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Artis Physio **Plus**

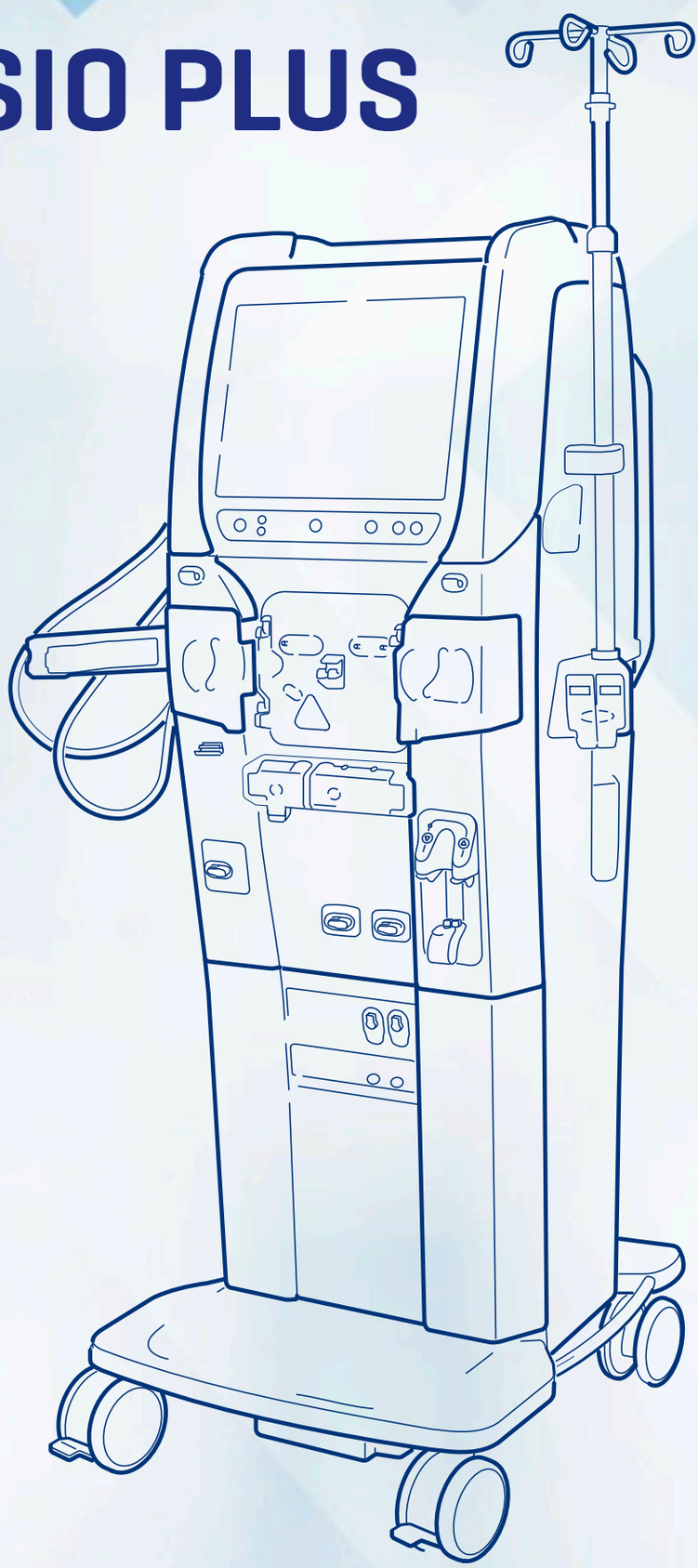
DIALYSIS SYSTEM

How to use the

ARTIS PHYSIO PLUS

Supporting material for the Student

SP01745 SW 9.05



Trainee: _____

Mentor: _____

Important Notice:

This material includes information about the use of the Artis Physio Plus Dialysis System and is provided for facilitating purposes only.

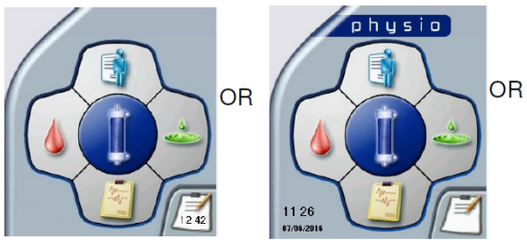
This material shall be used conjointly with the Operator's Manual and the Quick Reference Guide (QRG). The information included in this material does not supersede the information included in the Operator's Manual and in the QRG.

This material does not relieve any user of the Artis Physio Plus Dialysis System from his or her duty to carefully read the full text of the Operator's Manual before using the System.

Reviewing this material does not replace the need for the user to receive the necessary training program before using the System.

Table of contents

Note:
In this manual, the Artis screen figures may contain minor differences (position of date and time, commercial name). These differences are irrelevant for the correctness of the information provided to the operator.



NOTES

Artis Physio Plus SW 9.05

Chapter 1: Introduction and Preparation

Code 903334600
May 2019

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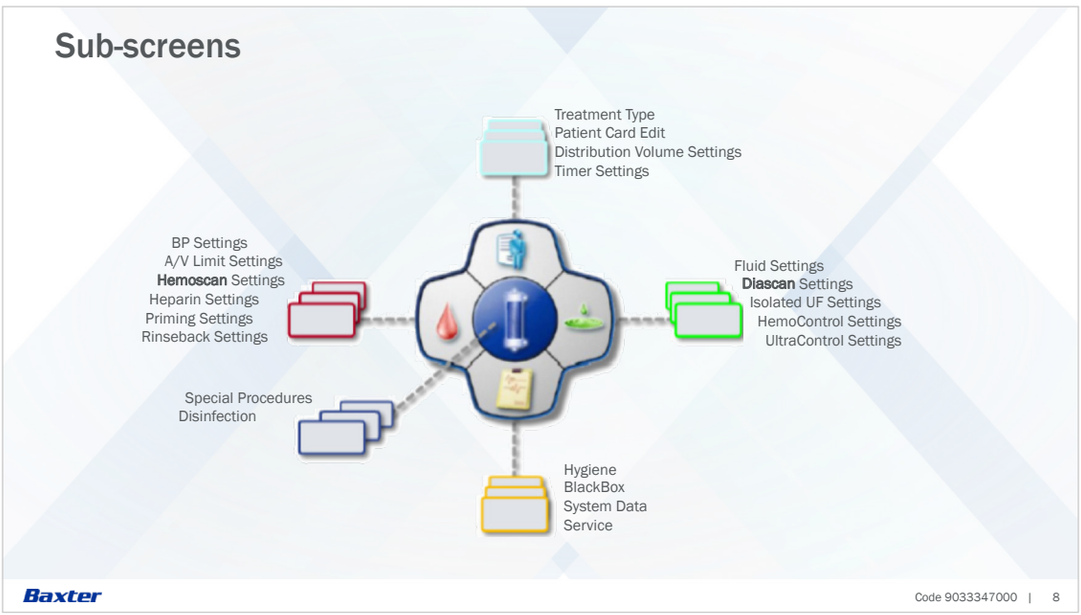
Artis in Practice

- Touch screen
- Intuitive user interface
- **BiCart Select**
- Self-loading blood tubing systems
- EvaClean
- One touch priming
- Alarm status and support

Intuitive User Interface

The NavPad

NOTES


Sub-screens
Treatment Type
Patient Card Edit
Distribution Volume Settings
Timer Settings
BP Settings
A/V Limit Settings
Hemoscan Settings
Heparin Settings
Priming Settings
Rinseback Settings
Fluid Settings
Diascan Settings
Isolated UF Settings
HemoControl Settings
UltraControl Settings
Special Procedures
Disinfection
Hygiene
BlackBox
System Data
Service
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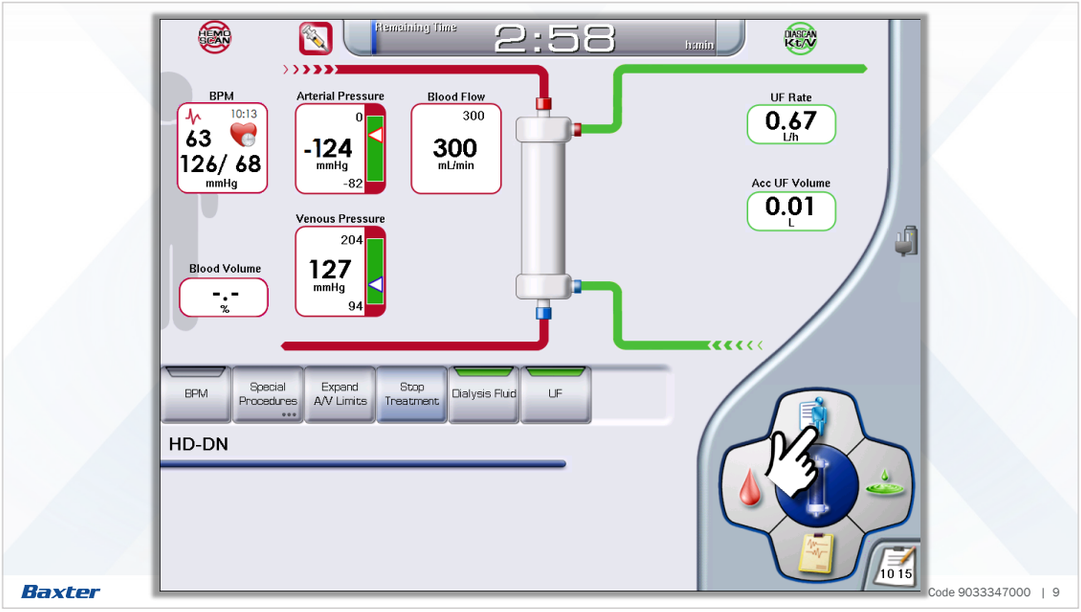
Remaining Time
2:58
h:min
BPM
10:13
63
126/ 68
mmHg
Arterial Pressure
0
-124
mmHg
-82
Blood Flow
300
300
mL/min
UF Rate
0.67
L/h
Acc UF Volume
0.01
L
Venous Pressure
204
127
mmHg
94
Blood Volume
-.-
%
BPM
Special Procedures
Expand A/V Limits
Stop Treatment
Dialysis Fluid
UF
HD-DN
10 15
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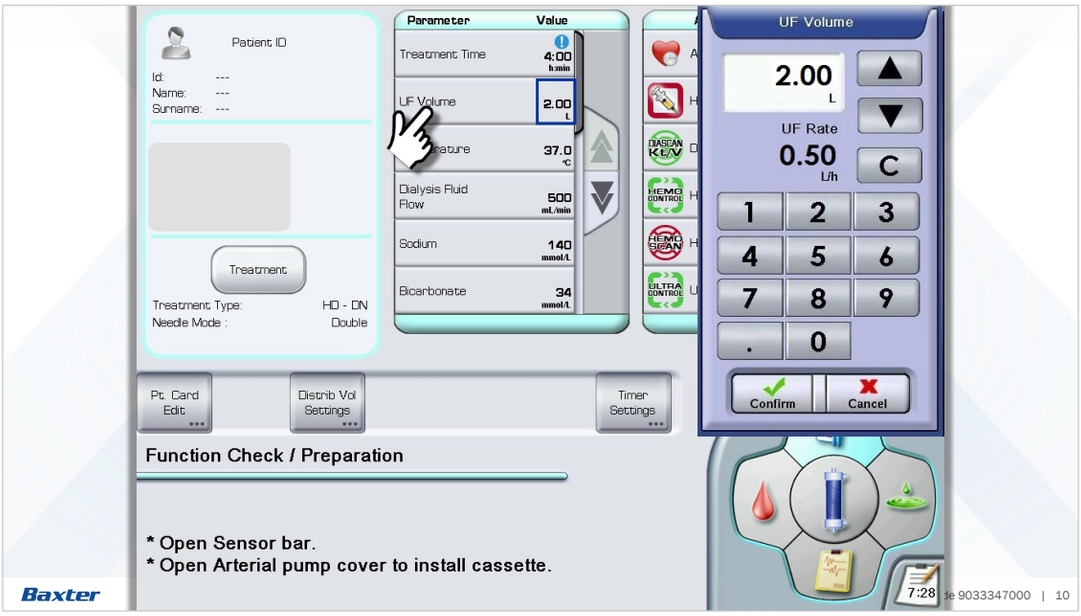
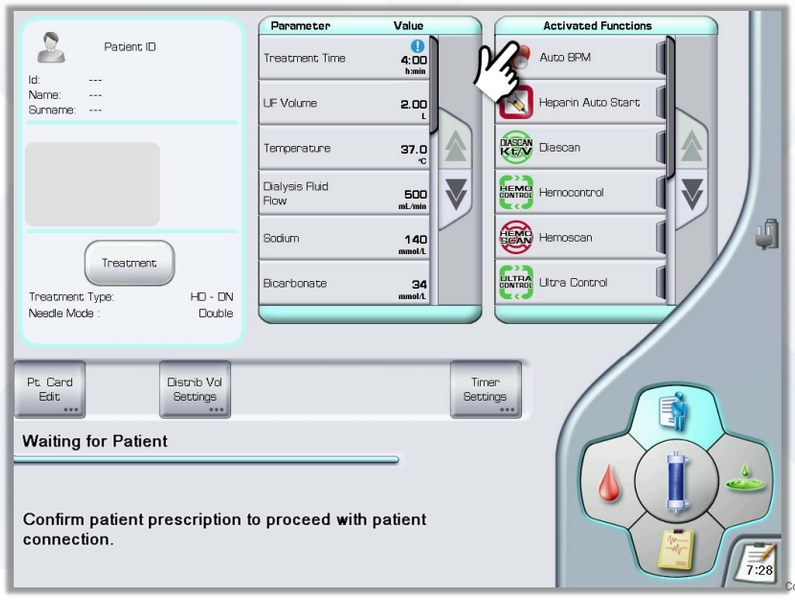
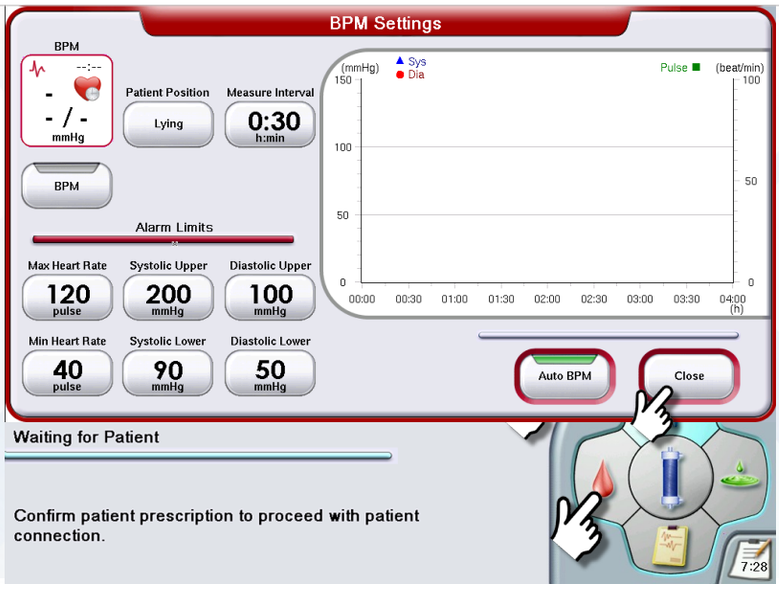
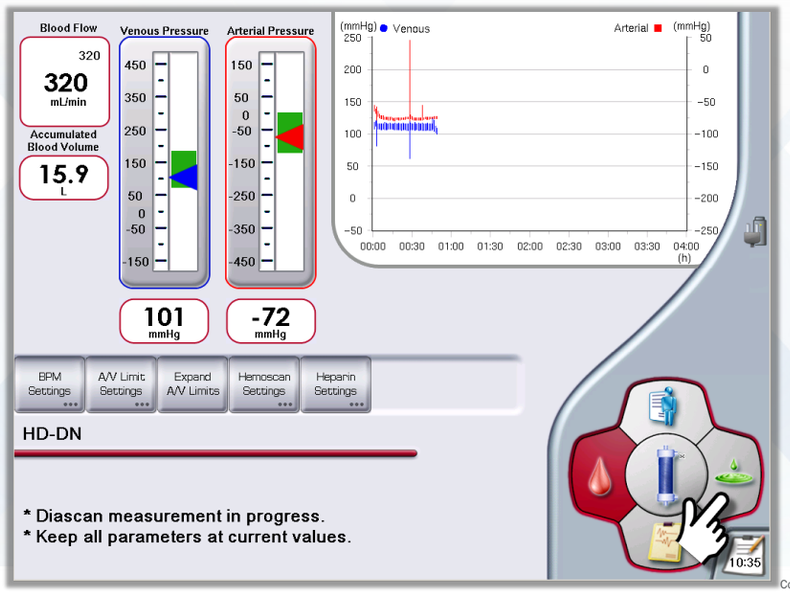

Patient ID
Id: ---
Name: ---
Surname: ---
Treatment
Treatment Type: HD - DN
Needle Mode : Double
Parameter
Value
Treatment Time
4:00
h:min
UF Volume
2.00
L
Temperature
37.0
°C
Dialysis Fluid Flow
500
mL/min
Sodium
140
mmol/L
Bicarbonate
34
mmol/L
UF Volume
2.00
L
UF Rate
0.50
L/h
C
1 2 3
4 5 6
7 8 9
. 0
Confirm
Cancel
Pt. Card Edit
Distrib Vol Settings
Timer Settings
Function Check / Preparation
* Open Sensor bar.
* Open Arterial pump cover to install cassette.
7:28
Baxter
Code 9033347000 | 10

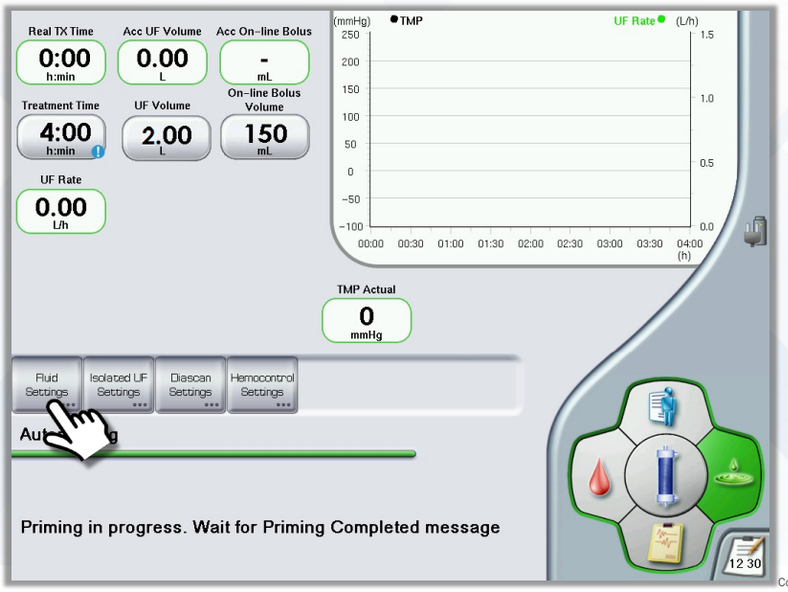
NOTES

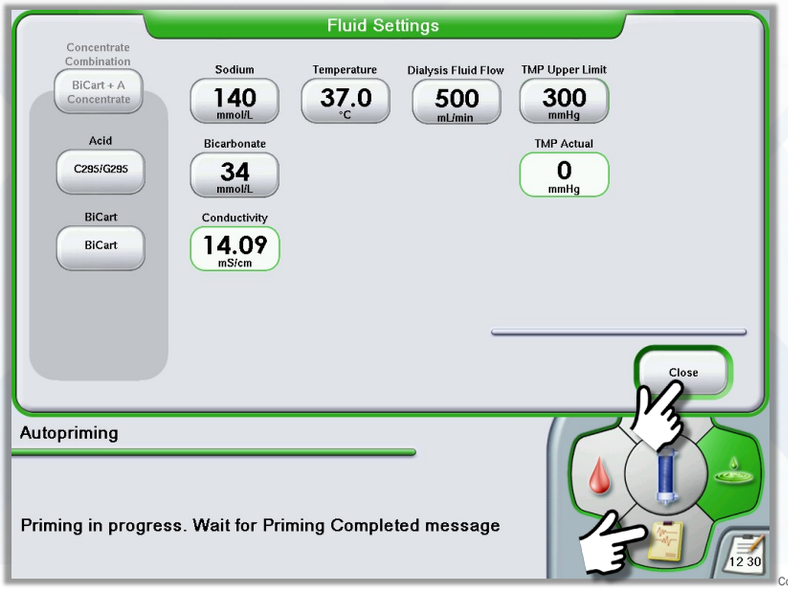

Patient ID
Id: ---
Name: ---
Surname: ---
Treatment
Treatment Type: HD - DN
Needle Mode : Double
Parameter
Value
Treatment Time 4:00 h:min
UF Volume 2.00 L
Temperature 37.0 °C
Dialysis Fluid Flow 500 mL/min
Sodium 140 mmol/L
Bicarbonate 34 mmol/L
Activated Functions
Auto BPM
Heparin Auto Start
Diascan
Hemocontrol
Hemoscan
Ultra Control
Pt. Card Edit
Distrib Vol Settings
Timer Settings
Waiting for Patient
Confirm patient prescription to proceed with patient connection.
7:28

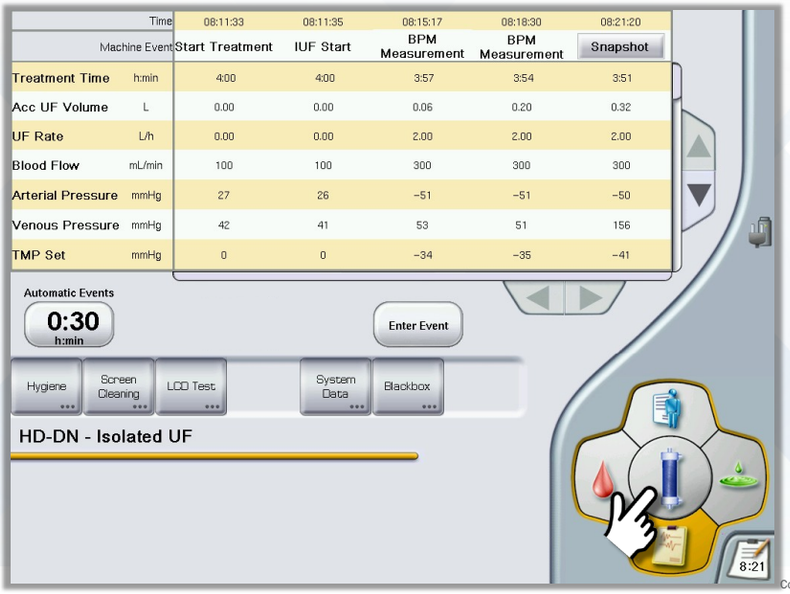

BPM Settings
BPM
--:--
- / -
mmHg
Patient Position
Lying
Measure Interval
0:30
h:min
BPM
Alarm Limits
Max Heart Rate
120
pulse
Systolic Upper
200
mmHg
Diastolic Upper
100
mmHg
Min Heart Rate
40
pulse
Systolic Lower
90
mmHg
Diastolic Lower
50
mmHg
(mmHg) Sys Dia Pulse (beat/min)
Auto BPM
Close
Waiting for Patient
Confirm patient prescription to proceed with patient connection.
7:28


Blood Flow
320
320
mL/min
Accumulated Blood Volume
15.9
L
Venous Pressure
Arterial Pressure
101
mmHg
-72
mmHg
(mmHg) Venous Arterial (mmHg)
BPM Settings
A/V Limit Settings
Expand A/V Limits
Hemoscan Settings
Heparin Settings
HD-DN
* Diascan measurement in progress.
* Keep all parameters at current values.
10:35

