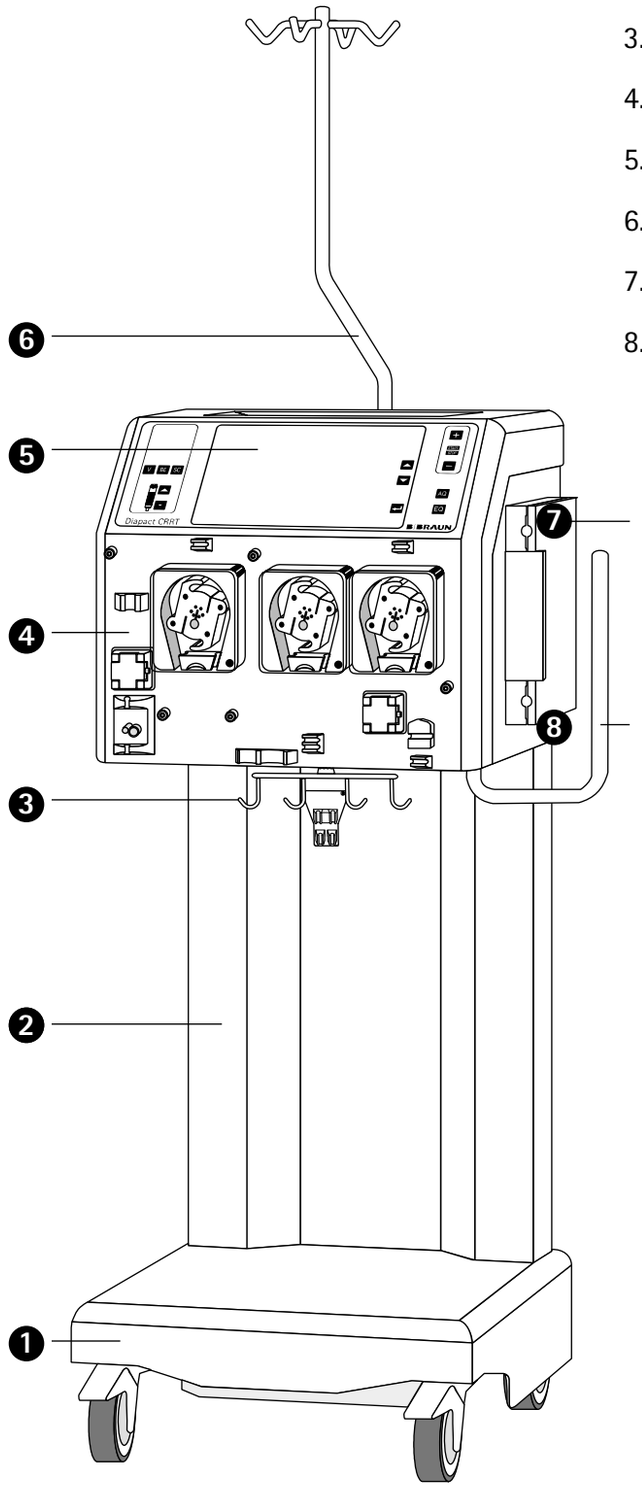
2. Equipment Description

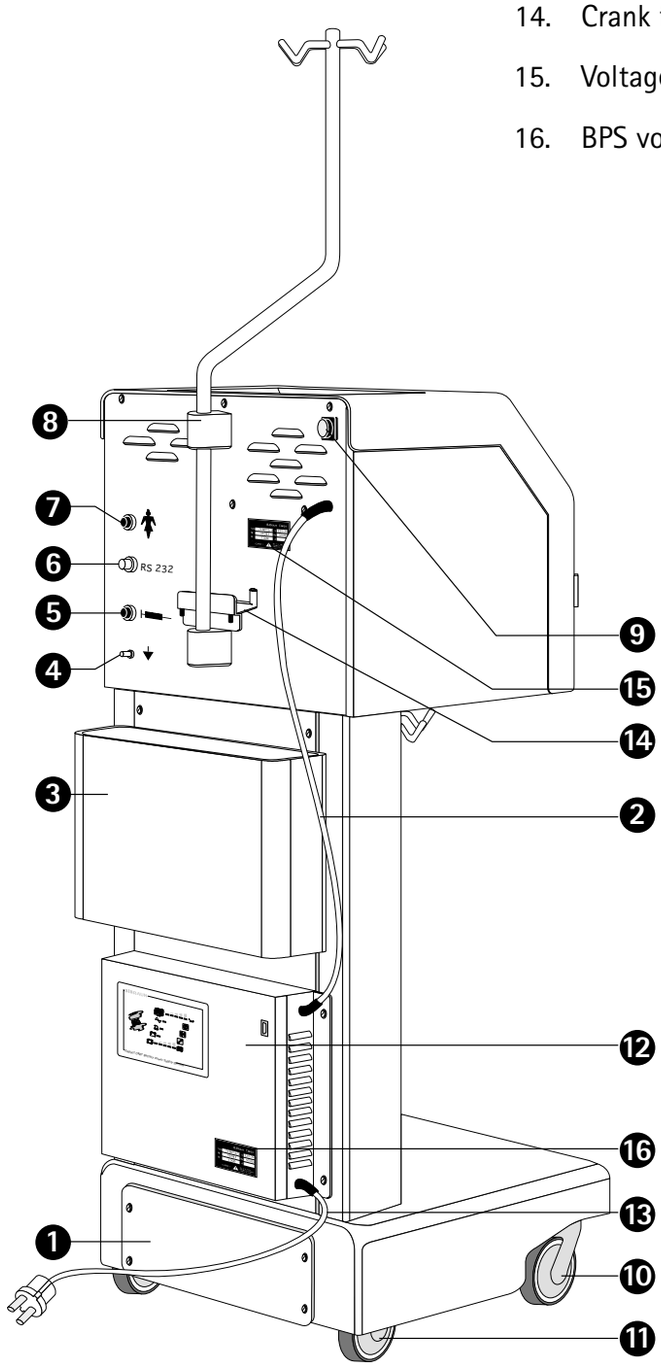
2.1 Front View

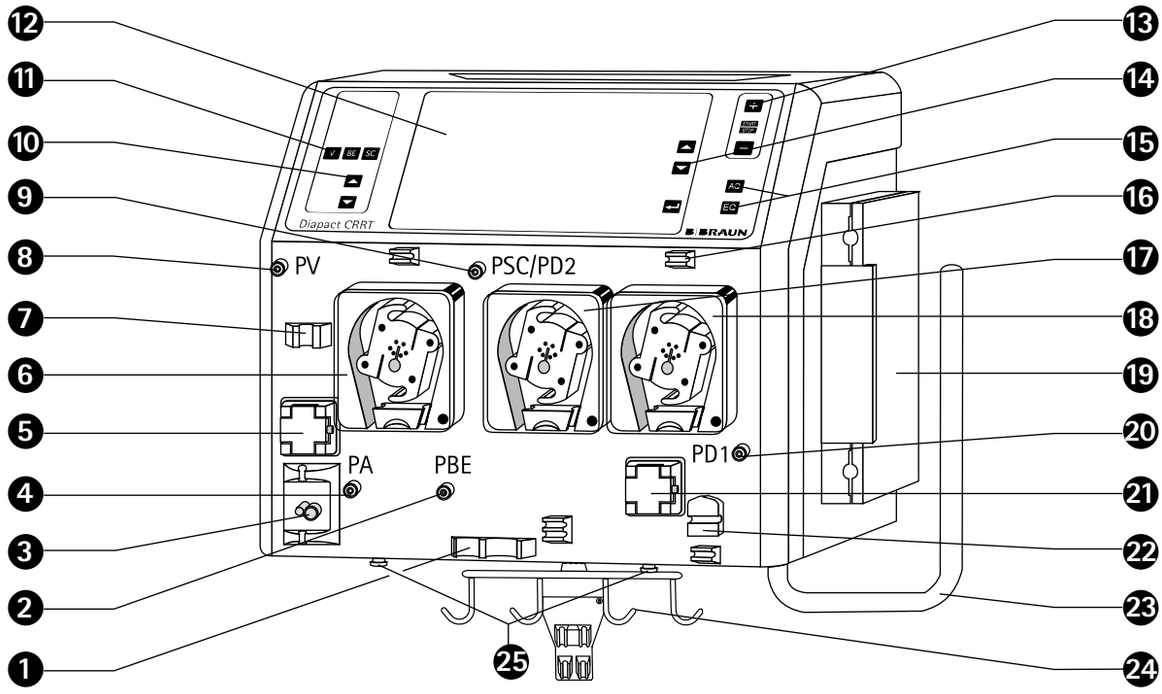
1. Trolley basement
2. Trolley
3. Bag holder (turnable)
4. Pump module
5. User interface screen
6. IV pole (movable)
7. Plate warmer
8. Filter holder (movable)



