Fill the syringe with the concentration and volume of heparin prescribed by the physician.

Confirm Select volume in syringe by pressing the Main selector button .

Adjust the heparin volume by turning the *Main selector button* left or right as required.

Confirm the volume input by pressing the *Main selector button* . The syringe driver moves to the correct position.

Clamp the heparin line.

Connect heparin syringe to heparin line.

Place heparin syringe in heparin pump.

Note: Ensure the syringe body and plunger flanges are engaged correctly into the pump.

**Figure 52**

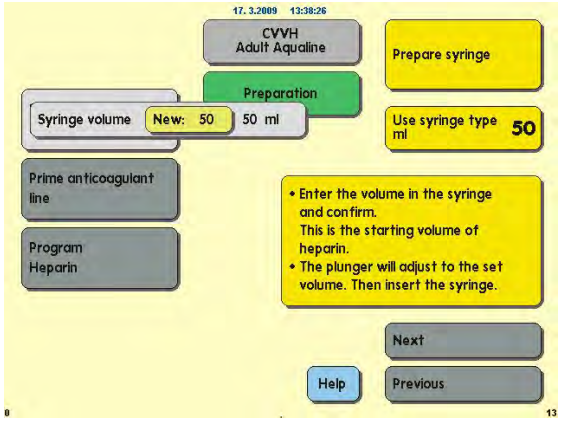



**Figure 53**

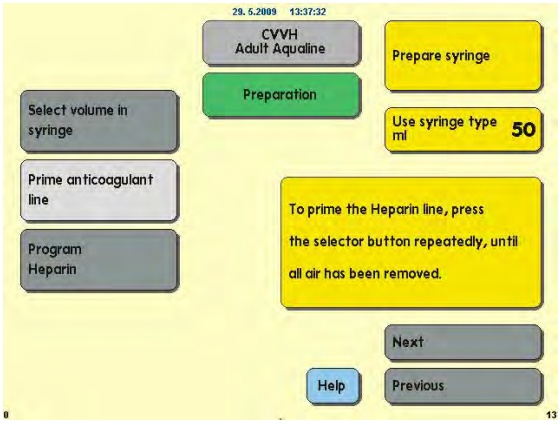



**Figure 54**

Un-clamp the heparin line.

Select Prime anticoagulant line by turning the Main selector button.

Press the *Main selector button* as many times as necessary until all air is removed from the line.

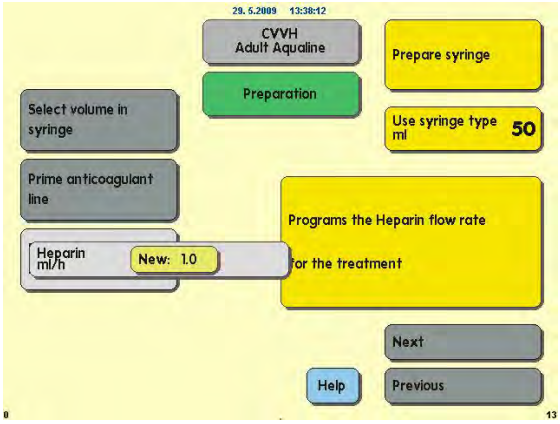



**Figure 55**

Select Program Heparin by turning the Main selector button.

Adjust heparin flow rate by turning the *Main selector button* left or right as required.

Confirm flow rate input by pressing the *Main selector button*.

Select and confirm *Next* to proceed.

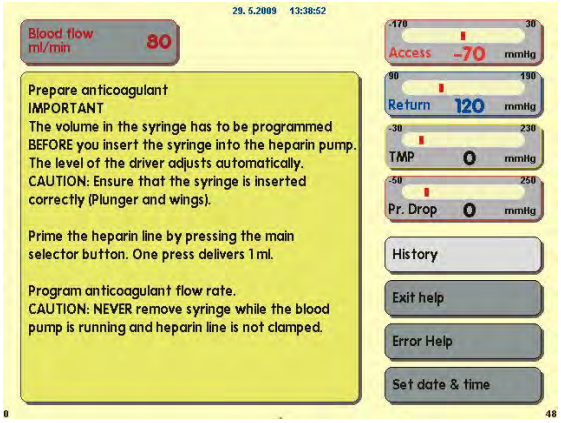



**Figure 56**

To enter *Priming mode* select and confirm *Start priming*.

Alternatively the operator has the choice to return to preparing an anticoagulant. To do this the operator must select and confirm *Prepare anticoagulant*.

*Help* function will provide further onscreen information.

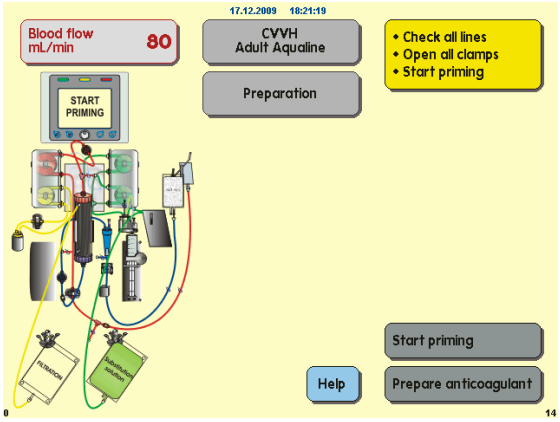



**Figure 57**

If *No Anticoagulant* has been selected, enter *Priming mode* by selecting and confirming *Start priming*.

Alternatively the operator has the choice to return to preparing an anticoagulant. To do this *Prepare anticoagulant* must be selected and confirmed.

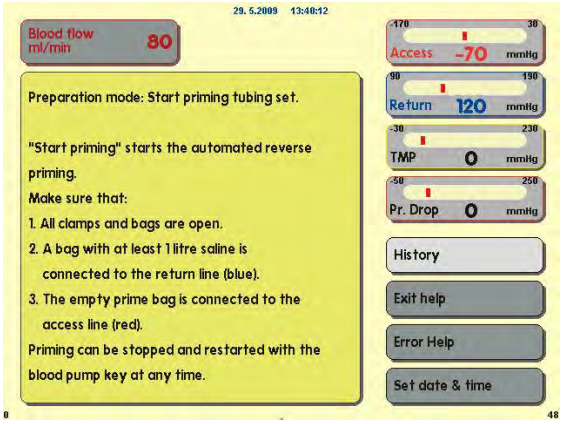
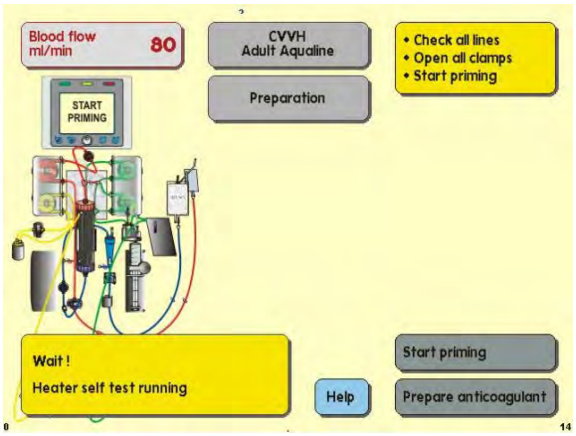



**Figure 58**

*Help* function will provide further onscreen information.




If *Start priming* is selected while the heater self test is still running a message appears on the screen and the Priming screen is not accessible.

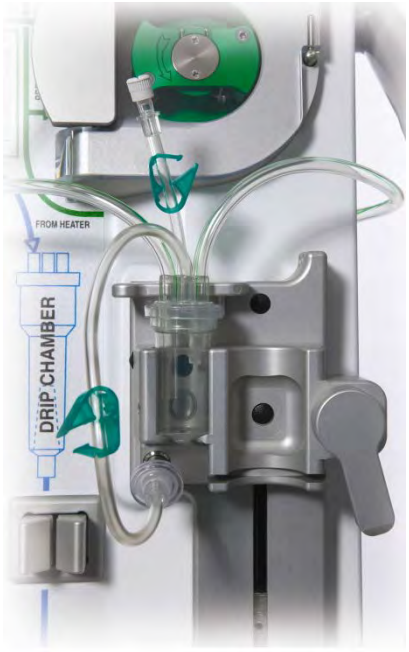
The message automatically disappears when the heater self test is completed.

Blood pump speed and Priming mode can be selected at the end of the Preparation Mode.

**Figure 59**

Priming the Aquarius system may be delayed due to high heater plate temperature from the previous treatment. The message Wait! Heater Self Test Running will be displayed until the *Start Priming* selection is available.

## 5.2 Automatic degassing unit priming and use




GENERAL DESCRIPTION OF ADU

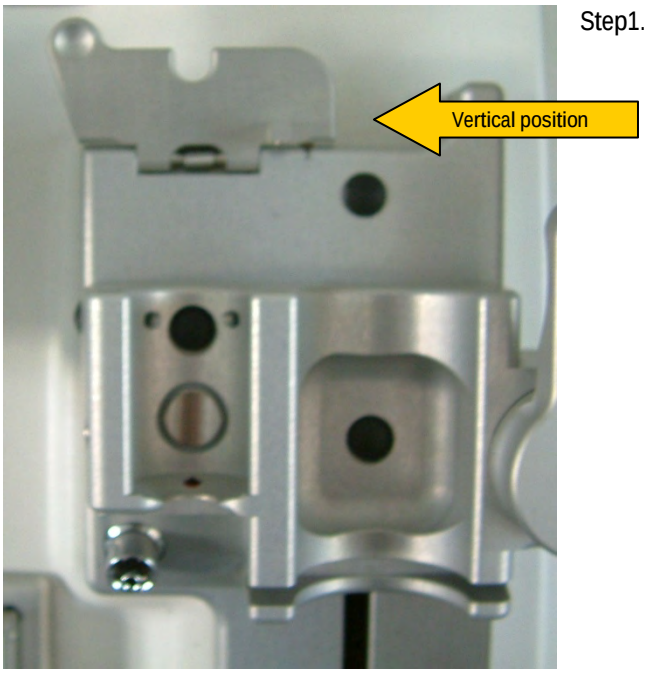
The Aquarius system automatic degassing unit (ADU) sets the level in the degassing chamber automatically (± 1cm around the light beam). Gas inside the substitution chamber, caused by degassing from substitution/dialysate fluid, is removed by a small pump inside the ADU box (placed inside the Aquarius system).

Two hydrophobic filters prevent the Aquarius system ADU from contaminating the substitution fluid. One hydrophobic filter is located outside, on the degassing tubing. A second filter is located inside the Aquarius system before the pressure unit. The level is controlled by an infra-red light beam and pressure.

The Aquarius system ADU is a microprocessor-controlled system. The ADU works independently from the Aquarius system, except for the power supply and the alarm display.

**Figure 60**

### 5.2.1 Aqualine Tubing Installation:




Step1. Move the ADU fixation clip into the vertical position.

**Figure 61**

Step 2. Place degassing chamber in the holder, ensuring that the short tubing is placed at the back of the fixation plate. Make sure that the holder switch is pressed ON by the chamber.

The longer clamped tube on the degassing chamber is the ADU sensor line. The chamber should be placed such that this line is positioned at the front of the holder.

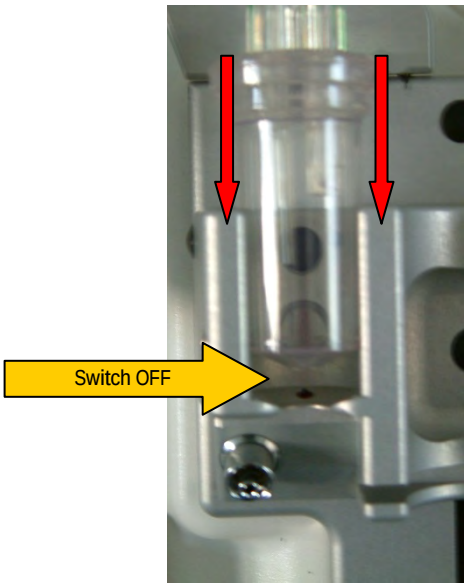



**Figure 62**

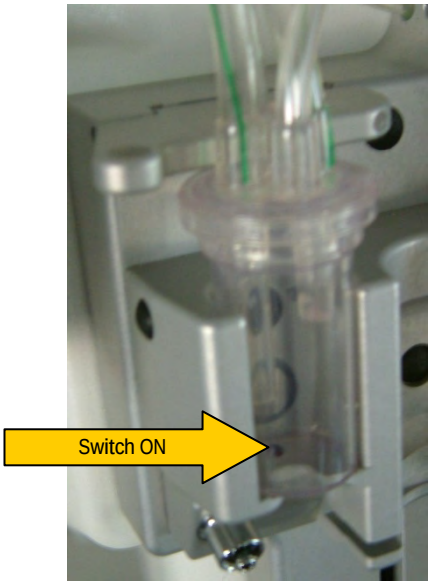



**Figure 63**

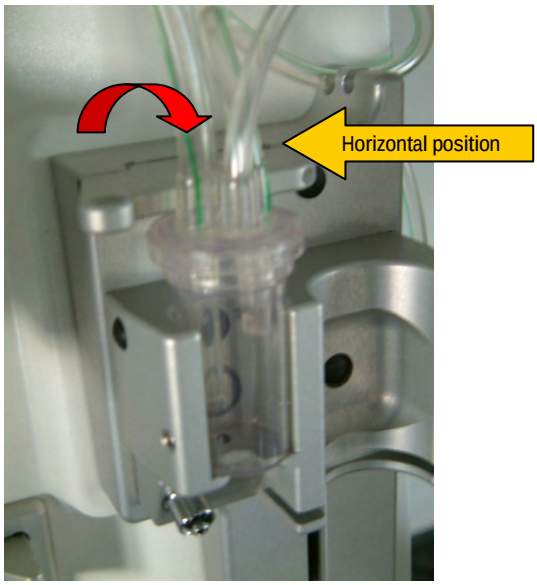



**Figure 64**

Step3.
Move the fixation clip to its horizontal position in order to fix the degassing chamber into its functional position.

In case the fixation clip is not well closed, the alarm *Degassing chamber missing* appears at the end of priming.

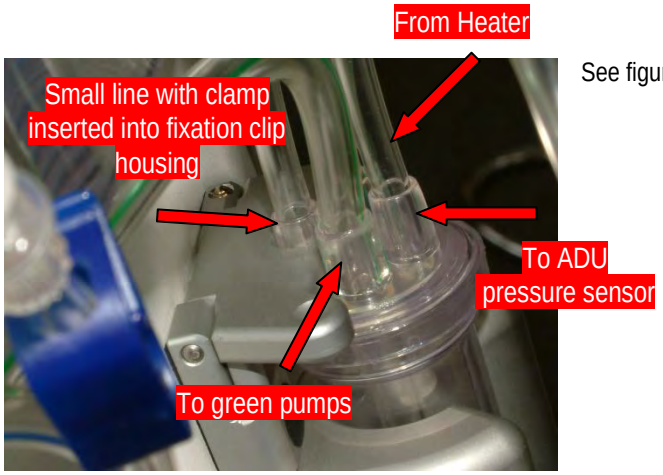
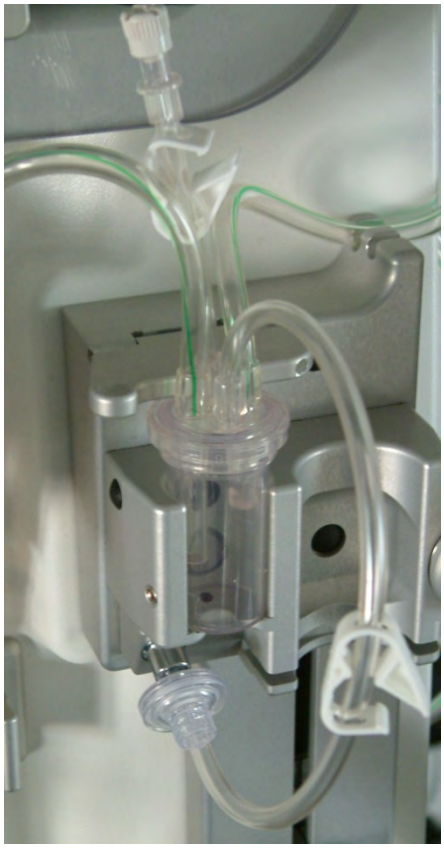



**Figure 65**

See figure 65 for correct positioning of the degassing chamber.



Step 4.
Connect the Luer-lock hydrophobic filter from the ADU pressure line to the ADU pressure sensor.

Do not forget to connect the degassing line to the pressure sensor.

**Figure 66**

Step 5. Leave the clamp of the hydrophobic filter tubing open, as shown in the figure above.

### 5.2.2 Priming:

The automatic degassing unit starts working during priming mode. When the ADU pressure sensor detects less than -30 mmHg (Post-dilution pump is running) it will automatically prime the degassing chamber AFTER 10 seconds FOR 10 seconds.

If the infrared sensor does not detect water after the initial prime, the pump will start again AFTER 2 minutes. For the second prime, the motor stops priming when liquid is detected at the infra-red sensor (second priming cannot run more than 25 seconds).

If the degassing line (with hydrophobic filter) is not connected to the pressure sensor, the message *Check degassing chamber* will appear after approximately 60 seconds with an audible signal. Priming is stopped and needs to be restarted.

After priming is complete, inspect the chamber to ensure it is filled!

### 5.2.3 Operational Mode:

During operational mode, if the fluid level in the ADU falls below the level of the light-sensor, the ADU will remove air, thus refilling the chamber with fluid for up to 3.5 s. If the chamber is not filled after this time, the pump will pause for 10 s and then automatically repeat this cycle until fluid is detected.

### 5.2.4 ADU Alarms and Controls:

The ADU generates audible and visible alarms (***Check degassing chamber*** alarm is displayed on screen in a yellow window) under the following conditions:

- If the motor works for more than 25 s without detecting a filled chamber.
- If the hydrophobic filter is blocked (measured pressure less than –300 mmHg).
- If the system detects a positive pressure higher than +30 mmHg.
- If the system detects degassing line disconnection (measured pressure between -30 mmHg and +30 mmHg)
- If the ADU system test fails.

In case of an alarm, the balance pumps stop. Check cause of alarm and try to rectify. In case of fluid in the ADU sensor line, proceed as follows:

- Clamp the ADU sensor line and remove the chamber from the holder
- Connect an air filled 10 ml syringe and inject 5-10 ml air gently down the sensor line until there is no fluid left in the line
- Replace the ADU chamber and sensor line, and unclamp the line.

When the ADU detects “normal conditions” (no blocked hydrophobic filter and a set level) the alarm can be cleared by pressing the Mute key. The balance pumps will restart.

During treatment the ADU system will keep the fluid level constant inside the degassing chamber (± 1cm around the light beam). In case the fixation clip is not in its horizontal functional position, ***No fluid chamber detected*** or ***Degassing chamber missing*** alarm occurs at the end of priming and during treatment mode.

When an ADU Alarm (***Check Degassing Chamber***, ***No Fluid Chamber Detected***, or ***Degassing Chamber Missing***) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call technical service.

## 5.3 Priming mode - Priming the Aquarius system

Before beginning priming ensure that:

- All line clamps are open.
- A bag with at least 1 l of saline is connected to the return (blue) line.
- The supplied waste bag is connected to the access (red) line.
  Ensure that the substitution tubing connector is connected to a bag of substitution/dialysate solution on the substitution scale.
- Ensure that all *access*, *return*, replacement and filtration tubing clamps are open.
- Ensure that the substitution degassing chamber and return drip chamber clamps are closed.

Priming the Aquarius system may be delayed due to high heater plate temperature from the previous treatment. The message **Wait! Heater Self Test Running** will be displayed until the *Start Priming* selection is available.

If TPE or Hemoperfusion therapy is selected, saline solution may be used in place of substitution/dialysate solution.

The *Blood pump* key and the *Mute* key are active during Priming mode.
The *Clamp* key and the *Start/Stop* key are inactive during Priming mode.

The priming procedure requires 800 ml of saline. The pre- and post-dilution lines are primed with fluid from the substitution/dialysate bag(s). The extracorporeal circuit and the filtrate lines are primed with fluid from the saline bag.

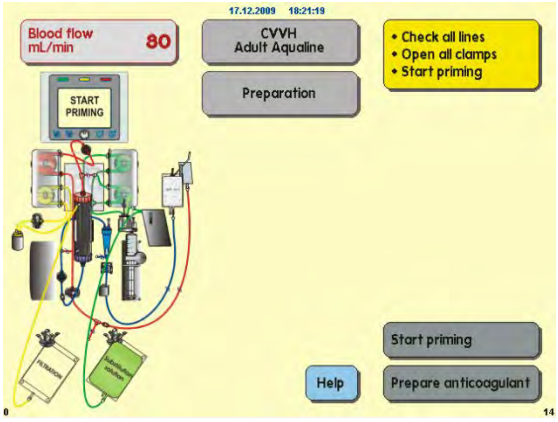



**Figure 67**

Select *Start Priming* by turning the *Main selector button*.
To begin the priming procedure, press the *Main selector button*.

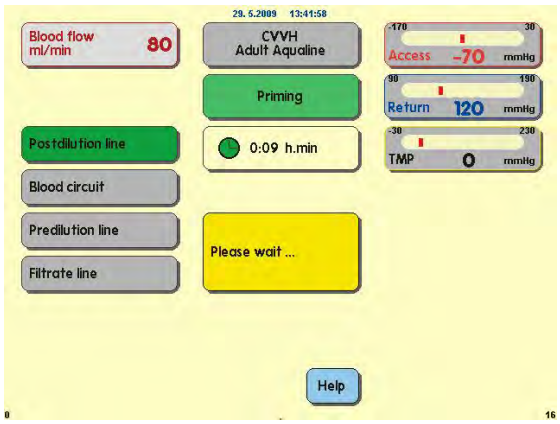



**Figure 68**

At this stage the screen displays *Access*, *Return* and *TMP pressures*. In the left part of the screen, the components of the circuit that are currently being primed are highlighted. The displayed clock indicates the remaining priming time.

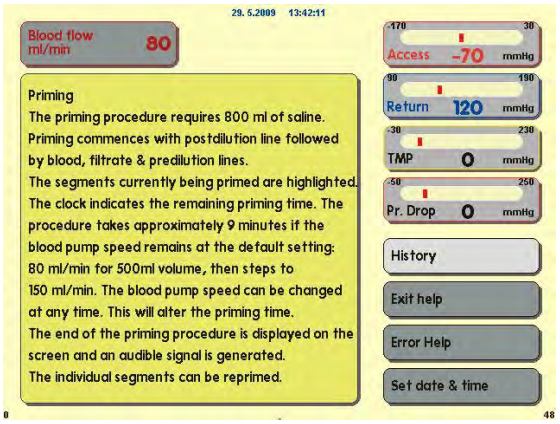



**Figure 69**

***Help*** function will provide further onscreen information.

The automated priming procedure takes approximately 9 min if the blood pump speed remains at the default setting determined during calibration. During this time, the operator can increase the blood pump flow rate to reduce priming time. The blood pump flow rate field is highlighted. Press the *Main selector button* to modify the flow rate. Enter the new flow rate by turning the *Main selector button* left or right and press the *Main selector button* to confirm. The new flow rate is displayed on the screen, the pump speed will alter and the clock will recalculate the remaining time.

Any air remaining in the degassing chamber can be removed by EITHER inversion of the chamber during priming OR aspiration via a syringe after priming.

If a *Check Degassing Chamber* alarm occurs during the first two minutes of priming (post-dilution line) and fluid is in the heater line, up to 120 ml of dialysate or substitution fluid may be pumped into the saline bag when the alarm is cleared and priming restarts.

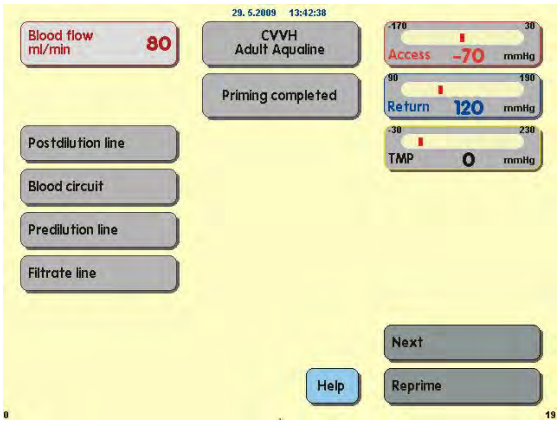



**Figure 70**

At the end of the priming procedure, the *Priming completed* message is displayed on the screen and an audible signal is generated.

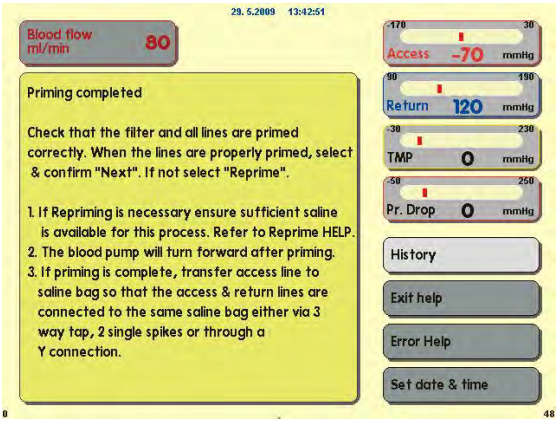



**Figure 71**

*Help* function will provide further onscreen information.

If the *Next* function is disabled, check if the filtration line and the blood leak detector line are correctly filled. If they are not, restart priming.

## 5.3.1 *Priming Mode* - Wrong tubing set selected or clamp closed message

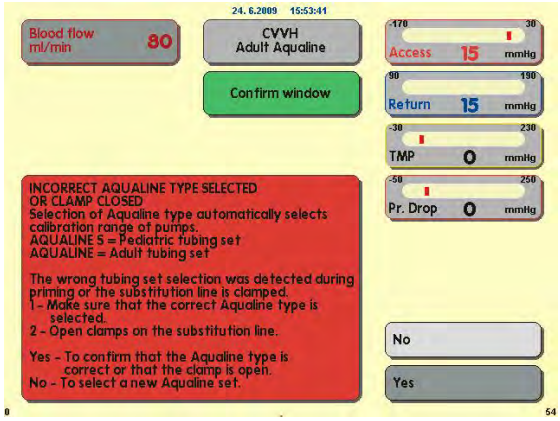



**Figure 72**

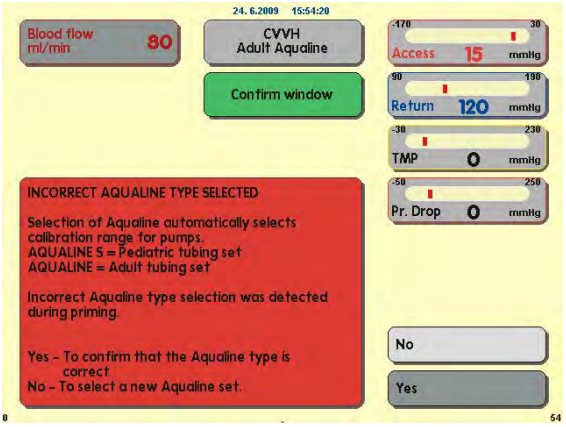



**Figure 73**

If the message *Incorrect Aqualine type selected or clamp closed* or *Incorrect Aqualine type selected* appears within the first 2 min of priming this could be due to
a) one clamp is closed on the substitution line or the substitution bag(s) are not open
b) the selected line (Aqualine tubing set for adult or Aqualine 'S' tubing set for pediatric) is not the one which has been installed on the Aquarius system by the operator.

Ensure that no clamp is closed on the substitution line and that substitution bag(s) are open and positioned correctly on the substitution scale.

- If the selected tubing set and used tubing set correspond, select *Yes* to confirm the selected line by turning the *Main selector button* and pressing it.
- If the selected tubing set and used tubing set are different, select *No* to change selection by turning the *Main selector button* and pressing it.

If an *Incorrect Aqualine type* confirm window appears and fluid is in the heater line, up to 120 ml of dialysate or substitution fluid may be pumped into the saline bag when *Yes* is selected to confirm the correct tubing set. When priming completes, replace the saline bag and reprime the blood circuit if the dialysate or substitution fluid is not indicated for infusion.