NOTES

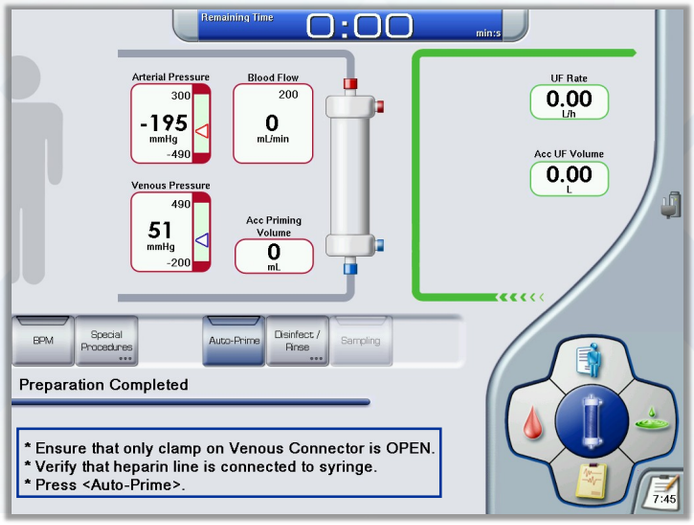

Real TX Time
0:00
h:min
Acc UF Volume
0.00
L
Acc On-line Bolus
-
mL
Treatment Time
4:00
h:min
UF Volume
2.00
L
On-line Bolus Volume
150
mL
UF Rate
0.00
L/h
(mmHg)
TMP
UF Rate
(L/h)
250
200
150
100
50
0
-50
-100
1.5
1.0
0.5
0.0
00:00
00:30
01:00
01:30
02:00
02:30
03:00
03:30
04:00
(h)
TMP Actual
0
mmHg
Fluid Settings
Isolated UF Settings
Diascan Settings
Hemocontrol Settings
Priming in progress. Wait for Priming Completed message
12 30


Fluid Settings
Concentrate Combination
BiCart + A Concentrate
Acid
C295/G295
BiCart
BiCart
Sodium
140
mmol/L
Temperature
37.0
°C
Dialysis Fluid Flow
500
mL/min
TMP Upper Limit
300
mmHg
Bicarbonate
34
mmol/L
TMP Actual
0
mmHg
Conductivity
14.09
mS/cm
Close
Autopriming
Priming in progress. Wait for Priming Completed message
12 30


Time
08:11:33
08:11:35
08:15:17
08:18:30
08:21:20
Machine Event
Start Treatment
IUF Start
BPM Measurement
BPM Measurement
Snapshot
Treatment Time h:min 4:00 4:00 3:57 3:54 3:51
Acc UF Volume L 0.00 0.00 0.06 0.20 0.32
UF Rate L/h 0.00 0.00 2.00 2.00 2.00
Blood Flow mL/min 100 100 300 300 300
Arterial Pressure mmHg 27 26 -51 -51 -50
Venous Pressure mmHg 42 41 53 51 156
TMP Set mmHg 0 0 -34 -35 -41
Automatic Events
0:30
h:min
Enter Event
Hygiene
Screen Cleaning
LCD Test
System Data
Blackbox
HD-DN - Isolated UF
8:21

NOTES

Operator Message Guidance

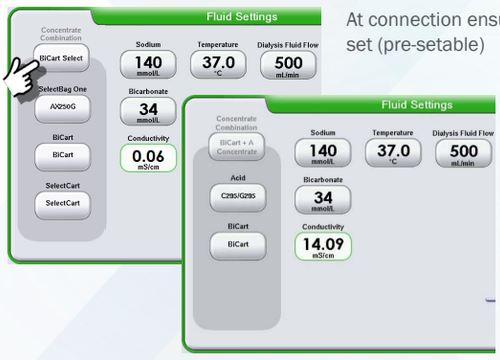


BiCart Select System

Concentrates are prepared on-line during treatment from the:

- The **BiCart** cartridge
- The **SelectCart** cartridge
- The **SelectBag One** container
- The **SelectBag Citrate** container

Concentrate Combinations



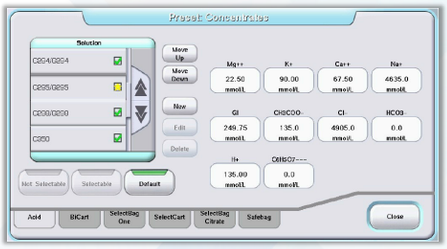
At connection ensure the correct concentrate combination is set (pre-setable)

- BiCart Select System
  - BiCart cartridge, SelectCart cartridge and SelectBag One container
  - BiCart cartridge, SelectCart cartridge and SelectBag Citrate container
- BiCart cartridge + A-concentrate
  - **SoftPac** container
  - Canister
  - Central distribution

After Preparation phase has started, it is no longer possible to change Concentrate Combination

NOTES

Compatibility with SoftPac

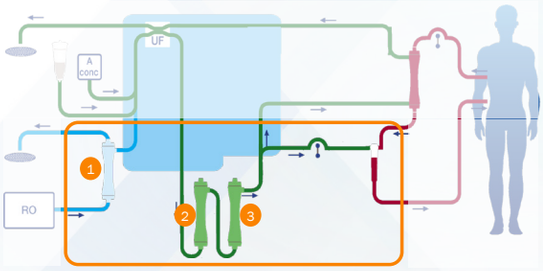


Preset: Concentrates sub-screen

- New compatibility with SoftPac Citrate containers.
- New concentrate combinations are available for the preparation of Dialysis fluid in Bicarbonate mode using SoftPac Citrate containers.
- A fixed number of the SoftPac Citrate container codes have been added to the preset list.

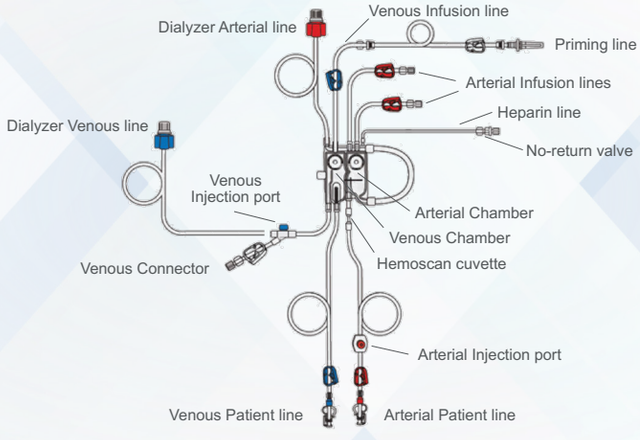
Available SoftPac Citrate							
C140	C150 / G150	C165/ G165	C1540/ G1540	C1550/G1550	C1565/G1565	C1575/ G1575	C240/G240
C250/ G250	C265/G265	C275/ G275	C2540	C2550	C2565/ G2565	C340/ G340	C350/G350
C365/ G365	C375/ G375	C3540/ G3540	C3550	C3565	C450	C465	C2040/ G2040
C2050/ G2050	C2065/ G2065	C2075/G2075	C3050/ G3050	C3065/G3065			

Fluid Circuit | Treatment



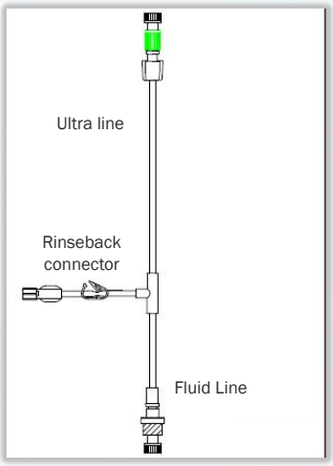
- Single pass fluid system
- Ultrafilters after water inlet and dialysis fluid mixing
- The third Ultrafilter for on-line treatments, previously included in the **ArtiSet** accessories, is now replaced by an internal Ultrafilter equal to the first two ones
- Clearance measurement after the dialyzer

ArtiSet HD DNL HC

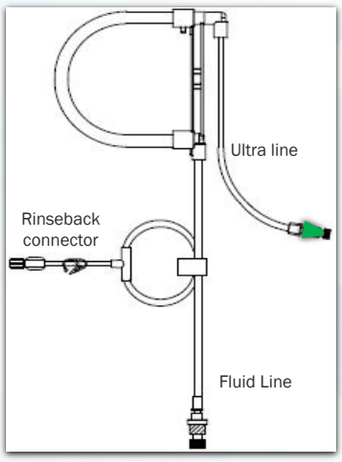


NOTES

Accessories for On-line Treatments



ULTRALINE HD



ULTRALINE HDF

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Bloodlines & Accessories

THERAPY	ARTIS PHYSIO PLUS ArtiSet	Accessory
HDF/HF-PRE HDF-POST	Artiset Pre-Post	ULTRALINE HDF Code: 955599
HDF-POST only	Artiset HD DNL HC or *Artiset Pre-Post*	ULTRALINE HDF Code: 955599
HD-DN with on-line Priming	Artiset HD DNL HC or *Artiset Pre-Post*	ULTRALINE HD Code: 955600
HD-SN with on-line Priming	Artiset HD SN HC	ULTRALINE HD Code: 955600

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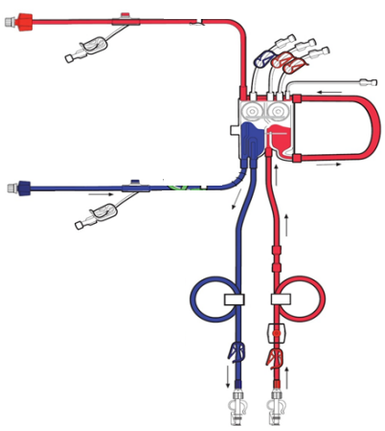
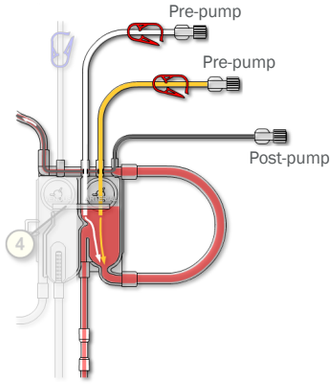
ArtiSet | Venous & Arterial Pathways





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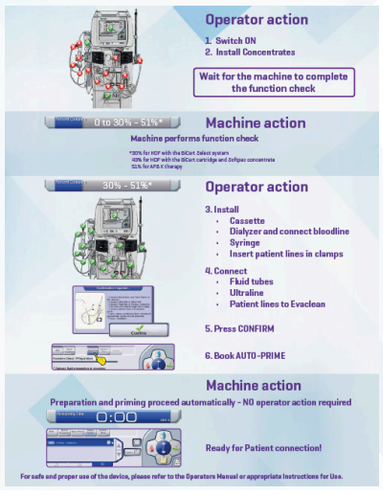
NOTES

Recommended Sequence for Dressing & Priming

The all-in-one sequence

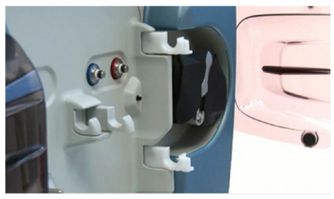
The 2-step sequence



Auto-loading Blood Tubing System

Follow operator's message for:

- Auto-loading of the ArtiSet blood tubing system
- Disposable set up / connections



All disposables are connected in one single series of action

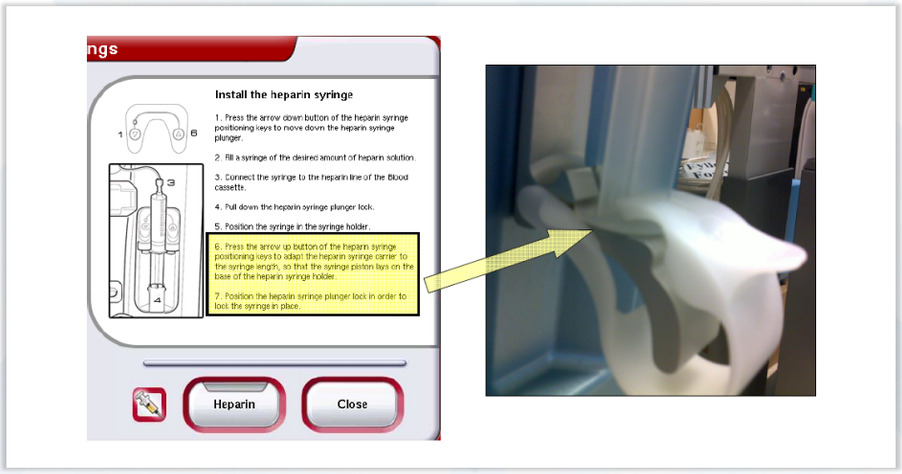
EvaClean

Priming fluid draining device i.e. no waste bag is needed

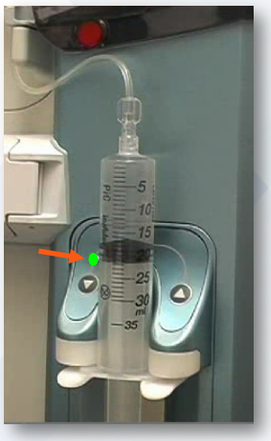
- **Designed to draw fluid** through the blood tubing system – where the A/V patient blood lines are connected
- **Anti-backflow** safety system embedded
- **Automatically disinfected** during the regular disinfection processes

NOTES

Heparin Syringe Installation

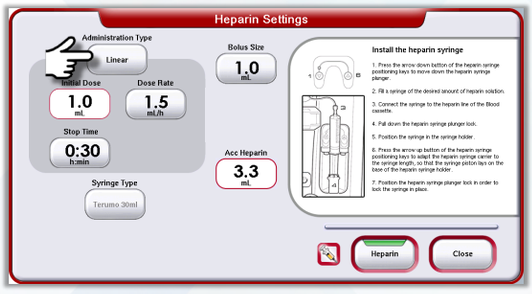


Heparin Administration



- The **heparin line is automatically primed** if the heparin administration function is activated before Auto-Prime starts
- If heparin administration function is *not* activated before Auto-Prime starts, the **heparin line can be primed manually** using the heparin ▲ position key
- During heparin administration the **light indicator on the pump panel is green lit**
- In the **Linear administration mode**, Artis performs a few "kicks" to open the one-way-valve
- The **Initial Dose is administered** when blood enters the arterial dialyzer line (30 ml processed)

Heparin Administration



30cc syringe is standard

Administration types available:

- Linear: range 1.5 to 10 mL/h
- Intermittent: dose range 0.5-12mL
- Manual: range 0.5 to 12mL

10 cc syringe kit (field option)

Administration type available:

- Linear: range 0.5 to 4 mL/h
- Intermittent: dose range 0.5-4mL
- Manual: range 0.5 to 4 mL/h

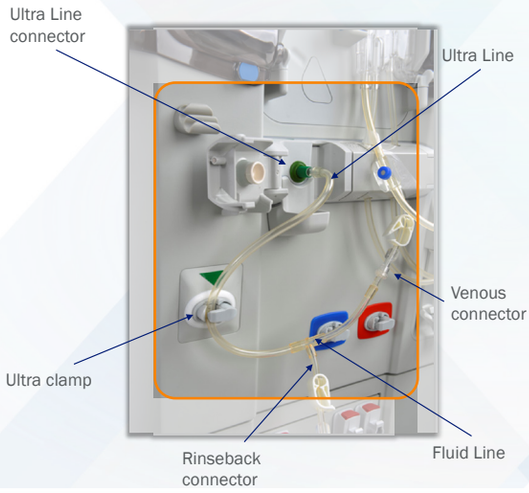
Options available:

- Initial Dose
- Automatic bolus is administered upon the Operator's confirmation (Extra Bolus)

Extra Bolus button becomes available after Start Treatment

NOTES

On-line Autopriming | ULTRA Prime Mode



It is set by default

- Can be changed to saline priming for a specific treatment until the ArtiSet blood tubing system loading procedure has been started (one way procedure).

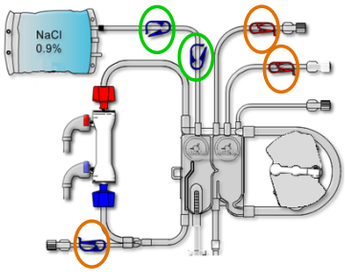
It requires the installation of the ULTRALINE HD.

Follow the operator messages for guidance.

Once the Ultra Prime has been turned off it cannot be switched back on for that treatment

Saline Autopriming | Saline Prime Mode

- Follow the operator messages for guidance;
- Close the venous connector clamp and the two arterial pre-pump infusion line clamps;
- Check that the venous infusion line and the saline line clamps are open.



Saline line is connected to the Venous Infusion line

Autopriming Settings | ULTRA Prime Mode

Treatment	ULTRA	SALINE
HD-DN	850 – 4000 ml	850 – 4000 ml
HD-SN	850 – 4000 ml	1100 – 4000 ml
HDF/HF	1100 – 4000 ml	N/A

Priming volumes are calculated and pre-settable in accordance with the respective dialyzer instruction for use adding a minimum of 500 ml

In ULTRA Prime the minimum priming volume required is 850 ml in HD-DN and HD-SN

NOTES

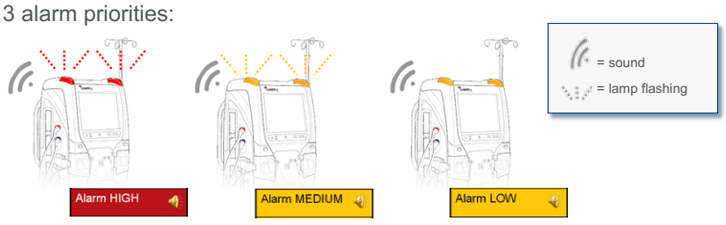
Auto-Prime | One Touch Priming

- Press the **Auto-Prime button** for “booking” automatic start of the priming process – the button indicator bar turns yellow.
- When the **function check is completed**, the automatic priming process starts – the button indicator bar turns green.
- The dialyzer is primed and de-aerated from bottom to top – there is **no need to rotate the dialyzer** during the Auto-Prime process.
- If a dialysis fluid sampling is to be done, the bloodline has not to be loaded.

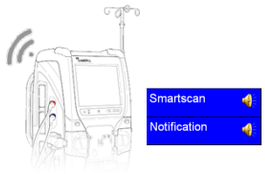
True auto-priming; simply dress, press and leave

Alarm Status & Support at a Glance

3 alarm priorities:



2 info messages:



Alarm messages appearance

Nice to know (1)

- **T1 Test** – Whenever the Artis Physio Plus system is switched on, a series of function checks are performed. If any of these checks fails a resetable alarm is generated. In case a General Safe State alarm appears the Protective System has identified an error preventing the use of the machine – Try to switch the Artis Physio Plus system OFF and then ON again.
- Dialysis fluid **sampling** – It should be performed *before* priming; do not book Auto-Prime when sampling is planned.
- Automatic priming of the **heparin line** – The Artis Physio Plus system performs a series of kicks to open the back valve and prime the line. The volume used is not added to the accumulated heparin volume displayed on the heparin settings screen.
- The **Evodial** dialyzer – Special attention is needed in regards to the Auto-Prime procedure and priming volumes, see Op. Man. section 2.6.

NOTES

Nice to know (2)

- **Differentiating Artis Physio Plus vs. Artis Physio – Artis Physio Plus** is associated with a **GREEN** color used on the logo and packaging of line accessories.

Hands on: Chapter 1.a: On-line Priming

- *Attach concentrates*
- *Attach dialyzer*
- *Load the Artiset tubing system, the ULTRALINE HD and connect lines*
- *Attach heparin syringe*
- *Set heparin prescription:*
  - *Linear 1.0mL/h, Initial Dose 2.0mL, Stop Time15 min)*
- *Clamp status*
- *Ready for priming?*
- *Book on-line Auto-prime*

Hands on: Chapter 1.b: Saline Priming

- *Attach concentrates*
- *Attach dialyzer*
- *Load the Artiset blood tubing system and connect lines*
- *Attach heparin syringe*
- *Set heparin prescription:*
  - *Linear 1.0 mL/h, Initial Dose 2.0 mL, Stop Time 15 min)*
- *Connect saline*
- *Clamp status*
- *Ready for priming?*
- *Book Auto-prime*

NOTES

Artis Physio Plus SW 9.05

Chapter 2: Treatment in Practice

Code 903334600
May 2019

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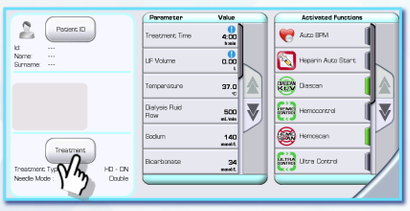
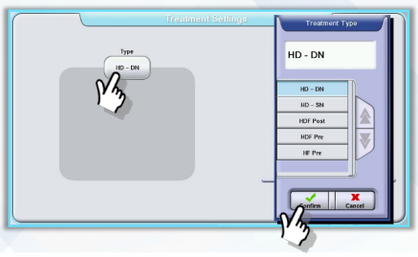
HD Treatment in Practice

- Treatment Type selection
- Prescription
- Time Reminder
- Automatic BPM
- Low Consumption State
- Start Treatment
- A/V Pressure Limit handling
- Stop Treatment
- Auto-Rinseback
- Unload ArtiSet blood tubing system

Treatment Type Selection





NOTES

What if Artis Physio & Artis Physio Plus are Running in the Same Clinic?

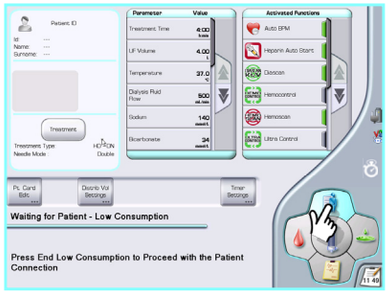
- Artis Physio and Artis Physio Plus can coexist in the same clinic
  - Ideally not in the same treatment room if both configurations deliver on-line HD/HDF treatments (on-line treatment shall be delivered in priority with Artis Physio Plus).
- Handling is identical for non on-line treatments.
- For on-line treatments, the ULTRALINE HDF is designed to prevent its use on the Artis Physio
  - See next slide.

Prescription Settings

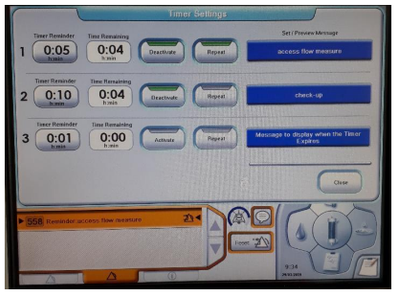
On the **Prescription screen** press:

1. **Parameter buttons** to set treatment related parameters
2. **Function buttons** to access the respective sub-screen for settings and activation.

Time Reminder Options



Prescription screen

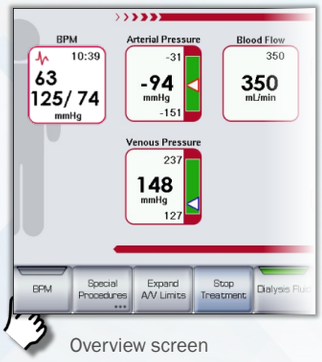


Timer Settings sub-screen

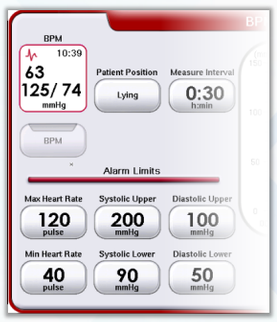
Time countdown starts immediately when the timer is activated

NOTES

Manual Blood Pressure Monitoring



Overview screen



BPM Settings sub-screen

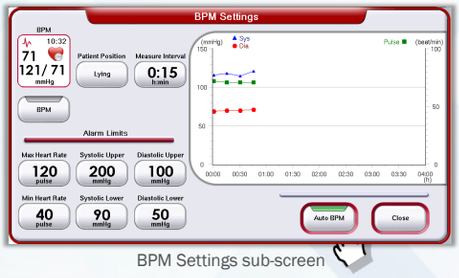
Time, blood pressure and pulse are displayed in the BPM value boxes and in the Event sub-screen tables from the Report screen

Automatic Blood Pressure Monitoring (BPM)

Set:

- Patient position
- Measuring interval
- Alarm limits

When activated, a clock appears on top of the heart icon in the BPM value box



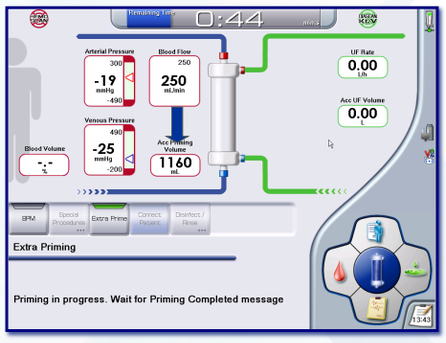
BPM Settings sub-screen

- Auto BPM values are plotted in the trend graph on the BPM Setting sub-screen.
- BPM values are displayed on the Overview screen, the BPM Settings sub-screen and are automatically transferred to the Event sub-screen tables from the Report screen.