2.2 Rear View

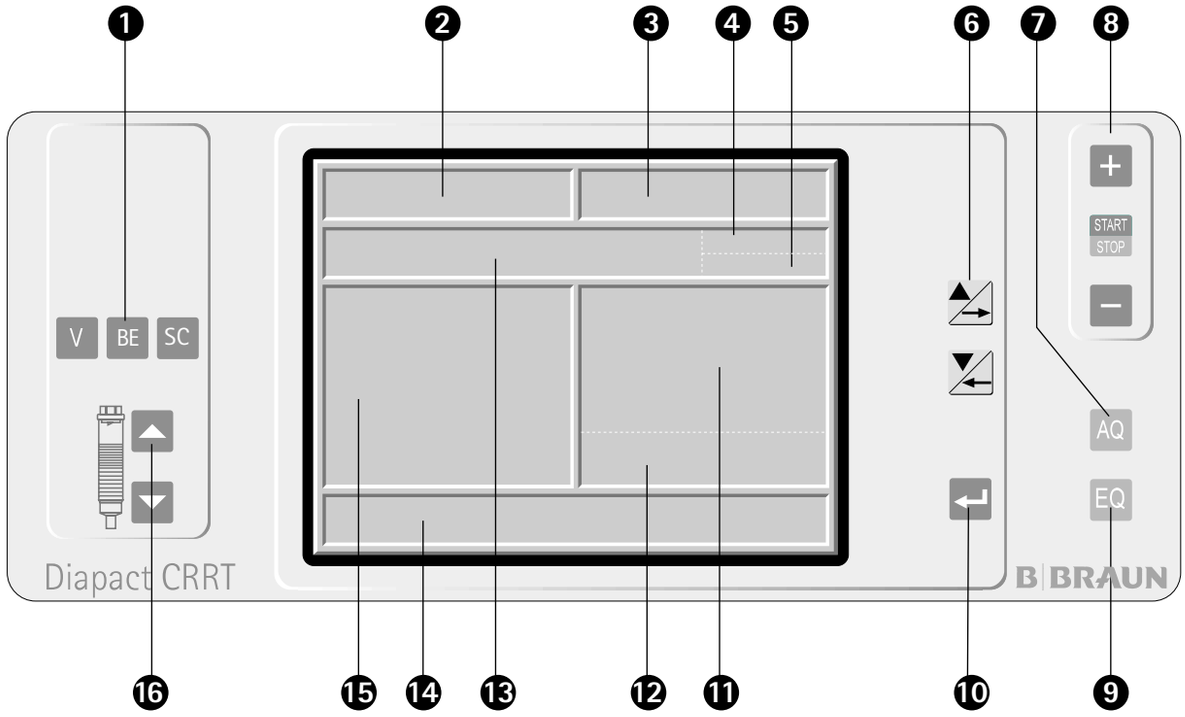
1. Battery package case
2. Main cable
3. Disposable kit container
4. Equipotential connection
5. External pump connection
6. RS 232 output connection for standard PC
7. Nurse call connection
8. IV pole holder
9. Main switch
10. Caster
11. Rear wheel
12. Battery Power Supply (option)
13. Battery Power Supply main cable
14. Crank for manual blood return
15. Voltage / identification label
16. BPS voltage / identification label





2.3 Pump Module

1. Prefilter and switching chambers holder
2. Connection for prefilter pressure measurement (PBE)
3. Safety clamp (SAK)
4. Connection for withdrawal pressure measurement (PA)
5. Safety Air Detector (SAD)
6. Blood pump (MP1)
7. Venous chamber holder
8. Connection for return pressure measurement (PV)
9. Connection for switching chamber pressure measurement in Single Needle mode or fluid outlet pressure measurement (PD2/PSC)
10. Up-and-Down chamber level adjustment push-buttons
11. Chamber selection push-buttons
12. "LCD" graphic display screen
13. Blood pump control push-buttons
14. Function selection and increase/decrease push-buttons
15. Alarm acknowledge (AQ) and enter acknowledge (EQ) push-buttons
16. Tube holder (single or double)
17. Fluid outlet pump (venous pump in Single Needle) (MP2)
18. Fluid inlet pump (MP3)
19. Plate warmer
20. Connection for fluid inlet press. measurement (PD1)
21. Air detector (AD)
22. Blood leak detector (BLD)
23. Filter holder
24. Bag holder
25. Holder for preassembled kit mounting