## 5.3.2 *Priming Mode* - Reprime mode

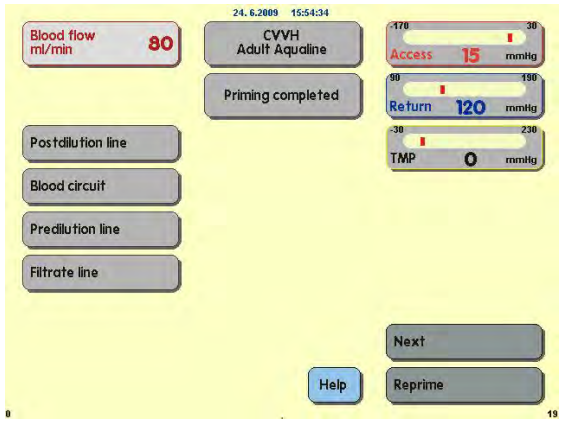



**Figure 74**

The operator can now select the *Reprime* function or the *Next* function to go to *Clamp and Pressure test* function.

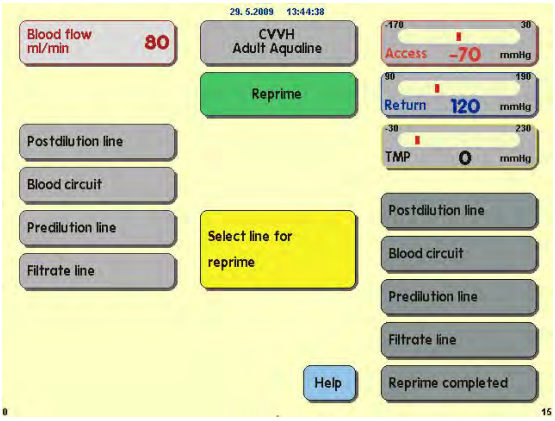



**Figure 75**

If the priming procedure needs to be repeated select and confirm *Reprime*. The screen will now display *Reprime mode*.

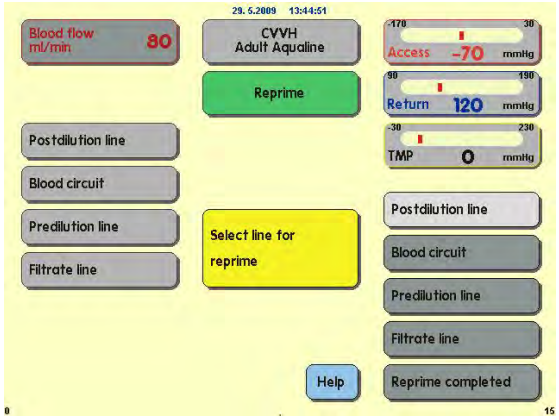



**Figure 76**

*Reprime* allows you to select an individual or multiple lines/circuit to be reprimed. All selectable lines/circuit are displayed on the right side of the screen: Post-dilution line, Blood circuit, Pre-dilution line and Filtrate line. When the blood line is reprimed, the filtrate line is reprimed. When the filtrate line is reprimed, the blood line is not reprimed. Select the line(s) requiring reprime and confirm to start. On the left side of the screen, the circuit or the tubing set currently being primed is highlighted.

Reprime may be stopped manually by selecting and confirming *Reprime completed*, but will stop automatically after the following volumes are pumped:

| | |
|---|---|
| Blood circuit + filtrate pump: | 800 ml |
| Post-dilution pump: | 160 ml |
| Pre-dilution/Dialysate pump: | 20 ml for SCUF, CVVH, TPE, HPF |
| | 500 ml for CVVHD, CVVHDF |

Note: If a complete system reprime is required, a minimum of 1 l of saline solution and a new priming collecting bag must be attached before the reprime procedure is started.

5.3.2.1.1.1 To prevent overfilling or rupturing of the priming collection bag, please ensure that the capacity of the priming collection bag is sufficient to allow a safe reprime or replace the priming collection bag with a new one.

In Hemoperfusion, the filtration pump is always disabled during repriming.

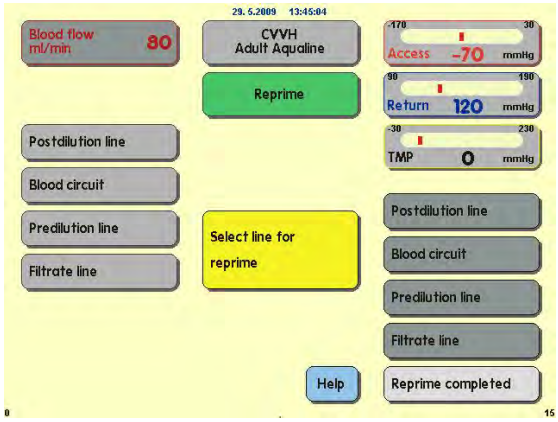



**Figure 77**

To return to *Priming completed* mode, select and confirm *Reprime completed*.

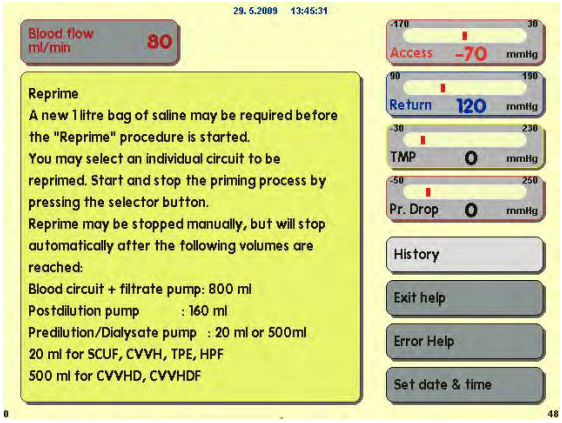



**Figure 78**

*Help* function will provide further onscreen information.

## 5.4 Clamp and pressure test

The *Blood pump* key and the *Mute* key are active during the Clamp and Pressure test.
The *Clamp* key and the *Start/Stop* key are inactive during the Clamp and Pressure test.

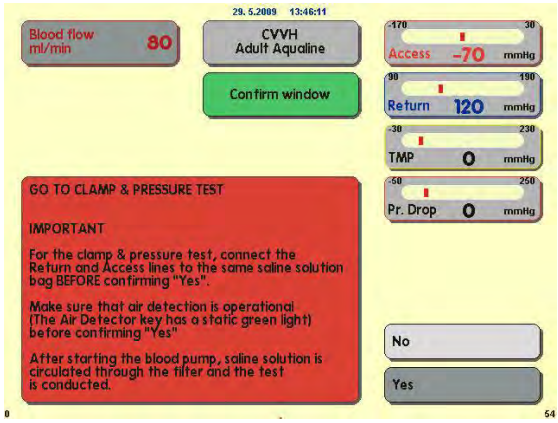



**Figure 79**

If the priming procedure is satisfactory select and confirm *Next*. The operator will be presented with a *Confirm window*. At this stage it is IMPORTANT to follow the onscreen instructions.

Select and confirm *Yes* to move to the Clamp and Pressure test OR confirm *No* to return to the previous step.

Before proceeding, ensure Return and Access lines have been connected to the same saline bag.

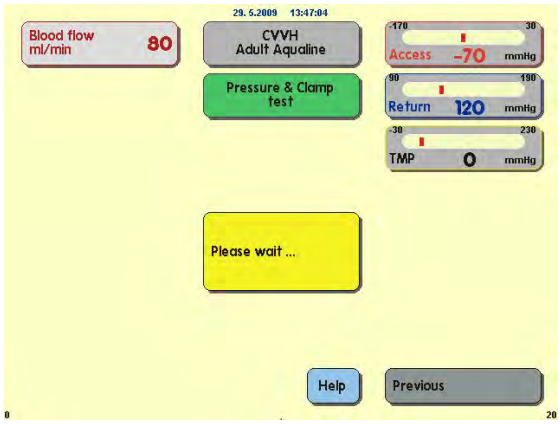



**Figure 80**

The *Clamp and Pressure test* must be performed before the Aquarius system proceeds to the *Start Connection* mode. This test is only possible if the air detector has determined that the extracorporeal circuit is free from air. An air free circuit is indicated by a steady green light in the clamp key.

A yellow message “Insert tube to air detector” is displayed at the end of priming if air is detected or if the tube is not correctly inserted into the air detection system.

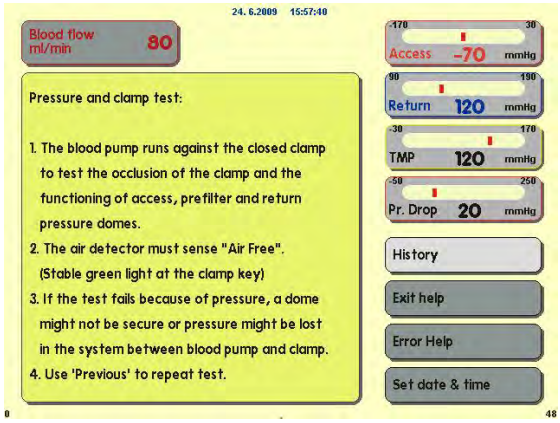



**Figure 81**

*Help* function will provide further onscreen information.

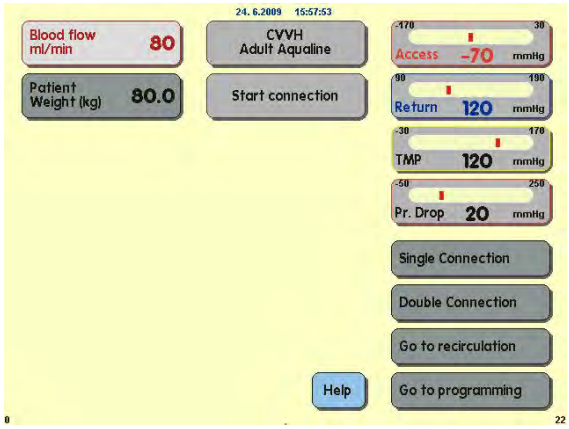



**Figure 82**

After the *Clamp and Pressure test* has successfully been completed the operator can select between *Go to programming*, *Go to recirculation*, *Single connection* or *Double connection*. These functions are listed in the lower right side of the screen and may be selected and activated using the *Main selector button* .

At this time it is possible to enter the patient body weight by selecting the *Patient Weight* window and modifying it. This data will be taken into account in the *Renal Dose* calculation for CVVH, CVVHD, and CVVHDF therapy modes.

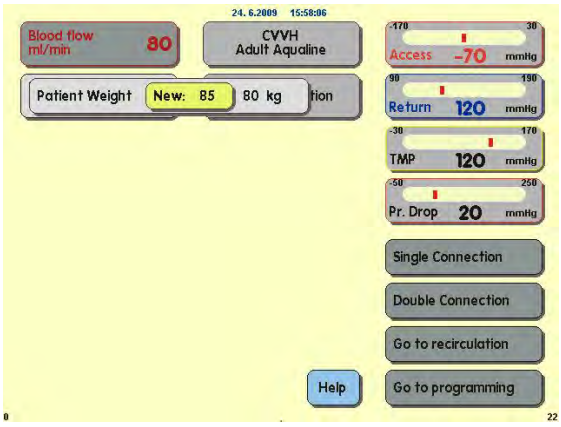



**Figure 83**

If patient body weight is not entered at this time, the *Renal Dose* calculation will not display on the screen during treatment.

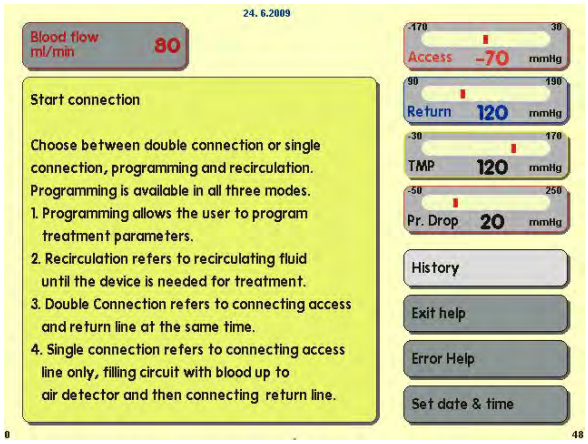



**Figure 84**

***Help*** function will provide further onscreen information.

After the *Clamp and Pressure test* has successfully been completed, the air detector and the blood leak detector are active.

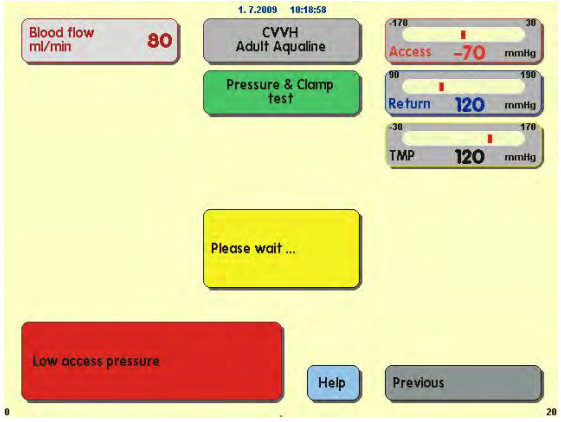



**Figure 85**

A *Clamp and Pressure test* failure will open a window describing the reason.

## 5.5 *Recirculation mode* - Recirculating saline solution

Recirculation can be used after priming OR during a treatment when a patient needs to be disconnected temporarily.

To start recirculation after priming select and confirm *Go to recirculation*. To use recirculation during a therapy, select and confirm *Recirculation* from the *Options* screen.

During the Recirculation mode, the *Blood pump* key, the *Mute* key and the *Clamp* key are active.

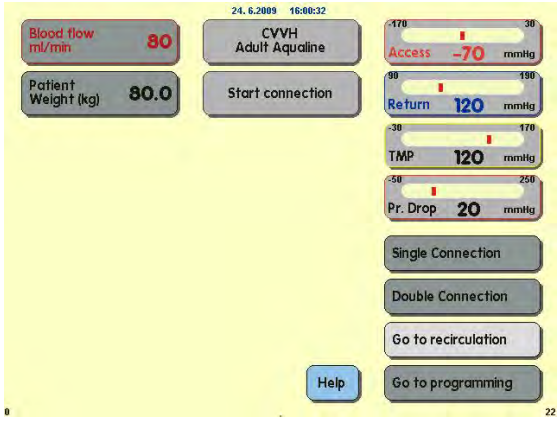



**Figure 86**

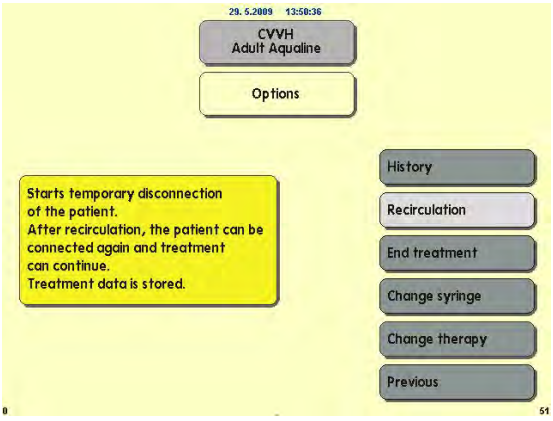



**Figure 87**

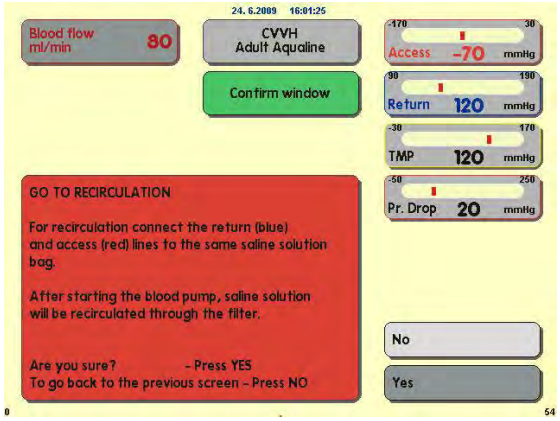



**Figure 88**

A *Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions. Select and confirm *Yes* to move into *Recirculation* mode OR confirm *No* to return to previous step.

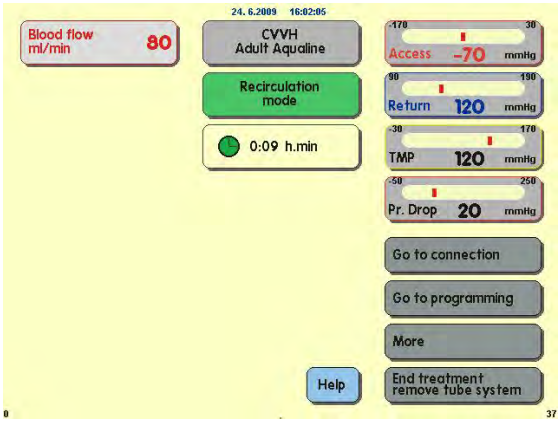



**Figure 89**

Press the *Blood pump* key to begin recirculation. While the system is recirculating saline solution, the patient parameters may be entered. The blood pump runs at the programmed speed until turned off by the operator, or until a blood circuit alarm condition is detected or until Connect Patient is selected.
The recirculation time is displayed on the main screen.

During recirculation only the blood pump circuit is active i.e. the balance system will not operate.

The operator can select between *Go to connection, Go to programming, More* or *End treatment remove tube system*. These functions are listed in the lower right side of the screen and may be selected and activated using the *Main selector button*.

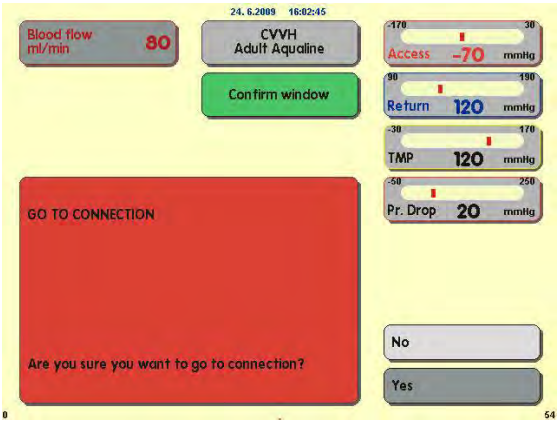



**Figure 90**

When *Go to connection* is selected, a *Confirm window* appears. Select and confirm *Yes* to move into *Connection* mode OR confirm *No* to return to previous step.

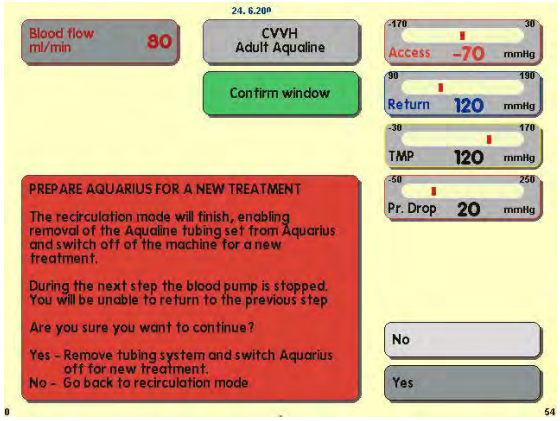



**Figure 91**

When *End treatment remove tube system* is selected, a *Confirm window* appears. At *this stage* it is IMPORTANT to follow the onscreen instructions. Select and confirm *Yes* to move into *End treatment* mode OR confirm *No* to return to previous step

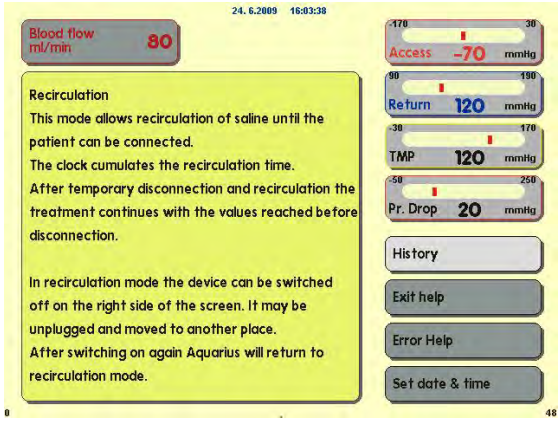



**Figure 92**

*Help* function will provide further onscreen information.

## 5.6 *Programming* - Entering Patient Parameters

The programming function can be accessed following priming, during recirculation mode and during a therapy. Programming allows the operator to alter program parameters. To commence programming select and confirm *Go to programming*.

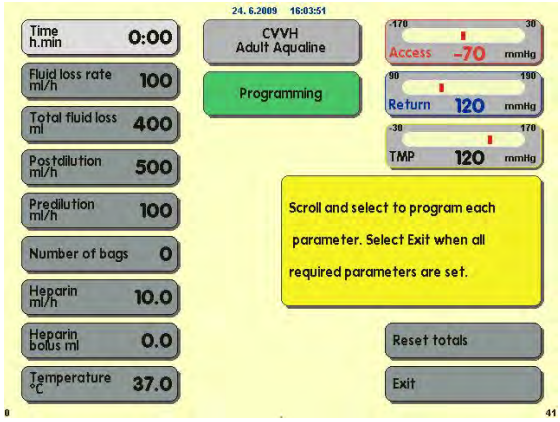



**Figure 93**

The active parameter available for input is highlighted. When confirmed by pressing the *Main selector button* , a short definition of the parameter appears in a yellow box to the right of the screen.

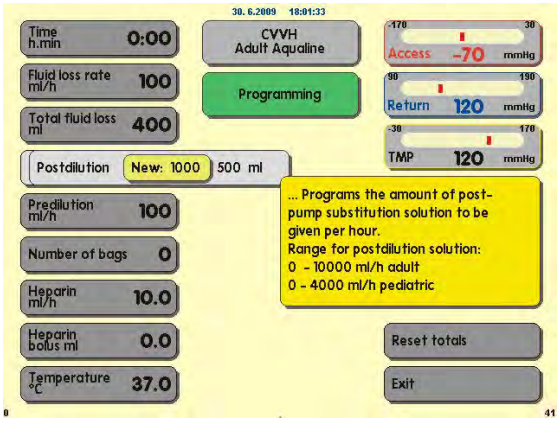



**Figure 94**

Press the *Main selector button* to open the input window. The current set value is displayed on the right. A small input window with the word *New* appears inside the parameter selected. By turning the *Main selector button* to the left or to the right, the new set value can be adjusted.

Confirm and store the input value by pressing the *Main selector button* . The new value is displayed and the next parameter is highlighted.

Press the *Main selector button* to open the input window and enter the desired value as described above. On the right side of the screen a short description of the current parameter is displayed as described above.

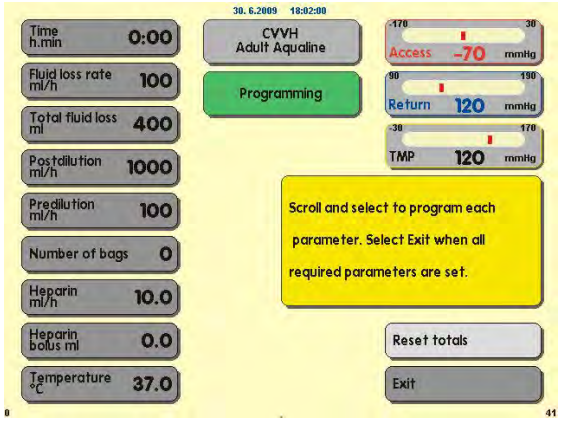



**Figure 95**

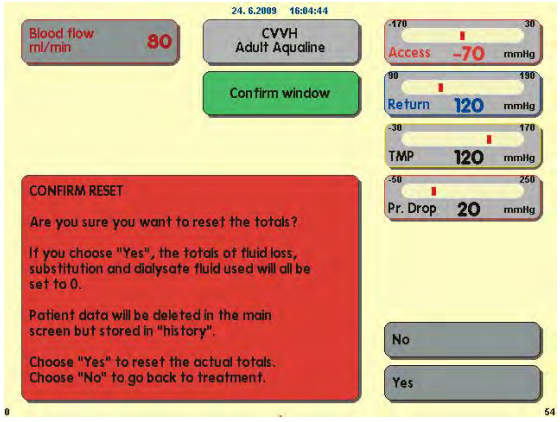



**Figure 96**

Selecting and confirming the *Reset totals* function will zero the following parameters after a confirm window: Fluid loss total, substitution fluid total, treatment clocks, pre and post-dilution and blood volumes pumped since last reset or commencement of therapy. These parameters are found in the Treatment and More screens.

When all parameters have been entered and confirmed, select *Next* to return to the *Start connection* screen, *Recirculation* mode or *Treatment* screen.

Note: Parameters displayed on the programming screen depend on the therapy choice and anticoagulant choice.

## 5.7 *Start Connection* - Connecting the Patient

The use of the Aquarius System is limited to patients weighing a minimum of 20 kg. In addition, the extracorporeal blood volume, including tubing set, filter and maximal fluid deviation (in ml), should not exceed 10% of the patient's blood volume.

For this reason, in some cases the minimum weight limit for the patient can be above 20 kg. The minimum patient body weight should be calculated for each tubing set and filter chosen, as follows:

$$\textbf{Extracorporeal blood volume (ml)} = [\textbf{Tubing priming volume (ml)} + \textbf{Filter priming volume (ml)} + \textbf{Maximal fluid deviation (ml)}]$$

$$\textbf{Patient minimum blood volume (ml)} = \mathbf{10}^{(*)} \times \textbf{Extracorporeal blood volume (ml)}$$

$$\textbf{Patient minimum weight (kg)} = \frac{\textbf{Patient minimum blood volume (ml)}}{\textbf{Blood volume per kilogram } (\frac{\textbf{ml}}{\textbf{kg}})}$$

(*) Being: $\textbf{Extracorporeal blood volume (ml)} = \mathbf{10\%} \times \textbf{Patient minimum blood volume (ml)}$

Example:

Aqualine tubing priming volume = 112 ml (this value assumes that the drip chamber is full)

Filter priming volume = 54 ml (in this example the Aquamax filter HF07 is used)

Maximal fluid deviation without alarm = 50 ml

Blood volume per kilogram chosen for this example (adult patient) = 80 ml/kg

$$\textbf{Extracorporeal blood volume} = (\mathbf{112\ ml} + \mathbf{54\ ml} + \mathbf{50\ ml}) = \mathbf{216\ ml}$$

$$\textbf{Patient minimum blood volume} = \mathbf{10} \times \mathbf{216\ ml} = \mathbf{2160\ ml}$$

$$\textbf{Patient minimum weight} = \frac{\mathbf{2160\ ml}}{\mathbf{80\ ml/kg}} = \mathbf{27\ kg}$$

In this example the minimum patient body weight that should be used with the Aquarius System must be 27 kg.

Be sure the patient blood access and connections are secured properly. Keep access connections uncovered and visible to allow immediate identification of any leakage. Careful monitoring of the patient for any evidence of extracorporeal blood loss is required to prevent serious injury or death.

Air entering the extracorporeal blood circuit can cause a fatal air embolism.

If the air detected alarm cannot be cleared, discontinue treatment and do not return the extracorporeal blood to the patient.

Be sure the patient blood access and connections are secured properly. As defined by the Association for the Advancement of Medical Instrumentation (AAMI), the return Pressure Monitor provides for the detection of bloodline separations. The return Pressure Monitor will trigger an alarm when the pressure decrease is greater than the limit. However, if the needle or cannula becomes dislodged from the return access and remains attached to the bloodline tubing, at typical blood access pressures and usual blood flow rates, the decrease in pressure from the dislodgment will not be sufficient to trigger an alarm condition. This is due to the resistance in the return needle or cannula which will maintain pressures above the recommended set limits of -75 to +25 mmHg.

Pressure monitoring technology should not be relied upon as the sole method for detecting a breach in the system. The healthcare professional attending the patient must be vigilant in securing the blood access needle or cannula. Careful monitoring of the patient for any evidence of extracorporeal blood loss is required to prevent serious injury or death.

Connecting or disconnecting the patient to or from the Aquarius system requires aseptic technique and continuous monitoring of all connections to prevent air from entering the system (air infusion) or blood from escaping from the system (blood loss). All system connections must be checked at regular intervals. All blood and fluid paths are sterile and non-pyrogenic.

Before connecting the patient and at regular intervals, ensure that the blood lines are not kinked. Kinked blood tubing may cause hemolysis (patient injury).

Make sure that the patient's needle has no direct contact to the vessel. When the patient's needle has direct contact to the vessel, failure in access pressure measurement can occur.

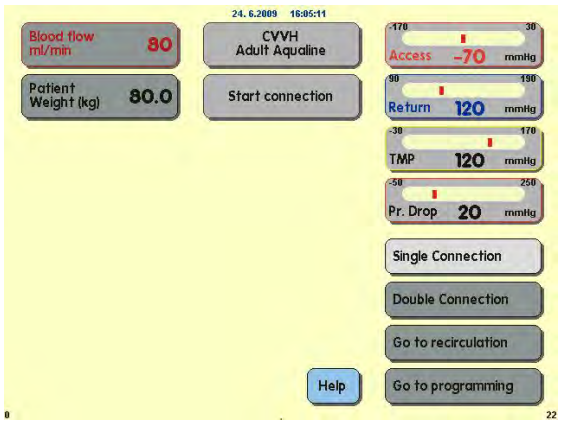
Note:

- When the Start treatment button is pressed after connection mode, the blood pump does not stop unless a related alarm is detected.
- During *Start connection mode*, *Go to recirculation* and *Go to programming* can be selected.