Whenever a BPM fails, it is indicated by question marks and an “X” over the heart in the BPM value box

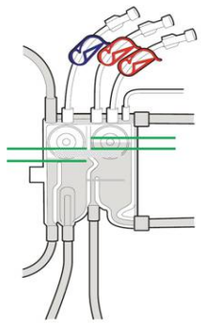
Extra Prime

- During priming, accumulated priming volume is displayed in the **Overview screen**
- Priming setting sub-screen is accessed via the **Blood screen** “Priming Settings” button



NOTES

Chamber Fluid Levels | Auto-Prime Completed



Levels might need to be adjusted at the end of priming due to:

- Empty saline bag during the priming
- Patient lines not properly connected to EvaClean ports
- Infusion line clamps not closed
- Inappropriate priming volume for the dialyzer in use

If the **fluid levels are significantly different** from optimal (extremely low):

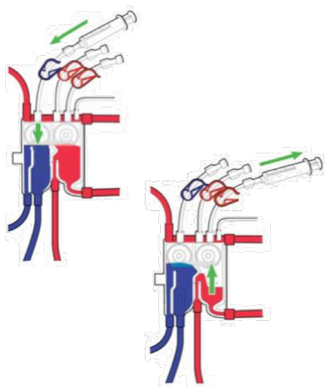
- Reset Prime in the Priming Settings sub-screen and activate Auto-Prime on the Overview screen

If the **fluid levels are *not* significantly different** from optimal:

- Connect Patient and adjust the blood levels manually after treatment start.

If auto-priming is suspected to be inaccurate, Reset Prime and then reactivate the Auto-Prime button (check for sufficient volume in the saline bag first)

Chamber Blood Levels | During Treatment



When adjusting the blood levels in the chambers during treatment:

- Attach a sterile *luer-lock* syringe to the respective chamber infusion line and adjust the level using the syringe
- Expand the A/V pressure limits but *do not* decrease the blood pump speed
- *Gently* aspirate or inject air to increase or decrease the fluid level.

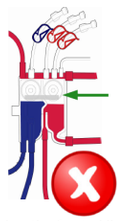
Check and adjust the chamber blood levels on a regular basis during the treatment

Blood Level Monitoring in Arterial Chamber | Simplifying the Message

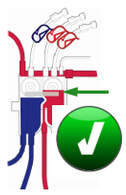
- It is always good practice to **check periodically the level** in the Arterial and Venous chambers;
- The **arterial level monitoring function** is designed to ensure the right level of blood in the cassette; a low level is notified with **Alarm #642**;
- **Incorrect blood level in the Arterial chamber** may lead to formation of micro bubbles and increase the occurrence of Alarm #4;
- Whenever Alarm #642 is triggered:
  1. **Check Arterial level** and proceed with adjustment if needed;
  2. If the level is good, it may be due to poor coupling with transducers; **consider a Cassette repositioning**;
  3. If **Alarm #642 still re-occurs**, consider changing Blood circuit or interrupt treatment; a cleaning/greasing of the pressure transducer is also recommended before installing a new blood circuit.

The alarm must be reset before performing the level adjustment.
The automatic monitoring of the blood level does not work if:

- the blood flow rate <150 ml/min
- the arterial pressure >-50 mmHg



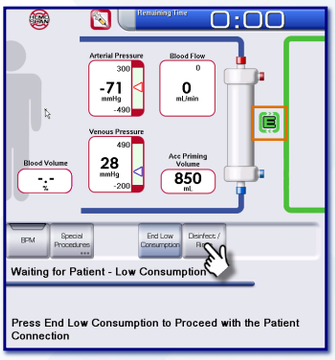
Below the frosted line



Above the frosted line

NOTES

Low Consumption State



Overview screen

- Reduction of water and concentrate consumption
- It should be activated in Service Level 2
- It starts automatically 1-10 min (preset) after priming is completed
- It is stopped via the **"End Low Consumption"** button
- When stopped, the **"Connect Patient"** button becomes available with a short delay.

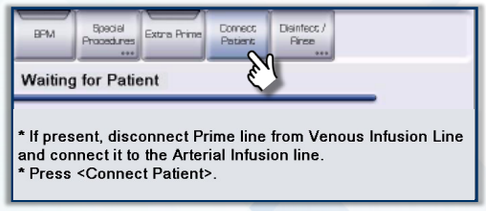
Low consumption state is automatically re-entered if Connect Patient button is not pressed within the preset time limit **PLUS** 5 minutes

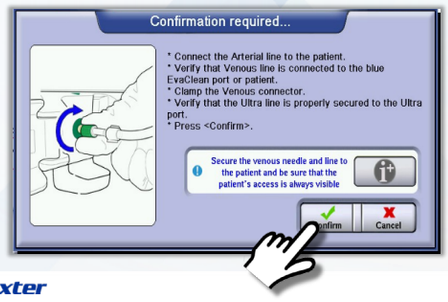
Patient Connection

Connect Patient button becomes available when Mandatory parameters are set and Auto-Prime is completed

► Check that the prescribed functions are activated before continuing

Overview screen



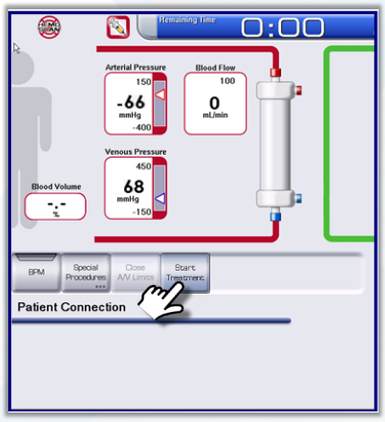


Three Patient Connection options:

- Straight connection (both lines)
- Bleed-out connection with the venous line connected to the EvaClean
- Bleed-out connection with the venous patient line connected to a waste bag

► Confirm *after* connection.

Blood Detection



When blood is detected the **Blood Pump** stops:

Verify that the Arterial and Venous Patient lines are connected to the patient;

► Restart the Blood Pump

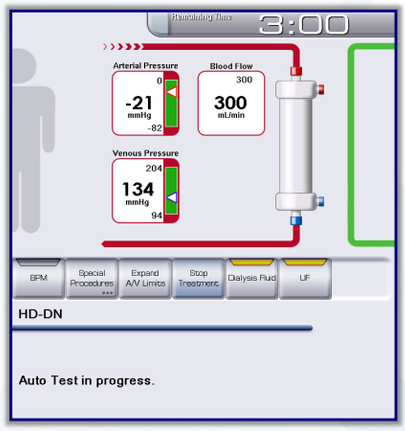
- Start Treatment button becomes available.

NOTES

Start Treatment

- ▶ Press **Start Treatment** button
  - – The Dialysis Fluid and UF buttons are displayed – indication bars are yellow lit
- ▶ Increase the Blood Pump speed
- ▶ Close the A/V pressure Limits when the pressures have stabilized

When the initial self test is completed, Dialysis Fluid and UF are automatically activated (indication bars turn green) and the “Real TX Time” value on the Fluid Screen starts decreasing.



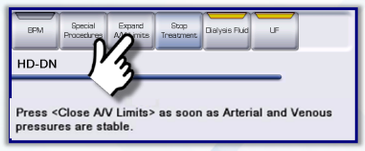
A/V Pressure Limit Handling

At treatment start:

- Follow operator’s message to close the predefined A/V Pressure Limits

During treatment:

- Press Expand A/V Limits to open the pressure limits for a short period of time
- When closing the A/V pressure limits the alarm window automatically adjusts to the current pressures
- The A/V Limits are automatically expanded and closed when the blood pump speed is changed



Overview screen

Blood screen

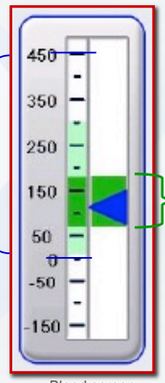
The operator is urged to close the A/V pressure limits if not done within 2 minutes after the “Start Treatment” button is pressed

Expand/Close Pressure Limits

machine upper pV limit

Expand Limits

machine lower pV limit



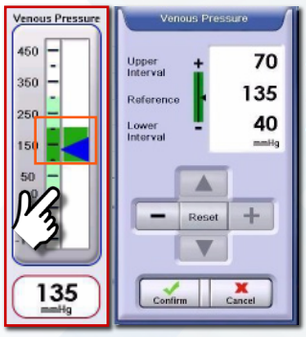
Blood screen

Close Limits

Default values (can not be modified)	mmHg
machine upper pA limit	150
machine lower pA limit	- 400
machine upper pV limit	450
machine lower pV limit	10

NOTES

A/V Pressure Alarm Limit Window



→ alarm limit = reference pressure + upper interval value

→ current value

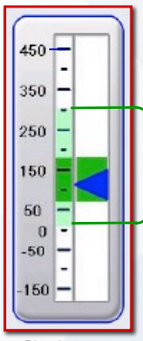
→ alarm limit = reference pressure – lower interval value

+/- to widen/restrict the alarm window

▲ to move the alarm
▼ window up/down

Default values	mmHg
pA upper value	60
pA lower value	-60
pV upper value	70
pV lower value	40

A/V Treatment Max & Min Pressures



Blood screen

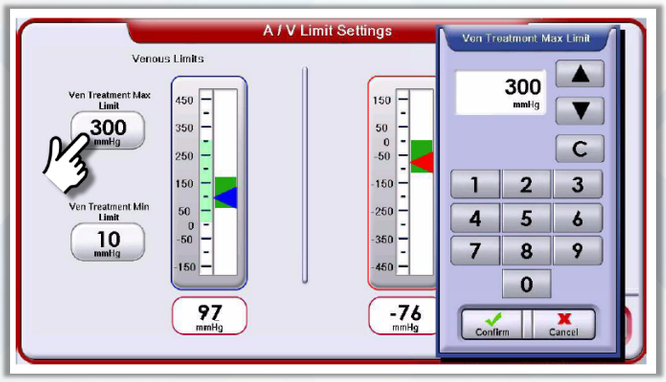
pV treatment max. limit

The range within which the **dark green** "window" may move during the treatment

pV treatment min. limit

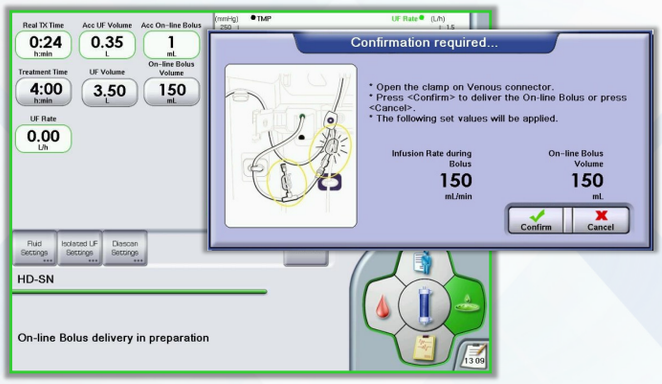
Default values (can be modified in preset)	mmHg
pA treatment max limit	0
pA treatment min limit	- 300
pV treatment max limit	300
pV treatment min limit	10

A/V Treatment Max & Min Pressures



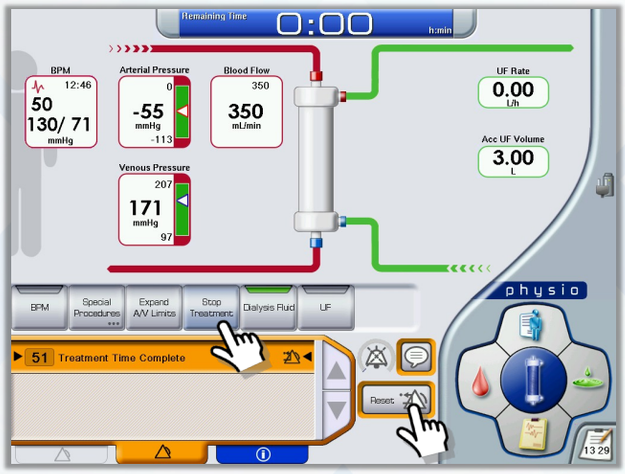
NOTES

On-line Bolus



- On-line bolus is available when Ultra feature is active (Ultra Priming performed). It requires the ULTRALINE HD.
- The operator can set the bolus volume to be infused. The bolus rate can not be changed by the operator.

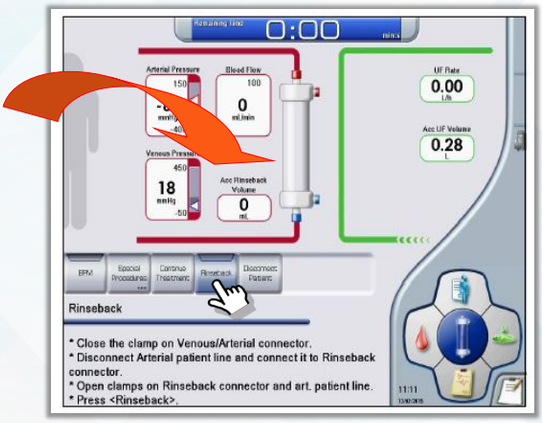
Stop Treatment



Stop Treatment

Follow Operator's Message for Rinseback and Disconnect Patient Procedure

- The accumulated rinseback volume is displayed in the Overview screen
- The Blood pump stops when the set rinseback volume is achieved
  - Blood pump can also be stopped manually
  - Extra Rinseback button becomes available
- Rinseback Settings sub-screen is accessed via the Blood screen



NOTES

Unload Cassette

- ► Press “Unload Cassette” and Confirm
  - – The pump rotor turns to its horizontal position
- ► Release the A/V patient lines and Ultra line from their automatic clamps
- ► Release the heparin syringe and line
- ► Open the Sensor bar door
  - – The cassette hooks are pushed out

Wait for the blood pump to stop before opening the cover

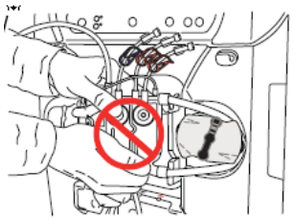
- ► Open the blood pump cover and remove the cassette
- ► Close the Sensor bar door and blood pump cover

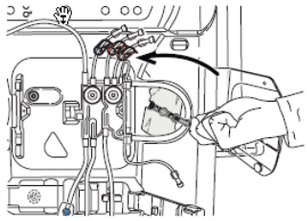
It is possible to activate a Disinfection / Rinse program before unloading the Cassette

Manual Unloading of the Pump Segment

If the pump cover is opened before the blood pump has stopped, the pump segment may not be fully released

Do not remove the cassette with the pump segment still in the pump rotor





- ► Extract the crank from the pump rotor
- ► Manually turn the pump rotor in a counter-clockwise direction while carefully releasing the pump segment
- ► Turn the pump rotor in order to align the crank with its axis and close the crank

Nice to know (1)

- Start Treatment – diffusion and UF start automatically when the initial UF system taration (= self test) is completed.
- Cartridges – do not have to be drained before removal.
- Unloading cassette – do not open the blood pump cover before the pump segment is released.
- EvaClean must be cleaned each time the Patient Connection procedure is performed keeping the venous patient line into the EvaClean port until the machine detects blood.
- The on-line priming sequences are modified in HD and HDF to improve the priming of some large surface area dialyzers, including those with air-permeable membrane.
- The Real Treatment Time and the Temperature Set Value have been added to the report screen.
- UFR for priming can be preset to customize the priming protocol.
- The BPM settings are restored after a Fast recovery.
- Confirmation Pop up of the Heparin settings activation when pressing the <Heparin> button.

NOTES

Nice to know (2)

- Alarm #506 “Flowmeter alignment failure” is changed from a Low to a High priority alarm.
- Alarm #4 “Air in venous line” troubleshooting paragraph of the Operator’s Manual has been updated to explain the reason why certain operations shall be performed.
- Concentrates containing hydrochloric acid – 2 mmol/L – can now be preset and used
- The minimum settable temperature is 34ºC.
- The Fluid Line on the ULTRALINE HD may never be connected to the Arterial connector (pre filter) if present.
- The arterial and venous patient lines are clamped when “Stop Treatment” and “Disconnect Patient” buttons are pressed.
- For the pump segment to be unloaded, the Arterial and Venous Patient lines and the Ultra Line must be released from their respective clamps – do not open the blood pump cover before the pump segment is released.
- Artis Physio and Artis Physio Plus can coexist in the same clinic, but not in the same treatment room if both configurations deliver on-line HD/HDF treatments.

Baxter

Hands on: Chapter 2

- *Treatment time 60 min*
- *UF volume 1.0 L*
- *Heparin program*
- *Auto BPM 15 min*
- *Set two reminders – one on repeat*
- *End low consumption mode*
- *Connect Patient – straight connection*
- *Start Treatment*
- *Stop/Start UF*
- *Stop/Start diffusion*
- *Heparin bolus*
- *On-line bolus*
- *Stop Treatment and Auto-rinseback*
- *Empty Circuit*
- *Unload Artiset blood tubing system*
- *Rinse*

Artis Physio Plus SW 9.05

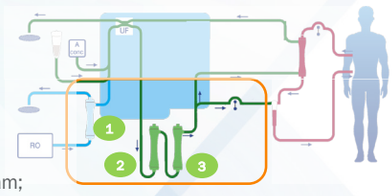
Chapter 3: Hygienic Maintenance

Code 903334600
May 2019

Baxter

NOTES

Ultrafilters on the Artis Physio Plus System

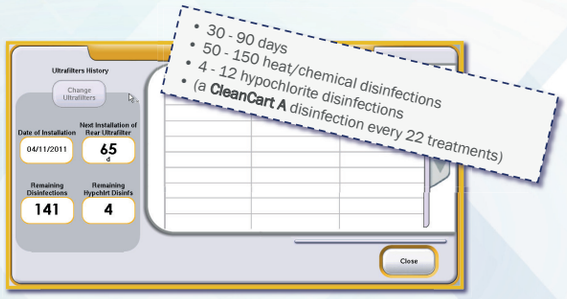


The U9000 Ultrafilters:

- Are disinfected at each disinfection program;
- Life expectancy depends on whichever comes first among:
  - the number of days in the circuit – max 90
  - the number of disinfections – max 150
  - the number of hypochlorite disinfections – max 12;
- Also the number of Heat + **CleanCart A** disinfections is to be considered (i.e., every 22 treatments).
- Are easily replaced (all the three must be changed at the same time);
- Reminder countdown starts 7 days or 12 disinfections or 3 hypochlorite disinfections before usage limit is reached - Alarm #402. An icon will be displayed to raise operator's attention;

When reached, changing the Ultrafilters is a prerequisite to get access to the next treatment – Alarm #571

Ultrafilter Change



- Ultrafilters change procedure is available in the standard environment
- Ultrafilters history table is always available
- Default values for Ultrafilters history counters correspond to the maximum authorized duration

After the Ultrafilters are changed, an Ultra disinfection is automatically started

Available Disinfection Programs (1)

Disinfection Program	Frequency	Cycle Time (min)	Chemical Solution
Heat	Daily – between treatments	34	---
Eco-Heat	Daily – between treatments (but not as the last disinfection of the day)	23	---
Integrated Heat	Synchronized with the water supply cleaning	34	---
Heat CleanCart C	Daily – after the last treatment	50	Citric acid
Heat CleanCart A	Every 22 treatments, in the middle of the working week	50	Sodium carbonate
Chemical (Low Peracetic)	Daily – between treatments	20 Dis. + 33 Rinse	Low peracetic acid
Chemical (Ultra Peracetic)	• Daily – between treatments • After Ultrafilters change	19 Dis. + 42 Rinse	Peracetic acid
Ultra Heat CleanCart C	After Ultrafilters change	85	Citric acid
Chemical (Hypochlorite)	Every 22 treatments	20 Dis. + 109 Rinse	Sodium hypochlorite

Stand-by weekend storage with Peracetic is also available

NOTES

Available Disinfection Programs (2)

Eco Heat disinfection

- intended to be done between treatments
- contributes to reduce the time between treatments
- NOT appropriate as the last disinfection of the day. It can not be the ONLY disinfection program applied to the **Artis** Dialysis System

Ultra disinfections

- are been implemented to maintain the microbiological quality of substitution fluid
- are not regular processes, but they are only mandatory after Ultrafilters change
- can be used in case of:
  - suspected microbial contamination or
  - machine long storage
- Perform an Ultra disinfection program if more than 7 days have elapsed after last disinfection was performed

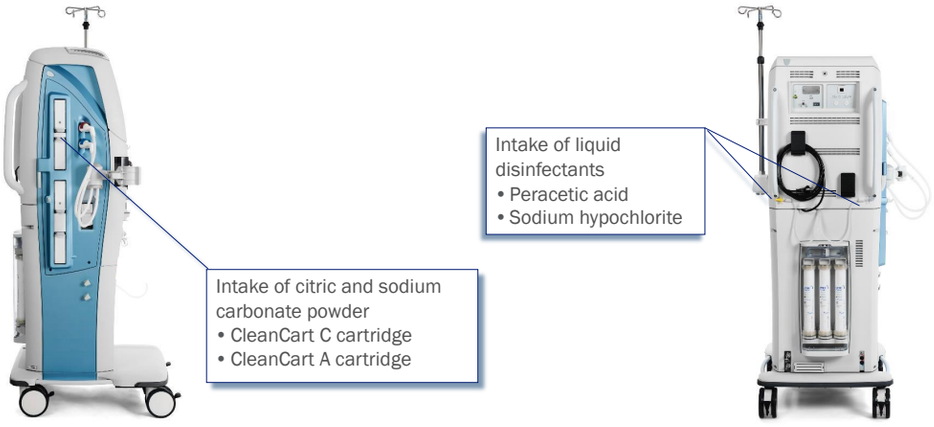
Good to know:
The alarm #678 “Disinfection required before treatment” is displayed when more than 72 hours elapsed since the last dsinfection has been performed, or the disinfection after the previous treatment has not been properly performed

pH Sensor Option

The pH sensor usage is ***highly recommended*** when ***sodium hypochlorite*** is included in the clinic’s policies and procedures for e.g.:

- Disinfection of machines
- Maintenance of the water plant
- Maintenance of the central concentrate delivery system

Disinfection | Heat/Chemical



NOTES

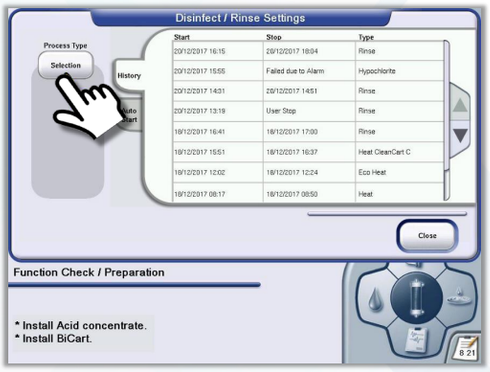
Disinfection / Rinse Settings

Overview screen

Program selection (Process Type button)

- History table
- Auto Start table

(Service Mode, level 1 & 2)



This screen is not available during treatments

The manual Rinse program may be interrupted if needed

Post Treatment Cleaning

Machine surfaces and components

- See table in Operator's Manual (Ethanol 60 or 70%, Isopropanol 60%, sodium hypochlorite 1.5%, liquid soap)
- Touch screen: Only Ethanol 60 or 70%, or Isopropanol 60%

EvaClean ports*

- Using a priming connector (and luer-lock syringe) - insert 15cc undiluted bleach (5.25 – 6 % sodium hypochlorite) into each EvaClean port when Artis is ON
- Perform a disinfection/rinse program in order to rinse out the undiluted bleach
- Disinfect the external surface of the EvaClean ports

* *Always clean the EvaClean ports each time the Patient Connection procedure is performed keeping the venous patient line into the EvaClean port until the machine detects blood, or if blood has accidentally entered any of the ports*

New Design of the Ultra Door

The Ultra door is designed to ensure automatic disinfection of the external luer connector during machine disinfections.

Hence, the Ultra Port **shall not** be cleaned any longer after a disinfection program.

The collector below the ultra port needs to be kept dry and free of any fluid.