2.4 User Interface

1. Chamber selection push-buttons
2. Display area of therapy mode (acronym and complete description)
3. Display area of treatment status
4. Display area of safety relevant data (Supervisor area)
5. Display area of range values during Parameter Setting procedure
6. Push-buttons for cursor shifting (up/right ; down/left)
7. AQ push-button (Acknowledge)
8. Push-buttons for blood pump control (Start/Stop, +,-)
9. EQ push-button (Confirmation)
10. Function-data enter push-button
11. Display area of fluid data and parameters
12. Display area of cycle time and therapy time
13. Display area of alarms, warnings and messages
14. Display area of function selection
15. Display area of blood data and parameters
16. Up-and-Down chamber level adjustment pushbuttons

2.4.1 Display

The LCD display is the main element of the user interface. The display enables the operator to:

- select treatment mode (e.g. CVVH, CVVHD etc.)
- adjust treatment parameters, select treatment phase: e.g. start, stop, priming, etc.
- monitor main parameters during the treatment (total overview, pressure overview, main parameters, etc.)
- read warnings and messages.

2.4.2 Screen organization

The screen is divided into areas, each of them with a specific purpose.

Therapy mode (2)

This field displays the therapy mode (e.g. SCUF, CVVH, etc.) acronym realised with special character types and its complete description.

Therapy status (3)

This field displays the therapy status (PREPARATION, THERAPY, END OF THERAPY) and the sub-phase (Stand-by, Running, Test, etc.)

Alarms, Warnings, Messages (13)

In this field the system displays:

- alarm messages (description)
- warning messages (possible cause)
- question messages and request for confirmation in the various procedures.

Safety relevant data (4), Supervisor area

In this field the new status and the value of safety relevant data (e.g. UF volume) are displayed after the status change command (i.e. End of Preparation) has been given and the Parameter Setting procedure completed.

Function area (14)

Before selecting the therapy, the field displays the messages: (i.e.)

- Select therapy mode and confirm
- Make new calibration or contact service.

After the therapy has been chosen, the field displays:

- Parameter setting
- Start/stop priming
- Back selection
- Therapy start
- Main parameters
- End of treatment
- Total overview
- Pressure overview
- SAD exclusion
- Back to treatment.

Parameter range (5)

During the parameters setting procedure the system displays the possible range values.

Blood data (15)

In this area all data and parameters concerning the extracorporeal blood circulation are displayed (flow rate, total treated blood, pressure value, etc.)

Fluid data (11)

In this area all data and parameters concerning the fluid circulation are displayed (flow rate, temperature, pressure value, total volume).

Therapy time (12)

In this area the system displays:

- cycle time (selectable and repeatable)
- total therapy time .

2.4.3 Keyboard functional description

Use of ▲, ▼ (6), and ↵ (10) push-buttons

These push-buttons operate as follows:

▲ moves the cursor up in the data/parameter area, moves the cursor from the left to the right in the function area;

▼ moves the cursor down in the data/parameter area, moves the cursor from the right to the left in the function area;

↵ gives the confirmation after selecting the required data or function.

Therapy selection

When "THERAPY SELECTION" status is displayed on the screen, the therapy can be selected by means of

Up-and-Down push-buttons:

↑ moves the cursor up, ↓ moves the cursor down, gives the confirmation after selecting the required therapy.

Function selection

The functions available during the Preparation and Therapy phases are displayed in the lower part of the screen.

The required function can be selected by means of Up-and-Down push-buttons:

moves the cursor from the left to the right,

moves the cursor from the right to the left;

gives the confirmation after selecting the required function.

Parameter setting

The parameters of each treatment are displayed in the screen widest areas (15, 11).

The parameter setting should be performed as follows:

Select the parameter to be set by means of cursors and .

Once the parameter value has been selected, push enter button .

Now the selected parameter can be increased or decreased by means of and buttons.

Once the parameter has been adjusted, confirm with button.

Then push again to quit the Parameter Setting function.