During ***Single connection*** mode, the operator is asked to connect the Aqualine access line (red) to the access port (red) of the patient's catheter. After pressing the ***Start blood pump*** key, the Aqualine tubing set is filled with blood up to the air detector. The blood pump automatically stops when the air detector detects blood. Treatment can then commence.

During ***Double connection*** mode, the operator is asked to connect the Aqualine access (red) and return (blue) lines to the access (red) and return (blue) ports of the patient's catheter at the same time. After pressing the ***Start blood pump*** key, the Aqualine tubing set is filled with blood. Once blood is detected by the air detector system, the Aquarius system automatically switches into ***Treatment mode***. Treatment can then commence.

## 5.7.1 Single connection




Select and confirm *Single Connection*.

**Figure 97**

A *Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions. Select and confirm *Yes*.

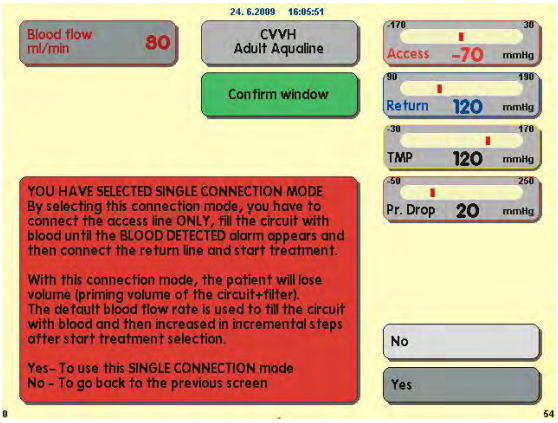



**Figure 98**

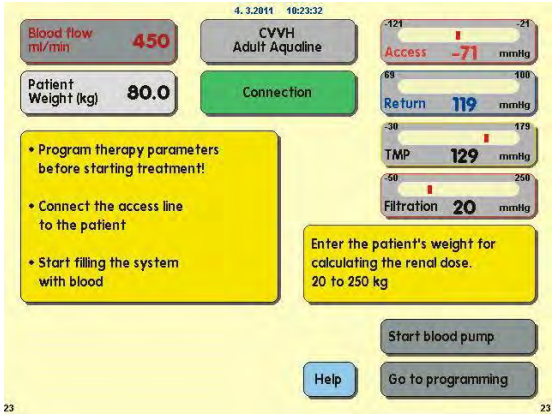



**Figure 99**

The message ***Connection*** mode is now displayed.

If proceeding with patient connection then follow the onscreen prompts: enter the patient's weight, program therapy parameters, connect the access line to the patient and start filling the system with blood.

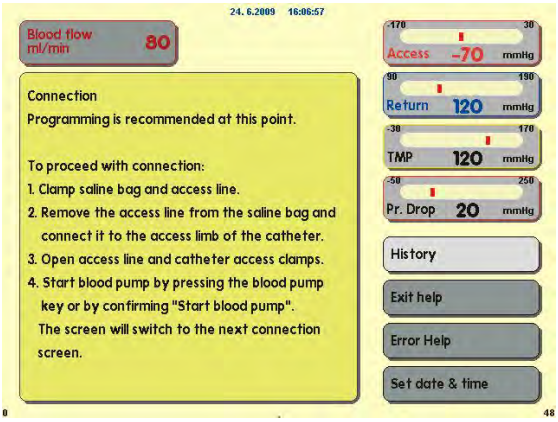



**Figure 100**

***Help*** function will provide further onscreen information.

Clamp saline bag and access line.

Disconnect the access line from the saline solution bag and connect to the access port (red) of the catheter.

Open access line and catheter access clamps.

Select and confirm ***Start blood pump*** function or press the ***Blood pump*** key . A default blood flow rate, between 50 and 80 ml/min for regular treatment and 10 and 50 ml/min for low blood flow treatment can be chosen during calibration of the machine. It is used to fill the circuit with blood and then can be increased in incremental steps after start treatment selection.

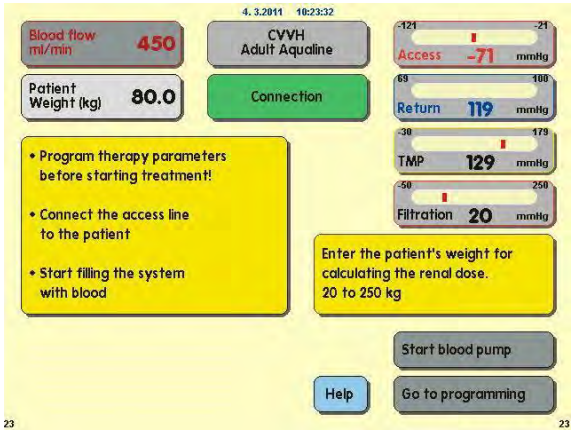



**Figure 101**

The extracorporeal circuit is now being filled with blood. The blood pump stops and an audible signal is generated when the air detector detects blood.

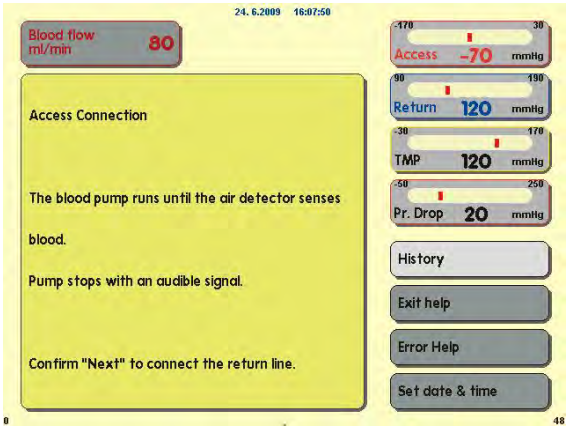



**Figure 102**

*Help* function will provide further onscreen information.

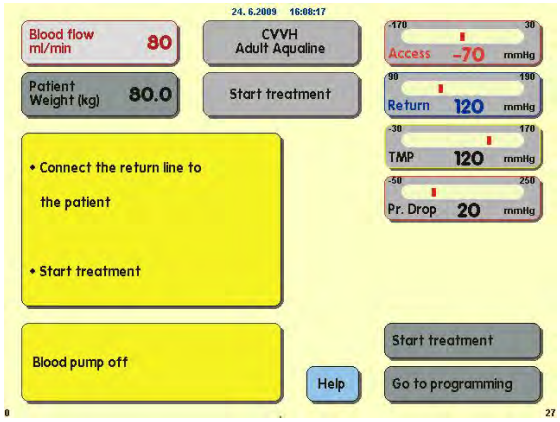



**Figure 103**

Select and confirm *Next* function. The screen *Start treatment* is now displayed.

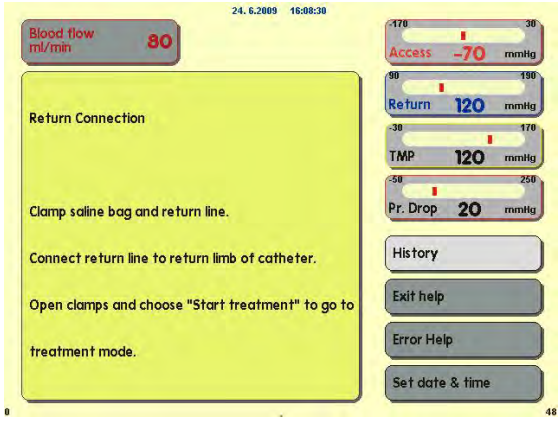



**Figure 104**

***Help*** function will provide further onscreen information.

Clamp saline bag and return line.

Disconnect return line from saline solution bag and connect to the return port (blue) of the catheter.

Open return line and catheter return clamps.

At this point the operator has the choice of ***Start treatment*** or *Go to programming*.

During *Patient Connection mode*, the air detector and the blood leak detector are active.

## 5.7.2 Double connection

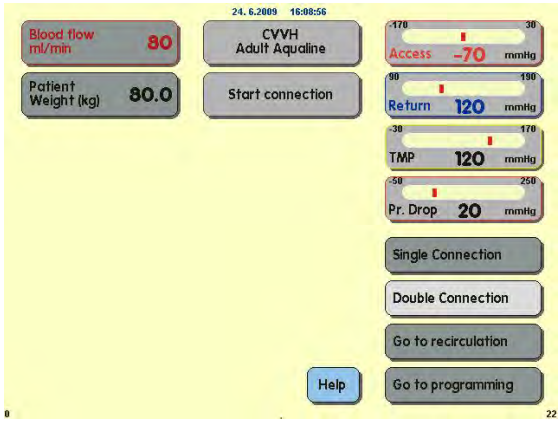



**Figure 105**

Select and confirm ***Double Connection***.

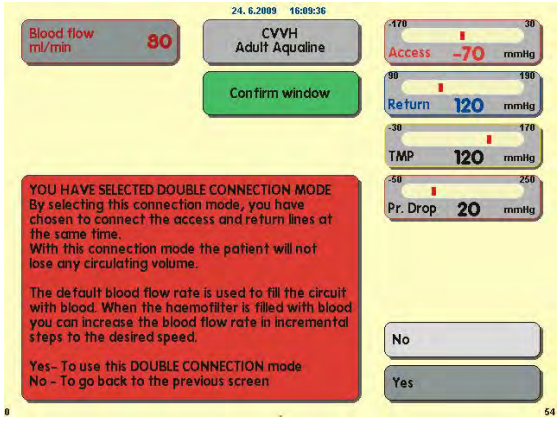



**Figure 106**

A ***Confirm window*** appears. At this stage it is IMPORTANT to follow the onscreen instructions. Select and confirm *Yes*.

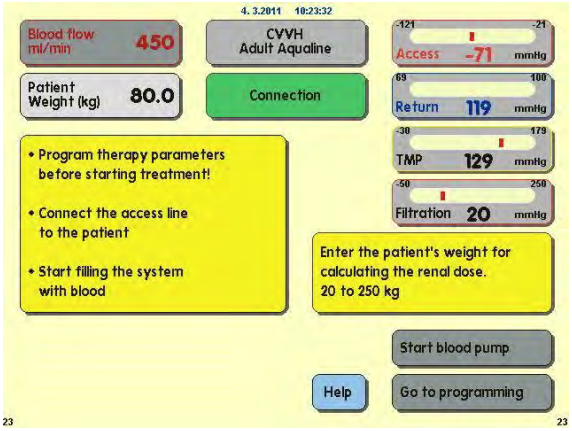



**Figure 107**

The screen ***Connection*** is now displayed.
If proceeding with the patient connection then follow the onscreen prompts: enter the patient's weight, program therapy parameters, connect the access line to the patient and start filling the system with blood.

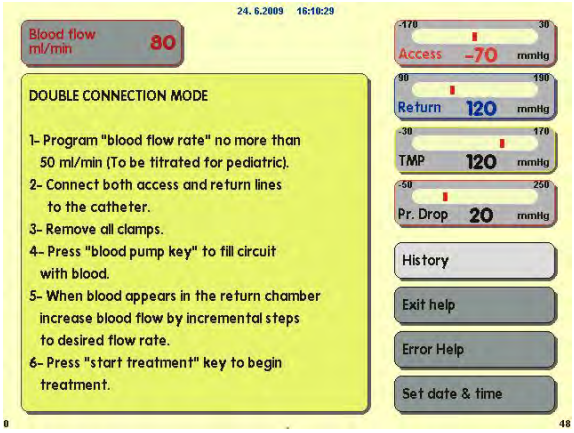



**Figure 108**

***Help*** function will provide further onscreen information.

Clamp saline bag, access line and return line.

Disconnect access line from saline solution bag and connect to the access port (red) of the catheter.

Disconnect return line from saline solution bag and connect to the return port (blue) of the catheter.

Open access line and catheter access clamps.

Open return line and catheter return clamps.

Select and confirm *Start blood pump* or press *Blood pump* key. A default blood flow rate, between 50 and 80 ml/h for regular treatment and 10 and 50 ml/h for low blood flow treatment can be chosen during calibration of the machine. It is used to fill the circuit with blood and then can be increased in incremental steps after start treatment selection.

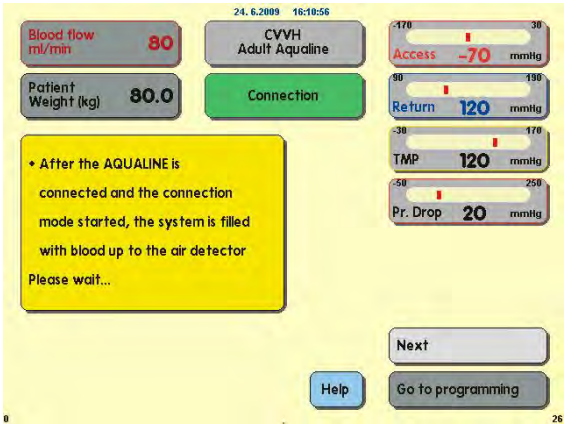



**Figure 109**

The extracorporeal circuit is now being filled with blood. When the air detector detects blood the system automatically switches to the ***Treatment*** mode.

While the circuit is being filled, ***Treatment*** mode can be accessed by selecting and confirming *Next*.

During *Patient Connection mode* the air detector and the blood leak detector are active.

## 5.8 *Treatment mode* - Description of functions throughout treatment

Patient parameters must be entered before starting treatment!
The blood flow rate needs to be programmed to the prescribed value before starting the treatment.

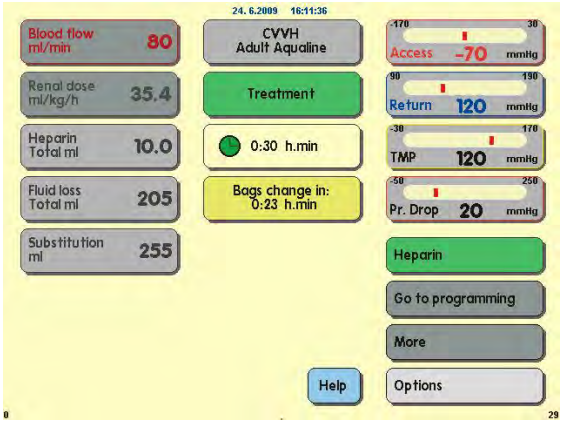



**Figure 110**

When *Single Connection* has been selected, selecting and confirming the *Start treatment* function begins treatment and *Treatment* mode is displayed.

When *Single Connection* has been selected, the LEDs in the *Blood pump* and *Balance Start/Stop* key flash and must be pressed to begin treatment. When pressed, the pumps will start.

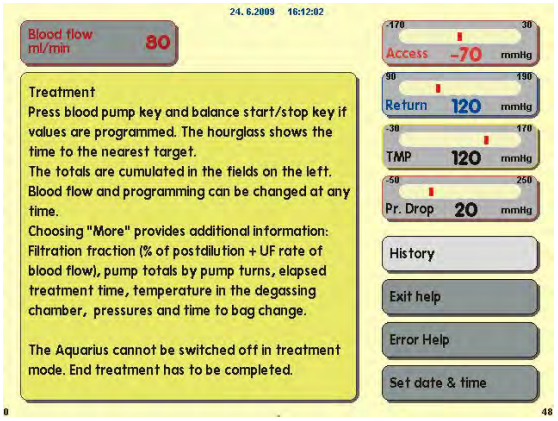



**Figure 111**

*Help* function will provide further onscreen information.

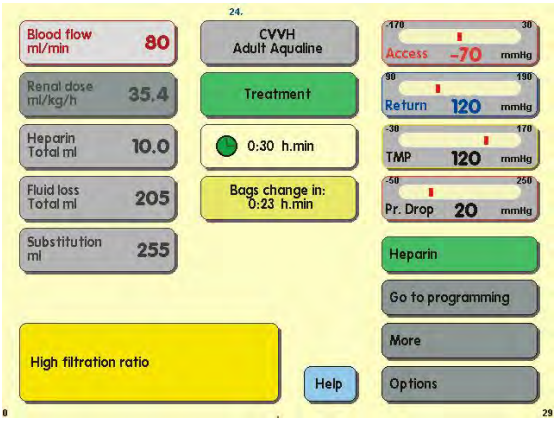



**Figure 112**

*Blood pump* key has to be pressed before *Start treatment* key .

*It is possible to gradually increase the Blood flow rate to the prescribed value.*

*Start treatment* key should be pressed only when the *Blood flow* rate has reached the prescribed/desired value. If not *High filtration ratio* message can appear.

When Double connection is operating, the system automatically switches to the *Treatment* mode.

When Double connection has been selected, the LED in the *Balance Start/Stop* key flashes and must be pressed to begin treatment. When pressed, the appropriate pumps will start. *Start treatment* key should be pressed only when the *Blood flow* rate has reached the prescribed/desired value. If not the *High filtration ratio* message can appear.

The treatment screen displays the main patient parameters. The timer shows the remaining treatment time and *Bags Change in* box shows the remaining time before bag(s) require changing. All safety controls and functions are active.
Pressing the *Balance Start/Stop* key suspends treatment. This may be necessary during treatment, for example, in order to change a bag on the scales. When the Aquarius system detects a full or empty bag it produces a bag change alert. This automatically stops the pre-dilution pump, the post-dilution pump and the filtrate pump. The blood pump continues to run. Treatment is resumed by pressing the *Balance Start/Stop* key after bags have been changed.
When air is detected in the return line during Treatment mode, the blood pump is automatically stopped, the return clamp closes and an air detected alarm is indicated.

During treatment the operator has three main choices:

*Go to programming* – enables changes to programmed parameters

*More* – provides additional information to that available on the main treatment screen.

*Options* – This activates another screen with 5 further information and function screens

Selecting and confirming *Options* opens the options screen.

The operator can choose from the following options: *History, Recirculation, End treatment, Change syringe* or *Change therapy*. These options are shown below in Figure 113.

## 5.8.1 History

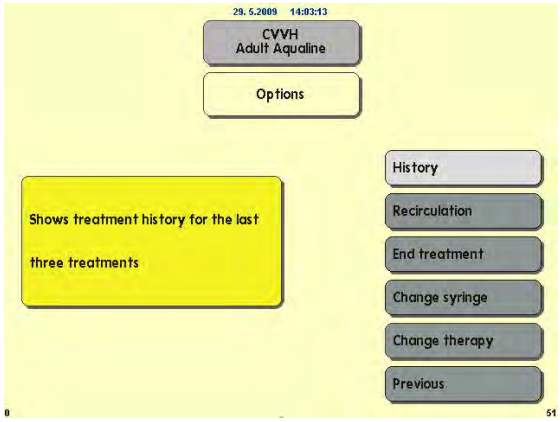



**Figure 113**

The history of the last three treatments is available in this menu. The data is visible as a list or as graphs. Pressures, programmed parameters, patient data, events (errors) are stored at 5 min intervals. The list of alarms is recorded and updated when a new alarm occurs. Treatment 1 is the current treatment with Treatment 2 as the previous treatment and so on.

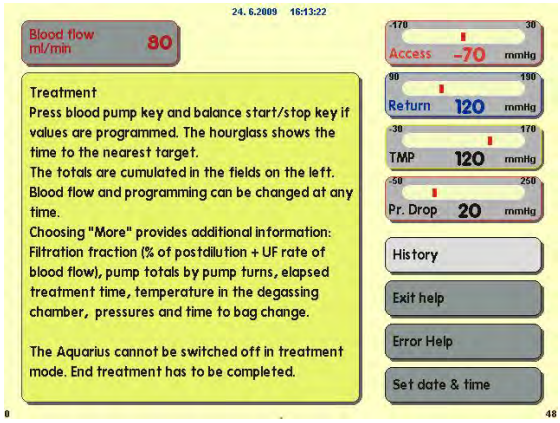
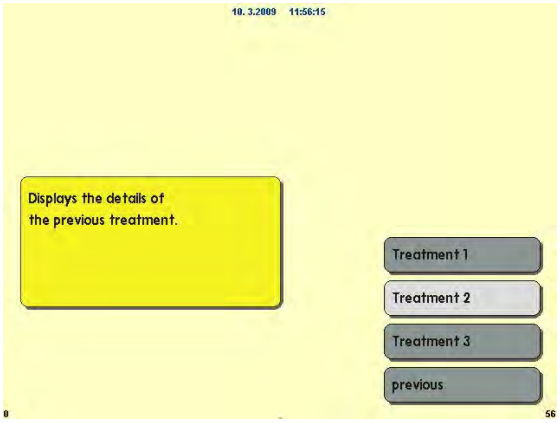


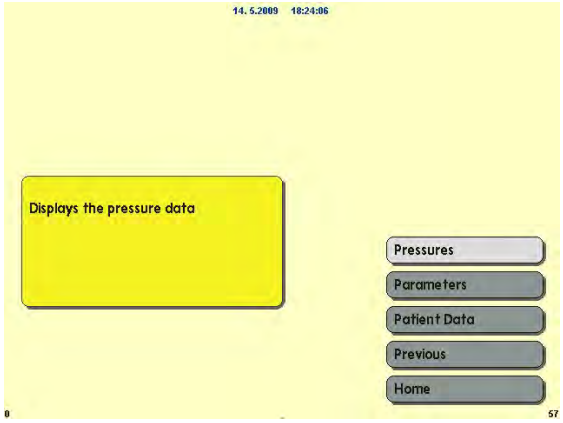

**Figure 114**

*History* screens can also be accessed from the *Help* screen in any running mode.



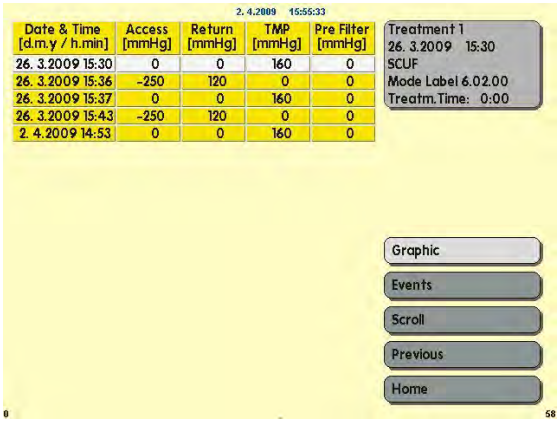

When History is selected, the right side of the screen allows the choice between displaying the current treatment, the last treatment or the second last treatment, as well as an option to return to the previous screen.

**Figure 115**



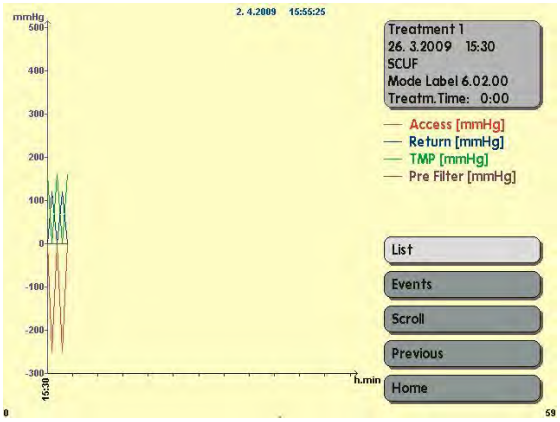

When one of the treatments is selected, the right side of the screen displays the following functions: *Pressures*, *Parameters*, *Patient data*, *Previous* (i.e. previous screen) and *Home* (i.e. main screen).

**Figure 116**




Example: Treatment 1, Pressure data

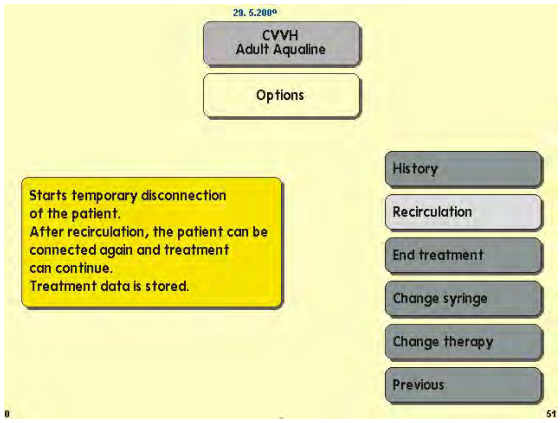
**Figure 117**




Example: Treatment 1, Pressure graph

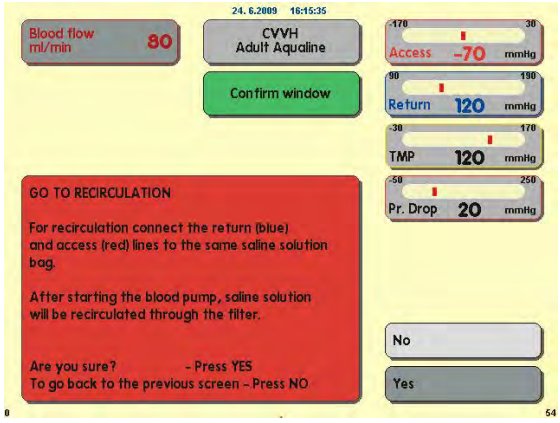
**Figure 118**

## 5.8.2 Recirculation




*Recirculation mode* can be accessed before connecting the patient, just after the clamp and pressure test. In this case there is no disconnection phase before accessing *Recirculation mode*.
Recirculation mode can be accessed as a temporary disconnection of the patient. The screen menu guides the operator through this disconnection procedure.

**Figure 119**




*Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions.

When *YES* is confirmed, the treatment is temporarily interrupted. All data is stored and disconnection mode for recirculation will open. The time of recirculation is displayed.

**Figure 120**

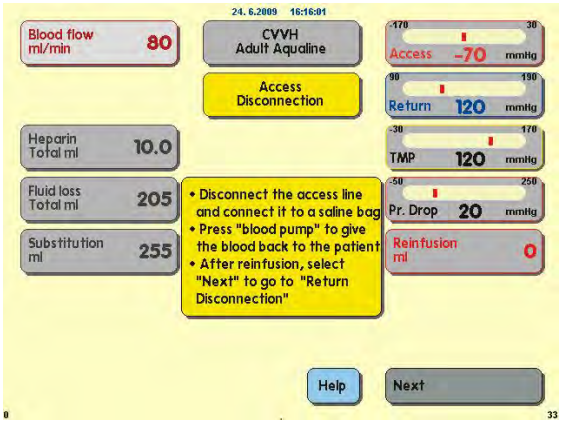



**Figure 121**

Disconnect access line from patient catheter and connect access line to a saline solution bag. Press *Start Blood pump* key to start rinsing the blood from the circuit.

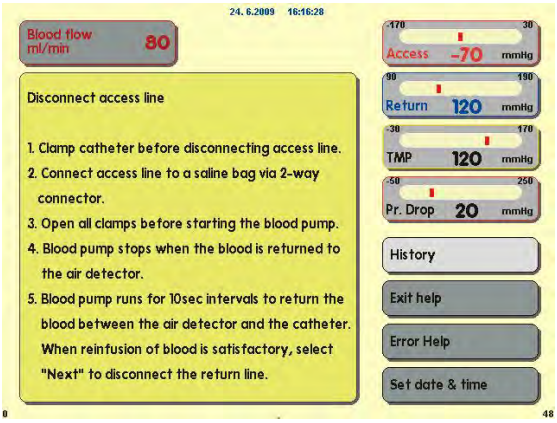



**Figure 122**

*Help* function will provide further onscreen information.

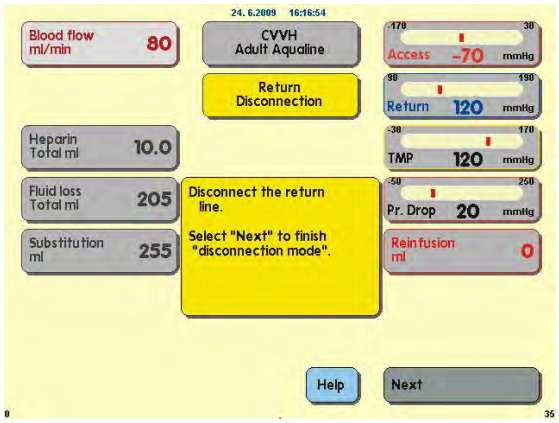



**Figure 123**

When clear fluid is detected in the air detection system, the *Next* screen (**Return disconnection**) will open automatically.

*Reinfusion* value onscreen is the volume of saline solution used to return blood to the patient during disconnection.

After the return line is disconnected from the patient, connect it to the same saline solution bag that the access line is connected to.