NOTES

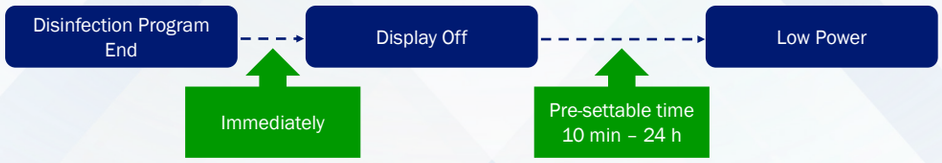
Display Off Mode

After a rinse or disinfection program, the Touch Screen immediately switches off:

- The On/Off indicator LED is lit **green**
- The machine is still powered (i.e. automatic clamps are still open)

Press the On/Off key on the hard key panel to start the Artis Physio Plus system

The Artis Physio Plus system will then start the self-test procedures



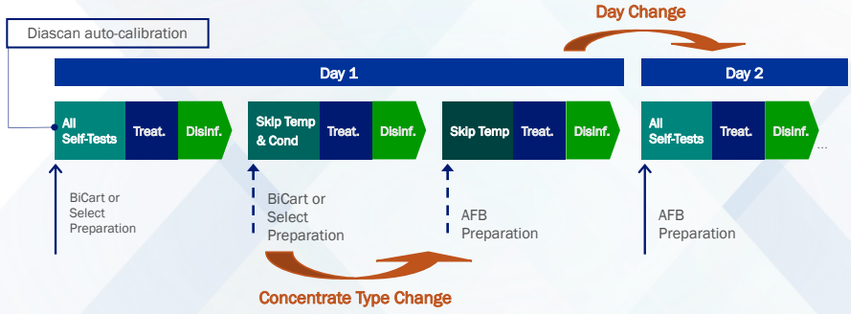
Low Power Mode

- The Hard Key panel On/Off key is lit (**green**)
- The Main Switch On indicator is **not** lit

- Press the On/Off key on the hard key panel to "wake up" the machine
- The machine will *boot-up and load the software* before it enables the start of preparation

To wake up the Artis Physio Plus system from the low power mode after a scheduled program, it may be necessary to press the On/Off key twice

Mean Time Between Treatments (MTBT)



If the machine is properly configured:

- Temperature self tests are skipped for the following three treatments in the same day;
- Conductivity self tests are skipped when same concentrate combination is used

3-5 minutes time reduction between treatments

NOTES

Auto Start Option

Automatic start scheduling of:

- Disinfection
- Rinse
- Preparation

Maximum 3 programs per day

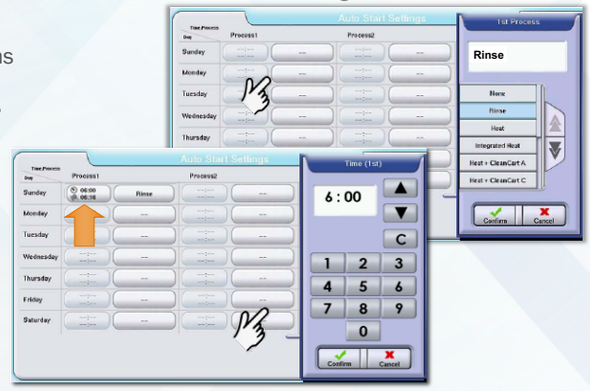
Conditions for Auto Start:

- The machine is either in display off or in low power (main switch ON)
- Within 48 hours after the machine has entered the low power mode
- Water supply must be connected
- Appropriate disinfectant connected

The Auto Start programs scheduled are displayed in the Disinfection/Rinse Setting screen

Auto Start Settings Screen

- Enter Service Level 1, code: 169000, to access the Auto Start settings screen via the Default Settings list
- The Select pad offers 6 programs
- When the program is confirmed, its Start Time button becomes available
- Set the Start Time and Confirm, the End Time is automatically calculated.
- Start and End time is displayed on the button



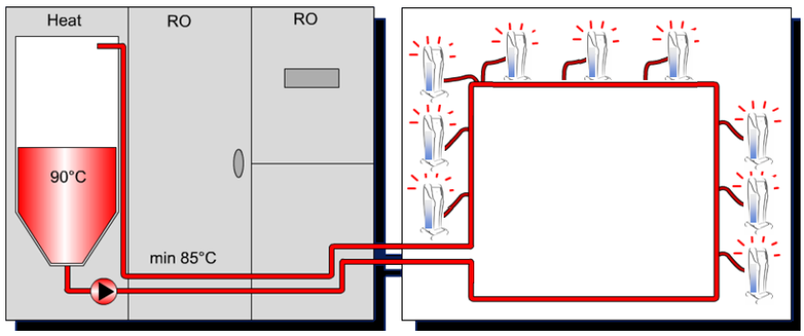
Auto Start can be preset before Auto-Prime start and after disinfection/rinse

Nice to know | Auto Start

- Verify set date and time on the Artis Physio Plus system before Auto Start is scheduled.
- If the On/Off key is pressed when the Artis Physio Plus system is in Display Off or Low Power mode, preparation starts and the scheduled program is aborted.
- If the Artis Physio Plus system Main Switch is turned OFF, the scheduled program is aborted. The alarm 562 will then appear when the Main Switch is turned ON again.
- In case of short power failure (less than 5 minutes), the scheduled program is anyway completed.
- In case of long power failure (more than 5 minutes), the scheduled program is never completed. The alarm 562 will then appear when the Main Switch is turned ON again.
- If the "Blood in dialysate (#28)" alarm occurs and the identified cause is "A break in the dialyzer membrane caused a blood leakage into the hydraulic circuit", perform a disinfection program before starting a new treatment.

NOTES

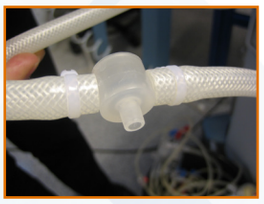
Integrated Heat Disinfection



It is possible to perform an integrated heat disinfection with the Central Water Plant (CWP).

Chemical Disinfection Residual Test

- Collect a test sample for disinfection residuals from the dialysis fluid tube port *before attaching concentrates* when the Artis Physio Plus system is disinfected with **sodium hypochlorite**.
- Collect a test sample for disinfection residuals from the dialysis fluid tube port *before connecting the patient* when the Artis Physio Plus system is disinfected with **peracetic acid**.
- When using the CleanCart C or A cartridges, no residual test needs to be performed.



Greasing of the Pressure Pod O-rings

To maintain the O-ring sealing capacity:

- Inspect the O-ring's surface and metal stem
  - Check for nicks, damage, wear, etc.
  - Replace if necessary
- Grease the O-ring's surface by applying a very thin layer of silicon grease, avoiding any grease entering the metal stem inside
  - Silicon grease tube spare part code 6975395
  - Grease dispenser spare part code 6977854
  - It is also possible to apply the grease by the use of a finger

This procedure should be performed on a weekly basis

NOTES

Hands on: Chapter 3

- *Chemical residual test*
- *Disinfection programs*
- *Disinfection history list*
- *Pressure Pod greasing*
- *Auto Start Settings*
- *Ultrafilter change*

Artis Physio Plus SW 9.05

Chapter 4: Functions in practice

Code 903334600
May 2019

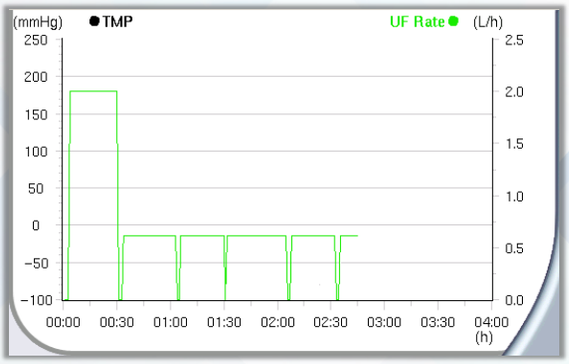
Baxter

Functions in Practice

- Isolated UF
- The **Hemoscan** function
- The **Diascan** function

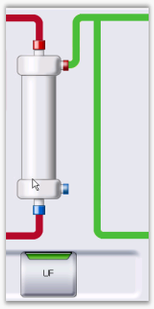
NOTES

Isolated UF



Fluid screen

Isolated UF



Overview screen

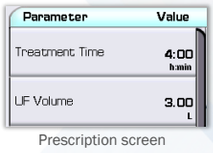
Separate phase:

- Can be activated and repeated at any time from start to stop treatment
- Max 120 min
- Max UFR 3 L/h

No diffusion, therefore

- Limited solute removal
- No electrolyte or base balance correction

Isolated UF Activation

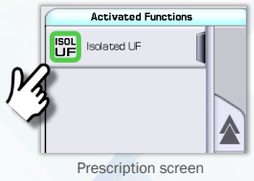


Prescription screen

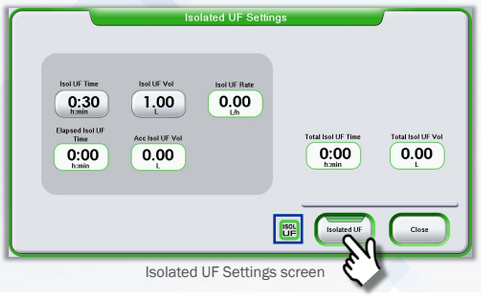
Set mandatory parameters:

- ▶ Treatment Time - ***Includes Isol. UF time***
- ▶ UF Volume - ***Includes Isol. UF volume***

Select Isolated UF function → →



Prescription screen



Isolated UF Settings screen

Set Isolated UF parameters:

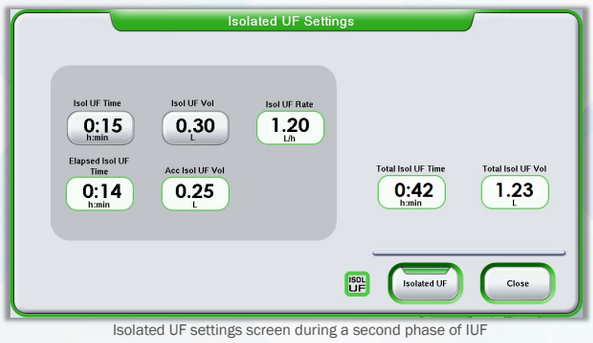
- ▶ Isolated UF Time
- ▶ Isolated UF Volume

- ▶ Activate

NOTES

Isolated UF Activation

It is possible to activate an Isolated UF phase at any point during the treatment.



Isolated UF settings screen during a second phase of IUF

When activated at the end of the treatment, treatment time and UF volume must be added in the prescription screen

Isolated UF Completed Alarm

Indicates:

- Set Isolated UF Time is completed
- No UF takes place
- No diffusion takes place

Diffusion and UF starts as soon as the alarm is reset

Isolated UF Completed

UF Volume Confirmation is Required

- The UF rate displayed on the key pad is calculated accordingly:

$$\text{Remaining UF Rate} = \frac{\text{Total UF Vol.} - \text{Acc. Isolated UF Vol.}}{\text{Remaining treatment time}}$$

Treatment time and/or UF Volume can be adjusted in the Fluid screen if needed

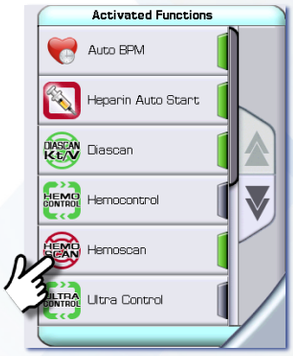
The treatment continues at the displayed UF rate when confirmed

NOTES

Nice to know | Isolated UF

- The mandatory parameters must be confirmed before the Isolated UF parameters can be set.
- When the prescription downloaded via the Patient Prescription card or the Patient ID card (Exalis) is confirmed, the exclamation mark on the UF volume set button disappears.
- The Isolated UF parameters should be included in the Treatment time and the UF Volume.
- The Isolated UF time must be set before the Isolated UF Volume.
- The Isolated UF must be deactivated to be able to activate any Special Procedures.
- Until the “Isolated UF completed” alarm is reset, no UF and no diffusion take place.
- Isolated UF is not resumed after “Pause Treatment” or “Change Circuit” procedures.

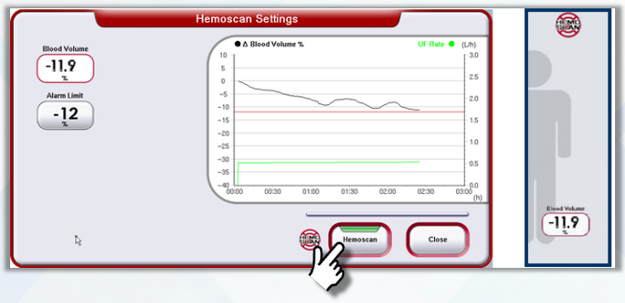
The Hemoscan Function in Practice



- The Hemoscan Monitoring System provides a continuous and non-invasive measurement of the relative blood volume change during a dialysis treatment.
- Self-test is performed on machine start up.
- Autocalibration is performed when the ArtiSet blood tubing system is loaded.
- The Hemoscan function must be activated before Start Treatment.

The Hemoscan function can be activated by preset

The Hemoscan Function During Treatment



- Blood Volume values are displayed on Hemoscan Settings sub-screen and *Overview* screen
- Blood Volume Alarm Limit can be set
- Blood Volume changes and UF rate are plotted in the trend graph.

NOTES

Nice to know | The Hemoscan Function

- To pass the Hemoscan function self-test at machine startup, the Artiset blood tubing system must be loaded with the Hemoscan cuvette properly inserted in the arterial sensor bar slot.
- If the Hemoscan function self-test fails, the setup procedure continues but the Hemoscan function is not activated (alarm).
- Whenever an ArtiSet blood tubing system is loaded, a Hemoscan auto calibration is performed. If the auto calibration fails an alarm is triggered, deactivate the Hemoscan function to solve the alarm.
- When the Hemoscan function is activated, the Auto-Prime button becomes available when calibration of the Hemoscan sensor is performed.
- At treatment start a reference hemoglobin concentration value is calculated – the first BV value is displayed appr. 6-7 minutes after treatment start.
- After a Fast Recovery procedure, the Hemoscan function is automatically deactivated.
- To properly measure blood volume, blood flow >180 ml/min and hemoglobin range 6-16g/dl are needed.

The Diascan Function in Practice

The Diascan Monitoring System allows real time, non-invasive and automatic monitoring of patient's and dialyzer's parameters that can be computed from conductivity measurements on the dialysis fluid side.

Availability:

- HD-DN / HD-SN* /HD-DNDP
- HDF-post / HDF Pre
- HemoControl treatment
- AFBK treatment (constant K)
- Hemoscan function
- Isolated UF

Must be activated before treatment start

- May be activated by preset

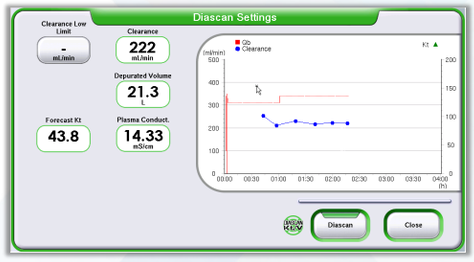
Measurement starts when Qb is ≥ 80 ml/min

- Measuring interval is 15 or 30 minutes

Once deactivated, the Diascan function cannot be activated again for the rest of the treatment

 *accuracy is not guaranteed

The Diascan Function Settings Sub-screen | Clearance



Rule of thumb: an adequate clearance should be at least 55% of the Qb – a SmartScan note will alert the operator is this level is not reached

Available set buttons:

- Clearance Low Limit (ml/min)

Values boxes:

- Clearance (actual)
- Depurated Volume (= Kt)
- Forecast Kt
- Plasma conductivity

Graph parameters:

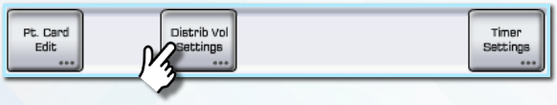
- Blood flow (Qb)
- Clearance
- Kt (depurated volume)

Updated during treatment:

- "Forecast Kt" value each minute
- "Clearance" and "Forecast Kt" after each measurement

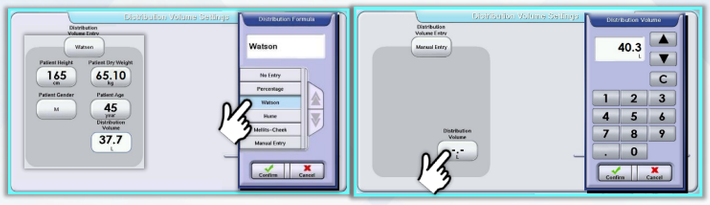
NOTES

Patient Distribution Volume



Needs to be calculated/confirmed for:

- The **Diascan** function Kt/V measurements
- The **HemoControl** function plasma sodium calculation



The **Diascan** Function Settings Sub-screen | Kt/V

Available set buttons:

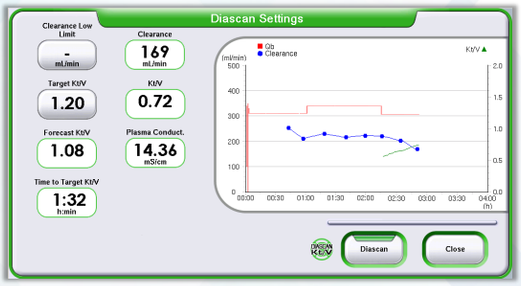
- Clearance low limit
- Target Kt/V

Value boxes:

- Clearance
- Kt/V (actual)
- Forecast Kt/V
- Time to target Kt/V
- Plasma conductivity

Graph parameters:

- Blood flow (Qb)
- Clearance
- Kt/V



Nice to know | The Diascan Function

- In case of an Autocalibration Failure alarm: switch OFF → wait 5 sec → switch ON, or deactivate the Diascan function.
- During measurements, the inlet conductivity is automatically adjusted by 1.0 mS/cm typically for 2 minutes.
- The Diascan function measurements will be interrupted if parameters directly affecting the measurement are changed (i.e. Qb, Qd, Na).
- If no Clearance Low Limit is set, a SmartScan notification will appear when clearance becomes less than 55% of the blood flow.
- A SmartScan notification is triggered in case the Forecast Kt/V measurement value is below the Target Kt/V.
- The Operator is alerted via a yellow alarm if a Diascan function measurement fails.
- After a Fast Recovery procedure, the Diascan function is automatically deactivated.

NOTES

Hands on: Chapter 4

- Set up HD double needle
- Treatment time 90 min,
- UF volume 2.5 L
- Heparin - linear
- Distribution volume
- The Diascan function
- The Hemoscan function
- Isolated UF – time 45 min, UF volume 1L
- Start treatment
- End treatment procedure

Artis Physio Plus SW 9.05

Chapter 5: Troubleshooting

Code 903334600
May 2019

Baxter

Troubleshooting

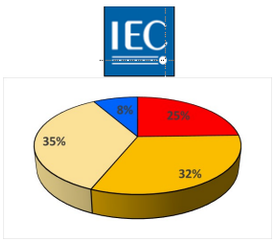
- Alarm Management
- Air in Venous Line Alarm
- A/V Pressure Alarm
- Malfunction Alarms
- SmartScan

NOTES

Alarm Classes & Distribution

Classes	Alarm Priority	Display Color	Sound	Light appearance
High	HIGH	RED	High sound 10 pulses/7sec	RED Flashing
Medium	MEDIUM	YELLOW	Med Sound 3 pulses/7sec	YELLOW Flashing
Low	LOW	YELLOW	Low sound 2 pulses/17sec	YELLOW Constant
Notification	N/A	BLUE	Tune every 90 sec	N/A
Smartscan	N/A	BLUE	Tune every 90 sec	N/A

GUI text, sound and light are in compliance with the IEC 60601-1-8 standard



Smart Alarm Management

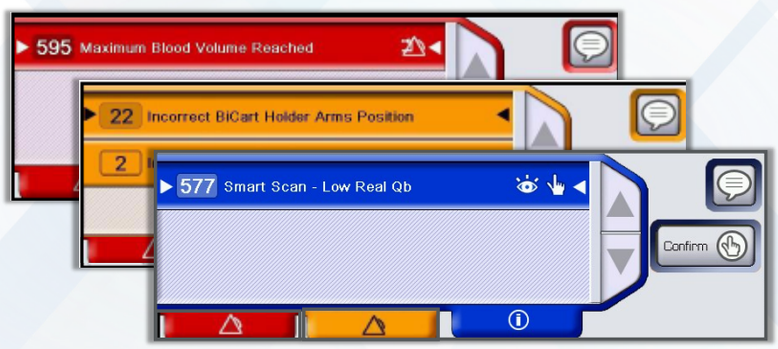
The **alarm code** and **message** displayed may include several related alarm codes.

Examples to the right:

- BiCart cartridge empty (#21)
- Acid/Acetate Concentrate Container Empty (#1)

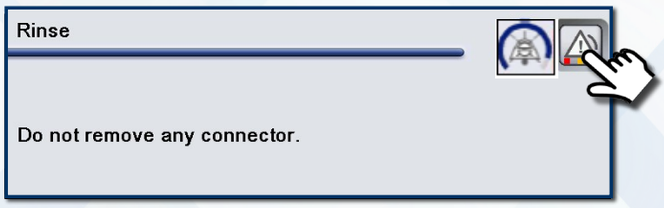
Root Alarm	Related Alarms
BiCart cartridge empty (#21)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag Concentrate Error (#369) • Bicarbonate/Safebag Concentrate Error (#370) } Dialysis fluid temp too low (#461) • Dialysate pH low (#368) • Dialysate pH high (#40) • Bicarbonate/K Conductivity too Low (#464) • Incorrect fluid conductivity detected (#496) • Select Concentrate Error (#590)
Acid/Acetate Concentrate Container Empty (#1)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag Concentrate Error (#369) • Bicarbonate/Safebag Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) • Dialysate pH high (#40) • Bicarbonate/K Conductivity too Low (#464) • Incorrect fluid conductivity detected (#496)

Alarm Appearance



NOTES

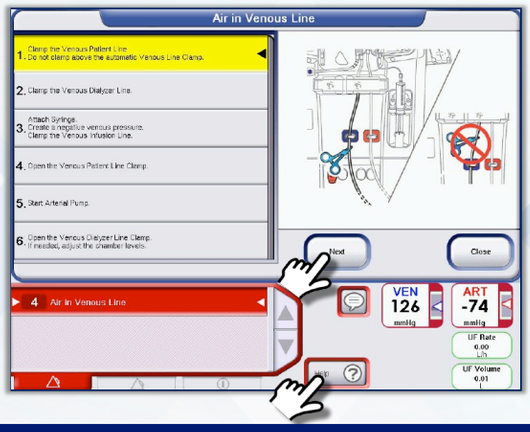
Alarm Management



Mute icon with 2 minute progress bar

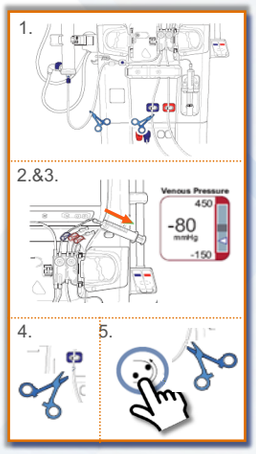
Only a blood leak alarm can be overridden

Alarm Help-on-line



Help-on-line is automatically closed if an alarm with higher priority occurs

Air in Venous Line



1. Manually clamp:
   - The venous patient line below the venous automatic line clamp and below any visible air
   - The dialyzer venous line
2. Attach a sterile luer-lock syringe to the venous infusion line and create a negative pressure of -80 mmHg in the venous chamber
3. When the venous automatic line clamp opens (listen) then clamp the venous infusion line clamp
4. Remove the manual clamp from venous patient line – check that no air is present in the line
5. Restart blood pump and remove the manual clamp from dialyzer line
6. *Check/adjust chamber fluid levels.*

As long as another red alarm is active it is not possible to start the blood pump

When resolving the alarm, the venous clamp closes again if the venous pressure reaches 40 mmHg

NOTES

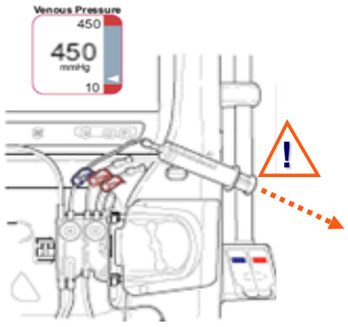
A/V Pressure Alarms

Arterial pressure alarm

- ► Once the arterial pressure stabilizes, press the Reset button to restart the blood pump

Venous pressure alarm

- ► Once the venous pressure stabilizes, press the Reset button to restart the blood pump - the venous clamp opens automatically
- ► Venous pressure above 450 mmHg requires the use of a luer lock syringe to decrease the pressure



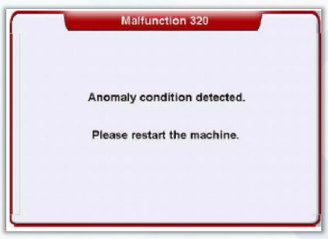
Malfunction Alarm | Call for Service

- Note the alarm code (check in the Operator's Manual malfunction list)
- Perform a "Fast Recovery" procedure (if applicable, see below)
- If the malfunction alarm is not resolved / recurs - turn the machine OFF and perform a Manual Rinseback
- Call for Service
- **Pay special attention to malfunction alarm code 59 and 64**
  - ► Code 59: Heater protection error
    - Switch the machine OFF
    - Perform a Manual Rinseback
  - ► Code 64: Safe state activated "Excessive Rinseback Volume"
    If this alarm code occurs during Rinseback
    - Switch the machine OFF
    - Disconnect the patient

Malfunction 320

When Malfunction 320 is triggered, the following happens:

- The touch screen is blocked
- A "Fast Recovery" procedure is required



It is not necessary to disconnect the patient

NOTES

Smartscan

It is intended as a treatment supervisor, alerting the Operator when the ongoing treatment may be improved by the adjustment of a parameter setting

Some of the Smartscan notifications can be managed in Preset environment

Examples of Smartscan Notifications

- Smartscan - High QD, code 514
- Smartscan - Low QD, code 513
- Smartscan - Low QB, code 512
- Smartscan - Low Real Qb, code 577
- Smartscan - High Sodium setting, code 606
- Smartscan - HemoControl: Refilling rate better than expected, code 635
- Smartscan - HemoControl: Unusual Status, code 636
- Smartscan - HemoControl: Refilling rate lower than expected, code 637
- Smartscan - HemoControl: UF volume may not be reached, code 638
- Smartscan - HemoControl: High Na Concentration, code 231
- Smartscan - HemoControl: Low Na Concentration, code 232
- Smartscan - Diascan: Low Clearance, code 530
- Smartscan - Diascan: Low KT/V, code 531

Nice to know | Flowmeter Technology

Because the Electromagnetic (EM) flowmeter technology is likely to be more sensitive to deposits, a monitoring of the number and frequency of the descaling procedures has been implemented to keep optimal performances of the flowmeters.