Blood pump (8)

The blood pump can be turned on/off by means of START/STOP push-button:

- pilot light on: the pump is OFF
- pilot light off: the pump is ON

This switch can be enabled by connecting the main switch on the rear panel.

The blood pump speed can be increased and decreased directly by means of „+" and „-" push buttons in steps of 10 ml/min, hence the blood flow can be mo-dified without recurring to the Parameter Setting procedure.

Push-buttons for blood level adjustment in the prefilter, venous and SN switching chambers (1-16)

The blood level adjustment in the prefilter, venous and SN switching chambers can be automatically achieved with the internal peristaltic pump.

V, BE and SC push-buttons select the chamber, respectively:

V - venous chamber

BE - prefilter chamber

SC - switching chamber in SN mode

Once the required chamber has been selected, the level can be adjusted by means of the and (up and down) buttons.

UP: when this button is kept pressed, the internal peristal tic pump creates a negative pressure and removes air, thus raising the blood level.

DOWN: when this button is kept pressed the internal peristaltic pump creates a positive pressure and inflow air, thus lowering the blood level.

Alarm management: AQ (Acknowledge) push-button (7)

Every alarm condition activates an acoustic and visual signal. The AQ pilot light is on and the alarm description is displayed on the screen. The operator should act as follows:

- silence the acoustic alarm by pushing this button once
- eliminate the description of the alarm
- push AQ again to reset.

E.g. an alarm condition is occurring:

1. The acoustic alarm and the AQ red pilot light arew activated.
2. The operator pushes AQ once: the acoustic alarm stops, the visual alarm is still on, the cause of the alarm is displayed on the screen.
3. The operator detects the alarm cause and eliminates it.
4. The operator pushes AQ again: the visual alarm disappears, the message on the screen is cleared. The machine runs normally again.

Confirmation of status changing and value of safety relevant data: EQ push-button (9)

EQ button is used to confirm status changing requests on the screen in fdifferent situations:

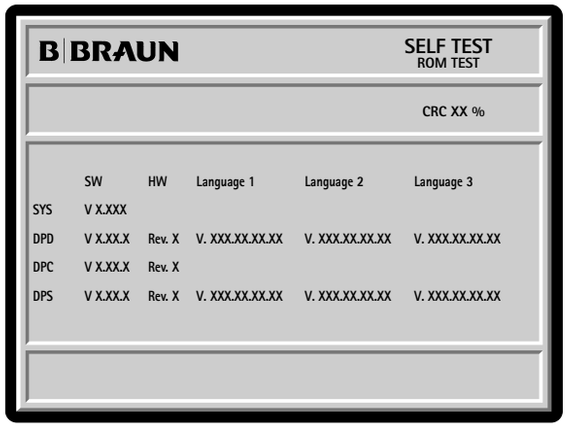
E.g. during the therapy selection phase or at the end of the parameters setting procedure in case of safety data variation.

2.4.4 Special funktions keys

By pressing together V and BE key as from the table below it is possible to select a special function.

Basic functions	ident. symbols	Special funktion (with V and BE)
Blood pump increase	BP+	back light up
Blood pump decrease	BP-	back light down
Event confirmation	EQ	(1 sec) TSM mode
Move up/Increase		contrast up
Move down/Decrease		contrast down
Activate operations		(1 sec) no restore
SN-chamber select	SN	language change
Chamber level up		skip priming
Chamber level down		service screen

3. General Options

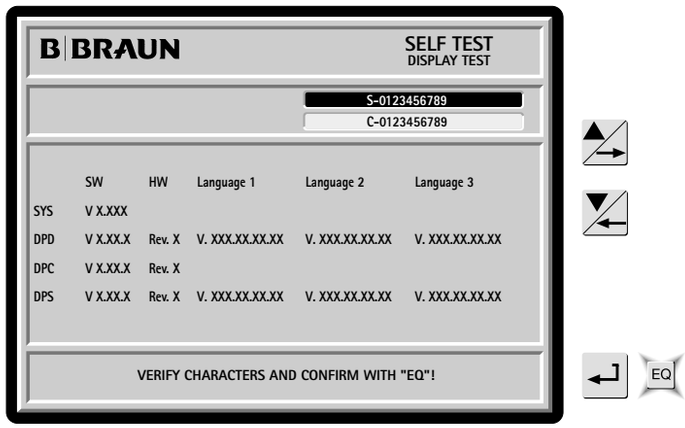


3.1 Start Up

After the installation is carried out according to the instructions in par. 9.1, the system is ready to operate.