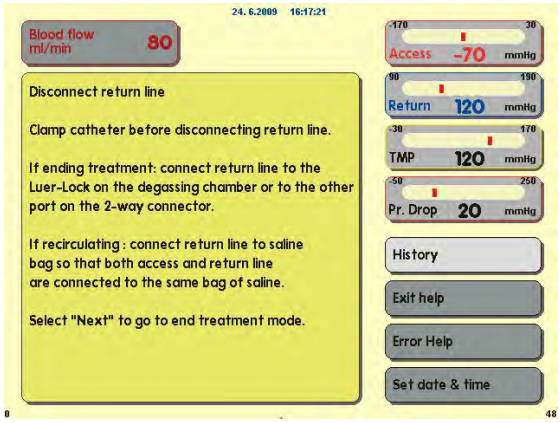



**Figure 124**

*Help* function will provide further onscreen information.

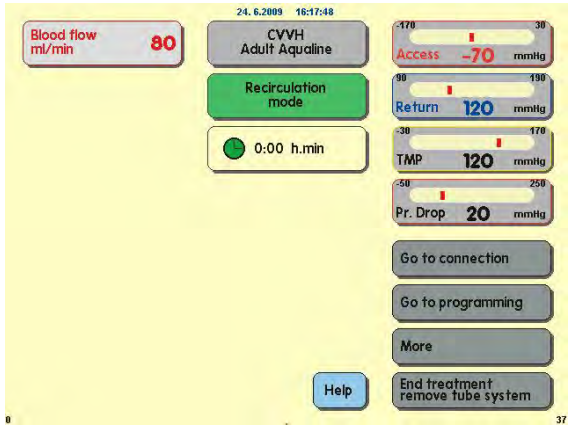



**Figure 125**

In this case there is no disconnection phase before accessing *Recirculation mode*.
Press *Start Blood pump* key to start the blood pump. Time in recirculation will be displayed on the screen. This is a cumulative total of all recirculation. To exit recirculation select *Go to connection* or *End treatment*.

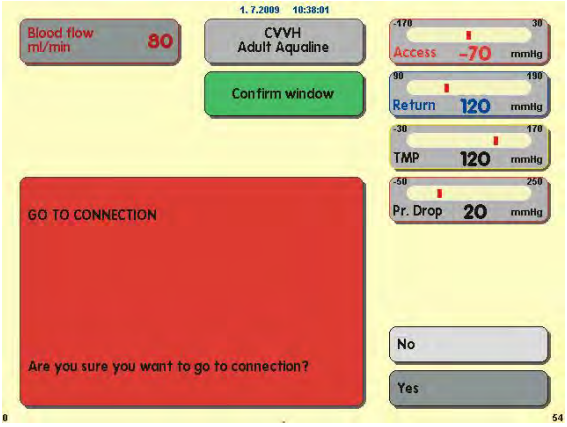



**Figure 126**

When *Go to connection* is selected and confirmed, a *Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions.

When *YES* is confirmed, *Connection mode* opens.

Following the onscreen instructions, the patient can be connected again and the treatment can continue.

The user has the possibility of confirming the blood flow or programming a new value.

## 5.8.3 End Treatment

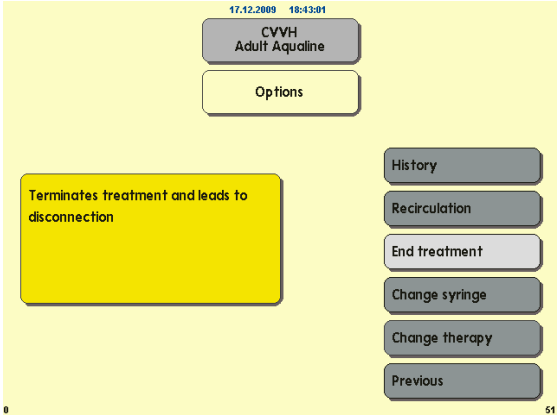



**Figure 127**

This option immediately terminates the treatment. Choosing *Yes* in the confirmation screen ends treatment and guides the operator to *Disconnection mode*.

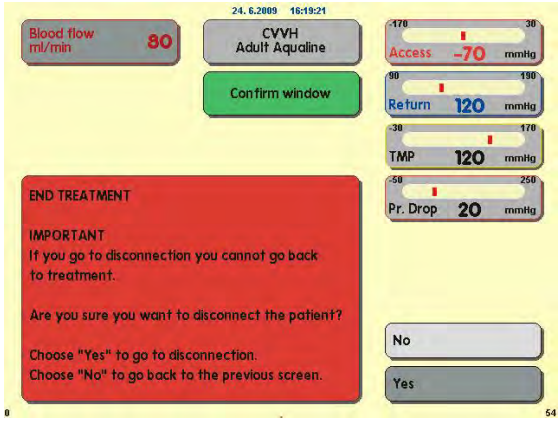



**Figure 128**

A *Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions.

When *Yes* is confirmed, all pumps will stop and the disconnection mode window opens as described in *Recirculation*.
No return to treatment is possible.

## 5.8.4 Change syringe

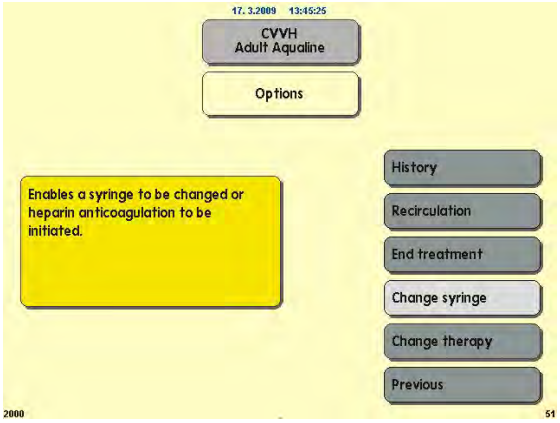



**Figure 129**

This option enables the operator to change the syringe or to stop anticoagulation.

If initially *No anticoagulant* was chosen anticoagulation can be started with this option.

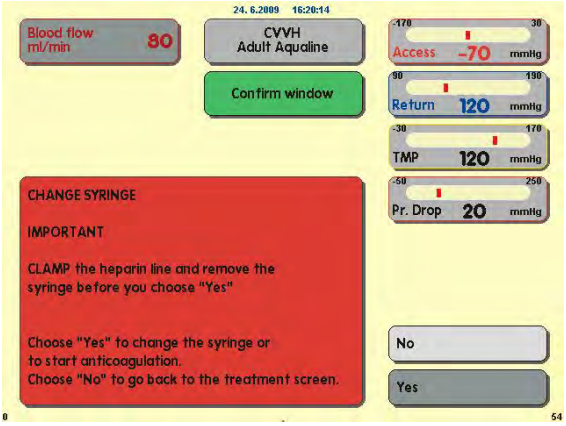



**Figure 130**

A *Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions. NOTE: Before proceeding, ensure that the heparin line is clamped.
Select and confirm *Yes* to move to a second *Confirm window* where the operator is again reminded to clamp the heparin line then remove the syringe **before** confirming. Confirming *No* simply returns the operator to the previous step.

On completion of this process it is necessary to reprogram the heparin rate as it is reset to zero.

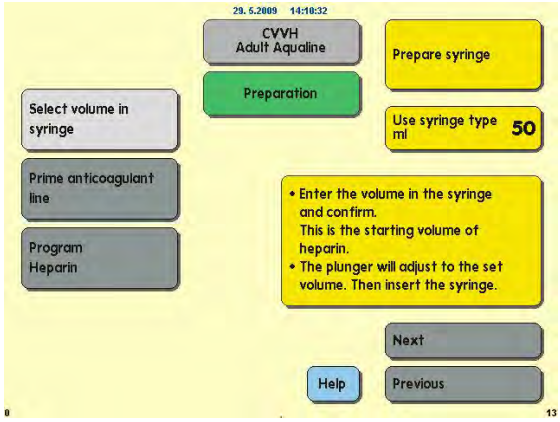



**Figure 131**

The complete process of syringe preparation is required at this stage as described in chapter 5.1.6 Preparation Mode – Preparing the anticoagulant.

At this stage it is IMPORTANT to follow the onscreen instructions.

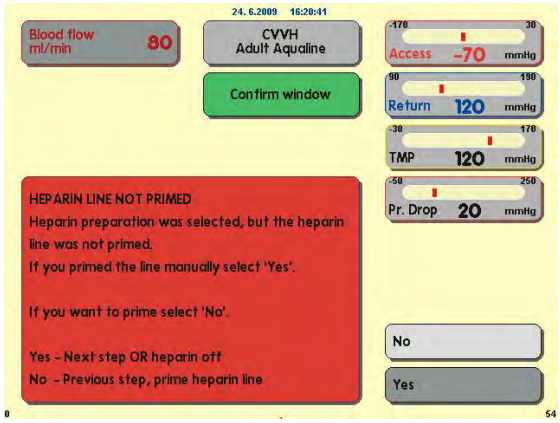



**Figure 132**

In case one step is missed in syringe preparation, a *Confirm window* appears depending on the step missing. At this stage it is IMPORTANT to follow the onscreen instructions.

## 5.8.5 Therapy Change

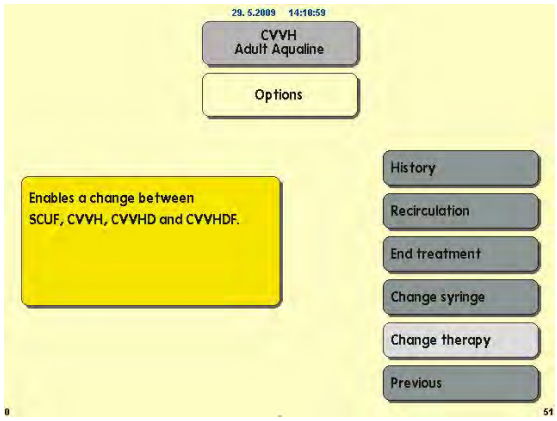



**Figure 133**

This option enables the operator to switch between SCUF, CVVH, CVVHD and CVVHDF.

Select and confirm the new therapy.

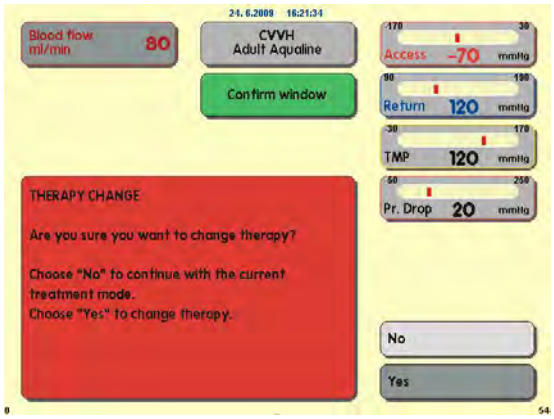



**Figure 134**

A Confirm window appears when the operator attempts any modality change.

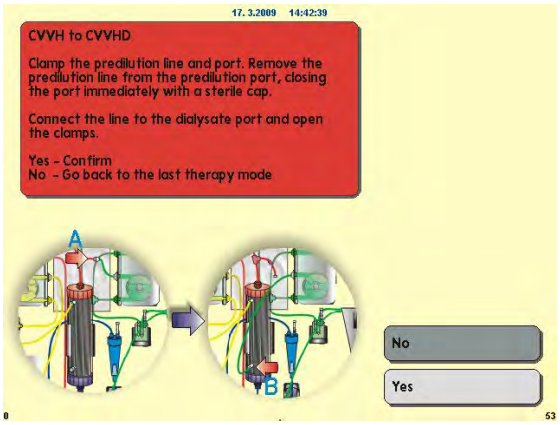



**Figure 135**

The screen will guide the operator to properly reconnect the pre-dilution/dialysate line and the filtrate line to fit the new treatment modality.

Select and confirm *Yes* to validate therapy change and new line positioning.

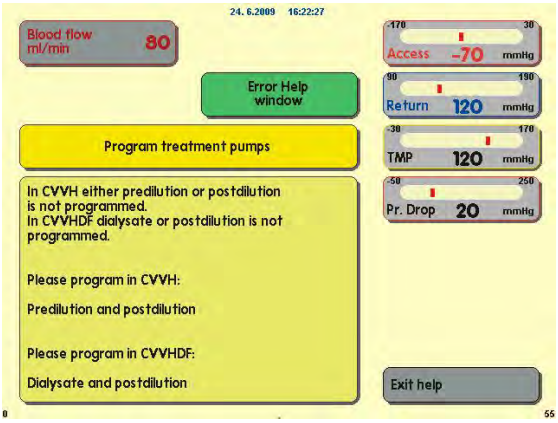



**Figure 136**

The programmed parameters must be reviewed to ensure they meet requirements of the new therapy. All totals are at 0 when the new treatment mode is started.

If the programming of the parameters is not completed, a message is generated. The message content depends on the missing programming parameter.

Pressing the *Balance Start/Stop* key starts the new treatment mode.

## 5.8.6 More Screen

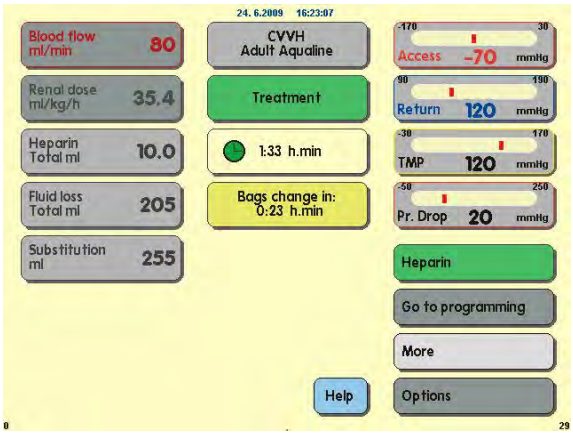



**Figure 137**

Additional information can be obtained by selecting and confirming the More screen from the main screen.

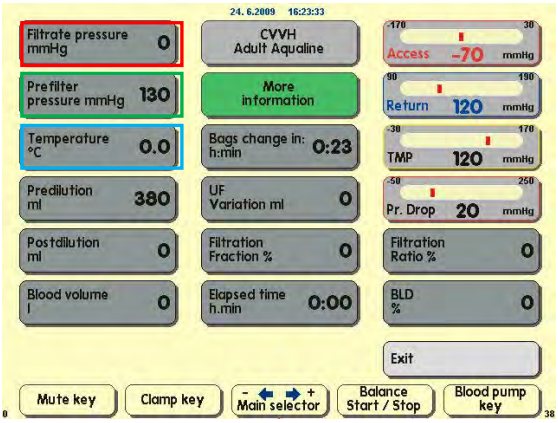



**Figure 138**

- *Filtrate pressure (mmHg)*

The actual pressure is displayed.

- *Pre filter pressure (mmHg)*

The actual pressure is displayed.

- *Temperature (ºC)*

The temperature displayed corresponds to the calculated temperature of the fluid inside the degassing chamber.

**!** DO NOT rely on the temperature displayed as a basis for clinical assessment of hypothermia or hyperthermia. The Aquarius device is not designed to monitor the patient's body temperature. The patient body temperature should be closely monitored to detect potential patient hypothermia or hyperthermia

The temperature displayed on the More Screen is NOT the temperature of the fluid infused into the blood and/or dialysate circuit.

The temperature of the fluid infused into the blood and/or dialysate circuit will be lower than the temperature of the fluid inside the degassing chamber due to heat energy loss in the tubing between the degassing chamber and infusion site(s) (refer to Section 7.6).

The temperature displayed on the More Screen is NOT the patient's body temperature or the temperature of the patient's blood. The accuracy of the calculated temperature displayed on the More Screen is affected by the ambient temperature.

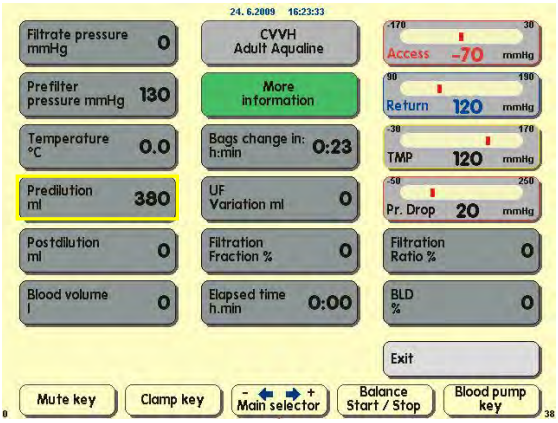



**Figure 139**

- *Pre-dilution (ml)*

This shows the amount of fluid that was delivered by the pre-dilution/dialysate pump by speedometer control. This is the value the pump estimates it has delivered, and may differ from the total in the treatment screen that shows the actual value detected by the scales. The scales regulate the pumps to cover any deviation caused by the differences in line sets. It is normal to see intermittent stoppage of the fluid pumps, as the scales regulate the fluid deviations.

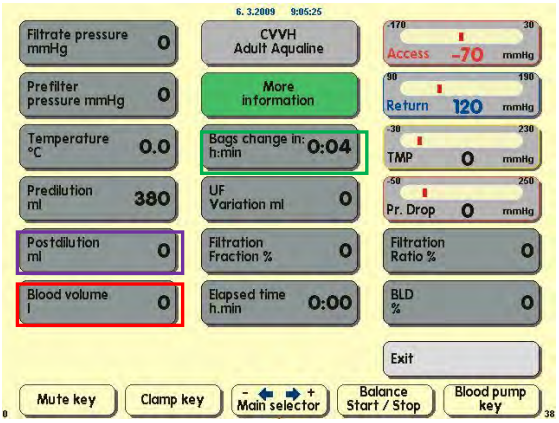



**Figure 140**

- *Post-dilution (ml)*

This shows the amount of fluid that was delivered by the post-dilution pump by speedometer control. This is the value the pump estimates it has delivered, and may differ from the total in the treatment screen that shows the actual value detected by the scales. The scales regulate the pumps to cover any deviation caused by the differences in line sets. It is normal to see intermittent stoppage of the fluid pumps, as the scales regulate the fluid deviations.

- *Blood volume (l)*

The cumulative amount of blood pumped through the circuit during treatment.

- *Bags change in (h:min)*

The time remaining until the next bag change. This is calculated by the mass sensed on the scales.

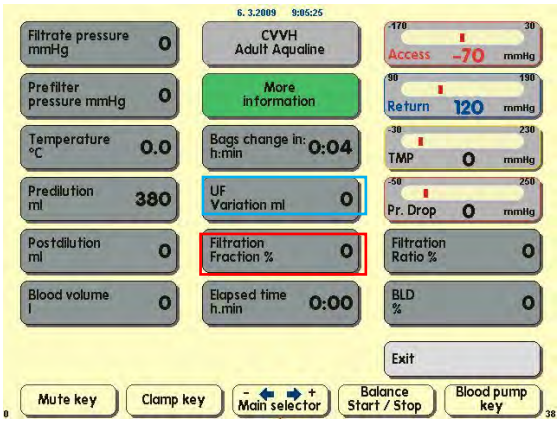



**Figure 141**

- *UF Variation (ml)*

The variation of the actual patient fluid loss in versus the expected fluid loss is displayed. A variation > 50 g for adult and >20 g for pediatric treatment will cause a balance alarm. The UF variation is calculated as follows:

$$UF\ Variation = Expected\ Fluid\ Loss - (Fluid\ Volume\ OUT - Fluid\ Volume\ IN)$$

- *Filtration fraction (%)*

The Filtration fraction % is calculated as:

$$\frac{Predilution\ flow\ rate + Postdilution\ flow\ rate + Fluid\ loss\ rate}{Predilution\ flow\ rate + Blood\ flow\ rate}$$

The pre-dilution pump rate programmed affects the calculation of the filtration fraction

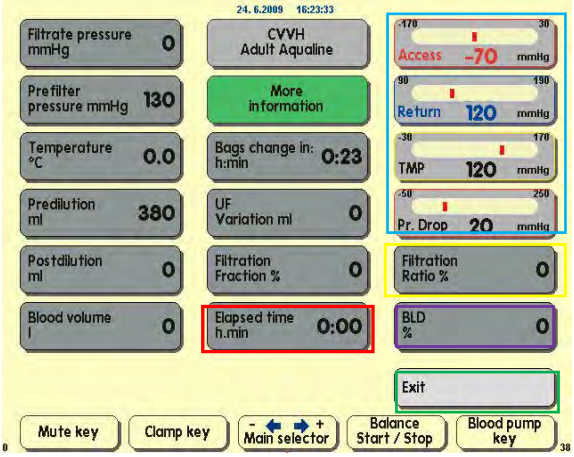



**Figure 142**

- *Elapsed time (h:min)*

The elapsed time of the programmed treatment is displayed.

- *Access, Return and TMP* pressure monitoring are displayed.

Pressures from the access, return and TMP sensors.

- *Filtration Ratio (%)*

Filtration Ratio is calculated as: Post-dilution flow rate (ml/h) + Fluid loss rate (ml/h) divided by Blood flow rate (ml/min). In post-dilution, it is generally kept below 25%. The Filtration Ratio is displayed to give an indication of hematocrit increases in the filter before the post-dilution solution replaces the filtrate removed. If the Filtration Ratio is too high it may lead to clotting in the filter. The calculation is not affected by the rates programmed on the dialysate pump.

- *BLD (%)*

Over 100%, Blood leak alarm is activated.

BLD is the measurement of clouding and is calculated as follows:

$$BLD\ (\%) = \frac{Optical\_calibration\_value - Actual\_optical\_value}{Optical\_calibration\_value - Optical\_alarm\_limit\_value}$$

- *Exit* key to go back to main screen or to connection mode.

- The control buttons at the bottom of the screen: *Mute* key, *Clamp* key, *Main selector button*, *Balance Start/Stop*, *Blood pump* key.

## 5.8.7 Therapy Target Achieved

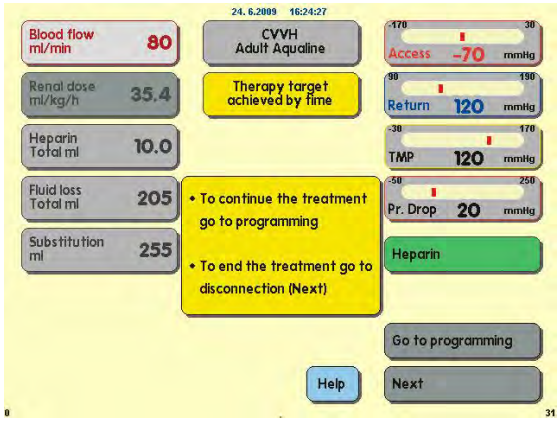



**Figure 143**

The treatment will proceed until it achieves a programmed target. This may be time or fluid loss. At this point the *Therapy target achieved by time* or *Therapy target achieved by fluid loss* is displayed and an audible alert is generated.

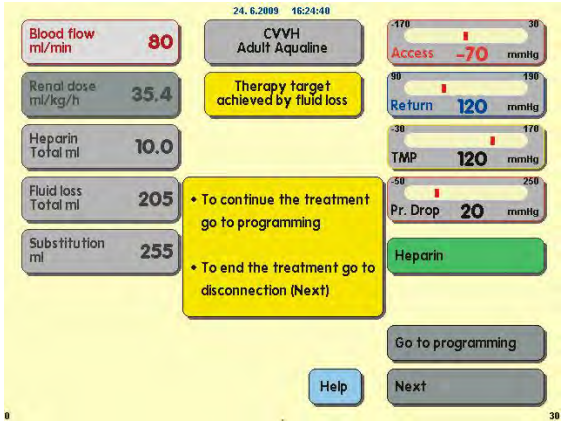



**Figure 144**

Throughout the *Therapy target achieved* phase the blood pump continues to move blood through the extracorporeal circuit at the programmed rate.

The operator can select *Go to programming* to set a new target OR the operator can select *Next* to go to *Access Disconnection* mode.

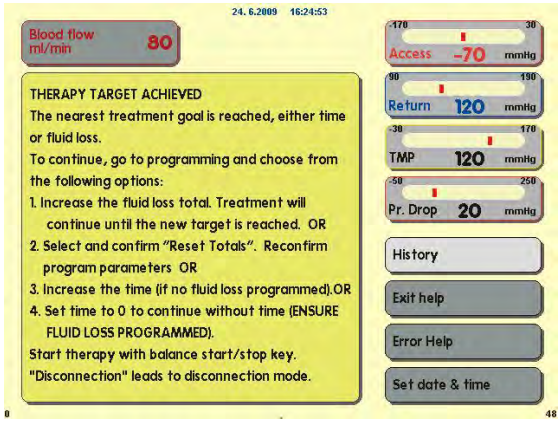
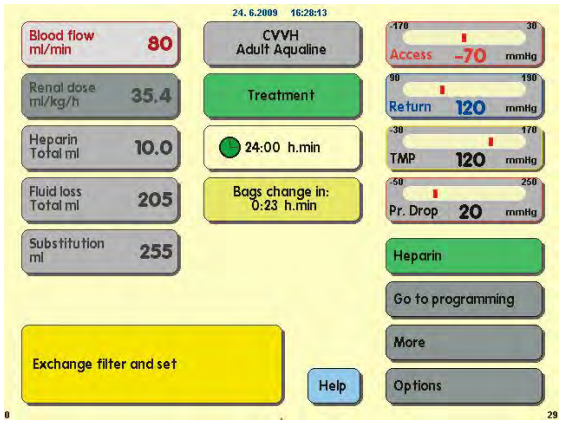



**Figure 145**

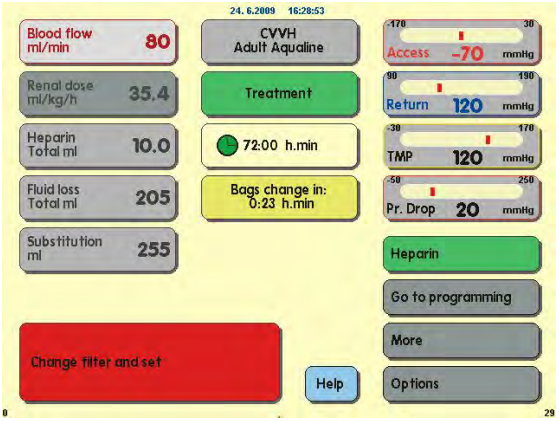
*Help* function will provide further information onscreen.

## 5.8.8 Treatment termination due to running time



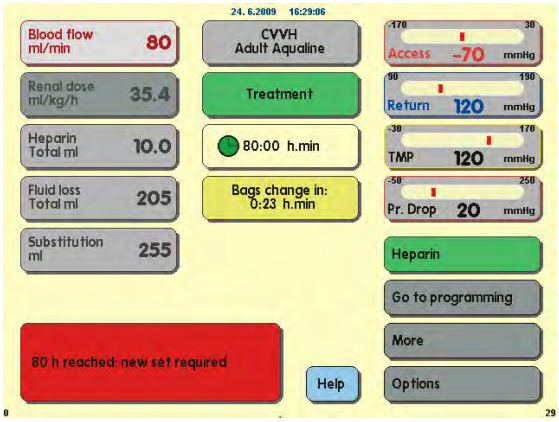

A yellow message is displayed notifying the operator that the machine has been running for 24 h. The message disappears when the reset button is pressed.

**Figure 146**




A red warning is displayed notifying the operator that the machine has been running for 72 h. It cannot be reset and stays on for 8h.

**Figure 147**




An alarm is displayed notifying the operator that the treatment will end if the machine has been running for 80 h. At that time the tubing sets and filter need to be disconnected and replaced by new ones.

**Figure 148**

## 5.9 *Access disconnection and return disconnection* - Disconnecting the patient

**!** Always follow hospital policy for standard precautions. Gloves, mask and a face shield should be worn when connecting or disconnecting blood lines from patients and removing tubing sets from the Aquarius system.

When *Next* is selected after the therapy target is achieved, the operator is directed to *Access Disconnection* mode.

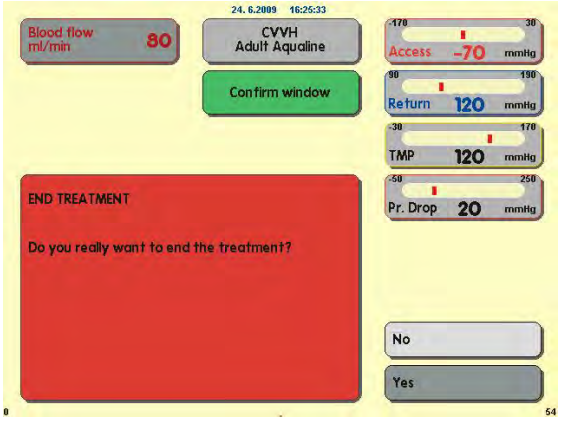



**Figure 149**

When the operator selects and confirms *YES*, a *Confirm window* appears. At this stage it is IMPORTANT to follow the onscreen instructions.