This is managed by 2 additional alarms 659 and 662:

1. A reminder is displayed: Alarm #659 “Reminder - Perform a Descaling Procedure”. This reminder is triggered from the start of the 18th (or 19th or 20th) treatment preparation if 17 (or 18 or 19) consecutive treatments have been completed **without any descaling**. The user can reset this alarm to carry on with the preparation, if he/she cannot proceed with the descaling at that time.
2. After the completion of the 20th treatment without any descaling, the alarm #662 “Preparation cannot start until **a Descaling procedure has been performed**” is triggered to prevent the start of the preparation. This alarm is resettable, a descaling procedure (one of the following: Heat CleanCart C, Ultra Peracetic or Low Peracetic, Stand-by Peracetic or Stand-by Low Peracetic) must be performed to initiate a preparation.

NOTES

Hands on: Chapter 5

- Change A/V pressure window
- Change A/V pressure limits
- Handle A/V pressure alarms
- Handle air in venous line alarm

Artis Physio Plus SW 9.05

Chapter 6: Special Procedures

Code 903334600
May 2019

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Special Procedures

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NOTES

Special Procedures

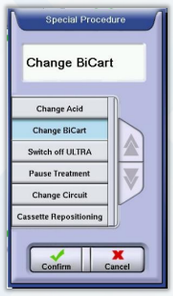
Special procedures is a common term for:

- Procedures available on the Select Pad via the *Overview* Screen “Special Procedures” button
  - The available procedures may differ depending on the ongoing process and treatment
  - On-line guidance is available
- Other procedures requiring special attention
  - Procedures having a more general purpose (Fast recovery, Manual Rinseback, Power Failure, etc.)
  - On-line guidance is not available

Special Procedures are covered in the Operator’s Manual Chapter 7, Other procedures in Chapter 8

Special Procedures

Available Special Procedures change depending on the current process



Standard HD:

Change Acid

Change BiCart

Switch off ULTRA

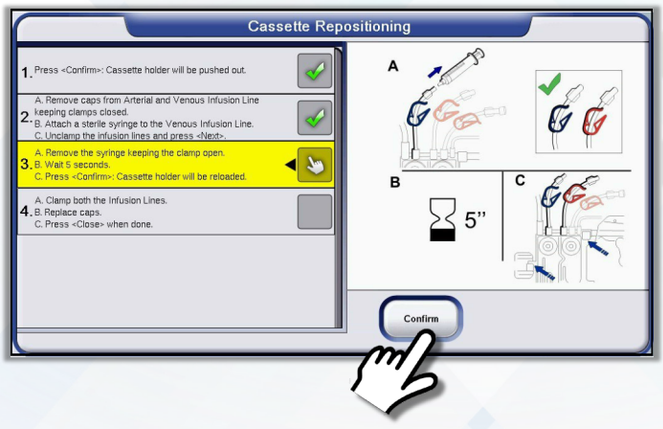
Pause Treatment

Change Circuit

Cassette Repositioning

Guidance is provided on how to perform the Special Procedures

Special Procedure Guidance



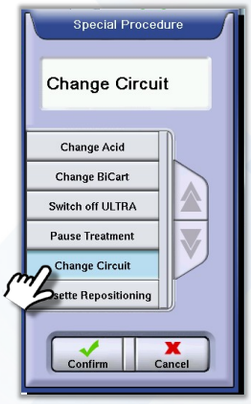
= action required

5” = wait

= ready; info bar turns grey

NOTES

Change Circuit



Available from Start Treatment to Stop Treatment

- ► *The Special Procedures button is not available as long as the Isolated UF is activated*

The complete Extracorporeal Circuit is changed.

Operator's messages are guiding the Operator through the process, which includes several phases.

The Artis Physio Plus system stores all treatment data, which are resumed once the treatment is restarted.

If activated:

- ► Heparin administration is resumed once blood is detected
  - *No initial dose is administered*
  - *Accumulated heparin volume is reset*
- ► Diascan is suspended and automatically resumed
- ► Hemoscan is automatically deactivated
- ○ *All blood volume data collected will remain available.*

Before initiating Change Circuit, check that the quantity of concentrates is sufficient to complete the procedure

Cassette Repositioning

The cassette's diaphragms may move from their neutral positions, which may cause:

- Inaccurate pressure monitoring
- Pressure alarms
- T1 Test failure

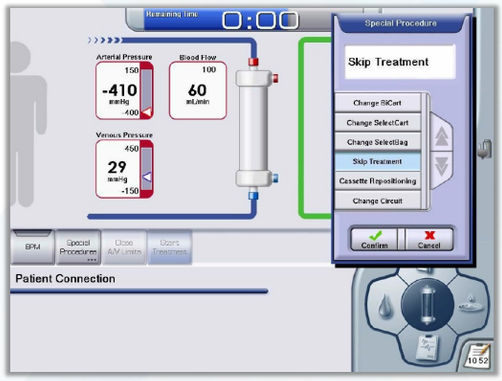
Cassette Repositioning should then be performed in order to restore their proper position

Cassette Repositioning is available for the:

- Blood cassette
- SN cassette

Before initiating Cassette Repositioning, decrease the BP speed and ensure the A/V chamber fluid levels are not too high

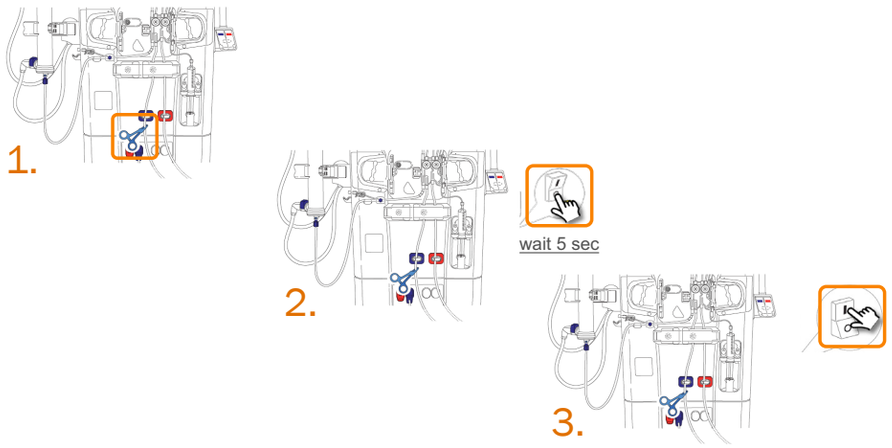
Skip Treatment



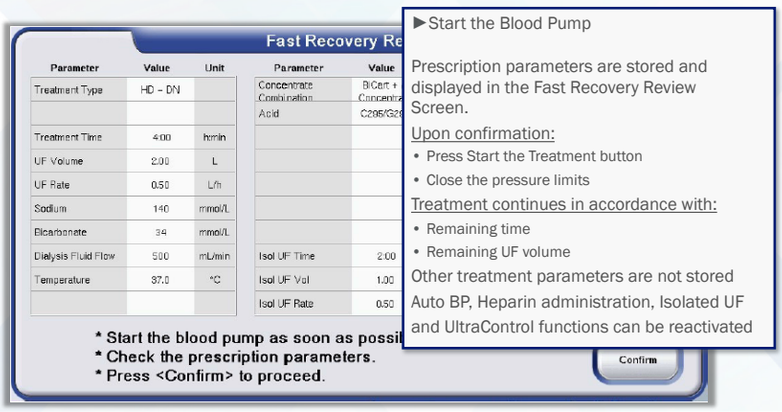
- This special procedure is available during the Connect Patient phase until the "Start Treatment" button is pressed.
- This procedure allows the operator to skip the treatment phase and to perform a patient disconnection.

NOTES

Fast Recovery Procedure



Fast Recovery | Parameters Saving



▶Start the Blood Pump

Prescription parameters are stored and displayed in the Fast Recovery Review Screen.

Upon confirmation:

- Press Start the Treatment button
- Close the pressure limits

Treatment continues in accordance with:

- Remaining time
- Remaining UF volume

Other treatment parameters are not stored

Auto BP, Heparin administration, Isolated UF and UltraControl functions can be reactivated

If the alarm reoccurs, Stop Treatment and finish off manually

Manual Rinseback HD-DN & HDF

In case of a machine malfunction, power failure or other emergencies a Manual Rinseback may be performed.

1. Clamp the Venous Patient line below the Venous Line Clamp and switch the machine OFF – **the alarm system is not active**
2. Prepare for Rinseback as per unit policy, then connect the Arterial Patient line to saline
3. Remove the Venous and Arterial Patient lines from the automatic clamps
4. Open the Sensor Bar and check for air bubble in the lines
5. Open the BP cover and pull out the BP rotor crank
6. ***Unclamp the Venous and Arterial Patient lines and the saline line for Rinseback***
7. Slowly turn the Arterial Pump Crank counter-clockwise to return the desired volume of blood
8. Clamp the Venous Patient line and disconnect.

While manually returning the blood, check for air in the venous patient line

NOTES

Power Failure | Battery Backup

"No Power – Using Battery Backup"

If the power failure lasts ***less than 5 minutes***, once the supply mains returns:

- The displayed alarm message disappears
- The interrupted process automatically restarts and no operator intervention is required

"No Power – Using Battery Backup"

If the power failure remains for ***more than 5 minutes***:

- ► In HD: stop the treatment and perform auto rinseback – switch the Artis Physio Plus System OFF
- ► In HDF On-line: switch to HD and perform auto rinseback – switch the Artis Physio Plus System OFF
- ► In Disinfection/Rinse: an alarm is triggered and the ongoing process is stopped – the Artis Physio Plus System automatically switches OFF after 5 minutes

Battery Charge

- To charge the battery the Artis Physio Plus system needs to be plugged into the mains supply with the Main Switch ON.
- After a power failure, the battery requires at least 12 hours recharging time.
- When the Artis Physio Plus system remains switched OFF, the battery gradually looses its charge.
- When the Artis Physio Plus system remains switched ON but not connected to the mains supply, the battery gradually loses its charge.

If a Power Failure occurs during a treatment and the battery backup is not charged, the machine enters the "Safe State Activated" mode:

► Perform a Manual Rinseback procedure

Hands on: Chapter 6

- Cassette repositioning
- Pause Treatment
- Battery backup
- Fast recovery
- Manual Rinseback
- Ultrafilter change
- Heat CleanCart-C

NOTES

Artis Physio Plus SW 9.05

Chapter 7: Report and Service Environment

Code 903334600
May 2019

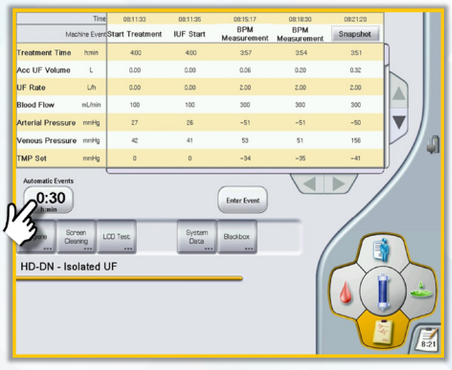
Baxter

Report & Service Environment

Report Screen Usability

Event List

- Automatic treatment records at regular intervals (default 30 min)
- Manual snapshot

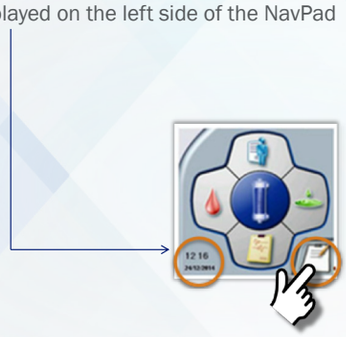


Press the Automatic Events button to change the records time interval

NOTES

NavPad Area

Time and date are displayed on the left side of the NavPad

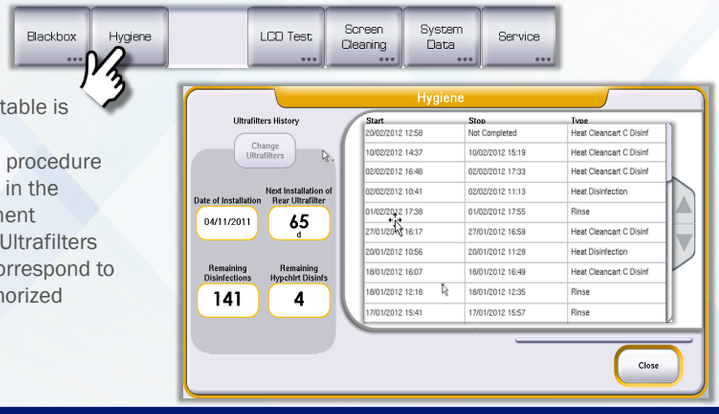


A manual snapshot of the treatment can be taken at any time with the button called “Treatment data record” at the bottom right corner of the screen; the “Time” cannot be used to snapshot. This button is available in all 5 Main screens.

Snapshot and Event Reporting

Press the Snapshot button or the Enter Event button to access Modify Snapshot Event screen

Hygiene Sub-screen



- Ultrafilters history table is always available
- Ultrafilters change procedure button is available in the standard environment
- Default values for Ultrafilters history counters correspond to the maximum authorized duration

Disinfection history table always available

NOTES

Button Bar Usability

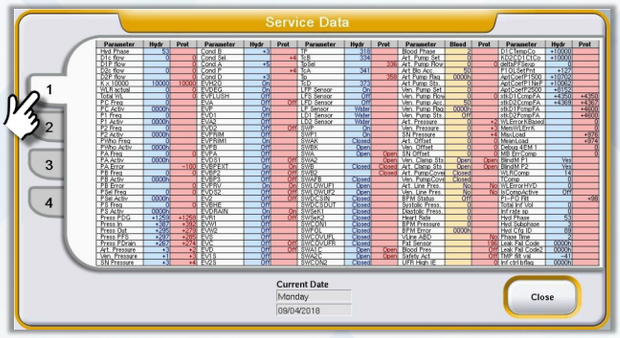
LCD test

The test should be performed if the Operator observes or suspects that data are not correctly displayed on the Touch Screen

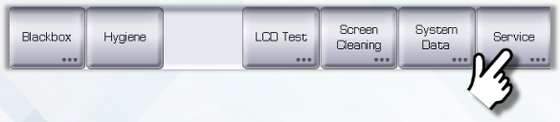
- ► Follow the instructions appearing on the screen (click = press)
- ► Call for service if not functioning correctly

Screen cleaning

Button Bar Usability | System Data



Artis Physio Plus System Service Mode | Two Levels



Two Service Levels with different access codes

Service Level 1:

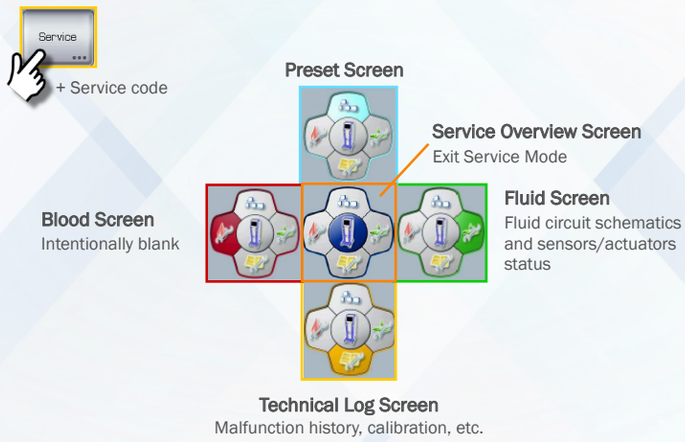
- Access code **169000**
- Date and time change
- Auto start preset
- Displays all preset parameters

Service Level 2:

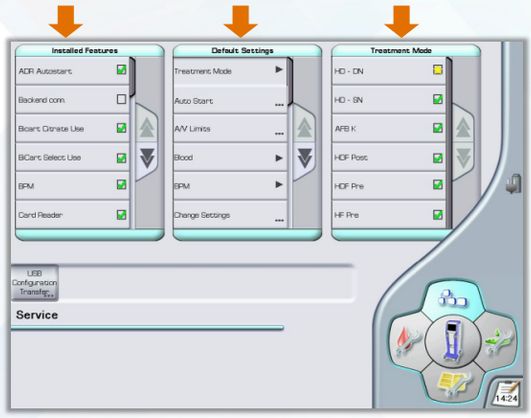
- Technicians access
- Preset environment
- Transfer of presets via an UBS key
- Calibration of sensors
- BlackBox downloading

NOTES

The Artis Physio Plus System Service Mode | NavPad Interface



The Artis Physio Plus System Service Mode | Preset Screen



All presets can be viewed by scrolling the different select pads

Service level 1

Possible to set/change:

- Time date
- Auto Start

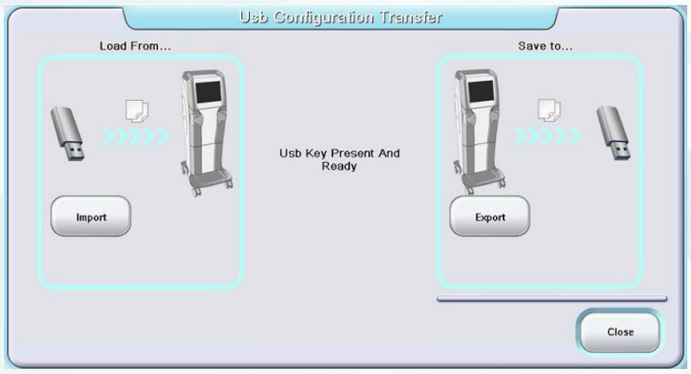
Service level 2

Possible to set/change:

- Installed features
- Default settings
- Treatment mode
- Preset transfer (next slide)

The Exit Service Mode button must always be pressed to save the changes and exit Service mode

The Artis Physio Plus System Service Mode | Preset Transfer



NOTES

The Artis Physio Plus System Service Mode | Blackbox

In the Blackbox, the Artis Physio Plus system stores the latest 1 to max 24 sessions, according to the principle "first in- first out".

Example of information stored:

- Treatment data
- Alarms
- Operator's action
- Machine processes and phases
- Actuators information status

Limiting factors:

- Blackbox 24 Mb memory size
- Sampling time, 10 sec > 0.7Mb/session.

Blackbox Files

The Blackbox can be downloaded to an USB key via the Report screen, requiring **Service Level 2** access code

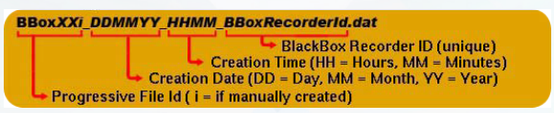
– During preparation until Auto-Prime is booked or when no process is running

The downloaded Blackbox files should be named accordingly: **Box(IBBox)nn_ddmmyy_hhmm.dat**

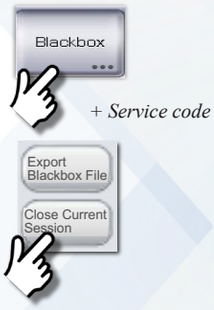
where:

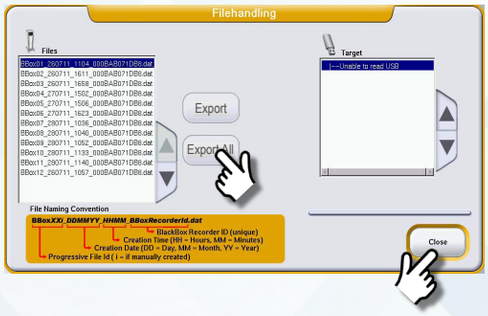
- **BBOx** = name of regular session starting with a dialysis treatment
- **IBBox** = name of session starting at the startup of the machine (if no old session was found) or in case of manual closure of the session
- **nn** = progressive ID of session (recycled from1 to 24)
- **ddmmyy** = date (day, month and year)
- **hhmm** = time of session start (hour, minute)

– Blackbox files can only be read with Mediartis Tech SW application.



Blackbox Downloading Procedure





- Place a USB stick in the Connectivity Panel USB port
- Press Blackbox button and enter Service Level 2 code in the key pad appearing
- Press Export Blackbox File button in the screen appearing
- Press Export All button → left window files are downloaded to the USB key
- Close Blackbox screens and remove USB key from the port
- Press Service Overview button and Exit Service Mode button.