Diapact CRRT is powered by the mains voltage through the main switch ON/OFF (I/0) on the rear panel.

WARNING!
During the ROM test that follows the switching on, all leds are on. The operator should especially verify that AQ and EQ lights are on.

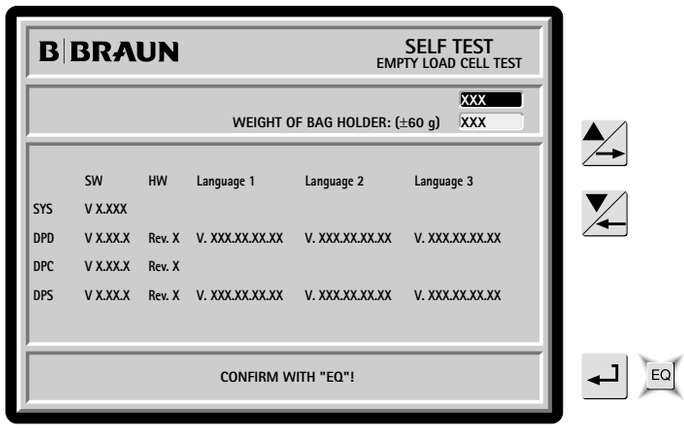


After turning this switch on, the machine performs two self-tests:

Display test

The operator must compare and confirm the character sets displayed on the screen by pushing EQ button.

WARNING!
At pressing EQ push-button, the safety system buzzer is activated for 2 seconds (functional check).

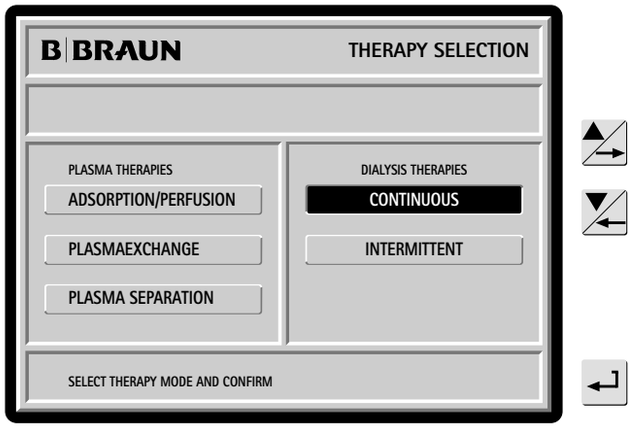


Empty load cell test:

The operator checks that the bag-holder is free, then confirms the weight value by pressing EQ button if the value is within the range.

The weight of empty load cell (bag holder only) is displayed in the text line. The maximum difference allowed between the controller value (white field) and the supervisor value (black field) is ± 60 g.

In case of error condition persist, the operator shall contact the Service to verify the calibration.

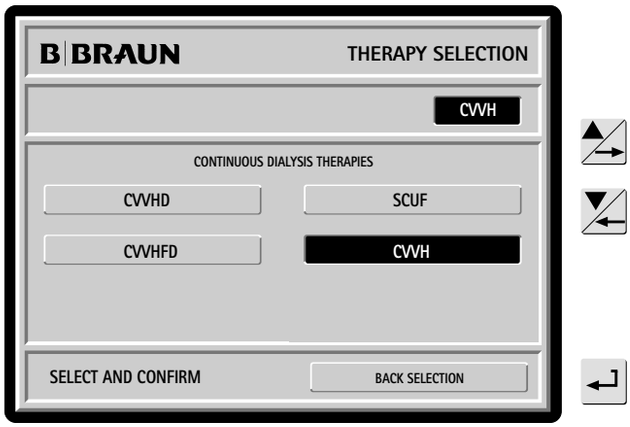


3.2 Therapy Selection

When the power-on self-tests are over, all possible therapies are displayed on the screen.

The operator selects the therapy by means of cursors ↑ and ↓. The choice will then be confirmed by pushing the ↵ button.

Once the machine is started, the cursor is positioned on the latest selected therapy. The operator can either confirm it or make another choice. The selected field is marked and can be confirmed by pushing the ↵ botton.