Select and confirm *Yes* to proceed.

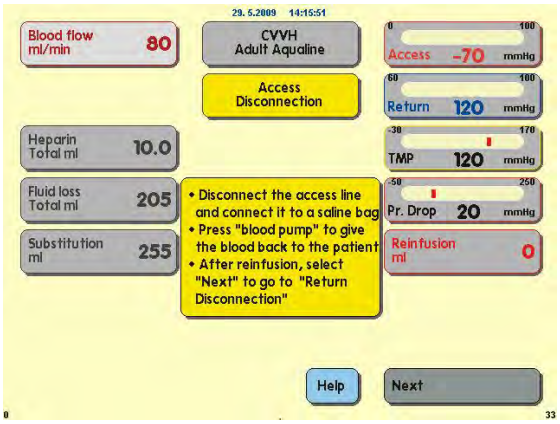



**Figure 150**

*Access Disconnection* is now displayed on the screen.

Follow onscreen instructions.

Clamp catheter access port and access line (red).

Disconnect the access line from the access port (red) of the patient's blood access and connect it to a saline solution bag by using a 2-way connector.

Unclamp access line and saline bag.

Press **Blood pump key** . The blood in the extracorporeal circuit is sent back to the patient. The blood flow rate is reduced to the default value if the programmed value at the start of the Disconnect Patient mode is higher. When the air detector detects saline solution instead of blood, the blood pump stops. An audible signal is generated.

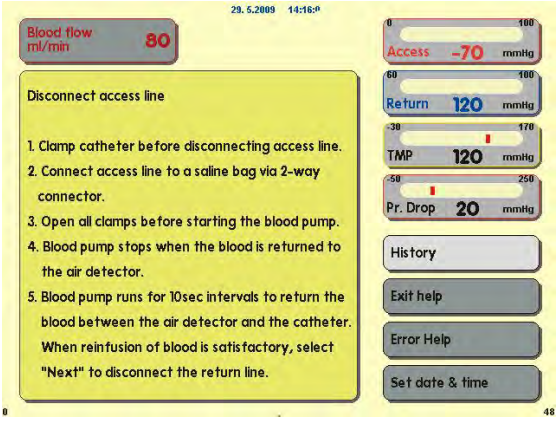



**Figure 151**

*Reinfusion* value onscreen is the volume of saline solution used to return blood to the patient during disconnection.

To return the blood between the air detector and the catheter, press the *Blood pump* key to start the blood pump which will run for a few seconds.

When satisfied with reinfusion, select and confirm the *Next* function (see Fig. 149).

*Help* function will provide further information onscreen (see Fig. 150).

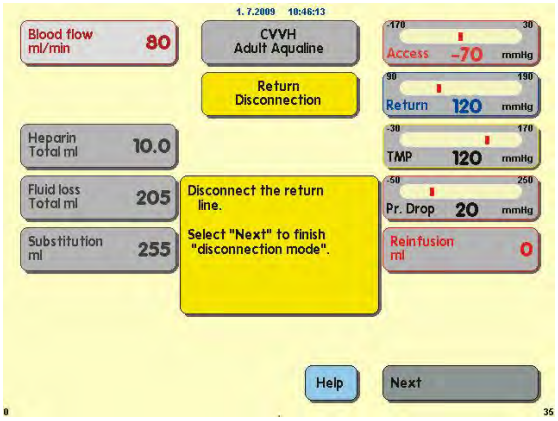



**Figure 152**

When clear fluid is detected in the air detection system, the *Next* screen (**Return disconnection**) opens automatically. ***Return Disconnection*** is now displayed on the screen.

- Clamp catheter return port and return line (blue).
- Disconnect return line from return port (blue) of the patient blood access.
- Connect return line to the saline solution bag or to the Luer lock fitting on degassing chamber.
- Unclamp the return line and the saline bag.

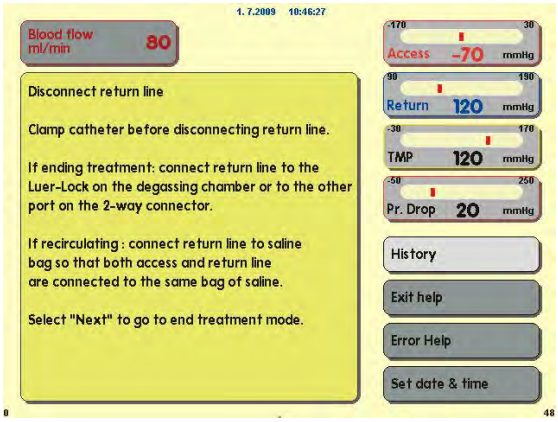



**Figure 153**

***Help*** function will provide further information onscreen.

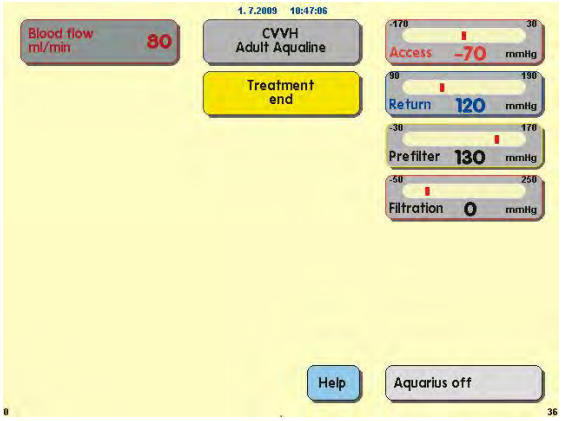
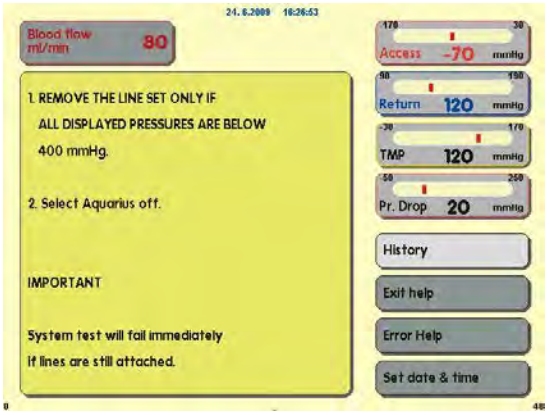



**Figure 154**

Select and confirm the *Next* function. ***Treatment end*** will now be displayed onscreen..

Before removing the pressure domes from the Aquarius system during Aqualine tubing set disconnection, make sure that all four pressure levels (filtrate, prefilter, access, and return pressures) are below 400 mmHg. If necessary, use a 50 ml syringe or an Aquasafe bag to decrease the pressure before removing a pressure dome from a pressure sensor. When pressure domes are removed from pressure sensors in over-pressure conditions, there is a risk that the pressure dome membrane may burst which could result in a blood leak from the extracorporeal circuit. (See 5.10 Safe removal of the Aqualine tubing set).

To avoid membrane burst, all clamps must be opened and all pump segments must be removed from their respective pump housings before the removal of the pressure domes of the Aqualine tubing set.




*Help* function will provide further onscreen information.

**Figure 155**

## 5.10 Safe removal of the Aqualine tubing set

This section contains **guidelines and recommendations to remove the Aqualine tubing set safely** from the Aquarius system at the end of a treatment.

**These instructions have to be followed and applied at the end of each treatment**, with special care when treatment termination is caused by clotting and when (for any other reason) there is blood remaining in the extracorporeal circuit after the patient's disconnection.

⚠ Never switch off the Aquarius system before complete removal of the Aqualine tubing set, in order to allow pressure monitoring during treatment termination.

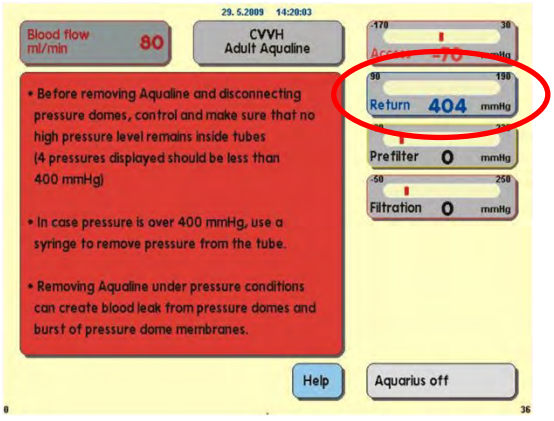
⚠ To avoid membrane burst, all clamps must be opened and all pump segments must be removed from their respective pump housings before the removal of the pressure domes of the Aqualine tubing set. Before removing the pressure domes from the Aquarius system during Aqualine tubing set disconnection, make sure that all four pressure levels (filtrate, prefilter, access, and return pressures) are below 400 mmHg.

⚠ In the event of clotting in the filter (or in other parts of the extracorporeal circuit), the high pre-filter pressure alarm, high TMP alarm and high return pressure alarm will not permit the re-infusion of blood to the patient. In this case do not remove Aqualine tubing pressure domes from Aquarius pressure sensors without first reducing the pressure level inside the tubing set below 100 mmHg for this procedure.

⚠ If the above warnings are not followed, the risk of pressure dome bursting and the operator being contaminated with biological fluid increases.

After patient disconnection from the Aquarius system, the operator has to remove the Aqualine tubing set from the Aquarius system according to the following steps:

1) Ensure that the return line is connected to the saline bag (or to the degassing chamber) and all clamps are open along the return line path.
2) Ensure that the access line is connected to the saline solution bag and all clamps are open along the access line path. Place the saline bag on the floor in a disposal container.
3) Ensure that the filtrate and the substitution or dialysate lines are connected to the corresponding filtrate and substitution or dialysate bags and that both lines are unclamped.
4) Remove the return line from the air detector and from the return line clamp.
5) Remove the pump tubing segments from the pumps in the following order:
    a. Filtrate pump (yellow)
    b. Pre-dilution or dialysate pump (green)
    c. Post-dilution pump (green)
    d. Blood pump (red)
6) Check if pressures are below 400 mmHg.




A **Warning Screen** is displayed if at least one of the four pressures (filtrate, prefilter, access, and return) is over 400mmHg.

**Figure 156**

Remove all pressure domes from the Aquarius system ONLY IF all pressures (prefilter pressure, filtrate, return pressure and access pressure) are below 400 mmHg,
If not all pressures are below 400 mmHg, refer to Sec. 5.10.1 Instructions to decrease pressure level.

7) Disconnect the bags as follows:
    a. Clamp the access line and disconnect the saline solution bag
    b. Clamp the filtrate line and disconnect the filtrate bag(s)
    c. Clamp the substitution or dialysate line and disconnect the substitution or dialysate bag(s)
8) Disconnect the hydrophobic connector line of the degassing chamber from the ADU unit.
9) Remove the heater coil line spiral from the heating unit.
10) When the Aqualine tubing set is completely removed from the Aquarius system, “Aquarius off” can be confirmed by pressing the *Main selector button* to switch off the Aquarius system.
11) Discard the tubing set according to the local regulation (see Sec. 3.4 Waste Management)

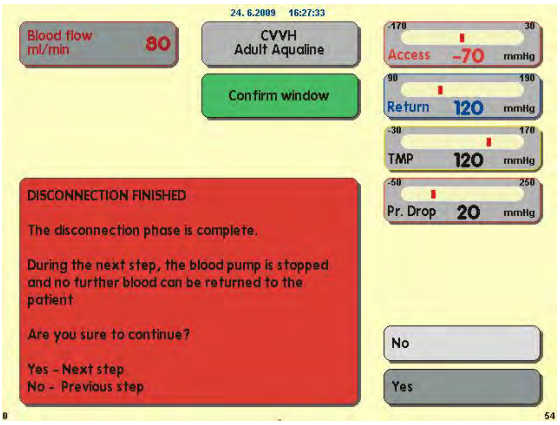



**Figure** 157

The operator can select and confirm *Aquarius off* or press the *ON/OFF* key located on the right side of the display screen to switch off the Aquarius system.

When the operator selects and confirms *Aquarius off*, the Aquarius system will shutdown.

Ensure that the Aquarius system is switched off by confirming *Aquarius off* or pressing the *ON/OFF* key located on the right side of the display screen before disconnecting the Aquarius system from main power (unplugging the cable or switching off the main switch) to avoid battery discharging.

## 5.10.1 Instructions to decrease pressure level

Use gloves and goggles as per ward protocol.

Step 1:

Prepare an empty 50 ml syringe or an Aquasafe bag.

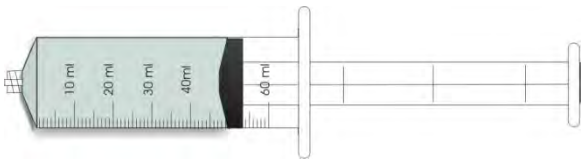



**Figure 158**

NOTE:

- The Aquasafe bag is an empty bag with 25 ml capacity used to release excessive pressure from the Aqualine tubing set.
- The Aquasafe bag has been successfully tested on the Aquarius system.
- See the Aquasafe bag instructions for use.

**Figure 159**

<u>In case of high prefilter pressure</u>:

Step 2: Close the clamp (red) on the predilution line (A)
Step 3: Connect an empty syringe or Aquasafe bag to the predilution access port (A) and open the line clamp.

<u>In case of high return pressure:</u>

Step 2: Close the clamp (blue) on the Luer lock connector fitting on the drip chamber (B)
Step 3: Connect an empty syringe or Aquasafe bag to the Luer lock connector fitting on the drip chamber (B) and open the line clamp.

<u>In case of high access pressure:</u>

Step 2: Close the clamp (red) on the access port line (C).
Step 3: Connect an empty syringe or Aquasafe bag to the access port (C) and open the line clamp.

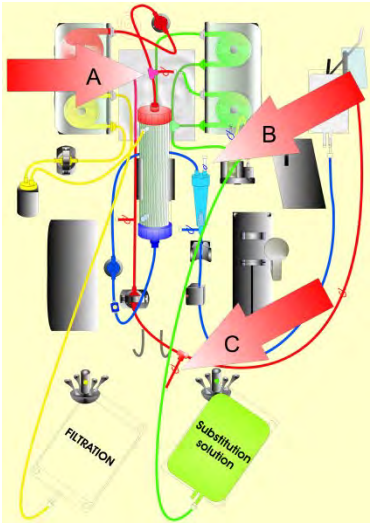



**Figure 160**

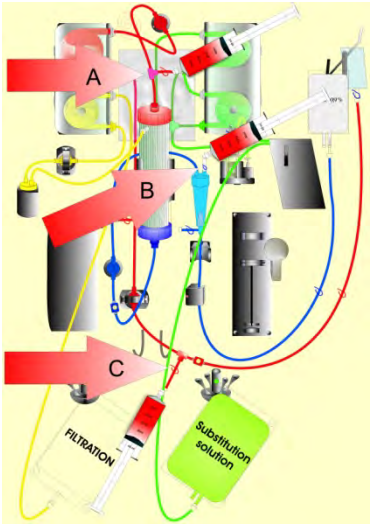



**Figure 161**

Step 4:

Fill the syringe(s) or Aquasafe bag(s) with fluid until the pressures value displayed on the screen is below 100 mmHg.
If any pressure is above 100 mmHg, go back to Step 2 and reduce it to a level below 100 mmHg.

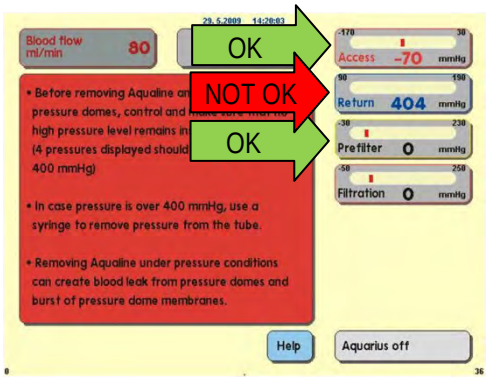



**Figure 162**

## 5.11 Aquarius system therapy modes

This section describes the therapies possible on the Aquarius system. For each therapy, a diagram illustrates how the tubing set should be installed.

The main differences between the therapies are as follows:

- All pumps are NOT always operated.
- Depending on the treatment, the patient parameters to be entered are different.
- The displayed patient parameters are different.
- During CVVH pre-dilution the *pre-dilution line* of the pre-dilution pump is connected to the pre-filter access line.
- During CVVHD or CVVHDF the free line of the pre-dilution pump is connected to the lower dialysate-in connection port of the filter.
- During TPE the free line of the pre-dilution pump can be connected either to the pre-filter access line, before the filter or to the lower dialysate-in connection port of the filter.

All pump segments must be loaded in the pump chambers and primed prior to treatment. The anticoagulant tubing must be primed with normal saline.

When priming the Aquarius system for SCUF, TPE and Hemoperfusion, the substitution line should be connected to a 1 l bag of saline solution.

When running SCUF or when not using the replacement solution heater, ensure that the patient's temperature is maintained. Cold solutions or operation in very cold environments can cause hypothermia.

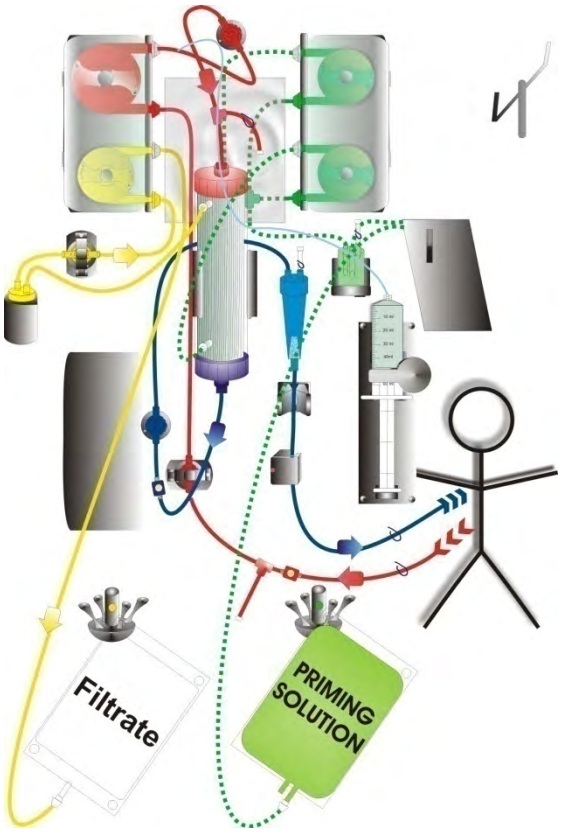
If temperature is set to 0 °C (Off), do not rely on the Aquarius system to detect substitution fluid that is outside of physiological range. An external heater device should be used to monitor and control the substitution fluid temperature.

In the following diagrams:

- Red shows the unfiltered blood path;
- Blue shows the blood path after the filter;
- Yellow shows the filtrate path;
- Green shows the substitution solution and dialysate path.

Dotted lines indicate that these pumps are not operating during the respective treatment.

### 5.11.1 SCUF (Slow Continuous UltraFiltration)




During slow continuous ultrafiltration the pre-dilution pump and the post-dilution pump are inactive. The blood is pumped through a hemofilter and reinfused to the patient.

The filtrate is collected in an empty bag hanging on the filtrate scale.

**Figure 163**

The following patient parameters are entered for a SCUF treatment:

| Parameter | Range | | Units | Increment | |
|---|---|---|---|---|---|
| | Adult | Pediatric | | Adult | Pediatric |
| Blood pump rate | [30; 450] | [10; 200] | ml/min | 10 ml/min | 2 ml/min |
| Time | [0; 99:59] | | h:min | 10 min | |
| Fluid loss rate | [0; 2,000] | [0; 1,000] | ml/h | 10 / 100 ml/h (both adult and pediatric) | |
| Total fluid loss | [0; 32,000] | [0; 15,000] | ml | 100 ml | 10 ml |
| Number of bags | [1; 4] | | 5 l | 1 Bag | |
| Anticoagulant | [0; 15] | | ml/h | 0.5 ml/hr | |
| Anticoagulant bolus | [0; 2.5] | | ml | 0.5 ml | |

The following patient parameters are displayed on the MAIN screen during SCUF:

a) Access pressure (mmHg)
b) Return pressure (mmHg)
c) TMP (mmHg)
d) Pressure drop (mmHg)
e) Blood flow (ml/min)
f) Anticoagulant Total (ml)
g) Total fluid loss (ml)
h) Remaining time (h:min)
i) Bag change in (h:min)

The following patient parameters are displayed on the MORE screen during SCUF:

a) Pre-filter pressure (mmHg)
b) Temperature (ºC)
c) Filtrate pressure (mmHg)
d) Pre-dilution (ml)
e) Post-dilution (ml)
f) Blood volume (l)
g) Next bag change in (h:min)
h) UF variation (ml)
i) Filtration fraction (%)
j) Elapsed time (h:min)
k) Filtration ratio (%)
l) Access pressure (mmHg)
m) Return pressure (mmHg)
n) TMP (mmHg)
o) BLD (%)
p) Pressure Drop (mmHg)

### 5.11.2 CVVH (Continuous Veno-Venous Hemofiltration)

During this treatment, the output of the ***pre-dilution*** pump MUST be connected to the ***pre-filter*** luer connection before the filter.

Warning! All substitution solutions used must be labeled for intravenous injection, of appropriate composition and prescribed by a physician.
Use of incorrect or outdated solutions can result in a patient hazard.

## 5.11.3 CVVH Pre-dilution

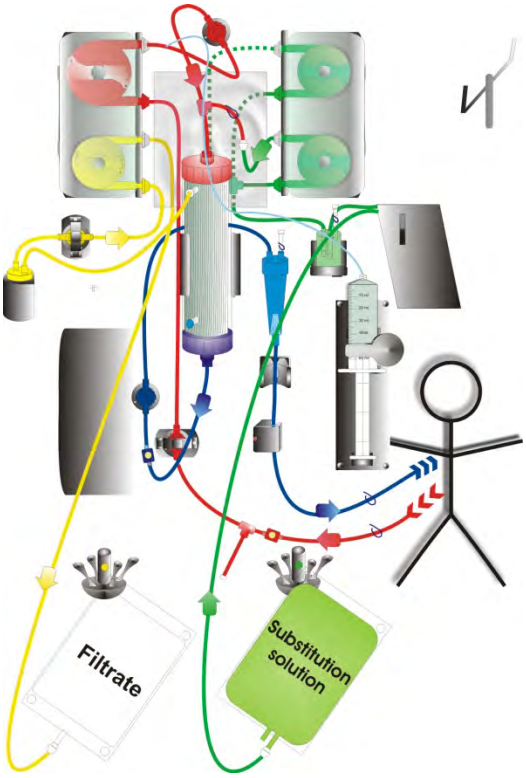



**Figure 164**

Notes:

- During this treatment the free line of the pre-dilution pump is connected to the pre-filter access line connection before the filter.
- During CVVH, blood is filtrated through a hemofilter and fluid is given back to the patient.
- During pre-dilution CVVH, the post-dilution pump is not active.
- During pre-dilution, the substitution solution is administered immediately before the filter
- The substitution fluid is hung on the substitution scale.
- The filtrate is collected in an empty bag hanging on the filtrate scale.

## 5.11.4 CVVH Post-dilution

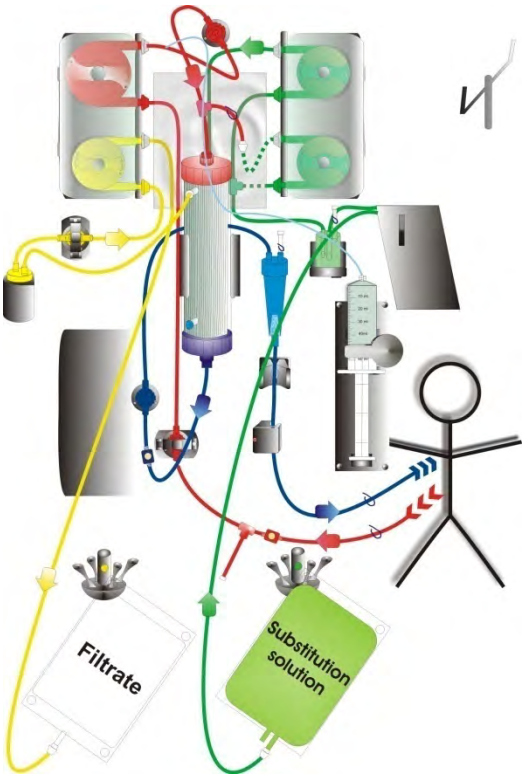



**Figure 165**

Notes:

- During post-dilution CVVH, the pre-dilution pump is not active.
- Blood is pumped through a hemofilter and reinfused to the patient.
- During post-dilution the substitution solution is administered after the filter at the return drip chamber.
- The substitution fluid is hung on the substitution scale
- The filtrate is collected in an empty bag hanging on the filtrate scale.

The following patient parameters are entered for a CVVH treatment:

| Parameter | Range<br>Adult | Pediatric | Units | Increment<br>Adult | Pediatric |
|---|---|---|---|---|---|
| Blood pump rate | [30; 450] | [10; 200] | ml/min | 10 ml/min | 2 ml/min |
| Time | [0; 99:59] | | h:min | 10 min | |
| Fluid loss rate | [-100; 2,000] | [0; 1,000] | ml/h | 10 / 100 ml/h (both adult and pediatric) | |
| Total fluid loss | [-1000; 32,000] | [0; 15,000] | ml | 100 ml | 10 ml |
| Pre-dilution rate | [0; 10,000 – post-dilution rate] | [0, 100; 6,000 – post-dilution rate] | ml/h | 100 ml/h | 10 ml/h |
| Post-dilution rate | [0; 10,000 - pre-dilution rate] | [0, 100; 4,000 – pre-dilution rate] | ml/h | 100 ml/h | 10 ml/h |
| Number of bags | [1; 4] | | 5 l | 1 Bag | |
| Anticoagulant | [0; 15] | | ml/h | 0.5 ml/h | |
| Anticoagulant bolus | [0; 2.5] | | ml | 0.5 ml | |
| Temperature | [0 (off) or 35; 39] | | °C | 0.5°C | |

The following patient parameters are displayed on the MAIN screen during CVVH:

a) Access pressure (mmHg)
b) Return pressure (mmHg)
c) TMP (mmHg)
d) Pressure drop (mmHg)
e) Blood flow (ml/min)
f) Anticoagulant Total (ml)
g) Fluid Loss Total (ml)
h) Substitution (ml and l)
i) Remaining time (h:min)
j) Bag change in (h:min)
k) Renal Dose (ml / kg / h)

Note: The Renal Dose is defined as the dose of treatment related to the patient's body weight (refer to 4.4.5 Clamp and Pressure test) and the pre- and post-dilution volumes.
At the start of treatment or after a programmed value change for blood flow rate, pre-dilution flow rate, post-dilution flow rate, or patient body weight, the programmed renal dose is displayed for the first 2 minutes after starting the balance system. After 2 minutes of uninterrupted therapy, the actual delivered renal dose is displayed based on the actual pump rates.

The following patient parameters are displayed on the MORE screen during CVVH:

a) Pre-filter pressure (mmHg)
b) Filtrate pressure (mmHg)
c) Temperature (ºC)
d) Pre-dilution (ml and l)
e) Post-dilution (ml and l)
f) Blood volume (l)
g) Next bag change in (h:min)
h) UF variation (ml)
i) Filtration fraction (%)
j) Elapsed time (h:min)
k) Filtration ratio (%)
l) Access pressure (mmHg)
m) Return pressure (mmHg)
n) TMP (mmHg)
o) Pressure drop (mmHg)
p) BLD (%)

## 5.11.5 CVVHD (Continuous Veno-Venous Hemodialysis)

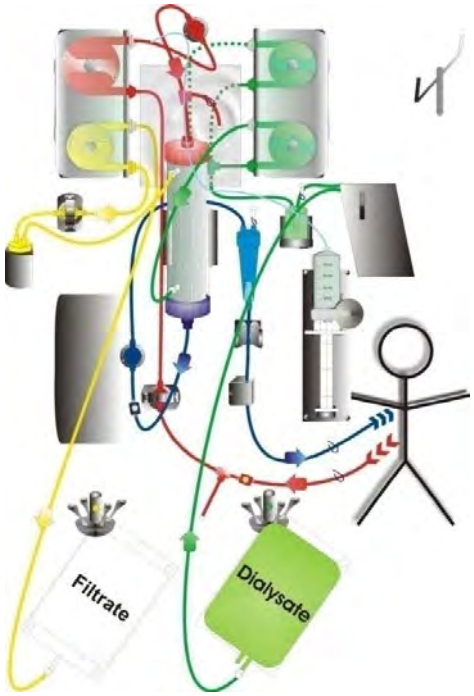



**Figure 166**

Notes:

- During continuous veno-venous hemodialysis the post-dilution pump is not active.
- Blood is pumped through a semi-permeable dialyzer and reinfused to the patient.
- The filtrate is collected in an empty bag hanging on the filtrate scale. The pre-dilution pump delivers the dialysate to the dialyzer, counter current to the blood flow.