NOTES

Hands on: Chapter 7

- *Event list*
  - *New reading/Snapshot*
  - *Time interval*
- *Hygiene screen*
- *LDC test*
- *Screen Cleaning*
- *Access Service Level 1 and 2*
- *Preset process*
- *Blackbox downloading*

Artis Physio Plus SW 9.05

Chapter 8: The HemoControl Therapy

Code 903334600
May 2019

Baxter

The HemoControl Therapy

- Enhances intradialytic hemodynamic stability
- Maintains sodium balance
- Facilitates dry weight accuracy

Baxter

NOTES

The HemoControl Therapy

Automatic profiling of

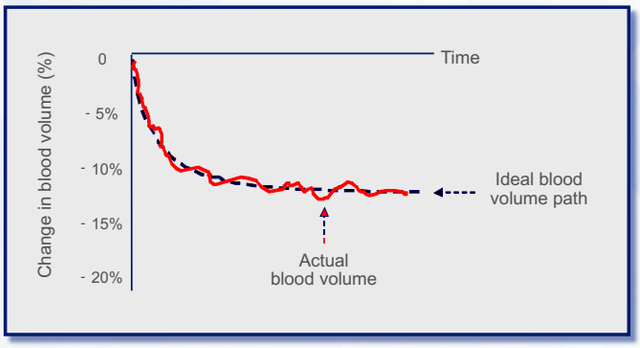
- Dialysis fluid sodium concentration
- Ultrafiltration rate

Based on

- Patient prescription
- The actual Blood Volume changes measured by the Hemoscan function

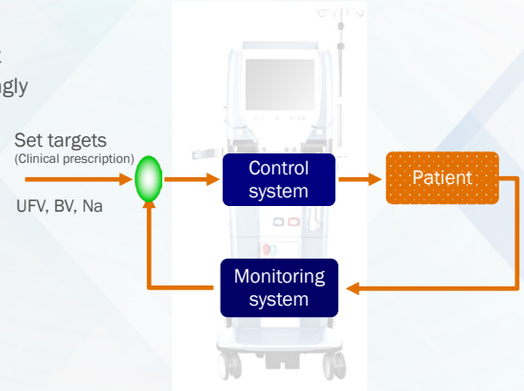
The HemoControl Therapy

The HemoControl therapy guides the actual blood volume along a pre-defined trajectory



The HemoControl Therapy

- Provides on-line information
- Compares it to the set target
- Adjusts parameters accordingly

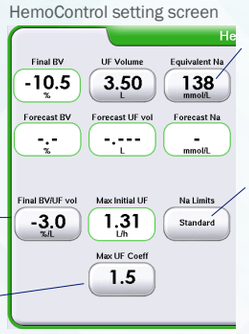


NOTES

The HemoControl Therapy Settings

Start by setting:
- Treatment time
- UF volume
- Distribution volume

HemoControl setting screen



It should be equal to the Sodium value which would be set in a standard dialysis

Sodium conc. band (mmol/l):
Narrow: -5 to 10
Standard: -5 to 15
Large: -7 to 18

Patient individual target ratio calculated over 3 – 6 treatments

Coefficient for calculation of "Max Initial UF"

The use of the Patient Card is recommended to simplify the settings of the HemoControl therapy parameters

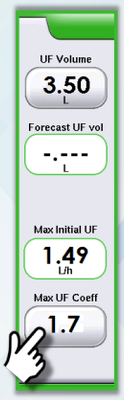
Setting Final BV/UF Volume Ratio

- The Final BV/UF volume value is a measure of the patient's average refilling rate:
  - The lower value (more negative), the lower average refilling rate during the treatment
- Patient individual target ratio should be determined over a period of 3 – 6 treatments
- In case of Intradialytic hypotension (IDH) episodes, consider BV% at first episode and UF volume achieved at end of treatment

#	Dialysis	Date	End BV (%)	UFV (L)	BV/UFV (%/L)
1	Treatment	2011-08-01	-8,4	2,7	-3,1
2	Treatment	2011-08-03	-7,6	2,5	-3,0
3	Treatment	2011-08-05	-6,8	2,3	-3,0
4	Treatment	2011-08-08	-8,5	2,9	-2,9
5	Treatment	2011-08-10	-7,1	2,6	-2,7
6	Treatment	2011-08-12	-6,9	2,2	-3,1
			Calculated average BV/UFV:		-3,0

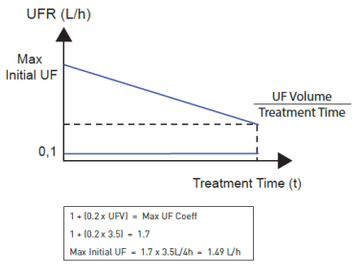
Follow the trend and adjust Final BV/UF volume over time

Defining the UF Rate Starting Point by the UF Coefficient



Max UF Coeff (setting range 1.2 – 2.0):
It is used for determining the Maximum Initial UF rate
Max Initial UF rate = Max UF Coeff x UF volume / trmt time
- Ex: Max Initial UF rate = 1.7 x 3.5 L/4h = 1.7 x 0,9 = 1.49 L/h
- May be calculated accordingly:
  - Max UF Coeff = 1 + (0.2 x UFV)

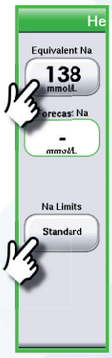
The Maximum Initial UF rate and the set UF rate provides the UF rate band used by HemoControl



It is better to optimize the Max. Initial UF rate at the beginning of the treatment

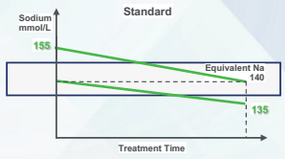
NOTES

Setting Equivalent Na & Sodium Limits



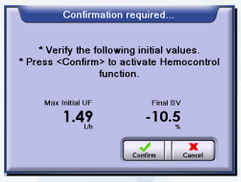
- The Equivalent Na value should be equal to the Sodium value which would be set in a standard dialysis treatment.
- Setting range: 135 – 150mmol/L
- The Na Limits defines the band within which the sodium in the dialysis fluid can be modulated.
- The Equivalent Na actual range depends on the Na Limit band selected.
- ***Only bands compatible with Equivalent Na are available for selection***

Set the sodium limits		
Sodium band	Range (mmol/L)	Average UFV (L)
Narrow	-5 to 10	1-2
Standard	-5 to 15	2-4
Large	-7 to 18	>4



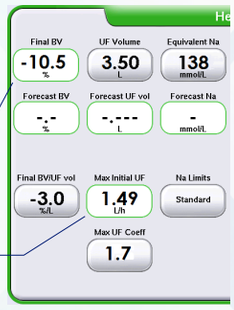
The modulation of dialysis fluid Na concentration within the Sodium bands is further restricted to never exceed the conductivity range of 13.4 to 15.6 mS/cm

Calculated Values



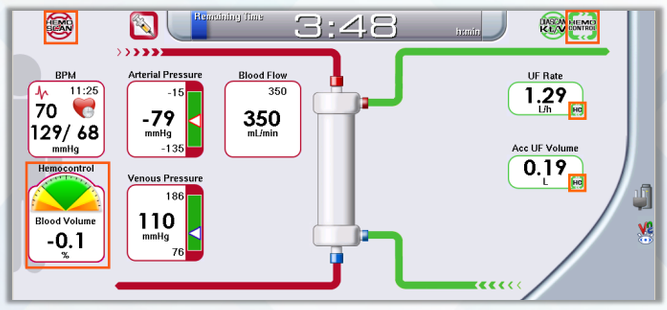
Final BV = Final BV/UF volume x UFV

Max Initial UF = Max UF Coeff x $\frac{\text{UFV}}{\text{Treatment Time}}$



The HemoControl activation button is not available until Treatment Time, UFV and Distribution Volume are set

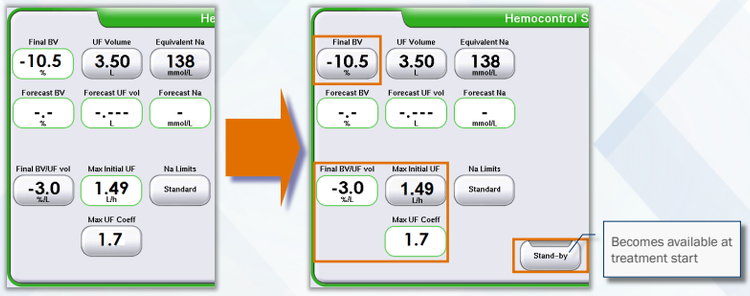
The HemoControl Therapy Activated



The Hemoscan function is automatically activated together with the HemoControl therapy

NOTES

Treatment Start



For changes affecting the BV during treatment, use the Stand-by button

The HemoControl Therapy Stand-by

The HemoControl therapy stand-by is recommended when an infusion has to be administered to the patient that may affect the relative blood volume measurement.

When the Stand-by button is activated:

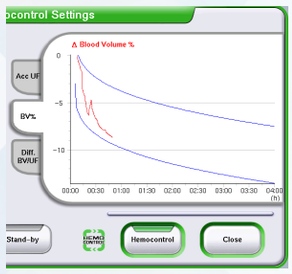
- The automatic profiling of the UF rate and Sodium parameters is suspended for 5 minutes.
- Recommended values are applied i.e. the value to apply in order to reach the prescription parameters (UF Volume and Equivalent Na).
- An on-going Diascan function measurements will fail.
- The Stand-by is automatically deactivated after 5 minutes – it may be manually deactivated before that.

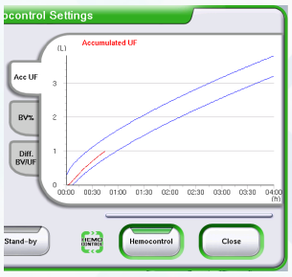
Do not use the HemoControl therapy during a blood transfusion

BV% & Acc. UF Trend Graphs

On HC settings screen the graphs are updated from treatment start

- Actual blood volume change (red line)
- Values should stay within the blue lines path





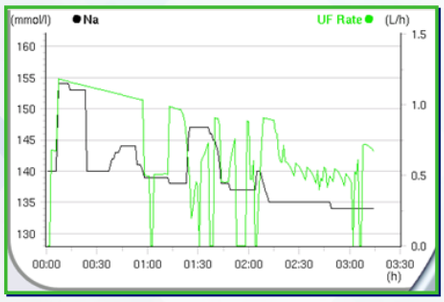
- Accumulated UF (red line)
- Values should stay within the blue line path

For accurate measurements, keep Q_B >180 ml/min

NOTES

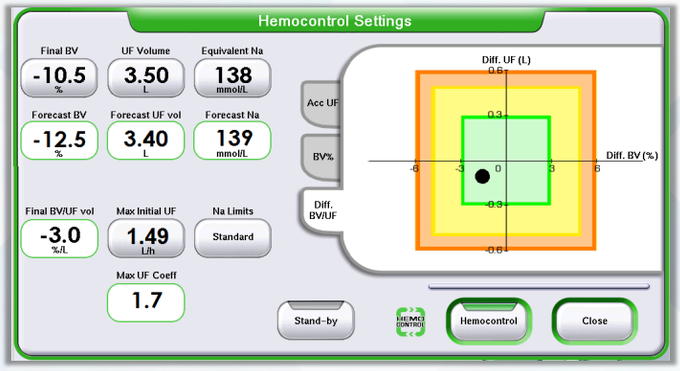
Dialysis Fluid [Na] & UFR Graph

On the Fluid screen graph, the dialysis fluid Na concentration and UF rate can be followed



Plasma Sodium Conductivity is displayed on the Diascan Setting scree and in the Event List

Forecast Values



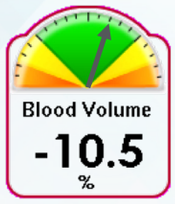
The forecast values are updated 45 minutes after treatment start, together with the:

- Diff BV/UF cross graph on the HC setting screen
- HemoControl plasma refilling indicator on the overview screen (next slide)

Plasma Refilling Indicator

Arrow =
Plasma refilling indicator

Blood Volume =
Actual BV change



HemoControl
Chart Panel

Green area = On prescription

Yellow areas = Prescription may not be reached, attention needed

Orange areas = Prescription may not be reached, action needed

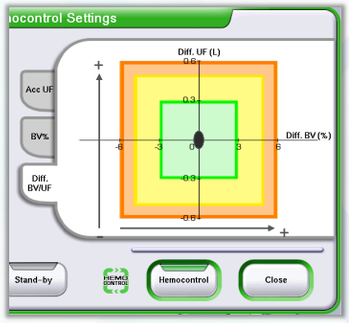
The arrow appears 45 minutes after treatment starts

NOTES

The Diff BV/UF Cross Graph

Diff. UF (y-axis)
Indicates the accumulated UF Volume deviation related to set targets (i.e., **$acc.UFV_{curr} - acc.UFV_{target}$**)

Diff. BV% (x-axis)
Indicates the current BV change deviation related to set targets (i.e., **$BV\%_{curr} - BV\%_{target}$**)



In the optimal case, the dot is in the absolute center when the treatment time is achieved

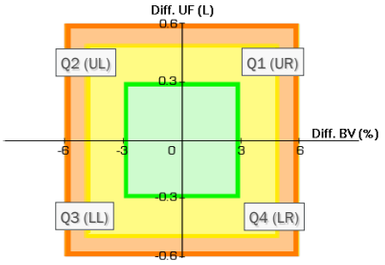
Interpretation of the Cross Graph

Q1(UR): Refilling rate better than expected; opportunity to remove more water

Q2(UL): Unusual status; if this status persists, deactivate HemoControl

Q3(LL): Refilling rate lower than expected; dry weight might not be achieved

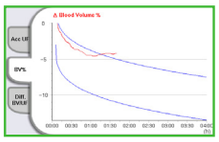
Q4(LR): UF volume may not be reached; fluid removal restricted by Max Initial UF

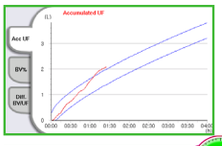


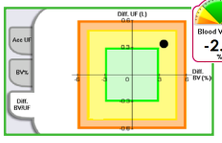
UL=Upper Left	UR=Upper Right
LL=Lower Left	LR=Lower Right

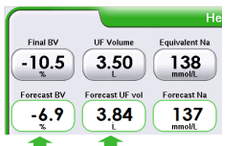
Evaluate whether to await the dot re-entering the green area or to adjust a treatment parameter

Out of Limits | Upper Right Quadrant









Refilling rate better than expected
- BV decreases less than expected
- UFV increases more than expected

▶ Check blood pressure (BP) and patient status

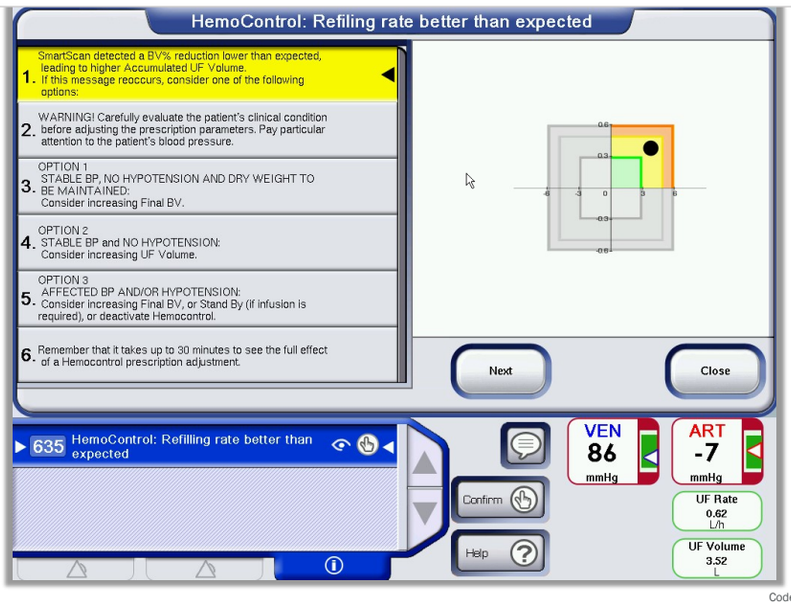
BP and patient's status are not affected
▶ Consider increasing the UFV
- an increase of 0.3L may be used

▶ If dry weight is to be maintained consider increasing the Final BV by making it less negative
- a change of +3% may be used

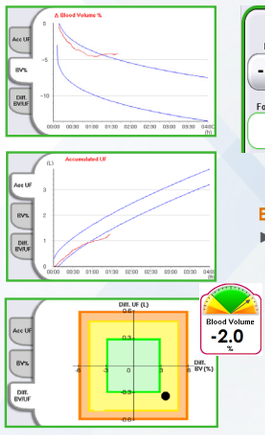
BP or patient's status is affected
In case of minor symptoms:
▶ Consider increasing Final BV by making it less negative
- a change of +3% may be used

If saline is administered:
▶ Consider using Stand-by or deactivate HemoControl

NOTES



Out of Limits | Lower Right Quadrant



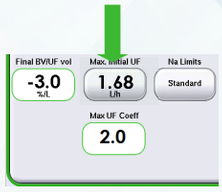
UF volume may not be reached

- BV decreases less than expected
- UFV increases less than expected

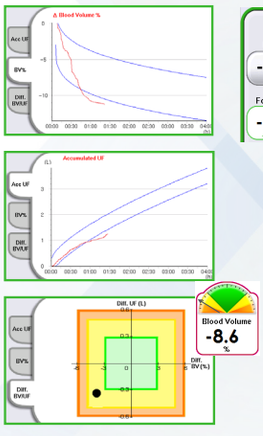
► Check BP and patient status

BP and patient's status are not affected

► If the BP is stable, consider increasing the Max Initial UF



Out of Limits | Lower Left Quadrant



Refilling rate lower than expected

- BV decreases more than expected
- UFV increases less than expected

► Check BP and patient status

BP and patient's status are not affected

►If the dry weight is to be maintained, consider decreasing the Final BV by making it more negative
- a change of -3% may be used

BP or patient's status is affected

In case of minor symptom:

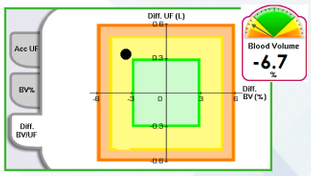
►Consider decreasing the UF volume
- a decrease of 0.3L may be used

If saline is administered:

►Consider using Stand-by or deactivate HemoControl

NOTES

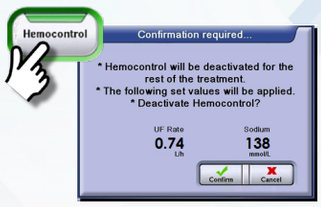
Out of Limits | Upper Left Quadrant



Unusual Status
This is a contradictory situation following an adjustment of a setting

Suggested action:
If the dot persists in this quadrant for more than 15 minutes

► Deactivate HemoControl



Once deactivated, HemoControl cannot be activated again

Adjustments During Treatment

Rules of thumb

- Avoid adjusting more than one parameter at a time.
- For adjustments during the treatment, a value of +/-3% or +/-0,3L respectively may be used.
- It takes approx. 20 minutes before the full effect of any adjustment is visible. Be patient and do not change any other parameter during this time.
- After an adjustment the forecast values should be disregarded during the first 10 minutes. The treatment progress can be followed via the BV and UF graphs.
- In general no more than one adjustment should be necessary during the treatment.
- When the dot of the cross graph is in the lower left quadrant (i.e. poor refilling suspected), a stable BP associated with high heart rate may indicate an approaching BP drop.

Follow the trend over time and consider patient prescription on a regular basis

Nice to know

- The HemoControl therapy is not available for on-line HDF, HD single needle and AFBK treatments.
- An initial value of Hgb above 14 g/dl may lead to a Hemoscan measure out of range alarm and will force the deactivation of the HemoControl therapy (Hgb operating range: 6 to 16 g/dl)
- When the UF volume is reached, the notification “Fluid removal completed #53” is displayed; if desired, the UF volume can be increased in the Fluid screen.
- At treatment end the Final BV may be ±3%, the Final UFV ±0.3L and the Equivalent Na ±3mmol/L compared to the set values while the plasma indicator is still within the green area.
- As an alternative to the observational phase, a Final BV / UF Volume value of -2.5 %/L could be used as a start value for most patients; in this case, some adjustments during treatment may be required.

NOTES

Hands on: Chapter 8

- *HemoControl treatment*

Artis Physio Plus SW 9.05

Chapter 9: HDF On-line Treatment

Code 903334600
May 2019

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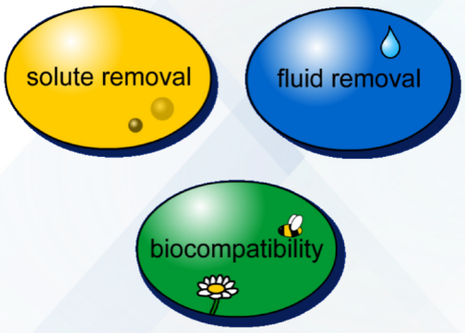
HemoDiaFiltration On-line



HDF On-line Postdilution

- Volume control
- Pressure control
- UltraControl

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NOTES

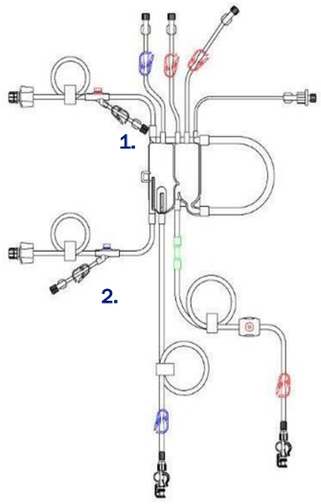
The ArtiSet PrePost Blood Tubing System

Components/part names:

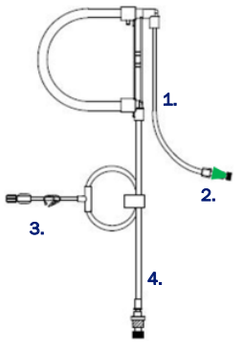
1. **Arterial connector** to connect for predilution
2. **Venous connector** to connect for postdilution

Color coding:

1. **Arterial connector**: clamp and cap in white – injection port in red
2. **Venous connector**: clamp and cap in white - injection port in blue



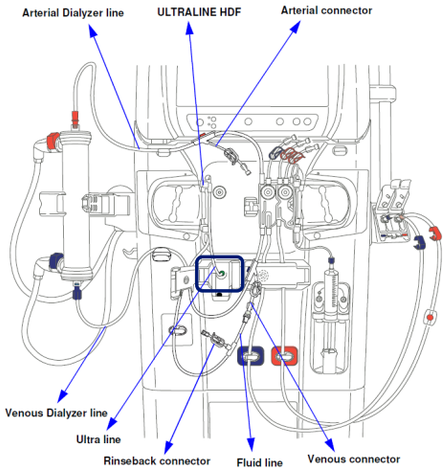
ULTRALINE HDF

Accessory	Blood Tubing System	Application
ULTRALINE HDF accessory 	Artiset PrePost	HDF Post treatment HDF Pre treatment HF Pre treatment
	ArtiSet HD DNL HC	HDF Post treatment

Components/part names:

1. **Ultra line** to describe the tubing connected to the Ultra port
2. **Ultra line connector**
3. **Rinse back connector**
4. **Fluid line** to describe the tubing connected the Arterial or Venous connector

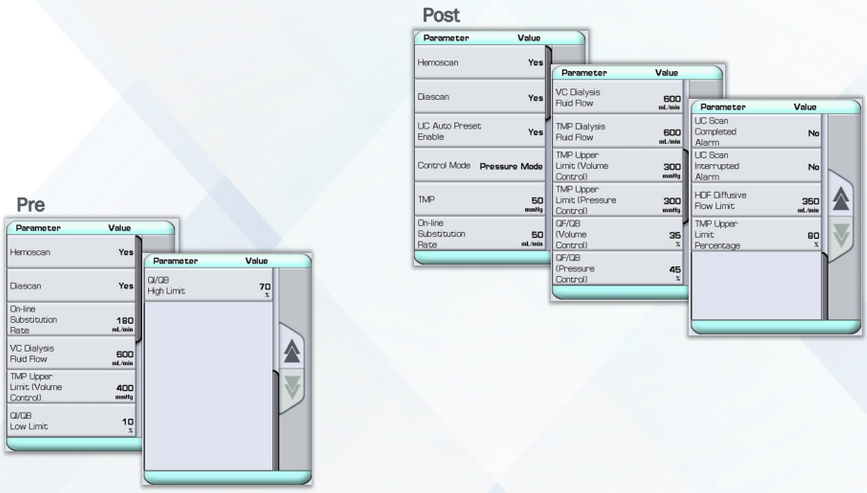
ULTRALINE HDF & the ArtiSet PrePost Blood Tubing System



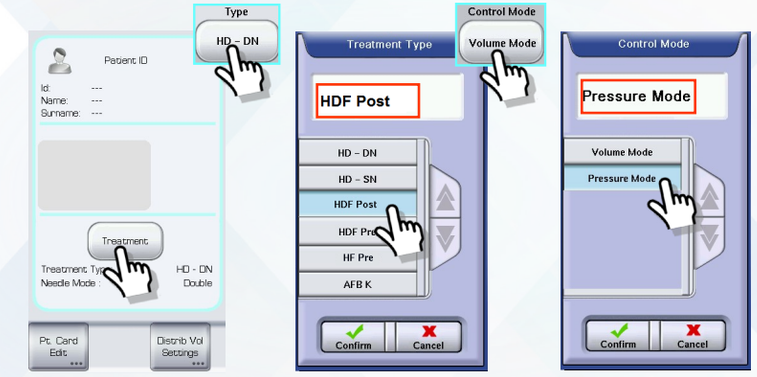
Thoroughly secure the ULTRA line connection to the ULTRA port