The following patient parameters are entered for a CVVHD treatment:

| Parameter | Range | | Units | Increment | |
|---|---|---|---|---|---|
| | Adult | Pediatric | | Adult | Pediatric |
| Blood pump rate | [30; 450] | [10; 200] | ml/min | 10 ml/min | 2 ml/min |
| Time | [0; 99:59] | | h:min | 10 min | |
| Fluid loss rate | [-100; 2,000] | [0; 1,000] | ml/h | 10 / 100 ml/h (both adult and pediatric) | |
| Total fluid loss | [-1,000; 32,000] | [0; 15,000] | ml | 100 ml | 10 ml |
| Dialysate rate | [0; 10,000] | [0, 100; 10,000] | ml/h | 100 ml/h | 10 ml/h |
| Number of bags | [1; 4] | | 5 l | 1 Bag | |
| Anticoagulant | [0; 15] | | ml/h | 0.5 ml/h | |
| Anticoagulant bolus | [0; 2.5] | | ml | 0.5 ml | |
| Temperature | [0 (off) or 35; 39] | | °C | 0.5°C | |

The following patient parameters are displayed on the MAIN screen during CVVHD:

a) Access pressure (mmHg)
b) Return pressure (mmHg)
c) TMP (mmHg)
d) Pressure drop (mmHg)
e) Blood flow (ml/min)
f) Anticoagulant Total (ml)
g) Fluid Loss Total (ml)
h) Dialysate (ml and l)
i) Remaining time (h: min)
j) Bag change in (h: min)
k) Renal Dose (ml / kg / h)

Note: The Renal Dose is defined as the dose of treatment related to the patient's body weight (refer to 4.4.5 Clamp and Pressure test) and the pre- and post-dilution volumes.

At the start of treatment or after a programmed value change for blood flow rate, dilysate flow rate, post-dilution flow rate, or patient body weight, the programmed renal dose is displayed for the first 2 minutes after starting the balance system. After 2 minutes of uninterrupted therapy, the actual delivered renal dose is displayed based on the actual pump rates.

The following patient parameters are displayed on the MORE screen during CVVHD:

a) Pre-filter pressure (mmHg)
b) Filtrate pressure (mmHg)
c) Temperature (ºC)
d) Dialysate (ml and l)
e) Blood volume (l)
f) Next bag change in (h:min)
g) UF variation (ml)
h) Filtration fraction (%)
i) Elapsed time (h:min)
j) Filtration ratio (%)
k) Access pressure (mmHg)
l) Return pressure (mmHg)
m) TMP (mmHg)
n) Pressure drop (mmHg)
o) BLD (%)

## 5.11.6 CVVHDF (Continuous Veno-Venous Hemodiafiltration)

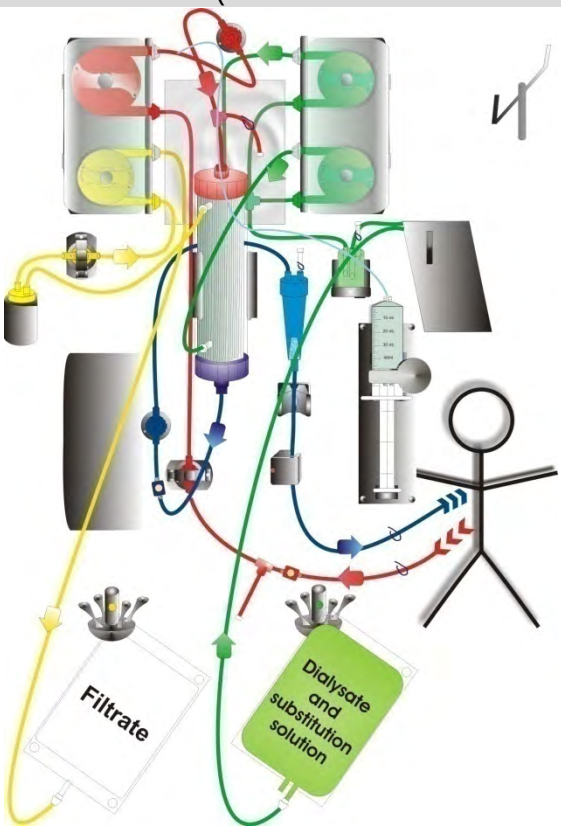



**Figure 167**

Notes:

- Substitution solution and dialysate solution are administered during CVVHDF. All pumps are in operation.
- Blood is pumped through a hemofilter and reinfused to the patient. The post-dilution pump is used to administer the substitution fluid
- The pre-dilution pump transports the dialysate to the dialyzer. The filtrate is collected in an empty bag hanging on the filtrate scale.

The following patient parameters are entered for CVVHDF:

| Parameter | Range<br>Adult | <br>Pediatric | Units | Increment<br>Adult | <br>Pediatric |
|---|---|---|---|---|---|
| Blood pump rate | [30; 450] | [10; 200] | ml/min | 10 ml/min | 2 ml/min |
| Time | [0; 99:59] | | h:min | 10 min | |
| Fluid loss rate | [-100; 2,000] | [0; 1,000] | ml/h | 10 / 100 ml/h (both adult and pediatric) | |
| Total fluid loss | [-1000; 32,000] | [0; 15,000] | ml | 100 ml | 10 ml |
| Dialysate rate | [0; 10,000 – Post-dilution rate] | [0, 100; 6,000 – Post-dilution rate] | ml/h | 100 ml/h | 10 ml/h |
| Post-dilution rate | [0; 10,000 – dialysate rate] | [0, 100; 4,000 – dialysate rate] | ml/h | 100 ml/h | 10 ml/h |
| Number of bags | [1; 4] | | 5 l | 1 Bag | |
| Anticoagulant | [0; 15] | | ml/h | 0.5 ml/h | |
| Anticoagulant bolus | [0; 2.5] | | ml | 0.5 ml | |
| Temperature | [0 (off) or 35; 39] | | °C | 0.5°C | |

The following patient parameters are displayed on the MAIN screen during CVVHDF:

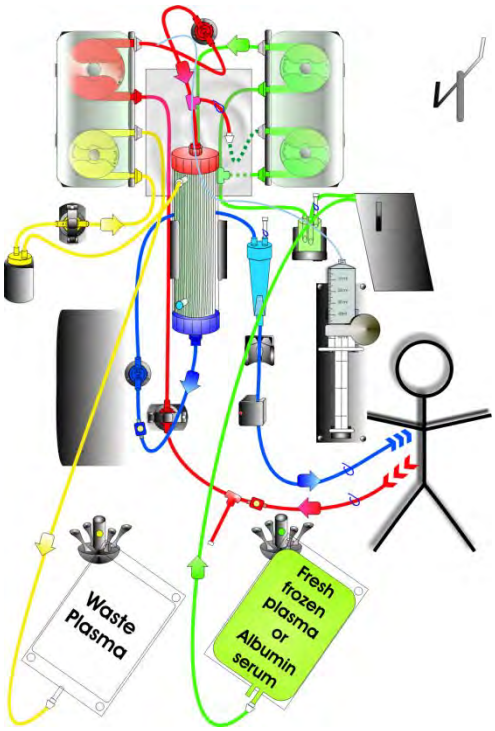
a) Access pressure (mmHg)
b) Return pressure (mmHg)
c) TMP (mmHg)
d) Pressure drop (mmHg)
e) Blood flow (ml/min)
f) Anticoagulant total (ml)
g) Fluid loss total(ml)
h) Remaining time (h:min)
i) Bag change in (h:min)
j) Renal Dose (ml / kg / h)
k) Dialysate (ml and l)
l) Substitution (ml and l)

Note: The Renal Dose is defined as the dose of treatment related to the patient's body weight (refer to 4.4.5 Clamp and Pressure Test) and the pre- and post-dilution volumes.
At the start of treatment or after a programmed value change for blood flow rate, dialysate flow rate, post-dilution flow rate, or patient body weight, the programmed renal dose is displayed for the first 2 minutes after starting the balance system. After 2 minutes of uninterrupted therapy, the actual delivered renal dose is displayed based on the actual pump rates.

The following patient parameters are displayed on the MORE screen during CVVHDF:

a) Pre-filter pressure (mmHg)
b) Filtrate pressure (mmHg)
c) Temperature (ºC)
d) Dialysate (ml and l)
e) Post-dilution (ml and l)
f) Blood volume (l)
g) Next bag change in (h:min)
h) UF variation (ml)
i) Filtration fraction (%)
j) Elapsed time (h:min)
k) Filtration ratio (%)
l) Access pressure (mmHg)
m) Return pressure (mmHg)
n) TMP (mmHg)
o) Pressure drop (mmHg)
p) BLD (%)

## 5.11.7 TPE (Therapeutic Plasma Exchange)




Notes:

- During TPE blood is pumped through a plasma filter. The corpuscular blood components are sent back to the patient.
- FFP (Fresh Frozen Plasma) or albumin solution is delivered to the patient via the post-dilution pump.
- The plasma is collected in an empty bag hanging on the filtrate scale.
- The pre-dilution pump is not operational during this treatment.

**Figure 168**

The following patient parameters are entered for a TPE treatment:

| Parameter | Range | | Units | Increment | |
|---|---|---|---|---|---|
| | Adult | Pediatric | | Adult | Pediatric |
| Blood pump rate | [30; 450] | [10; 200] | ml/min | 10 ml/min | 2 ml/min |
| Time | [0; 99:59] | | h:min | 10 min | |
| Plasma flow rate | [0; 3,000] | [0; 1,200] | ml/h | 10 ml/h | |
| Total plasma volume | [0; 10,000] | | ml | 10 ml | 10 ml |
| Container weight | [0; 100 to 5,000] | | g | 10 g | |
| Anticoagulant | [0; 15] | | ml/h | 0.5 ml/h | |
| Anticoagulant bolus | [0; 2.5] | | ml | 0.5 ml | |
| Temperature | [0 (off) or 35; 39] | | °C | 0.5°C | |

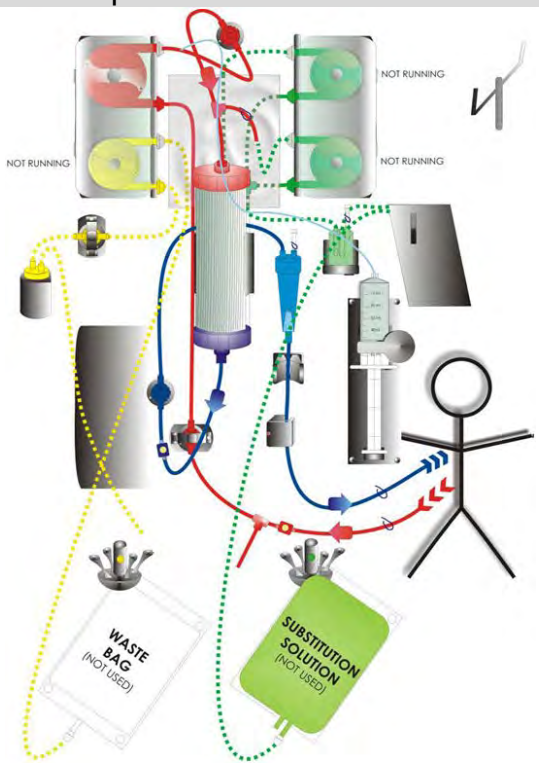
The following patient parameters are displayed on the MAIN screen during a TPE treatment:

a) Access pressure (mmHg)
b) Return pressure (mmHg)
c) TMP (mmHg)
d) Pressure drop (mmHg)
e) Blood flow (ml/min)
f) Anticoagulant total (ml)
g) Total Plasma (ml)
h) Remaining time (h:min)
i) Bag change in (h:min)

The following patient parameters are displayed on the MORE screen during TPE:

a) Pre-filter pressure (mmHg)
b) Filtrate pressure (mmHg)
c) Temperature (ºC)
d) Pre-dilution (ml)
e) Post-dilution (ml and l)
f) Blood volume (l)
g) Next bag change in (h:min)
h) UF variation (ml)
i) Filtration fraction (%)
j) Elapsed time (h:min)
k) Filtration ratio (%)
l) Access pressure (mmHg)
m) Return pressure (mmHg)
n) TMP (mmHg)
o) Pressure drop (mmHg)
p) BLD (%)

## 5.11.8 Hemoperfusion




Notes:

- During hemoperfusion blood is pumped through a hemoperfusion cartridge.
- Certain substances (e.g. toxins) are adsorbed and the cleansed blood is reinfused to the patient.
- Only the blood pump is in operation.

**Figure 169**

The following patient parameters are entered for a hemoperfusion treatment:

| Parameter | Range | | Units | Increment | |
|---|---|---|---|---|---|
| | Adult | Pediatric | | Adult | Pediatric |
| Blood pump rate | [30; 450] | [10; 200] | ml/min | 10 ml/min | 2 ml/min |
| Time | [0; 99:59] | | h:min | 10 minutes | |
| Anticoagulant | [0; 15] | | ml/h | 0.5 ml/h | |
| Anticoagulant bolus | [0; 2.5] | | ml | 0.5 ml | |

The following patient parameters are displayed on the MAIN screen during a hemoperfusion treatment:

a) Access pressure (mmHg)
b) Return pressure (mmHg)
c) TMP (mmHg)
d) Pressure drop (mmHg)
e) Blood flow (ml/min)
f) Anticoagulant Total (ml)
g) Remaining time (h: min)
h) Bag change in (h: min)

The following patient parameters are displayed on the MORE screen during TPE:

a) Pre-filter pressure (mmHg)
b) Filtrate pressure (mmHg)
c) Temperature (°C)
d) Pre-dilution (ml)
e) Post-dilution (ml)
f) Blood volume (l)
g) Next bag change in (h:min)
h) UF variation (ml)
i) Filtration fraction (%)
j) Elapsed time (h:min)
k) Filtration ratio (%)
l) Access pressure (mmHg)
m) Return pressure (mmHg)
n) TMP (mmHg)
o) Pressure drop (mmHg)
p) BLD (%)

The TMP value displayed in hemoperfusion therapy is not transmembrane pressure. It is the pressure inside the cartridge. The hemoperfusion principle is based on adsorption. The cartridge does not have a membrane. TMP does not exist for hemoperfusion therapy.

# 6 Aquarius system alarms and messages

## 6.1 Description of alarm operation

In the event of an alarm or system error:

- Visual and audible signals will be generated. Audible signals can be muted for 2 min by pressing the *Mute* key . However, if the alarm is not corrected after 2 min, the audible signal will start again. In addition, if another alarm or system error occurs during the mute period, an audible signal will be given immediately.
- The red status light located in the operation status display will be illuminated.
- The main screen will be displayed, except when in programming screen.
- The cause of the alarm or system error will be shown in a red window on the screen. With respect to multiple alarms, the alarm with highest priority will be displayed first.
- The *Help* function will provide further information onscreen about the alarm. In the case of multiple alarms, the *Help* screen will only display information about the highest priority one.
- Once the alarm cause has been corrected, the treatment can be resumed by pressing the *Balance Start/Stop* key.

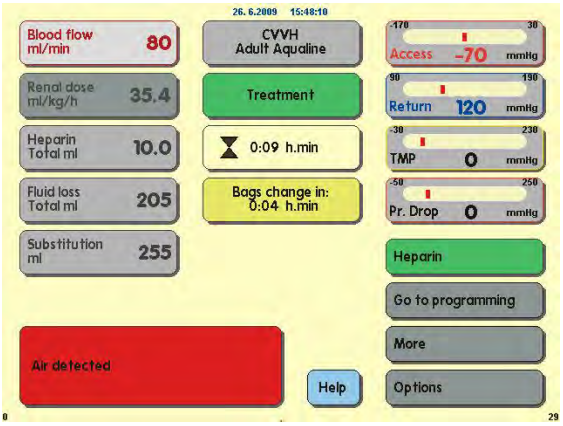



**Figure 170**

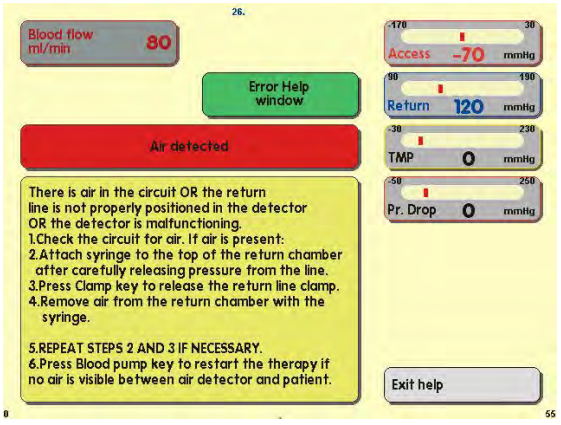



**Figure 171**

In the event of a message:

- Visual and audible signals will be generated.
- The yellow and green status lights located in the operation status display will be illuminated.
- The main screen will be displayed.
- The cause of the message will be shown in a yellow window on the screen.
- The *Help* function will provide further information onscreen about the alarm.

Blood circuit alarms

In the event of a blood circuit alarm:

- Visual and audible signals will be generated.
- All pumps will stop.
- The LEDs in the *Blood pump* and *Balance Start/Stop* keys will flash.
- If air or micro-foam is detected or the *return* pressure drops below the lower alarm limit, the *return* line clamp will close.

To reset a blood circuit alarm:

- Correct the cause of the alarm.
- Press the *Blood pump* and *Balance Start/Stop* keys to resume treatment.

### 6.1.1 Fluid (filtrate, substitution, dialysate) circuit alarms

In the event of a fluid circuit alarm:

- Visual and audible signals will be generated.
- The *Filtrate, Pre-dilution* and *Post-dilution* pumps will stop.
- The LED in the *Balance Start/Stop* key will flash.

To reset a fluid circuit alarm:

- Correct the cause of the alarm.
- Press the *Balance Start/Stop* key to resume treatment.

### 6.1.2 Aquarius Solution Heater

The Aquarius system has an integrated heater, which may be used to warm the substitution fluid before it is given to the patient.

When the treatment pumps stop for more than 15 seconds and the plate temperature is above 43°C, the fluid temperature in the heater coil can rise. In this case, the Aquarius system starts the Heater Cool Down management: the plate temperature is reduced to the programmed temperature and a yellow message is displayed on the screen indicating Heater Cools Down.

Heater Cool Down management may take up to 10 minutes. When the temperature of the heater plate is below 42°C, the Heater Cools Down message disappears and the treatment restarts automatically. In the case when the Heater Cool Down message was preceded by a Balance Alarm, the Fluid Loss management is activated.

Heater Cool Down management: The treatment is paused until the temperature is in a safe condition (below 42° C). Substitution pumps will run at a slow rate to help cooling (Exception: during TFL compensation balance substitution pumps will not run).

If the temperature value on the More Screen exceeds 40.0°C and/or the heater plate temperature exceeds 57°C at any time, a red High Temperature alarm is generated. The fluid pumps stop until the temperature displayed on the More Screen is below 40.0°C and the heater plate temperature is below 57 °C. During this time, the red High Temperature alarm is displayed on the screen.

When the High Temperature alarm disappears, the treatment pumps restart automatically.

### 6.1.3 Total Fluid Loss (TFL) management

Treatment pumps run to achieve the programmed ultrafiltration volume (or fluid loss volume). The balance scales measure the difference between the substitution volume and the filtration volume, which is the ultrafiltration volume. A balance alarm occurs in an adult case when a 50 g (20 g for pediatric) difference is detected between the programmed ultrafiltration volume and the actual ultrafiltration volume. When the pumps are reactivated by pressing the *Balance Start/Stop* key, the volume discrepancies are automatically compensated for by the system. This function is Total Fluid Loss (TFL) management.

When a balance alarm occurs, a yellow box will indicate the number of counted balance alarms detected during a 20 minute period. If within 20 minutes 5 counted balance alarms are detected, a red box will be displayed to inform the operator that the treatment has stopped. Only the blood pump continues. At this time press the *Next* button, to go to disconnection mode. Follow the instructions in section 5.9.

The balance alarm count will reset to zero only after the Aquarius system operates for 20 minutes continuously without stopping the pumps. An alarm that stops the balancing system or the user manually stopping the balancing system, will re-start the 20 minute period.

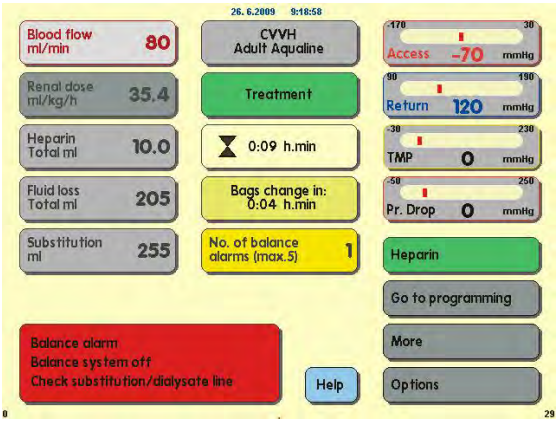



**Figure 172**


**Figure 173**

TFL volume compensation may be delayed if a Heater Cools Down message is displayed. When the Heater Cools Down message disappears, the balance alarm fluid discrepancy will be automatically compensated for by the system.

Weight deviations greater than ± 120 g may be caused if, during treatment, the user does not stop the balance system when adding or removing a bag from the scale, or if there is a large fluid leak, or if the Aquarius system is moved while the balance system is active. Although this will generate a balance alarm, the balance alarm count will not increase, the UF variation will be reset to the value displayed before the deviation occurred, and the weight deviation will not be compensated when treatment is restarted because it is not related to patient fluid deviation.

During TFL compensation, the message *Balance initializing...* is displayed.

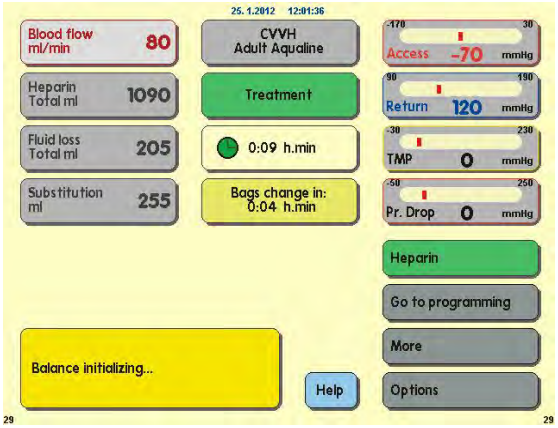



**Figure 174**

## 6.2 Alarms, messages, system errors and removal options

### 6.2.1 Alarms

Red indication

If the Aquarius system detects an out-of-range condition during the system test or during operation or if parameters exceed or drop below the respective limits, an alarm message is generated and the Aquarius system switches to the safety mode. Please note that some alarms require a manual restart of the blood pump.

Do not repeatedly clear alarms and restart the treatment without having identified and solved the alarm cause.