NOTES

HDF Presets



HDF Treatment Settings

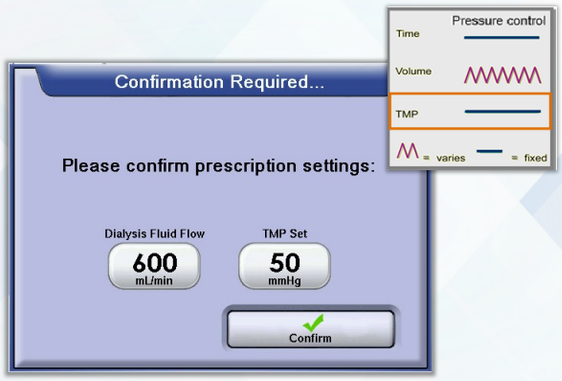


Treatment Settings sub-screen | Treatment Type | Control Mode

The settings displayed are presetable

Pressure Control

Confirmation Required

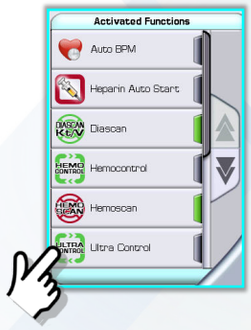


The parameters in this confirmation window are presetable

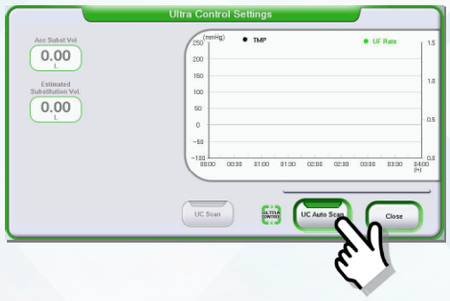
NOTES

Activating the UltraControl Therapy

Select Ultra Control

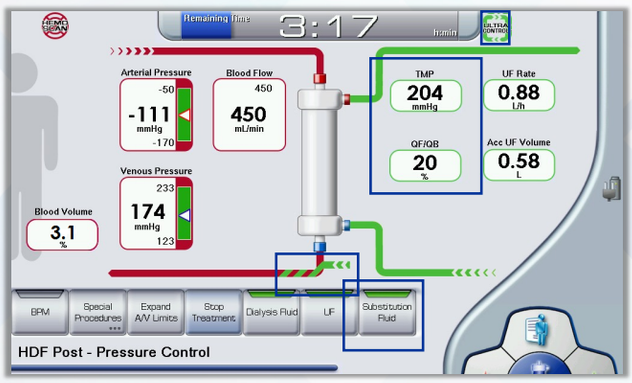


Activate UC Auto Scan



Before the UltraControl therapy can be activated, HDF Pressure control mode must be set

Treatment Overview During Treatment



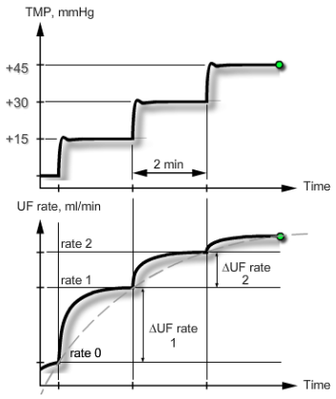
When using the UltraControl therapy, the QF/QB ratio could be as high as 45%, especially early in the treatment

Fluid Screen | Pressure Control

The On-line Bolus activation button is available from treatment start

NOTES

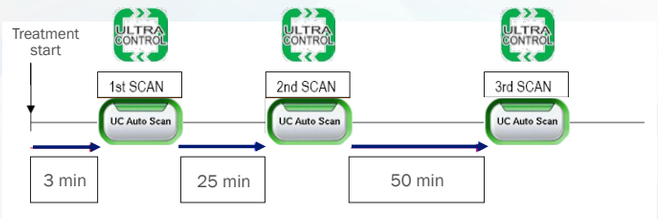
The UltraControl Therapy | Automatic TMP Scans



Automatic TMP Scanning

- From a starting value, the TMP is increased in fixed steps while the UF rate increase is monitored
- The TMP and Qinf are allowed to increase until predefined limits are reached, when the TMP scan is aborted

Auto Scan Schedule



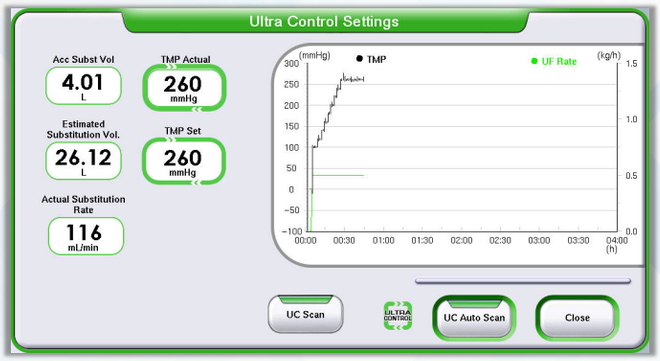
From the 3rd auto scan forward:

► Automatic scans are performed 50 min after completion of previous scan until 60 minutes before treatment time completion

► A TMP step down by 15 mmHg will be applied based on the TMP value defined during the last scan

Manual UC scans are also available 

UC Auto Scan

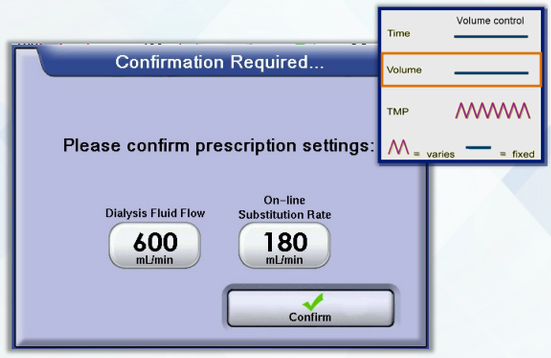


TMP Upper Limit can be set to 500 mmHg

NOTES

HDF Post | Volume Control

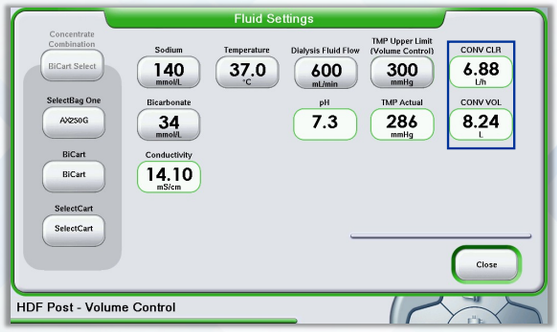
Confirmation Required



Substitution Fluid Rate Setting

In volume control the QF/QB should be approximately 30%

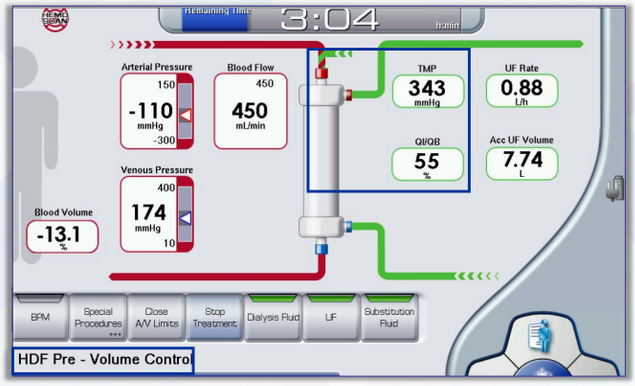
Convection Values



- CONV CLR – The rate at which convection is taking place
- CONV VOL – The accumulated volume of convective clearance

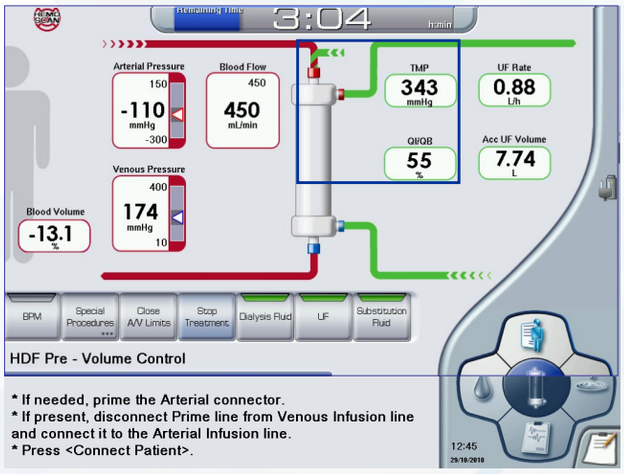
NOTES

Switch to HDF Predilution
(“Switch to Pre” Special Procedure)



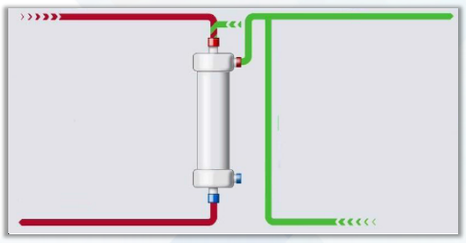
It is not possible to switch back to Post from Pre

HDF Pre & HF Pre



- They are “Treatment Type” set via the Prescription screen
- The ArtiSet PrePost cassette is to be used. This is to be configured in postdilution for priming
- The Fluid line is moved to the Arterial connector before patient connection.

HF Pre

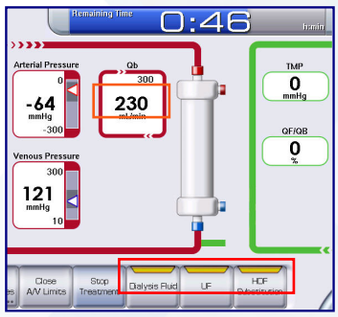


Flow path diagram

The infusion volume is set in the fluid screen in the same way as in HDF Post in volume control and in HDF Pre

NOTES

Blood Pump Automatic Control



The broad red Q_B-frame indicates:

- The machine controls the blood pump
- The venous pump is standing still (or an on-line bolus is administered)
- Dialysis fluid, UF and HDF substitution fluid are temporarily disabled

The blood pump automatic control prevents pressure alarms

New Management of Blood Flow when On-line is Interrupted

To avoid blood pressure increase in the venous compartment and to maintain the blood hemodynamics in a physiological range when the on-line substitution is interrupted, the user can no longer interrupt the Automatic Control Loop of the blood pump.

The blood flow can be still slightly changed - in a limited range - during the time the blood pump is in Automatic Control Loop. The new flow will be set as soon as the control loop is completed:

- **If QB ≤ 150 ml/min**, the blood flow can be changed in the range of 60 to 150 ml/min
- **If QB > 150 ml/min**, the blood flow can be changed from 60 to the original blood flow set value (value before the treatment interruption).

Bolus Infusion

During Bolus Infusion:

- TMP is frozen (0 mmHg)
- Ultrafiltration process is stopped
- Convection and diffusion are stopped
- A/V pressure alarm limits are open
- UC Auto Scan function is paused
- UC Auto Scan button is dimmed
- BP automatic control is active

After on-line bolus administration:

►Press the Substitution Fluid button to continue treatment

►A new UC Auto Scan is initiated after

NOTES

HDF / HF Specific Special Procedures

On-line HDF:

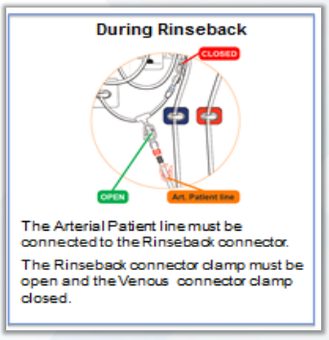
- Switch off Ultra
- Switch to Pre
- Change Circuit

On-line HF:

- Switch off Ultra
- Change circuit

Control mode (volume/pressure) is changed via the “Treatment” button on the Prescription screen

HDF/HF | Stop Treatment



- ► Connect the Arterial Patient line to the Rinseback connector
- ► Press Rinseback

If running out of concentrate during Rinseback, switch off Ultra and use saline

Microbiological Sampling | Dialysis fluid

- The “Sampling” button becomes available on the Main screen when the dialysis fluid preparation is completed
- Sterile collection bag GMB SP06 can be used (remove and discard the pre-connected tube adapter)

The sampling procedure is available in the following cases:

	HD	HDF	HF	AFBK
At the end of the preparation phase *Note:* the “Sampling” button is enabled only if the cassette is not loaded	X	X	X	X
End of treatment		X	X	

Do not load the cassette if a microbiological sampling is required

NOTES

Nice to know

- An alarm is triggered if the substitution fluid infusion is stopped for more than 5 minutes.
- If the Substitution Pump speed is lower than 10 ml/min for more than 5 sec a “TMP set too low” notification is triggered.
- Substitution fluid flow rate is ramped up when resumed i.e. after Auto-test, BP auto control, etc.
- When the UC Auto Scan button is dimmed, the Artis Physio Plus system is preparing a new scan.
- If a manual UC scan has been performed before UC Auto scan is activated, the ordinary auto scan schedule will start 3 minutes after the activation.
- When changing from Volume Control to Pressure Control, the current TMP is suggested as start value.
- Alarms related to UC scan completion and abortion is presetable.

Hands on: Chapter 9 – HDF Treatment

- HDF double needle
- Activate the UltraControl therapy
- Load the ArtiSet PrePost blood tubing system and the ULTRALINE HDF
- On-line priming
- Start treatment
- Switch to Volume control
- Switch to Pre
- Auto-rinseback
- Unload cassettes

Hands on: Chapter 9 – HF Treatment

- Load the ArtiSet PrePost blood tubing system and the ULTRALINE HDF
- On-line priming
- Start treatment
- Auto-rinseback
- Unload cassettes

NOTES

Artis Physio Plus SW 9.05

Chapter 10: HD-SN DP Treatment

Code 903334600
May 2019

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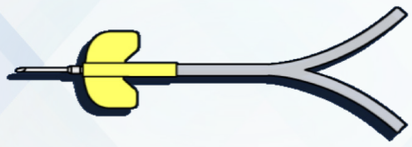
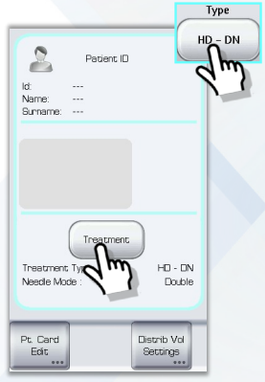
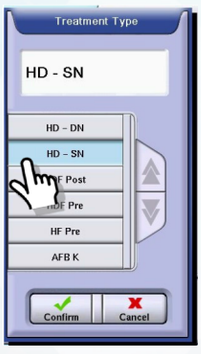
HD-SN Double Pump

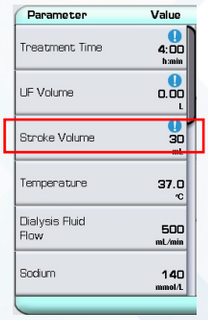


HD-SN DP Treatment Settings



Treatment Settings sub-screen

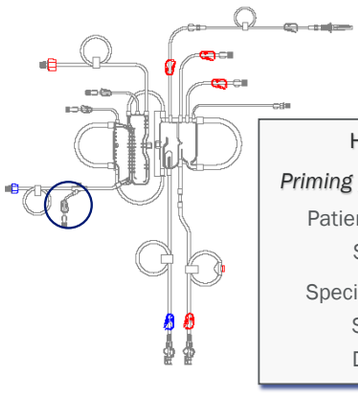




Always set the HD-SN Treatment before starting the HD-SN cassette loading procedure

NOTES

HD-SN DP



HD SN HC

Priming performed in SN

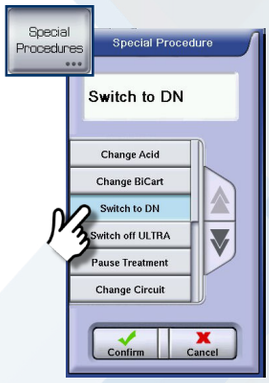
Patient Connection

SN or DN

Special Procedures

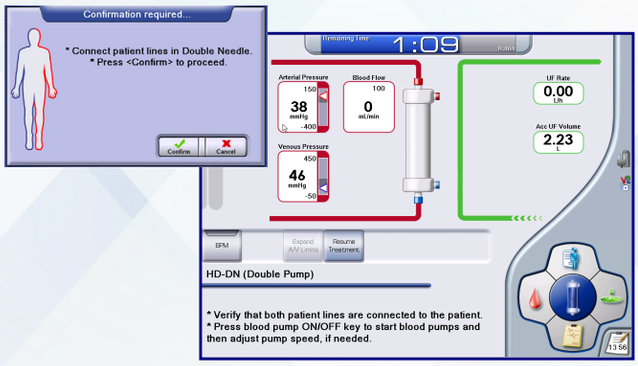
SN → DN

DN → SN



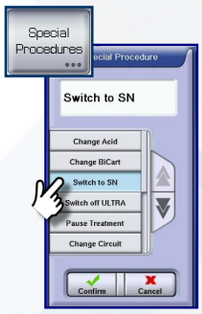
Needles mode switch is available, from Connect Patient until Stop Treatment keeping the SN cassette installed

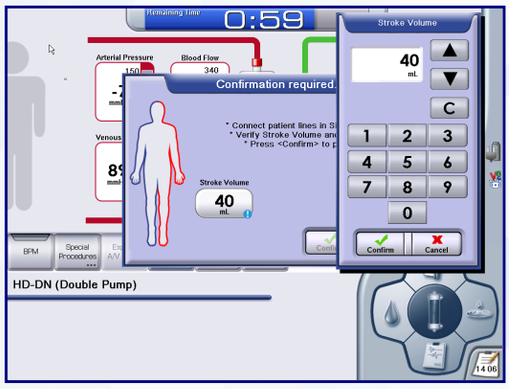
Switching from SN to DN (DP)...



Control loop on Venous pump with system pressure fixed at 100 mmHg

... and from DN to SN (DP)

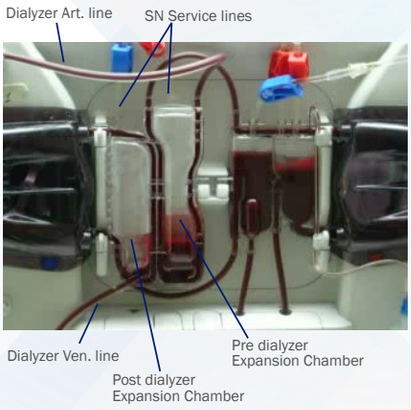




Needle mode switch is possible as many times as needed

NOTES

The ArtiSet HD-SN DP Blood Tubing System



- Integrated blood circuit including two expansion chambers and a venous pump segment
- Automatic loading of the complete blood circuit
- Automatic priming and chamber level adjustment

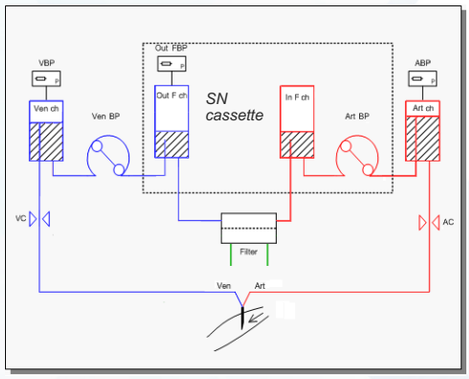
Blood Levels in the Chambers

Blood level adjustment during SNDP treatment (if needed):

- Arterial chamber
  - During the arterial phase (i.e., when the arterial automatic clamp is open);
- Venous chamber
  - During the venous phase (i.e., when the venous automatic clamp is open);
- Expansion chambers *(if blood levels in the two expansion chambers become greatly different; e.g. after an alarm situation):*
  - Decrease the “Stroke Volume” to 25 ml and the “Mean Blood Flow” to 50 ml/min and wait at least one cycle (arterial + venous phase) before stopping the blood pumps;
  - Attach a sterile luer-lock syringe (at least 20cc) to the Service Line on the expansion chamber with the higher blood level and gently adjust the blood level in accordance with the other expansion chamber;
  - Restart the blood pumps and adjust the Mean Blood Flow and “Stroke Volume”.

SNDP Principle

- **Arterial phase**; Arterial blood pump (Art BP) is running until the automatically calculated post dialyzer pressure limit is met (SN pressure max) – venous line is clamped (VC)
- **Venous phase**; Venous blood pump (Ven BP) is running until the fixed low system pressure limit is met. (SN pressure min) – arterial line is clamped (AC)
- Almost constant blood flow through the dialyzer due to the two expansion chambers situated pre- and post- the dialyzer
- The stroke volume is achieved by the automatic control of the blood levels in the expansion chambers and the Ven BP speed



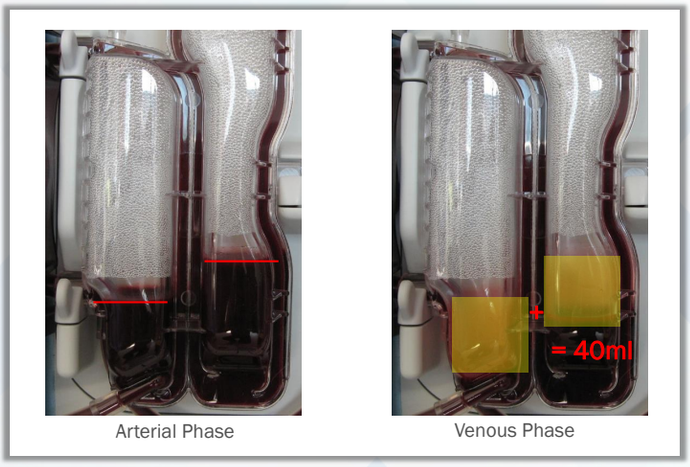
Access preserved by the pump/pressure controlled blood flow; withdrawal and return

NOTES

SNDP Parameters

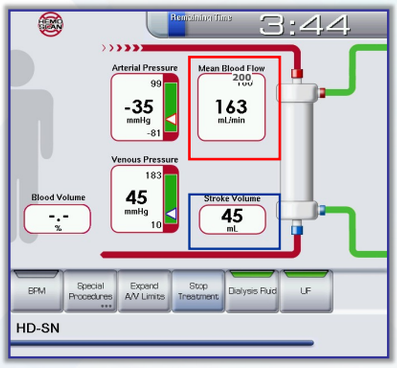
Mean blood flow rate	The effective blood flow rate during one cycle (20 to 270 mL/min, 10 mL/min step)
Stroke volume	The volume of blood passing through the dialyzer during a cycle (25 to 60 mL, 5 mL step)
SN pressure	Actual pressure in the post dialyzer chamber
SN pressure max	Automatically calculated in accordance with the set stroke volume
SN pressure min	Fixed at 40 mmHg

Stroke Volume



Arterial Phase Venous Phase

Overview Screen



- Mean Blood Flow
  directly adjustable with BP hard keys
- Stroke Volume value box

Adjustable mean blood flow

NOTES

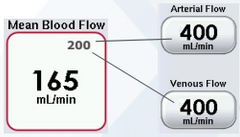
Blood Screen

- Stroke volume set button (also available on Prescription screen)
- Stroke Volume value box
- Arterial and Venous pressure values and trend graph
- Blood Settings button

Adjustable Stroke Volume

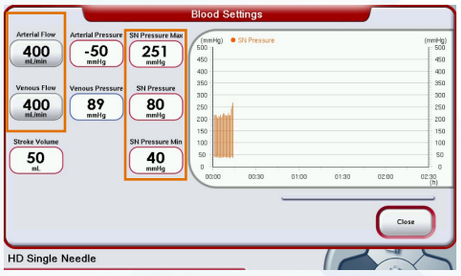
Blood Settings Sub-screen

- Arterial flow set button
- Venous flow set button



The Mean Blood Flow is automatically recalculated when Arterial or Venous Flow values are changed

- pSN: post dialyzer chamber pressure
- pSN Max, dependent of the stroke volume
- pSN Min, fixed at 40mmHg



Usually the venous pump runs about 30% faster than the arterial pump

SNDP Supervision

Operator control: Mean blood flow and Stroke Volume
Arterial and Venous flow adjustment (blood pump speed) for fine-tuning

System control: Post dialyzer pressure management; Arterial and Venous phases are managed according to the pSN Max and pSN Min values calculated on the basis of the Stroke Volume set

During Rinseback the A/V pumps run synchronously

NOTES

Nice to know

- Available with SNDP: The Diascan* & Hemoscan functions, Isolated UF
- The fluid level in the SN Venous Chamber is normally quite low
- The Blood setting button becomes available at blood detection
- When the Blood Setting sub-screen is open, the BP hard keys ▼ and ▲ are disabled
- When a SN parameter is changed, a few cycles are required for the change to become valid
- Switching needle mode:
- Isolated UF and the Hemoscan and Diascan* functions are available when the treatment is started in HD DN or SN DP mode.
- The Isolated UF function must be deactivated before switching Needle Mode (not available in the Select pad) and cannot be reactivated after the switch.
- The HemoControl function is available when the treatment is started in DN. When switching to SN (DP or SP), the HemoControl function is deactivated upon the Operator's confirmation of UF rate and dialysis fluid sodium concentration.