| Display: | Cause: | Options for error removal: |
|---|---|---|
| High access pressure | Access pressure has exceeded the upper alarm limit.<br>• Coagulation in the return drip chamber<br>• Problem with the catheter<br>• Lines are kinked | √ Change the Aqualine tubing set.<br>√ Check position of patient access.<br>√ Check access blood line, including access and pre-filter sensors, for kinks or occlusions.<br>√ Press the *Blood pump* key to resume treatment. |
| Low access pressure | Access pressure has dropped below the lower alarm limit.<br>• Catheter not in the correct position<br>• Problem with the catheter<br>• Lines are kinked | √ Check blood flow rate. Note: if blood flow rate is changed, check the filtration ratio displayed on the MORE screen.<br>√ Check position of the catheter and of the patient access.<br>√ Reprime catheter or change it.<br>√ Check access blood line, including access and pre-filter sensors, for kinks or occlusions. |
| Air Detected | • Return tubing line contains air or micro-foam.<br>• The return line is not properly positioned.<br>• The blood level is too low in the return chamber.<br>• The detector is malfunctioning. | √ Make sure that the tubing line does not contain air.<br>√ Check access and filter connections for sources of air leaks.<br>√ When you clear the Air Detected alarm, make sure there is no air or foam trapped in the line between the drip chamber and the patient end.<br>√ To remove air from the tubing line:<br>Step 1. Attach syringe to the top of the return chamber after carefully release the pressure from the line.<br>Step 2. Press the *Clamp* key  to open the *return* line clamp.<br>Step 3. Remove all air from return chamber with the syringe.<br>Step 4. Place the tubing back into the air detector and put it back in place.<br>Step 5. If level in drip chamber is correct and the bubbles are out of the tubing, press the *Clamp* key to close the return line clamp.<br>Step 6. Resume treatment by pressing the *Blood pump* key.<br>If the air detected alarm does not clear and air is visible in the return drip chamber, disconnect the patient from the instrument and recirculate per your centre's procedure.<br>Note: You may see micro bubbles smaller than the air detector sensitivity. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| Balance alarm<br>Check substitution/dialysate line<br>Or<br>Balance alarm<br>Check filtration/effluent line | If the Balance Alarm is counted (see the alarm counter in the yellow box on the Main Screen) it indicates that:<br>• The patient's fluid balance deviates more than 50 g in adult treatment or 20 g in pediatric treatment for more than 15s. The deviation is less than 120 g<br>• The deviation could not be compensated during TFL<br>Possible causes are:<br>– Fluid lines/manifold set is kinked or clamped.<br>– Snap connection on fluid bag is not broken.<br>– Bags are swinging on scales or touching the cart frame of the Aquarius.<br>– When multiple bags are hung on the scale, if the bags are touching each other or the tubing lines are resting on the cart frame, the draining of the bags can cause them to shift position, resulting in a temporary weight change on the scale.<br>– Tubing lines are supported by and are resting on the cart frame.<br>– Fluid is leaking or a bag is detached from the scale.<br>– Touching the filtrate or substitution bags while the balance system is active.<br>– Adding or removing a bag without stopping the Balance system.<br>– Moving the Aquarius system while the Balance system is active | √ If the Balance Alarm is counted, ensure that:<br>– All clamps are open.<br>– Lines and bags are hanging freely.<br>– Lines and bags are not kinked or blocked.<br>– Bag connections are correct<br>– Bags and lines are not resting on the cart frame<br>√ Restart the balance pumps by pressing the Balance Start/Stop key |
| | If the Balance Alarm is NOT counted (see the alarm counter in the yellow box on the Main Screen) it indicates that:<br>• The patient's fluid balance deviates more than 120 g for more than 15 seconds.<br>Possible causes are:<br>– Bags are swinging on scales or touching the cart frame of the Aquarius.<br>– When multiple bags are hung on the scale, if the bags are touching each other or the tubing lines are resting on the cart frame, the draining of the bags can cause them to shift position, resulting in a temporary | √ If the Balance Alarm is NOT counted, ensure that:<br>– All bags are hanging on the scale<br>– All bags are hanging freely and do not move<br>√ Restart the balance pumps by pressing the Balance Start/Stop key |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| | weight change on the scale.<br>– A bag is detached from the scale.<br>– Adding or removing a bag without stopping the Balance system.<br>– Moving the Aquarius system while the active Balance system | |
| Balance system off | The balance system has been off for 5 min. All fluid pumps have stopped. | √ Correct the cause and switch balance system on again. |
| Check substitution/dialysate line<br>Or<br>Check filtration/effluent line | Balancing deviates from the set values entered by the operator. | √ Check flow rates of the pumps.<br>√ Check fluid removal and turnover input parameters.<br>Note: Potentially, pumps cannot deliver program with very high volume because of pressure peaks.<br>√ Check bag hanging on scale (filtration or substitution).<br>√ Check tubing set for narrow sections (filtration or substitution) |
| Blood flow failure | The number of revolutions of the blood pump exceeds or falls below the alarm limits by ± 5%. | √ Check blood flow rate.<br>√ Check blood pump tubing.<br>√ Check tubing set for narrow sections. |
| Blood leak | • Filtrate / plasma contains blood.<br>• Filter membrane is damaged / ruptured.<br>• During treatment the BLD chamber has been removed from its housing.<br>• BLD chamber not filled with fluid.<br>• Dust on mirror of housing. | √ Discontinue treatment.<br>√ Exchange circuit.<br>√ Reposition the BLD chamber.<br>Go to “reprime” and choose ultrafiltrate line.<br>√ Remove mirror.<br>√ Clean and replace as found. |
| Blood pump off | The blood pump has not been running for 1 min. | √ Press *Blood pump* key to switch blood pump on again. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| Check degassing Chamber | • The motor works for more than 25s. without detecting a filled chamber.<br>• The hydrophobic filter is blocked (measured pressure less than –300 mmHg).<br>• The system detects a positive pressure higher than +30 mmHg.<br>• The system test fails.<br>• The fluid is detected in the ADU sensor line.<br>• A Check Degassing Chamber alarm occurs during the first two minutes of priming (post-dilution line) and fluid is in the heater line, up to 120 mL of dialysate or substitution fluid may be pumped into the saline bag when the alarm is cleared and priming restarts. When priming completes, replace the saline bag and reprime the blood circuit if the dialysate or substitution fluid is not indicated for infusion. | √ Check if all clamps are open.<br>√ Check if the substitution line is kinked.<br>√ Check if the 4 way connector is kinked.<br>√ Check if the frangible pins of the bags are well broken.<br>√ Clamp the line to the hydrophobic filter.<br>√ Open the clamp to the substitution line or from the 4 way connector.<br>√ Disconnect the line with the hydrophobic filter.<br>√ Open the clamp and reconnect it.<br>√ Press the *Mute* key.<br>√ After system test: degassing pressure sensor or degassing module defect. Do not use the Aquarius system and call technician.<br>√ During use: pressure sensor detects less than -300 mmHg. Degassing filter is wet. Clamp the pressure line, disconnect filter from sensor and use a syringe to dry it. Reconnect the line and unclamp it.<br>√ When an ADU Alarm (*Check Degassing Chamber, No Fluid Chamber Detected,* or *Degassing Chamber Missing*) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call technical service<br>If in treatment mode and an ADU alarm cannot be cleared, select *Go to programming* and set the *Temperature* to 0 °C to prevent delivering overheated solution to the blood circuit.<br>√ |
| Check transducer connections | The pressure domes have not detected any pressure change for 15 s. | √ Ensure the domes are properly connected.<br>√ Press the ***Blood pump*** key to resume treatment.<br>√ IMPORTANT: do not remove any pressure sensors.<br>√ If domes are in place: increase blood pump speed if return pressure reading is low. |
| Clamp heparin line | The heparin syringe has been removed. | √ Clamp heparin line |
| Degassing chamber missing | The substitution degassing chamber is not properly inserted or the sensors are defective. | √ Insert the substitution chamber properly.<br>√ Ensure the chamber is in contact with the sensor of the holder.<br>√ Start balance pumps.<br>√ When an ADU Alarm (Check Degassing Chamber, No Fluid Chamber Detected, or Degassing Chamber Missing) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call technical service.<br>If in treatment mode and an ADU alarm cannot be cleared, select *Go to programming* and set the temperature to 0 °C to prevent delivering overheated solution to the blood circuit. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| High filtrate pressure<br><br>Low filtrate pressure | Filtrate pressure exceeds or falls below the alarm limits. | √ Check pressure sensor.<br>√ Check tubing set for narrow sections.<br>√ Check filter and exchange circuit if required.<br>√ Check blood flow to filtration ratio. |
| Filtrate flow failure | The number of revolutions of the pump exceeded or fell below the alarm limits by ± 5%. | √ Check filtration flow rate.<br>√ Check filtration tubing.<br>√ Check tubing set for narrow sections. |
| Keyboard failure | A key press longer than 60s was detected by the master CPU. | √ If alarm does not clear, call technical service. |
| Line/Substitution failure | A substitution deviation is detected that influences the patient balance | √ Check lines.<br>√ Check clamps.<br>√ Check bags.<br>√ Check for leakages. |
| Master key transfer | • A key press longer than 60 s was detected by the master CPU.<br>• Short disturbances in the communication between the master and the controller CPU. | √ Alarm should be cleared by pressing the Blood Pump button (the error is automatically cleared by the system; the alarm is to notify the user that an issue occurred only).<br>√ If alarm does not clear, call technical service. |
| Main battery high | A high voltage has been detected in the main battery. | √ Control charging voltage/unit.<br>√ Control/change battery.<br>√ Control AD-converter/CPU. |
| Postdilution failure | The number of revolutions of the post-dilution pump exceeded or fell below alarm limits by ± 5%. | √ Check post-dilution flow rate.<br>√ Check post-dilution tubing.<br>√ Check tubing set for narrow sections. |
| Predilution failure | The number of revolutions of the pre-dilution pump exceeded or fell below alarm limits by ± 5%. | √ Check pre-dilution rate.<br>√ Check pre-dilution tubing.<br>√ Check tubing set for narrow sections. |
| High pre-filter pressure<br><br>Low pre-filter pressure | The pre-filter pressure exceeds upper alarm limit.<br><br>A rapid increase in pre-filter pressure without any change in parameters indicates filter clotting or coagulation in the return drip chamber. | √ Check pressure sensor.<br>√ Check filter and exchange circuit if required.<br>√ Check blood flow.<br>√ Check tubing set for narrow sections.<br>√ Check access line for kinks or occlusions.<br>√ Press the ***Blood pump*** key to resume treatment (in case of low pre-filter pressure).<br><br>In case of clotting, prepare to end treatment; increase pre-dilution flow rate and blood flow rate on next circuit. |
| High return pressure | • Return line is kinked or clamped.<br>• Return chamber is clotting.<br>• Return line is occluded or clotted. | √ Check return line for kinks or occlusions.<br>√ Prepare to end treatment.<br>√ Check position of patient access.<br>√ Check return pressure transducer. In the case of a faulty transducer, stop treatment and call technical service. |
| Low return pressure | • Blood flow rate is too low.<br>• Blood pump has stopped.<br>• Return line is disconnected. | √ Increase blood speed.<br>√ Clear any initial alarm and restart blood pump.<br>√ Reattach the return line to the catheter. |
| Pump door | One of the pump doors is open. | Close the door. |
| Syringe removed | • Heparin rate has been programmed and no syringe has been inserted in the plunger.<br>• The syringe is not inserted properly. | √ Correctly insert heparin syringe if heparin is needed.<br>√ Set anticoagulant rate to zero if anticoagulant is not required.<br>√ Press the ***Blood pump*** key to resume treatment. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| High temperature | • Temperature value on the More Screen exceeds 40.0°C. (For more information regarding the temperature displayed on the More Screen, see Section 5.8.6.)<br>• The Aquarius device detects a plate temperature of the heater above 57°C. | √ Check for air inside the heater coil. If air is present, remove the air by shaking the heater coil when the pumps have restarted. Ensure that the heater door is closed after reinsertion of the heater coil.<br>√ Wait until the temperature has cooled down<br>√ If the alarm disappears the treatment pumps will start automatically. |
| Low temperature | The heater plate temperature has been below 33°C for more than 10 min. | √ Check substitution temperature setting.<br>√ Ensure that the substitution solution bags are warm enough (ambient temperature) for infusion. |
| Temperature controller | High temperature of the heater at the controller. | √ Refer to "High temperature" options for error removal.<br>√ If the alarm persists, contact Technical Service.. |
| High TMP | • TMP has risen slowly – filter is clogging.<br>• TMP has risen rapidly – filtrate line or bags clamped or kinked.<br>• High TMP from the start. | √ Check MORE screen for pressure details. The rate of change over initial TMP (with same filtration and exchange rate) indicates pressure changes in the filter.<br>√ Reduce post-dilution flow rate and increase pre-dilution flow rate.<br>√ Unclamp or remove kink from line.<br>√ Check blood flow / exchange ratio.<br>√ Increase blood flow rate accordingly. |
| Low TMP | • Filtrate pump runs slower than the dialysate pump.<br>• The filtrate line is closed between filter and bag. | √ Check MORE screen for pressure details. The rate of change over initial TMP (with same filtration and exchange rate) indicates pressure changes in the filter.<br>√ Modify blood flow rate and/or fluid exchange, this will impact the blood flow-to-fluid removal or blood flow-to-turnover ratio. |
| Turnover failure | Balance pump speed is consistently higher (or lower) than the programmed speed for more than 20 consecutive minutes to ensure accurate fluid delivery.<br>Possible causes are:<br>– Fluid leakage<br>– Fluid delivery restrictions due to:<br>o Incorrect line installation (kinked tubes, closed or partially closed clamps, twisted lines)<br>o Incorrect bag installation (incorrect spiking of the substitution bag, spike or frangible pin blocking the fluid path, frangible pin only partially broken, bag not hanging freely, bag swinging)<br>o Pump calibration out of range.<br>o Filter inappropriate for fluid delivery rates | √ Stop the balance pumps and:<br>– Check for fluid leakage.<br>– Ensure lines and bags are hanging freely.<br>– Ensure lines and bags are not kinked or blocked.<br>– Check that all clamps are open.<br>– Ensure that the bags are not swinging.<br>– Ensure filter is capable of the prescribed flow rates. If necessary, use a larger surface area filter.<br>√ Restart the balance pumps.<br>If the problem persists contact Technical Service. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| Change filter and set | Notifies the operator that the machine has been running for more than 72 h. It cannot be reset and stays on for 8h | √ Exchange filter and tubing set.<br>√ Disconnect and start a new treatment with new filter and a new tubing system. |
| 80 h reached: new set required | The machine has been running for 80 h. The treatment will be terminated. | √ Exchange filter and tubing set.<br>√ Disconnect and start a new treatment with new filter and a new tubing system. |

### 6.2.2 Messages

Yellow indication

If the Aquarius system detects out-of-range conditions or reminders that do not conform to the intended use of the system, the operator gets detailed information defined for the individual conditions and the system switches to the safety mode.

Do not repeatedly clear messages and restart the treatment without having identified and solved the message cause.

| Display: | Cause: | Options for error removal: |
|---|---|---|
| Air detected<br>OR<br>Pressure test disabled | Air detection system does not detect “air free” tubing.<br>The clamp and pressure test is disabled. | √ Make sure that tubing set does not contain air.<br>√ Make sure that the return line is properly installed in the clamping system of the air detector.<br>√ Ensure that the return line is not scratched at the contact part. |
| Balance initializing... | Scales and fluid pumps initialize when the balance system is started. | √ This is just a reminder.<br>√ Occurs each time the balance system is turned ON.<br>√ Occurs during TFL volume compensation. |
| Balance system off | The balance system is off, all fluid pumps have stopped. | √ Correct the cause and switch the balance system on again. |
| Blood detected | During the connection or recirculation phase blood is detected in the return line. | √ The blood pump stops and starts for 5 s.<br>√ Switch to treatment mode. |
| Blood pump off | The blood pump was manually switched off. | √ Press *Blood pump* key to switch blood pump on again. |
| Change substitution/dialysate bag<br>OR<br>Change filtrate/effluent bag | The filtrate bag has reached maximum permissible weight or the substitution solution bags do not contain solution. | √ Replace full filtrate bag with empty bag.<br>√ Replace empty substitution solution bag with new bag filled with solution.<br>√ Open the bag(s). Ensure the line is not kinked or clamped.<br>√ Ensure proper placement of bags on the scale hooks.<br>√ Inlets should always hang from the bottom.<br><br>Note: If substitution bag is far from empty: check that the number of bags on program screen is equal to bags on scale. If yes, change filtrate bag (s) alone. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| Check access transducer | • The access / return transducer does not register a pressure change with the blood pump running.<br>• During clamp and pressure test no pressure increase is found when the clamp is closed. | √ Check dome connection.<br>√ To reconnect:<br>1. Stop blood pump.<br>2. Wait for 15 s.<br>3. Properly connect the dome.<br>4. Start blood pump. |
| Check degassing Chamber | Refer to "Check degassing chamber" causes as stated in Section 6.2.1:Alarms. | Refer to "Check degassing chamber" options for error removal as stated in Section 6.2.1:Alarms. |
| Check transducer connections | The pressure domes have not detected any pressure change for 15 s. | √ Ensure the domes are properly connected. |
| Check lines | The post-dilution pump has been stopped for longer than 3 min to regulate the fluid loss. | √ Check that the substitution line, the filtration line and all bags are open, all clamps are removed and the tubes and bag inputs are not kinked. |
| End of Treatment | End of Treatment | √ Disconnect patient or reprogram patient parameter |
| Exchange filter and set | This message is displayed every 24h of use of the same filter and line set (including priming, connection, recirculation and treatment time).<br>It is possible to clear this message if the filter and line have been used for less than 72h. | √ Exchange filter and tubing set.<br>√ Disconnect and start a new treatment with new filter and a new tubing system. |
| Filt./effluent bag change soon | Filtrate/effluent bag change in less than 10 min. | √ Prepare the new Filtrate/effluent bag change. |
| Function not available | During treatment the 'Off' key is used | √ To switch off the machine: select 'End treatment' and perform the disconnection program until the 'Aquarius off' mode appears. |
| Heater cools down | • Balance system has stopped for more than 15 s and the heater plate temperature is above 43°C. | √ Ensure the balance system is active (indicated by steady green light on balance key).<br>√ The treatment is paused until the temperature is in a safe condition (below 42° C). Substitution pumps will run at a slow rate to help cooling (Exception: during TFL compensation balance substitution pumps will not run).<br>√ Heater cool down management may take up to 10 minutes. The treatment will restart automatically. |
| Heater self test running | Heater self test is in progress when the start priming screen is reached. | √ Wait until heater self test is completed.<br>√ During the heater self test, the green status light is illuminated, whilst the yellow status light is flashing. When the heater self test is finished, the yellow status light stops flashing. |
| Heparin syringe missing | • A heparin rate has been programmed and no syringe has been inserted in the | √ Insert heparin syringe if heparin is needed<br>√ Set heparin rate to zero if no |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| | plunger.<br>• The heparin syringe is not inserted properly. | anticoagulant is required. |
| High filtration ratio | • Fluid removal rate exceeds 30% of the blood flow rate.<br>• Exchange of fluid or plasma across the membrane is too high in comparison to the blood flow rate.<br>• The post-dilution substitution rate is higher than what is acceptable for the current blood flow rate. | √ Decrease fluid removal or plasma exchange rate.<br>√ Increase blood flow rate.<br>√ Evaluate ratio of pre- vs. post-dilution substitution solutions. |
| Indication battery low | Power failure indication (beep) battery is low | √ The battery is automatically charged if you go on with this treatment.<br>√ This message indicates that in the event of a power failure the Aquarius system will beep for less than 2 min. |
| Insert BLD-chamber | The blood leak detector is not properly inserted into the blood leak chamber. | √ Correctly insert the chamber.<br>√ Reprime to correctly fill up the chamber.<br>√ Ensure no scratches or marks are present on the Aqualine tubing chamber. |
| Insert tube<br>Insert tube to air detector | The air detection system is not operational after priming. | √ Insert correctly the return line into the air detection system.<br>√ Make sure that the air detection system is well inserted, if not push it back firmly.<br>√ Ensure the green diode of the *Clamp* key is on. |
| Main battery low | After a power failure, the main power supply battery must be charged. | √ The battery is automatically charged if you go on with this treatment.<br>√ This message indicates that in the event of a power failure the Aquarius system will run for less than 2 min. |
| Negative UF | A negative UF is programmed. | √ This is a reminder. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| No bag | Less than 45g are detected on one scale.<br>Possible causes are:<br>– No bag installed on filtration scale.<br>– Bag weighs less than 45 g<br>– Incorrect bag installation (lines or spike touching the Aquarius cart frame or lines twisted)<br>– Aquarius system test performed with bag (s) hanging on the scales.<br>– Scale calibration out of tolerance. | √ Ensure that the filtrate bag is hanging on the filtration scale.<br>√ Check the filtration line and make sure they are not resting on the Aquarius cart frame and that it is not twisted. Make sure the filtration bag hangs freely from the scale.<br>√ Ensure that a correct waste bag is used (refer to Section 3.3 of the Instructions for Use of the Aquarius system)<br>√ Use an additional bag on each scale:<br>– Go to "Programming" window.<br>– Program 2 bags.<br>– Ensure that 2 empty effluent bags are hanging on the filtration scale and connect both filtration bags to the filtrate line.<br>– Ensure that 2 substitution bags are hanging on the substitution scale and connect both substitution bags to the substitution line.<br>√ If the above mentioned measures do not solve the issue, start a new treatment and ensure that during the system test there is no weight on the scales.<br>If the problem persists contact Technical Service. |
| No fluid chamber detected | The substitution degassing chamber is not inserted. | √ Insert the chamber correctly.<br>√ When an ADU Alarm (Check Degassing Chamber, No Fluid Chamber Detected, or Degassing Chamber Missing) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call technical service.<br>If in treatment mode and an ADU alarm cannot be cleared, select *Go to programming* and set the Temperature to 0 °C to prevent delivering overheated solution to the blood circuit. |
| Please program | Hourly fluid loss or fluid loss total is not programmed. | √ Select programming mode and program both hourly fluid loss and fluid loss total.<br>√ In CVVH, CVVHD and CVVHDF, if no fluid loss is required, treatment time must be programmed. |
| Power Failure | The power supply is interrupted. Depending on the charge status of the main battery the blood pump will run for around 2 min. | √ Start blood pump.<br>√ Check power cord connection.<br>√ Use crank handle to manually return blood to the patient if the power failure lasts longer than the battery supports. |

| Display: | Cause: | Options for error removal: |
|---|---|---|
| Pressure test disabled | During the pressure and clamp test a failure occurred. | √ Check pressure sensors.<br>√ If the problem persists contact technical service. |
| Program dialysate | In CVVHD, dialysate rate is not programmed. | √ Select programming and program a dialysate rate. |
| Program goal | Treatment goal is not programmed. | √ Select programming and program time, fluid loss and fluid loss total. |
| Program treatment pumps | In CVVH/CVVHDF pre- and post-dilution/post-dilution and dialysate are not programmed. | √ Select programming and program pre- and post-dilution or post-dilution and dialysate rate. |
| Pump door open | One of the pump doors is open. | √ Close pump door. |
| Read error help instructions | To solve the alarm further information is needed. | √ Further information is available from the help screens. |
| Return pressure low | The return pressure is below 20 mmHg. | √ During the first minute of treatment this is a reminder. |
| Subst./dialysate bag change soon | Substitution/dialysate bag change in less than 10 minutes. | √ Prepare substitution and/or dialysate bag change. |
| Syringe empty:change in OPTIONS | The syringe located in the heparin pump is empty. | Follow instructions on "change syringe" screens – remove syringe ONLY when directed.<br>√ Clamp heparin line.<br>√ Take syringe out of pump and disconnect from line.<br>√ Fill new syringe with heparin.<br>√ Enter syringe volume and confirm.<br>√ Place syringe in pump and connect line.<br>√ Ensure that plunger and wings are inserted.<br>√ Open clamp and confirm.<br><br>Note: If using BD syringe: ensure the grooves on the plunger are running towards the machine. |
| Syringe pump off | The heparin rate is programmed to zero. | √ If heparin is not required proceed to next screen.<br>√ If heparin is required, insert a syringe containing heparin and program the desired heparin rate. |
| Too much weight | One of the scales has detected more than 20 kg. | √ Ensure that the same number of substitution solution and filtrate bags hang on the scale hooks.<br>√ Note: The maximum number of bags on each scale is 4. |
| Wait ! | The balance system is stopped. | √ This is an indication that the system will start automatically after some minutes. |

## 6.2.3 System Errors

Red indication

During the system test (after switching the system on) and also during operation, the Aquarius system automatically performs tests to check the safety-critical components. If errors occur during these tests, the system switches to the safety mode and generates a red system error message as well as an audible alarm. This error message appears with the abbreviation CPU1 (control processor unit 1) or CPU2.

If the following system errors cannot be corrected, please call technical services.

| | | Test frequency |
|---|---|---|
| CPU1: error1 CPU | Master CPU Register test failed | Initial self-test |
| CPU1: error2 CPU | Master CPU RAM test failed | Initial self-test |
| CPU1: error3 CPU | Master CPU jump test failed | Initial self-test |
| CPU1: XRAM | Master CPU extern RAM failed | Initial self-test |
| CPU1: CODE | Master CPU program code test failed | Initial self-test |
| CPU1: EEPROM | Master CPU calibration data test failed | Initial self-test |
| CPU2: error1 CPU | Controller CPU Register test failed | Initial self-test |
| CPU2: error2 CPU | Controller CPU RAM test failed | Initial self-test |
| CPU2: error3 CPU | Controller CPU jump test failed | Initial self-test |
| CPU2: XRAM | Controller CPU external RAM test failed | Initial self-test |
| CPU2: CODE | Controller CPU program code test failed | Initial self-test |
| CPU2: EEPROM | Controller CPU calibration data test failed | Initial self-test |
| CPU1: program run | Program failure Master CPU | Initial self-test |
| CPU2: program run | Program failure Controller CPU | Initial self-test |
| CPU1: ADC/Voltage CPU2 | Voltage supply or AD-converter failure | < 2 $s^{-1}$ |
| CPU1: sensor voltage | Voltage supply or AD-converter failure | < 2 $s^{-1}$ |
| CPU2: ADC/Voltage CPU1 | Voltage supply or AD-converter failure | < 2 $s^{-1}$ |
| CPU2: balance alarm | Controller CPU balance alarm | < 1 $s^{-1}$ |

| Display: | Cause: | Options for error removal: | Test frequency |
|---|---|---|---|
| Access sensor | • Access pressure sensor values deviate from limits.<br>• During clamp and pressure test no pressure increase is detected. | After system test:<br>√ Ensure that no tubing is on the machine during the system test.<br>√ Repeat the system test. If it fails again, call technical service.<br>During pressure and clamp test:<br>√ Ensure the access dome is positioned properly.<br>√ Press the ***Blood pump*** key to reset the alarm and to continue the pressure and clamp test. | Continuous:<br>< 2 $s^{-1}$ |
| ADC/Voltage | • Voltage supply or AD-converter failure – the master CPU detects high or low voltage at the power supply for the controller-CPU. | √ End the treatment and call technical service. | Continuous:<br>< 2 $s^{-1}$ |
| Air detector | • Air detector test failed.<br>• Master-CPU and controller-CPU have different information regarding air alarm. | √ Repeat the system test. If it fails again, call technical service.<br>√ Press ***Blood pump*** key. If error cannot be reset, put system out of operation and notify technical support. | Continuous:<br><1 $s^{-1}$ (Master)<br><3 $s^{-1}$ (Protection) |

| Display: | Cause: | Options for error removal: | Test frequency |
|---|---|---|---|
| Backup | No dates at the backup | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support. | Initial self-test |
| Balance filtration | • Check filtration scale<br>• Values between protective and control system deviate from each other (outside of limits).<br>• Actual values are outside of limits. | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support. | Initial self-test |
| Balance substitution | • Check substitution scale<br>• Values between protective and control system deviate from each other (outside of limits).<br>• Actual values are outside of limits. | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support. | Initial self-test |
| BLD | Blood leak detector (BLD) does not work properly. | √ Press the ***Blood pump*** key  . If the system error cannot be reset, put system out of operation and notify technical support. | Continuous:<br>< 5 $s^{-1}$ |
| Blood pump | • Flow rate test failed.<br>• Blood pump drive defective.<br>• Blood pump did not stop.<br>• Actual value of number of revolutions deviates from set value outside of limits. | √ Ensure the pump door is closed.<br>√ Switch system off and on again after approximately 1 min (no tubing must be installed).<br>√ Press ***Blood pump*** key  <br>√ If the error cannot be removed, notify technical support. | Continuous:<br>< 25 $s^{-1}$ |
| CPU 2: balance alarm | Protective system detects different value from master.<br>The balance alarm is not counted and not compensated. | √ Note the alarm in the treatment protocol<br>√ Restart the balance pumps by pressing the Balance Start/Stop key<br>√ If the alarm appears repeatedly, terminate treatment and call technical service | Continuous:<br>< 1 $s^{-1}$ |
| Clamp doesn't close<br>Clamp doesn't open | • Clamp test failed.<br>• Clamp does not close.<br>• Clamp does not open. | √ Correct tubing set position in clamp.<br>√ Press ***Blood pump*** key  . If the error cannot be reset, put system out of operation and notify technical support. | Continuous:<br>< 1 $s^{-1}$ |
| CODE | • Controller CPU program code test failed<br>• Master CPU program code test failed | √ Restart system (no tubing may be installed).<br>√ If the error cannot be reset, put system out of operation and notify technical support | Initial self-test |
| Commu control system | The communication between master and controller failed. | √ If the message cannot be reset, turn off the Aquarius system and turn it back on. | Continuous:<br>< 5 $s^{-1}$ |

| Display: | Cause: | Options for error removal: | Test frequency |
|---|---|---|---|
| Commu front system | The communication between the master-CPU and the display failed. | √ Set up safety mode for the patient.<br>√ Switch system off and on again after approximately 1 min (no tubing must be installed).<br>√ If the error cannot be reset, put system out of operation and notify technical support. | Continuous:<br>< 5 $s^{-1}$ |
| Commu protection system | • Error during data transfer.<br>• Power supply for protective system is defective. | √ Press *Blood pump* key or *Balance Start/Stop* key.<br>√ Switch system off and on again after approximately 1 min. If the error cannot be reset, put system out of operation and notify technical support. | Continuous:<br>< 2 $s^{-1}$ |
| EEPROM | • Master CPU calibration data test failed<br>• Controller CPU calibration data test failed | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support | Initial self-test |
| Blood detected | Blood at optic sensor (air detector) | √ Restart system (no tubing may be installed).<br>√ If the error cannot be reset, put system out of operation and notify technical support. | Initial self-test |
| Error1 CPU | • Master CPU Register test failed<br>• Controller CPU Register test failed | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support | Initial self-test |
| Error2 CPU | • Master CPU RAM test failed<br>• Controller CPU RAM test failed | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support | Initial self-test |
| Error3 CPU | • Master CPU jump test failed<br>• Controller CPU jump test failed | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support | Initial self-test |
| Error blood detection | Blood at optic sensor (air detector) | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support. | √ Initial self-test |
| Filtration pump | • Flow rate test failed.<br>• Filtrate pump drive defective.<br>• Filtrate pump did not stop.<br>• Actual value of number of revolutions deviates from set value outside of limits. | √ Ensure the pump door is closed.<br>√ Switch system off and on again after approximately 1 min (no tubing must be installed).<br>√ Press *Balance Start/Stop* key  .<br>√ If error cannot be reset, notify technical support. | Initial self-test<br>Continuous:<br>< 30 $s^{-1}$ |

| Display: | Cause: | Options for error removal: | Test frequency |
|---|---|---|---|
| Heater | During system test:<br>The heater failed the system test. | √ Repeat the system test.<br>√ If message appears again, call technical service.<br>√ The system cannot be used for treatment. | Initial self-test |
| | During treatment:<br>Master and controller detect different values at the temperature sensors | √ Check for air in the heater coil. If air is present, remove air as follows:<br>• Large amounts of air - approximately more than 1/3 of the heating coil - or in pediatric treatment: the air may be removed via the access port on the degassing chamber using a syringe.<br>• Small amounts of air - approximately less than 1/3 of the heating coil: remove heater coil from heater, clear the alarm, wait for treatment pumps to start, and then shake the heater coil gently while the treatment pumps are running. The air will be automatically removed by the degassing chamber.<br>√ Ensure that the heater door is closed after reinsertion of the heater coil.<br><br>If problem still persists call technical service | Continuous<br>< 1 $s^{-1}$ |
| Heparin pump | • Actual values of control and protective systems deviate from each other (outside of limits)<br>• Actual values deviate from limits<br>• Pump stall<br>• The plunger is incorrectly positioned. | √ After system test: Restart system (no tubing must be installed). If the error cannot be reset, put system out of operation and notify technical support.<br>√ During treatment:<br>1. Check the heparin line is not clamped.<br>2. Go to "Options" and "Change syringe", following the onscreen text. Note: It is not necessary to remove the syringe during this process<br>3. If problem persists, program the pump to 0, clamp the line and remove the syringe. If problem still persists, end treatment and call technical service. | Continuous:<br>< 2 $s^{-1}$ |

| Display: | Cause: | Options for error removal: | Test frequency |
|---|---|---|---|
| Operation mode | The mode detection between master-CPU and controller-CPU failed. | √ Press *Blood pump* key  to start a new check.<br>√ If the alarm appears again, call technical support. | Continuous:<br>< 2 $s^{-1}$ |
| Postdilution pump | • Flow rate test failed.<br>• Post-dilution pump drive defective.<br>• Post-dilution pump did not stop.<br>• Actual value of number of revolutions deviates from set value outside of limits. | √ Ensure the pump door is closed.<br>√ Switch system off and on again after approximately 1 min (no tubing may be installed).<br>√ Press *Balance Start/Stop* key  .<br>√ If the error cannot be reset, put system out of operation and notify technical support. | Continuous:<br>< 30 $s^{-1}$ |
| Predilution pump | • Flow rate test failed.<br>• Pre-dilution pump drive defective.<br>• Pre-dilution pump did not stop.<br>• Actual value of number of revolutions deviates from set value outside limits.<br>• The pump is not running at the correct speed. | √ Ensure the pump door is closed.<br>√ Switch system off and on again after approximately 1 min (no tubing must be installed).<br>√ Press *Balance Start/Stop* key  .<br>√ If the error cannot be reset, put system out of operation and notify technical support. | Continuous:<br>< 30 $s^{-1}$ |
| Program run | • Program failure Master CPU.<br>• Program failure Controller CPU. | √ Press the *Blood pump* key to reset the alarm.<br>√ If message appears repeatedly, end the treatment and call technical service. | Continuous:<br>< 25 $s^{-1}$ |
| Return sensor | • Return pressure sensor values deviate from limits.<br>• During clamp and pressure test no pressure increase is detected.<br>• Error during data transfer. | After system test:<br>√ Ensure that no tubing is on the machine during the system test.<br>√ Repeat the system test. If it fails again, call technical service.<br>During clamp and pressure test:<br>√ Ensure the return and pre-filter domes are positioned properly.<br>√ Press the *Blood pump* key to reset the alarm and to continue the pressure and clamp test. | Initial self-test<br>Continuous:<br>< 2 $s^{-1}$ |
| Sensor Voltage | • High or low voltage is detected at the power supply for the sensors.<br>• Voltage supply or AD-converter failure | √ Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support. | Continuous:<br>< 2 $s^{-1}$ |

| Display: | Cause: | Options for error removal: | Test frequency |
|---|---|---|---|
| Timer | Timer deviation between master and controller. | √ Press *Blood pump* key to clear the message.<br>√ If the message appears repeatedly, end the treatment and call technical service. | Continuous:<br>< 2 $s^{-1}$ |
| TMP sensor | The TMP calculation or the filtrate pressure sensor is out of range. | √ Ensure no tubing is on the machine during the system test.<br>√ Repeat the system test. If it fails again, call technical service. | Continuous:<br>< 2 $s^{-1}$ |
| Vcc Master/communication | • A high or low voltage has been detected at the master power supply.<br>• RAM, EPROM or EEPROM are defective.<br>• Values between protective and control system deviate from each other (outside of limits). | √ Press the *Blood pump* key to reset the message.<br>√ If it appears repeatedly, end the treatment and call technical service. | Continuous:<br>< 2 $s^{-1}$ |
| XRAM | During system test the RAM of the controller-CPU was found to be defective. | Restart system (no tubing may be installed). If the error cannot be reset, put system out of operation and notify technical support. | Initial self-test |

# 7 Aquarius system technical data

This chapter contains information about individual components and general technical information about the Aquarius system.
For more detailed technical information please contact the Aquarius system manufacturer.