(*=accuracy not guaranteed for SN)

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Hands on: Chapter 10

- SNDP
- Switch between the needle modes

Artis Physio Plus SW 9.05

Chapter 11: The AFB K Therapy

Code 903334600
May 2019

Baxter

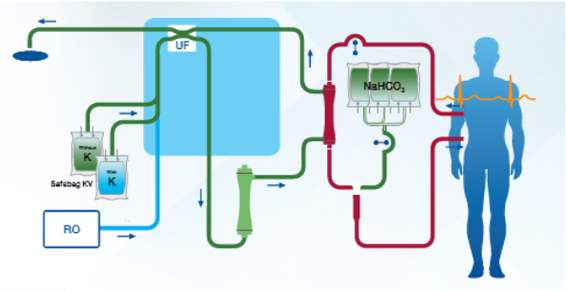
NOTES

AFBK

The AFB K Treatment

The AFB K modality enables potassium profiling for the management of potassium kinetics

- AFB K is a diffusive-convective HD modality characterized by acetate-free dialysis fluid complemented by infusion of sodium bicarbonate.
- Specific concentrate bags provide an easy and accurate individualization of the potassium in dialysis fluid.
- An advanced K profiling mode can be used to manage the K gradient between plasma and dialysis fluid



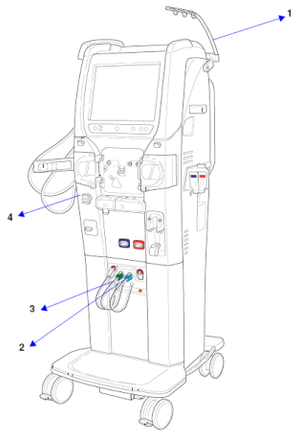
The AFB K Therapy on the Artis Physio Plus System

- Hardware / Software
- User interface principles
- Disposables
- Preparation
- Treatment delivery
  - K profile
  - K constant
- Surveillance system
- Special procedures
- Nice to know

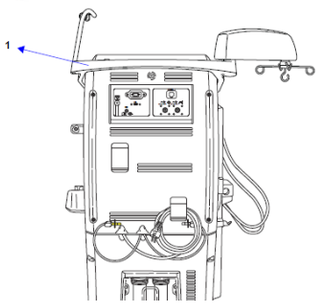
NOTES

Hardware | AFB K Configuration (1)

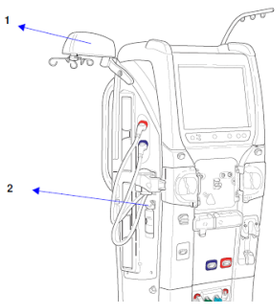
1. Infusion pole for Saline fluid
2. Green concentrate connector
3. Blue concentrate connector
4. Lines guide device for the:
   - AFB K infusion accessory line
   - Hospasol infusion inlet line
   - Venous Dialyzer Line



Hardware | AFB K Configuration (2)



1. AFB K infusion and scale support



1. AFB K scale
2. Hospasol Infusion Line Guide

The AFB K Therapy Software

AFB K must be preset to ON – or as default – in Service mode 2.

When the scale is effectively connected to the monitor, the Scale icon appears in the system icons area.

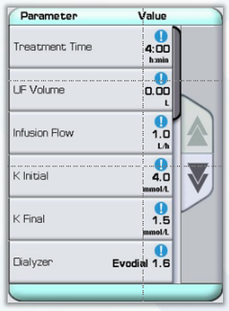
Scale icon

NOTES

User Interface | Mandatory Parameters Added

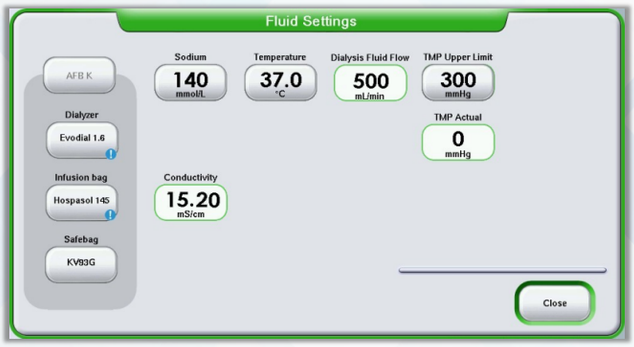
AFB K is available via the Prescription screen Treatment button.
Two dedicated control modes:
- K profile
- K constant (default)

A different set of mandatory parameters.
A dedicated flow path diagram, infusion flow rate and accumulated infusion volume is shown in the Overview screen.
Bicarbonate infusion parameters are also shown in Fluid screen.
AFB settings and K settings sub-screens are available via dedicated buttons in the Fluid screen button bar.
New concentrate composition taken into account in the Fluid settings sub-screen.



Note: Also the Hospasol bag bicarbonate concentration is a mandatory parameter (not visible in this screen shot)

The AFB K therapy | Fluid Settings Sub-screen



The AFB K Therapy | Disposables

- Dialyzer: the AFB K therapy is only compatible with the Evodial dialyzer.
- Safebag KV concentrates: The acetate- and buffer-free dialysis fluid concentrate in a double-compartment bag facilitating potassium profiling.
- Sterile bicarbonate solution: Hospasol infusion bag is the unique sodium bicarbonate infusion bag used in the AFB K therapy.
- Bloodlines: The standard ArtiSet HD DNL HC must be used in combination with a dedicated accessory: **evoset** AFB K infusion.

NOTES

Disposables | The Evodial Dialyzer

- The Evodial dialyzer is pre-heparinized.
- It enhances the stability of the bicarbonate clearance over the course of treatment.
- Priming volume should be set according to the Evodial dialyzer surface area:

Evodial dialyzer	Minimum priming volume
Evodial dialyzer 1.0, 1.3, 1.6	1500 mL
Evodial 2.2	1750 mL

Disposables | Safebag KV Connection

Safebag KV:

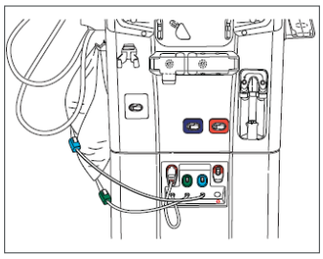
Two-compartment dialysis fluid concentrate bag

- Sodium chloride solution containing Ca^{2+} and Mg^{2+} - **green** connector
- Sodium chloride solution containing K^{+} - **blue** connector

KeyWay connectors:

Color coded (**green** and **blue**)

Mechanical key to facilitate safe connections



Disposables | Safebag KV

Safebag KV concentrates - 2 compositions, 3 codes

Safebag KV 1.9 + 3.6 L (1+34)		Electrolyte concentration after dilution						
Product code	Product name	Na^{+} mmol/L	K^{+} mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^{-} mmol/L	Acetate mmol/L	Glocose g/L
106890	Safebag KV93G 1.9 + 3.6 GB/S/I/ES	139	2.60 average	2	0.37	146	0	1
106981	Safebag KV93G 1.9 + 3.6 GB/D/F/NL	139	2.60 average	2	0.37	146	0	1
107193	Safebag KV95G 1.9 + 3.6 GB/FR/IT/ES	139	2.60 average	1.50	0.37	145	0	1

The Safebag KV does NOT contain any acetate

NOTES

Na^+ Setting & Conductivity in the AFB Therapy

	Na^+ mmol/l	K^+ mmol/l	Ca^{++} mmol/l	Mg^{++} mmol/l	HCO_3^- mmol/l	Cl^- mmol/l	CH_3COO^- mmol/l	Glucose g/l (mmol/l)
Safebag KV93G	139	2	2.00	0.37	0	145,50	0	1 (5.55)
BD* G294	140	2	1.75	0.50	34	109.50	3	1 (5.55)

Dialysis fluid conductivity (mS/cm)	AFB	BD
	15.20	14.13

*bicarbonate dialysis

The AFB K Therapy | Potassium Settings

K profiling:

- Requires to set initial and final [K^+]:
  - [K^+] initial: 3.1 mmol/l to 5.5 mmol/l
  - [K^+] final: 1.0 mmol/l to 3.0 mmol/l;
- Follows a degressive exponential-like curve;
- Is delayed by a few minutes not to interfere with the initial taration;
- Can be switched off at any time during treatment (K balance needs consideration).

K constant:

- Can be set within the range of:
  - [K+]: 1.5 to 3.5 mmol/l;
- [K+] set value can be adjusted at any time, which opens a possibility for manual profiling.

Disposable | Bicarbonate Solution

Hospasol sodium bicarbonate infusion solution:

- Prescription is always defined by the physician
- 2 compositions: 145 mmol/l and 167 mmol/l
- 2 formats: 3 L and 5 L
- Many codes: labeled per group of languages.

HOSPASOL

Captive product in the AFB K therapy used on the Artis Physio Plus system.

Hospasol is classified as a drug:

- Cannot be advertised (and sold) as other HD products.

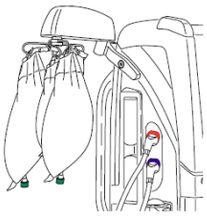
NOTES

Preparation | AFB K Scale

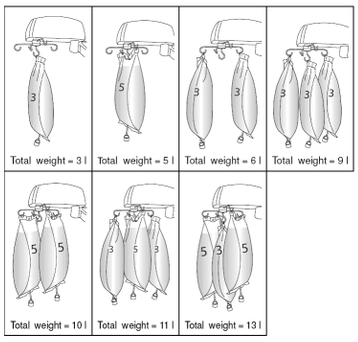
To install the Hospasol infusion bags, the scale must first be moved into its working position.

Turn the AFB K scale 90 degrees to the left; a click is heard when the scale rotation is completed and the device is locked in place.

The hooks of the AFB K scale must then be “opened” and positioned as shown in the figure.



Preparation | How to Hang the Infusion Bags



Hang the bags on the scale so that the weight is evenly balanced, using the different hooks (see the illustrations).

For accurate weight monitoring it is important nothing is interfering with the infusion bags; the bags must not be touched and should hang freely from the machine.

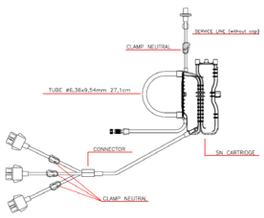
The maximum weight handled by the scale is 20 Kg.

Do NOT move the machine once the treatment has started

Preparation | The Extracorporeal Circuit

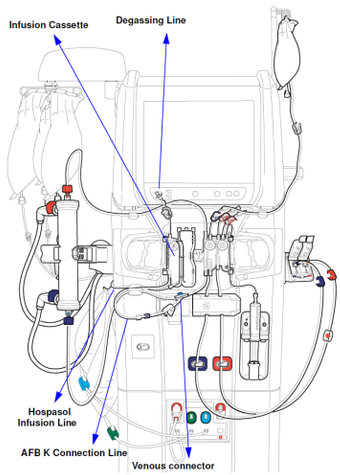
Bloodlines:

- The standard ArtiSet HD DN HC blood tubing system must be used in combination with
- The dedicated accessory: evoset AFB K infusion cassette



Function Check / Preparation

* Open Sensor Bar Door.
* Open Arterial and Venous Pump Covers to install the Blood and Infusion Cassettes.



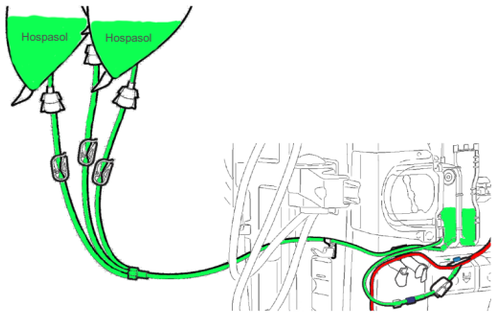
NOTES

Hospasol Infusion Connection

SAFE-LINK

A mechanical key to make the connection safe and easy.

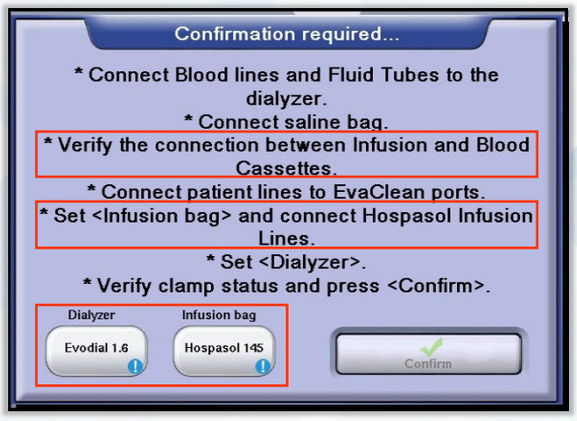
The perforator is included in the male connector of the infusion line.



Hospasol infusion

- Secured connection to the Hospasol bags
- Secured connection to the blood cassette post dialyzer

Preparation | The Extracorporeal Circuit



CADDY | Bicarbonatemia Surveillance System

Objective:

To check the adequacy of the infusion flow prescription all along the treatment considering the:

- Blood flow rate set – Hospasol bag concentration – Dialyzer – UF rate set

At start of treatment:

It checks the prescription set.

It prevents setting a value not consistent with the bicarbonatemia target, by triggering a notification alarm.

During treatment:

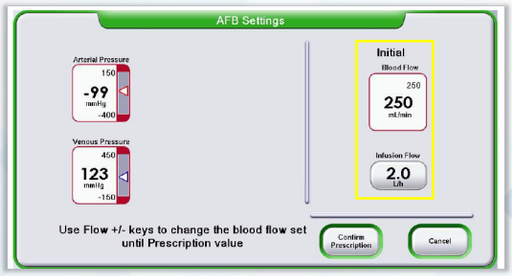
It monitors any change in:

- Blood Flow rate – Infusion Flow rate – UF rate (treatment time & UF)

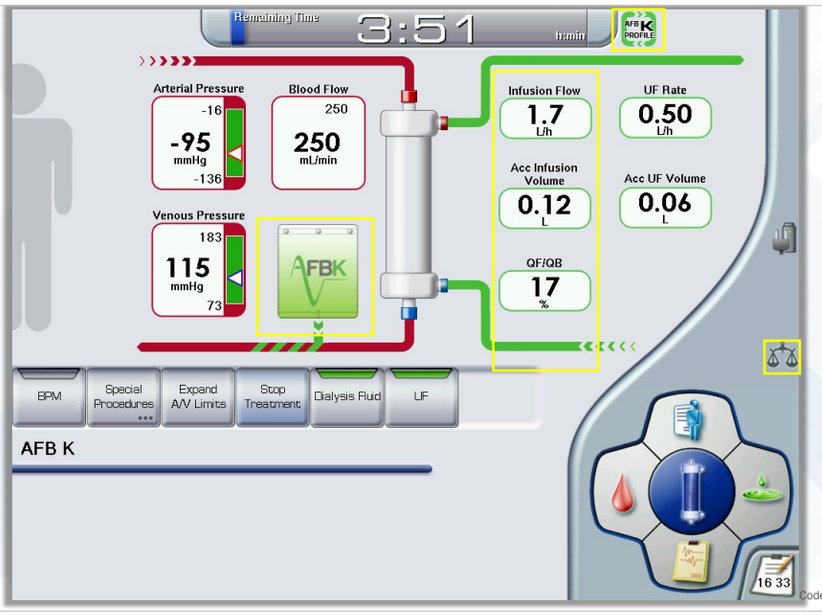
Any change not consistent with the Infusion Prescription will trigger an alarm.

NOTES

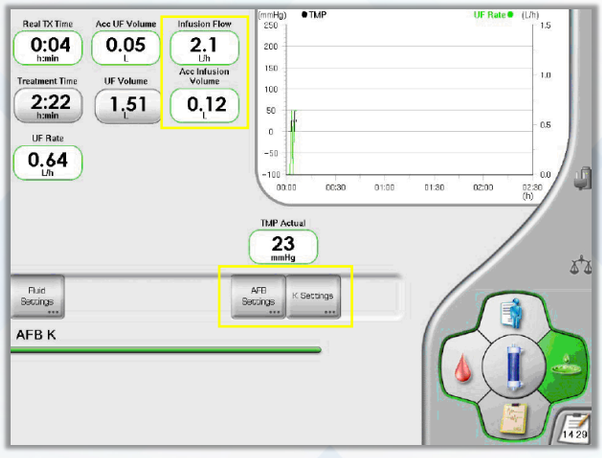
Set the Initial Infusion Prescription



- When the Start Treatment button is pressed – after the blood flow has been set – the AFB settings sub-screen is automatically displayed.
- Check the blood flow and bicarbonate infusion flow rates and press Confirm Prescription – the treatment starts.
- The set value is then used by the monitoring system as reference value for the rest of the treatment.



During Treatment | AFB K Fluid Screen



NOTES

CADDY | Blood Flow Change

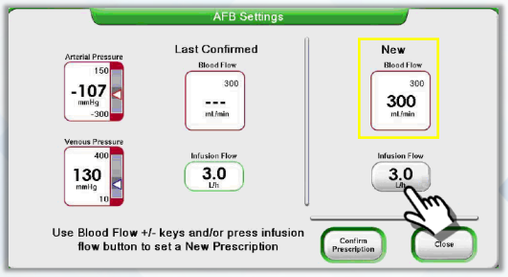
Any blood pump flow (QB) change after the treatment start, i.e. infusion prescription is set and confirmed, will be checked by the CADDY system for consistency with the bicarbonatemia target.

- If QB change may affect the patient's final bicarbonatemia, a specific alarm is triggered: "Infusion Settings Invalid Prescription #79".
- If the QB set results to be outside the current infusion prescription but inside the final bicarbonatemia target, an information message appears (#102).

- When Confirmed, a Confirmation Required window opens suggesting an Infusion Flow in compliance with the QB set and which guarantees the final bicarbonatemia is reached.

- If the final bicarbonatemia cannot be reached, no Infusion flow is proposed (----).
- In this case the QB has to be adjusted to meet the bicarbonatemia target.

CADDY | New Prescription



- The Blood flow rate as well as the Infusion flow rate may be manually adjusted.
- In case the final bicarbonatemia is then out of the acceptable range, the Confirm Prescription button will stay dimmed until the set value is within the allowed range.
- In case the CADDY system does not recognize the confirmed prescription valid, an alarm is triggered ("Infusion settings invalid prescription #79").

During Treatment

When deactivating the "UF" button:

- Only the weight loss UF process is interrupted
- The Dialysis Fluid button stays active
- The bicarbonate infusion continues

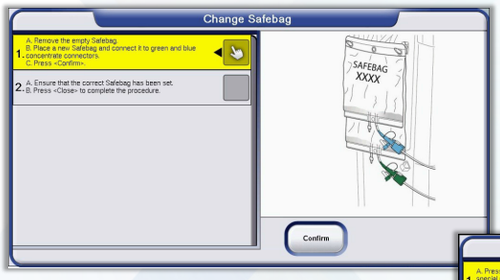
When deactivating the "Dialysis Fluid" button:

- The infusion UF process is interrupted
- The bicarbonate infusion is stopped
- The UF button stays active (weight loss)
- The Real Tx Time (diffusion) is not updated

The dialysis fluid button also controls the bicarbonate infusion. The UF button only controls the weight loss.

NOTES

AFB K Special Procedures (1)

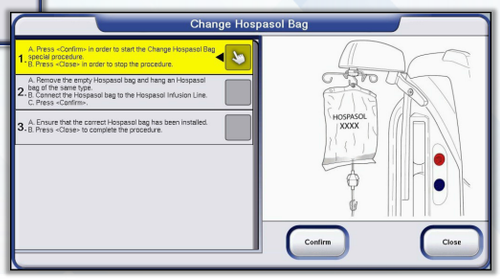


Change Safebag:

When one of the two bags are empty an alarm is triggered (#610 or #611)

Change Hospasol bag:

Do NOT hang or remove any bag without first confirming the Special Procedure



AFB K Special Procedures (2)

Adjust Chamber Level in Infusion Cassette:

When the fluid level in the AFB K infusion cassette is below the middle of the cassette, the level should be adjusted accordingly:

1. Press the “Dialysis Fluid” button to deactivate the dialysis fluid flow;
2. Remove the blood catcher from the Service Line and attach a sterile syringe to the Service Line;
3. Open the clamp of the Service Line and adjust the fluid level in the Infusion Cassette chamber by using the syringe until it reaches the middle of the Infusion Cassette;
4. Close the Service Line clamp and remove the syringe from the Service Line;
5. Press the “Dialysis Fluid” button to activate again the dialysis fluid.

Nice to know

- It is not possible to activate the K profile mode after treatment has started in K constant mode. However, it is possible to switch from K profile to K constant mode at any time.
- In K constant mode, it is possible to set a new K dialysis fluid concentration at any time.
- The Diascan function is compatible with the K constant mode, and can be used if this mode has been set at treatment start.
- As long as a change in blood flow results in an infusion flow rate in the acceptable range, a new infusion flow rate value is proposed by the Surveillance System.

NOTES

Safety Notice | Pump Rotor Damaged

- A partial automatic loading of the pump segment, followed by a rushed manual unloading may result in a damaged pump rotor.
- The pump will not work properly (not occlusive anymore), and this may lead to a patient adverse event.
- If the pump rotor is damaged, DO NOT use the machine for treating patients, until service has been involved for maintenance.
- Use the crank when unloading the set manually, and do not pull the cassette out if the hooks of the cassette loader have not been pushed out.

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Hands on: Chapter 11

- Select the AFB K therapy
- K profile mode
- Load ArtiSet blood tubing system + AFB K infusion
- Auto-priming
- Start treatment
- Change blood flow / infusion flow
- Change Hospasol bags
- Switch to K constant
- Auto-rinseback
- Unload cassettes

Artis Physio Plus SW 9.05

Chapter 12: Communication

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NOTES

The Artis Physio Plus System Connectivity Panel

The connectivity panel at the rear of the machine is equipped with some communication ports.

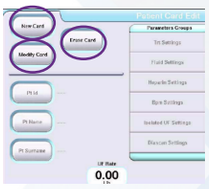
The Artis Physio Plus System Native IT Features (1)

The Contact-less Patient card

The Artis Physio Plus system allows to fully handle the card (format/read/write). No other devices or software products are needed.

- *Patient identification*
- *Prescription download to the Artis Physio Plus system*
- *The contact-less technology makes it fast and secure*
- *The Artis Physio Plus system reads the prescription from the card or from the network.*
- *The patient card can be modified from start to Connect Patient and additionally from the dialyzer emptying phase onwards.*

Patient Card Handling



The 3 operations (New Card – Modify Card – Erase Card) can be directly made on the machine (no other device or software are needed).

How to read: the Patient Card must be brought straight in front of the reader (located above the EvaClean device).

When download of the prescription is possible:

- only when the Prescription screen is displayed and until patient connection
- out of treatment and during disinfection.

When the prescription is downloaded, a review window is displayed. The operator must verify the adequacy and confirm. The same mandatory parameters (identified with an exclamation mark symbol) as the manual prescription must be confirmed before patient connection.

When Exalis is in use, the Patient Card can be configured as a patient ID Card, allowing to download the patient prescription from the network without any manual search/ID typing.

NOTES

The Artis Physio Plus System Native IT Features (2)

Universal Serial Bus

The Artis Physio Plus system hosts a USB port on its back-side. This port allows to:

- *Use a USB key to copy settings from a machine to another;*
- *Retrieve black-box sessions;*
- *Perform software upgrades of the Artis Physio Plus system.*

The Artis Physio Plus System Native IT Features (3)

Exalis connectivity (V1.16)

The Artis Physio Plus system is natively able to be integrated with Exalis 1.16. The communication protocol between the Artis Physio Plus system and Exalis is performed by means of a proprietary protocol that runs on TCP/IP.

Co-working of the Artis Physio Plus system with Exalis allows:

- *Automatic data collection (treatment results, alarms and operating phases)*
- *Data management (patient history files, treatment report, ...)*
- *Data export from Exalis to 3rd parties according to HL7 protocol*
- *Prescription download*
- *Data storage*
- *Pre/post dialysis recording*

exalis

Nice to know

- Activation of the Patient Card reader and of the Exalis connection is done in Service 2.
- Connection to Exalis, as well as Mediartis or any Clinical Software, requires the network parameters to be preset.
- In case of Exalis connection, the Patient Card shall be preset as “ID Card only”.
- The <Patient ID> button is displayed in the prescription screen only if the machine is effectively connected to Exalis.

NOTES

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