## 7.1 Dimensions and weight

| | |
|---|---|
| Height: | 175 cm (without I. V. pole) |
| Width: | 65 cm |
| Depth: | 75 cm |
| Floor space: | approx. 55 cm (W) x 65 cm (D) |
| Weight: | approx. 90 kg |

## 7.2 Electrical power supply

Voltage

230 V ~ (Alternating voltage) $\pm$ 10% = 207 VAC to 253 VAC, 50/60 Hz for GE-F096-00
115 V ~ (Alternating voltage) $\pm$ 10%, = 104 VAC to 126 VAC 60 Hz for GE-F097-00

Currents

2.2 A with 230 V
4 A with 115 V

Power Consumption

350 Watt with 230V
350 Watt with 115V

## 7.3 Electrical safety

(Complying with EN 60601-1 2nd edition)
Manner of protection against electrical shock

Degree of protection against electrical shock:
The Aquarius system is classified in class 1.

The applied parts of Aquarius system are classified as type B (body)

Symbol: 

Fuses: Main Fuses:

2 x T 3.15 A, fine fuse with time delay, glass body for GE-F096-00
2 x mT 4 A, fine fuse with time delay, glass body for GE-F097-00
Nominal voltage: 250 V AC max.
Fuse switch value 3.15 A / 250 V AC

Heater Fuse:

1 x T 3.15 A, 20 x 5 fine fuses with time delay, glass body
Nominal voltage: 250 V AC max.
Fuse switch value 3.15 A / 250 V AC

Battery Fuses:

T 1 A, plastic body soldered on secondary power supply
Nominal voltage: 250 V AC max.
Fuse switch value 1 A / 250 V AC

1 x T 3.15 A, 20 x 5 fine fuses with time delay, glass body
Nominal voltage: 250 V AC max.
Fuse switch value 3.15 A / 250 V AC

After BG-E414-02:

1 x T 3.15 A, plastic body soldered on secondary power supply
Nominal voltage: 250 V AC max.
Fuse switch value 3.15 A / 250 V AC

Storage battery:

Maintenance-free lead storage battery, LC-R061R3PG
Capacity: 6 V, 1.3 Ah

## 7.4 Power outage operation

If the mains power supply fails during a treatment, the Aquarius system automatically switches to storage battery power supply, until the emergency mains power supply is available. Storage battery operation is indicated via an audible signal. On the screen the "Power fail" message is displayed. During this period, the fluid circuit (substitution and filtrate) is stopped. Circulation through the blood circuit is maintained.

⚠ The system will operate for a minimum of 2 minutes during a power failure with a fully charged battery.

If the power supply is restored, the fluid circuit may be resumed.

If the power supply is not restored before the end of battery operation, after approximately 2 minutes, the Aquarius system will be switched off (safety mode) and all pumps will stop. The return line clamp is still open to enable manual return of blood from the extracorporeal circuit. At the back of the scale system a removable hand-crank is mounted. This can be used to manually turn the blood pump in case the pump stops.

If the Aquarius system is stored over a longer period the manufacturer recommends connecting the system to the power outlet and charging the storage battery for 15 h every half year. Also charge the storage battery for 15 h before initial set up and installation.

Important: The battery has to be changed every 2 years.

## 7.5 Technical data of individual components and essential performance data

| Component | Specification |
|---|---|
| Access pressure sensor | Measurement method: Contact measurement<br>Measuring range: -250 to +200 mmHg, step 1mmHg<br>Measuring accuracy: ± 5mmHg<br>Upper alarm limit: automatic setting between -50 and +200 mmHg<br>Lower alarm limit: automatic setting between -250 and 0 mmHg<br>Alarm window size during treatment: ±100 mmHg around the actual value |
| ADU Audible Alarm | 1 Hz +/- 0.5 Hz |
| ADU Constant level | ± 1cm around the light beam |
| ADU Infra-red diodes | 50 Hz +/- 10% |
| ADU Pressure working range | -300 mmHg to - 30 mmHg |
| ADU Pressure alarm | Low pressure: < - 300 mmHg<br>High pressure: > +30 mmHg<br>Zero pressure / disconnection: [-30 mmHg; +30 mmHg] |
| ADU Power supply | From Aquarius system : + 24 V |
| ADU gas removal volume | 10 ml/min |
| Air detector | Method: Ultrasonic air bubble detection at 2.3 MHz<br>Sensitivity: Air bubbles at a volume of 1 µl at a blood flow rate of 200 ml/min<br>Alarm trigger: 20 µl air bubble or accumulation of 20 µl of 1 µl air bubbles within 1min at a blood flow rate of 200 ml/min |
| Alarm | The alarm signal may be muted for a period of 2 min.<br>The alarm loudness is 65 dB (A) within a distance of 1 m. |
| Blood leak detector | Measurement of clouding<br>Optical calibration value –Actual optical value =BLD (%)<br>Optical calibration value – Optical alarm limit value<br>Sensitivity: 2 ml of blood in 1000 ml (± 10%) of filtrate at a filtrate pump flow rate of 100 ml/h up to 12000 ml/h (at a hematocrit of 32%)<br>Sensitivity for TPE: 4ml of blood in 1000 ml |
| Blood pump** | Input range adult: 30 ml/min – 450 ml/min<br>Step-by-step: 10 ml/min<br>Input range pediatric: 10 ml/min – 200 ml/min<br>Step-by-step: 2 ml/min<br>Accuracy:<br>Adult: ±5 ml/min from 30 to 100 ml/min<br>±5% from 101 to 450 ml/min<br>Pediatric: ±6 ml/min from 10 to 60 ml/min<br>±10% from 61 to 200 ml/min<br><br>Pressure range for the specified accuracy: see defined values for access pressure and pre-filter pressure<br><br>Alarm limits: -10 to +10% from set point<br><br>Aqualine tubing set pump insert size is:<br>ID x OD: ø6.36 (± 0.10) x 9.54 (± 0.10) mm / Length: 24 (± 0.50) cm<br>Aqualine 'S' tubing set pump insert size is:<br>ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm / Length: 24 (±0.50) cm |

| Component | Specification |
|---|---|
| Dialysate pump** | In CVVHD and CVVHDF, the pre-dilution pump is used as dialysate pump with the following specifications:<br>Input range adult: 0 or 100 – 10,000 ml/h<br>Step-by-step: 100 ml/h<br>Input range pediatric: 0 or 100 – 6,000 ml/h in CVVHDF<br>0 or 100 – 10,000 ml/h in CVVHD<br>Step-by-step: 10 ml/h<br>Accuracy: ±5%<br><br>Pressure range for specified accuracy: see specified values for return pressure |
| Display monitor | 10.4 " TFT color monitor<br>Minimum resolution: 640 x 480 pixels |
| Filtrate and substitution solution scale | Measurement method: via strain gauge<br>Max. load: 0 to 20 kg, max. 4 bags with 5 l of substitution fluid each<br>Accuracy of scale: 0.1%<br>Turnover <= 6000 ml/h<br>Patient fluid balance error: max. +/- 100 ml or 0.45%<br>Turnover > 6000 ml/h<br>Patient fluid balance error: max. +/- 150 ml or 0.5% |
| Filtrate pressure sensor | Measurement method: Contact measurement<br>Measuring range: -400 to +800 mmHg, step 2 mmHg<br>Measuring accuracy: ± 10 mmHg<br>Upper alarm limit: +400 mmHg<br>Lower alarm limit: - 400 mmHg |
| Filtrate pump** | Input range adult: 0 or 100 – 12,000 ml/h<br>Input range pediatric: 0 or 100 – 11,000 ml/h<br>Accuracy: ± 5%<br>Pressure range for the specified accuracy: see defined values for filtrate pressure<br><br>Fluid loss Adult: -100 to 2,000 ml/h<br>Step-by-step 10 ml/h<br>Maximum total fluid loss: 32,000 ml<br>Fluid loss Pediatric: 0 or 10 – 1,000 ml/h<br>Step-by-step 10 ml/h<br>Maximum total fluid loss: 15,000 ml<br><br>Note: Fluid can be added at a maximum rate of 100 ml/h, a maximum positive balance of 1 l is permissible for adult treatment.<br><br>Aqualine tubing set pump insert size is:<br>ID x OD : ø4.7 (±0.10) x 7.2 (±0.10) mm / Length: 22.5 (±0.50) cm<br>Aqualine 'S' tubing set pump insert size is:<br>ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm / Length: 22.5 (±0.50) cm |
| Heating unit** | Adjustable substitution temperature 35°C to 39°C, adjustable in 0.5°C increments, or 0 (Off).<br>Alarm is triggered if temperature displayed on More Screen is > 40°C.<br>Plate working range 21°C to 53°C.<br>Alarm is triggered if heater plate temperature is > 57°C.<br>Capacity: 5 l/h |
| Heparin pump | Syringe pump uses 50 ml syringes (Calibration necessary).<br>Input range: 0 or 0.5 – 15 ml/h, Steps: 0.5 ml/h<br>Flow rate accuracy: ± 2 ml/h<br>Heparin bolus: 0.5 – 2.5 ml/bolus via patient parameter function, step 0.5ml<br>Max. back pressure value, which does not influence the flow rate accuracy: 650 mmHg |
| PD (Pressure Drop) | Pre-filter pressure - Return pressure + 35<br>(35 is the offset value. It is the distance between the pre-filter and the return sensors in cm divided by 1.3)<br>Working range: +5 mmHg to +250 mmHg, step 1mmHg<br>Measuring accuracy: ±10 mmHg<br>Alarm limits: +5 to +250 mmHg |

| Component | Specification |
|---|---|
| Post-dilution pump** | Input range adult: 0 or 100 – 10,000 ml/h<br>Step-by-step: 100 ml/h<br>Input range pediatric: 0 or 100 – 4,000 ml/h<br>Step-by-step: 10 ml/h<br>Accuracy: ± 5%<br>Pressure range for specified accuracy: see specified values for return pressure<br><br>Aqualine tubing set pump insert size is:<br>ID x OD: ø4.7 (±0.10) x 7.2 (± 0.10) mm / Length: 22.5 (±0.50) cm<br>Aqualine S pump insert size is:<br>ID x OD: ø3.3 (±0.10) x 5.7 (±0.10) mm / Length: 22.5 (±0.50) cm |
| Pre-dilution pump** | Input range adult: 0 or 100 – 10,000 ml/h<br>Step-by-step: 100 ml/h<br>Input range pediatric: 0 or 100 – 6,000 ml/h<br>Step-by-step: 10 ml/h<br>Accuracy: ± 5%<br>Pressure range for specified accuracy: see specified values for return pressure<br><br>Aqualine tubing set pump insert size is:<br>ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm / Length: 22.5 (±0.50) cm<br>Aqualine 'S' tubing set pump insert size is:<br>ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm / Length: 22.5 (±0.50) cm |
| Pre-filter pressure sensor | Measurement method: Contact measurement<br>Measuring range: -500 to +800 mmHg, step 2mmHg<br>Measuring accuracy: ±5 mmHg<br>Upper alarm limit: +400 mmHg<br>Lower alarm limit: -100 mmHg |
| Processors | 2 x CPU 80517 and 1 x Intel |
| Return line clamp | With no power applied, the clamp is open<br>Minimum occlusion of line 350 mmHg |
| Return pressure sensor | Measurement method: Contact measurement<br>Measuring range: -80 to +300 mmHg, step 1mmHg<br>Measuring accuracy: ±5 mmHg<br>Upper alarm limit: automatic setting between 120 and 300 mmHg<br>Lower alarm limit: automatic setting between 20 and 200 mmHg<br>Alarm window size during treatment: 100 mmHg |
| TMP | $\frac{\text{Return pressure + Pre-filter pressure}}{2}$ - Filtrate pressure<br>Working range: -50 to +450 mmHg, step 1 mmHg<br>Measuring accuracy: ± 10 mmHg<br>Upper alarm limit:<br>CVVH, CVVHD, CVVHDF, SCUF, HP: automatic setting between +30 and +400 mmHg<br>TPE (Plasma therapy): automatic setting between +30 and +100 mmHg<br>Lower alarm limit at - 30 mmHg |

Note: The double star symbol (**) used as subscript for a parameter indicates that the correspondent performance data shown in the table, such as blood flow, filtrate flow, pre- and post- dilution, are considered as essential performance data.

## 7.6 Heater performance data

The Aquarius system has a heater system to warm up the substitution fluid. The programmed temperature range is [OFF; 35°C to 39°C]. To control the heater system, four temperature sensors are used: two are situated on the housing heater plate and two on the degassing chamber holder.

The resulting temperature of the substitution fluid depends on the following conditions:

1. Programmed temperature

2. Substitution fluid rate
3. Substitution fluid temperature in the bag
4. Environment temperature
5. Gas in the heater coil

The relationship between substitution flow rate and maximal heating of the substitution fluid is shown in the following Figure:

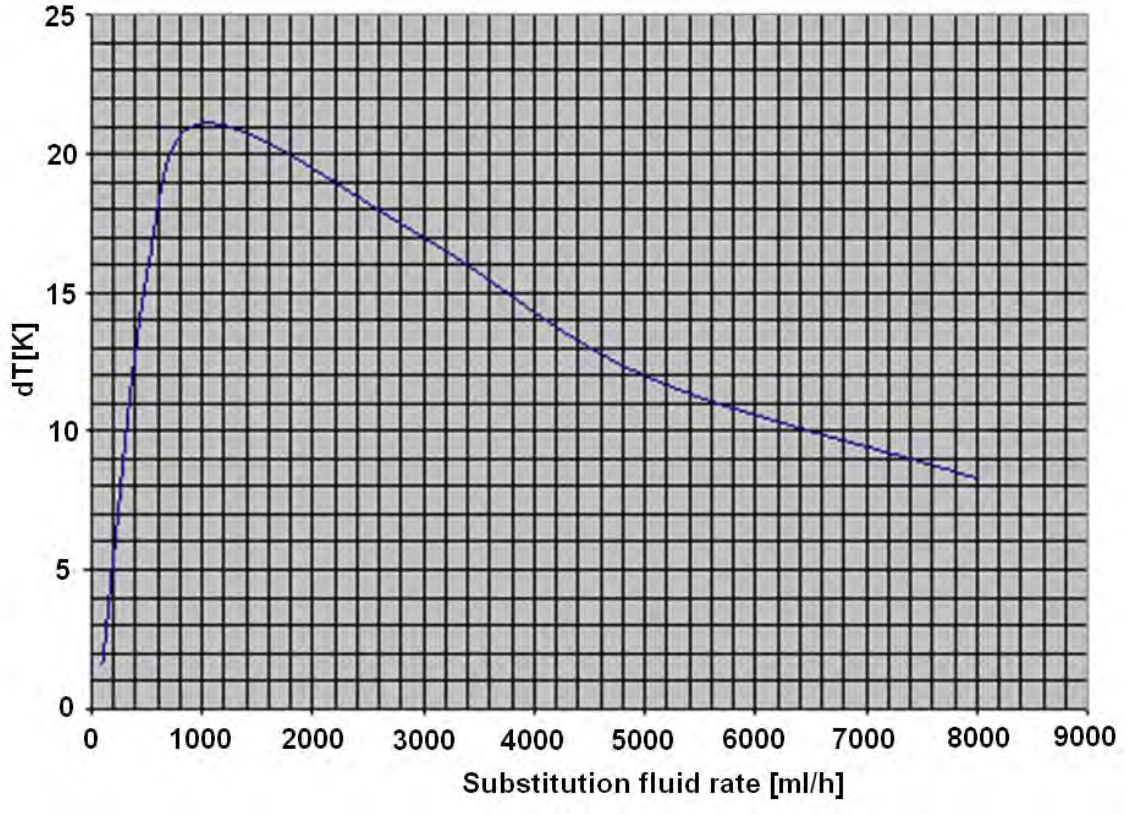



**Figure 175**

This curve describes the amount of degrees the Aquarius system can heat up the substitution solution (Accusol) in dependence of the programmed substitution fluid rate.
Y - axis: Maximum heating capacity achievable by the heater (dT[K])
X - axis: Substitution fluid rate in ml/h

Example:

| Substitution fluid rate: | 3000 ml/h | 3000ml/h | 5000ml/h |
|---|---|---|---|
| Capacity to heat up: | 17°C | 17°C | 12°C |
| Temperature Accusol: | 22°C | 19°C | 22°C |
| Maximum substitution temperature: | 39°C | 36°C | 34°C |

The maximum substitution temperature depends on the programmed temperature and it is limited by the heating capacity described in Figure 175. Due to safeguards designed into the system, the temperature of the fluid infused into the blood and/or dialysate circuit is less than 41°C.

DO NOT rely on the temperature displayed on the More Screen as a basis for clinical assessment of hypothermia or hyperthermia. The accuracy of the calculated substitution fluid temperature displayed on the More Screen is affected by the ambient temperature.

In vitro data shows that, under certain conditions, the temperature of the fluid infused into the blood and/or dialysate circuit can vary by as much as 8°C from the temperature displayed on the More Screen depending on the ambient temperature and substitution flow rates. However, due to safeguards designed into the system, the temperature of the fluid infused into the blood and/or dialysate circuit is less than 41°C.

# 8 Guidance and manufacturer declaration – Electromagnetic emissions

## 8.1 Safety rules – Electromagnetic compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility. In respect of this, the installation and operating notes must be kept in accordance with the guidance and manufacturer declarations.

The emission and the immunity characteristic of the device are in accordance with the requirements for non life-supporting devices in a typical clinical environment under consideration of normal use.

Care should be taken when using portable and mobile radio frequency (RF) communication equipment, such as cellular phones, laptops with W-LAN / Bluetooth and other similar equipment, close to the Aquarius system.

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Unauthorized variations, modifications, reparations, services and the use of unregistered equipment may result in increased emissions and/or decreased immunity of the device, therefore this is not permitted.

## 8.2 Guidance and manufacturer declaration – Electromagnetic emissions and immunity

| *Table I - Guidance and manufacturer declaration- Electromagnetic emission* | | |
|---|---|---|
| The Aquarius system is designed for use in the electromagnetic environments specified below. The operator of the Aquarius system has to ensure that the device is used in such an environment. | | |
| Radiation measurement | Conformity | *Electromagnetic area* |
| RF-Emission (CISPR 11) | Group 1 | The Aquarius system uses RF-energy only for its internal function. Therefore the RF-emissions are very low. It is unlikely, that electronic systems in the area of the Aquarius system are disturbed. |
| RF-Emission (CISPR 11) | Class B | The Aquarius system 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 current emissions (IEC 61000-3-2) | Class A | |
| Voltage fluctuation and flicker (IEC 61000-3-3) | Confirms | |

| *Table II - Guidance and manufacturer declaration- EMC Immunity*<br>The Aquarius system is designed for use in the electromagnetic environments specified below. The operator of the Aquarius system has to ensure that the device is used in such an environment. | | | |
|---|---|---|---|
| Immunity test | IEC 60601-test level | Compliance-Level | Electromagnetic environment – Guidance |
| EMS-Electrical static discharge (IEC 61000-4-2) | ± 6 kV direct-discharge<br>± 8 kV air-discharge | ± 6 kV direct-discharge<br>± 8 kV air-discharge | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| EMS-Bursts (IEC 61000-4-4) | ± 2 kV power supply input lines and PE<br>± 1 kV for input and output lines | ± 2 kV power supply input lines<br>n.a. | Mains power quality should be that of a typical commercial or hospital environment. |
| EMS-Surges (IEC 61000-4-5) | ± 1 kV differential mode<br>± 2 kV common mode | ± 1 kV differential mode<br>± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| EMS-Voltage dips, short interruptions and voltage variations on power supply input lines<br>(IEC 61000-4-11) | < 5% $U_T$<br>(> 95% dip in $U_T$ for ½ cycles)<br>40% $U_T$<br>(60% dip in $U_T$ for 5 cycles)<br>70% $U_T$<br>(30% dip in $U_T$ for 25 cycles)<br>< 5% $U_T$<br>(> 95% dip in $U_T$ for 5 seconds) | < 5% $U_T$<br>(> 95% dip in $U_T$ for ½ cycles)<br>40% $U_T$<br>(60% dip in $U_T$ for 5 cycles)<br>70% $U_T$<br>(30% dip in $U_T$ for 25 cycles)<br>< 5% $U_T$<br>(> 95% dip in $U_T$ for 5 seconds) | Mains power quality should be that of a typical commercial or hospital environment. If the operator of the Aquarius system requires continued operation during power mains interruptions, it is recommended that the Aquarius system be powered from an uninterruptible power supply or a battery. |
| EMS-Power frequency (50/60 Hz) magnetic field<br>(IEC 61000-4-8) | 3 A/m | 3 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. | | | |

*Table III - Guidance and manufacturer declaration- EMC Immunity*

The Aquarius system is designed for use in the electromagnetic environments specified below. The operator of the Aquarius system has to ensure that the device is used in such an environment.

| Immunity test | IEC 60601-test level | Compliance-Level | Electromagnetic environment – guidance |
|---|---|---|---|
| EMS-Conducted Disturbances (IEC 61000-4-6) | 3 $V_{rms}$ 150 kHz to 80 MHz | 3 $V_{rms}$ 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the Aquarius system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br>$d = 1.167 \cdot \sqrt{P}$<br>$d = 1.167 \cdot \sqrt{P}$ for 80 MHz to 800 MHz<br>$d = 2.33 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz<br>Where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer specifications and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| EMS-Radiation (IEC 61000-4-3) | 3 V/m 80 MHz to 2.5 GHz | 3 V/m 80 MHz to 2.5 GHz | |

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2: The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 Aquarius system is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorienting or relocating the Aquarius system.

b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

*Table IV - Recommended separation distances between portable and mobile RF communications and the Aquarius sytem*

The Aquarius system is designed to operate in an electromagnetic environment, in which radiated RF-disturbances are controlled. The customer or the operator of the Aquarius system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aquarius system as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of the transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1.167 \cdot \sqrt{P}$ | 80 MHz to 800 MHz $d = 1.167 \cdot \sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.33 \cdot \sqrt{P}$ |
| 0.01 | 0.1167 | 0.1167 | 0.233 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.167 | 1.167 | 2.33 |
| 10 | 5.30 | 5.30 | 7.4 |
| 100 | 11.67 | 11.67 | 23.33 |

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 transmitters, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: For 80MHz and 800MHZ, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# 9 Aquarius system cleaning and disinfection

## 9.1 Cleaning

The surfaces of the Aquarius system, of the cabinet and the wheeled base may be cleaned with a soft, damp cleaning cloth. For surface disinfection, use a mild standard surface disinfection agent for medical equipment. Follow the instructions of the manufacturer regarding use, concentration, fields of application and safety.
The overlay may be cleaned with a soft, damp cleaning cloth.

## 9.2 Disinfection

The Aquarius system components do not come into contact with the patient's blood. Therefore, disinfection of internal components is not required. Only the tubing sets and the filters have direct blood contact. These items are disposables that are discarded after every treatment.
For surface disinfection, use a standard surface disinfection agent for medical equipment with bactericide, fungicide, or virucide agents.

# 10 Aquarius system warranty and liability

The manufacturer can only guarantee the safety, reliability and performance of the Aquarius system, if the operator follows the instructions contained in this Instructions for Use.

Warranty includes the repair and replacement of defective parts, as long as these are defects due to construction, fabrication and material.

The following actions immediately void the warranty:

- If modifications and repair work of the Aquarius system is done by unauthorized persons.
- If the intended use of the Aquarius system is ignored.
- If the Aquarius system is operated improperly.
- If valid standards regarding electrical installations are not fulfilled.
- If errors or system malfunction is caused by improper operation or normal wear.

# 11 References


Ambalavanan S, R. G., Cheung A: High-efficiency and high-flux haemodialysis. [Online]. 2003.

Bellomo R, P. G., Love J, Boyce N: The use of continuous Haemodiafiltration: an approach to the management of acute renal failure in the critically ill. Am J Nephrol 12:240-245, 1992

Brunet S, Leblanc M, Geadah D, Perent D, Courteau S, Cardinal J: Diffusive and convective solute clearances during continuous renal replacement therapy at various dialysate and ultrafiltration flow rates. Am J Kidney Dis 34:486-492, 1999

Cole L, B. R., Journois D, Davenport P, Baldwin I, Tipping P: High-volume haemofiltration in human septic shock. Intensive Care Med 27(6):978-986, 2001

DiCarlo JV, P. L., Ed. (2001). Paediatric Critical Care Textbook. Stanford University, California, USA.

Ricci Z, Ronco C, Bachetoni A, D'Amico G, Rossi S, Alessandri E, Rocco M, Pietropaoli P: Solute removal during continuous renal replacement therapy in critically ill patients: convection versus diffusion. Crit Care 10:R67, 2006

Ronco C, B. A., Bellomo R: Current technology for continuous renal replacement therapies. Critical Care Nephrology Kluwer:1269-1308, 1998

Ronco C, e. a.: Achievements and New Directions in Continuous Renal Replacement Therapies. New Horizons 3(4), 1995

Vesconi S: Continuous veno-venous haemofiltration in critically ill patients with multiple organ failure. Int J of Artif Organs 16(8):592-598, 1993

Wynckle A, Cornillet J, Bene B, Stolz A, Lepouse C, Paris B, Chanard J: Improved removal of small proteins using continuous hemofiltration to treat acute renal failure. ASAIO J 50:81-84, 2004

NOTICE

The AQUARIUS devices manufactured before 2011 (serial numbers below 5000) are labeled with EDWARDS LIFESCIENCES as the manufacturer.
Nikkiso Europe GmbH acts as manufacturer of the AQUARIUS devices since 1st October 2010. Nikkiso Europe GmbH supports all existing AQUARIUS devices in the market with post market activities.

The Instructions for Use AQUARIUS System software 6.02 published by NIKKISO Europe GmbH is valid for all AQUARIUS devices including devices labeled with EDWARDS LIFESCIENCES if the software 6.02 is installed.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AQUARIUS, REF: GE-F097-00
Instructions for Use Aquarius System
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