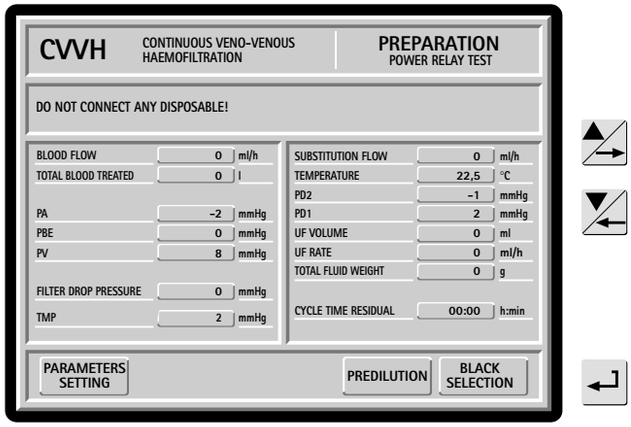


Selecting a therapy (i.e. CVVH)

In Therapy Selection, after activating the appropriate therapy, a blinking inverse string appears at the supervisor position for a few seconds and the EQ key lights up.

If the user doesn't press the EQ key, the blinking string disappears (the light of EQ key goes out) and the machine remains in Therapy Selection status.

If the user presses the EQ key while the blinking string is on the Preparation phase will be started. The status line changes to PREPARATION.

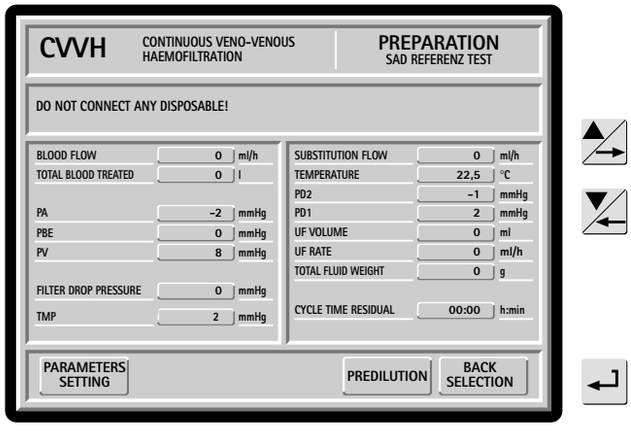


3.2.1 Hardware-Test

Before starting the connection of the disposables and the priming phase, the system performs a series of hardware self-tests. The disposables should not be connected during this phase, as from the indication on the display. The hardware tests performed are the following:

Power relay test

The power relay that commutes +24V voltage is tested for functionality.

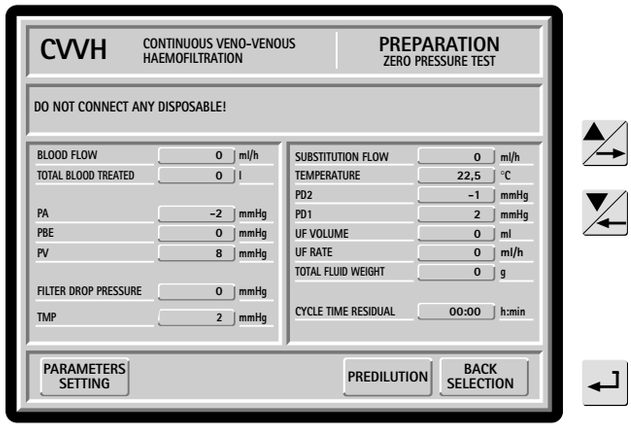


SAD reference/counter test

Two functional tests are performed in sequence on the Safety Air Detector:

reference test

counter test



Zero pressure test

When the disposable has not been connected yet and the connectors are, therefore, free, the zero pressure values of the main pressure transducers (PA, PV, PD2/PSC) are tested and compared one another. When the hardware test is over, the system informs the operator that the disposable connection is now possible. The lines are to be set up stepped according to the instructions list given on the screen. More details and drawings about disposable setting-up are available in the chapters describing each therapy.

3.3 Disposable Kit Setting Up

When the hardware test is over, the system informs the operator that the disposable connection is now possible. The lines are to be set up stepped according to the instructions list given on the screen. More details and drawings about disposable setting-up are available in the chapters describing each therapy.

WARNING!

In this phase, the operator shoud pay attention and hear the acoustic confirmation given out by the system. The operator should also perform the required actions as per the instructions on the screen.

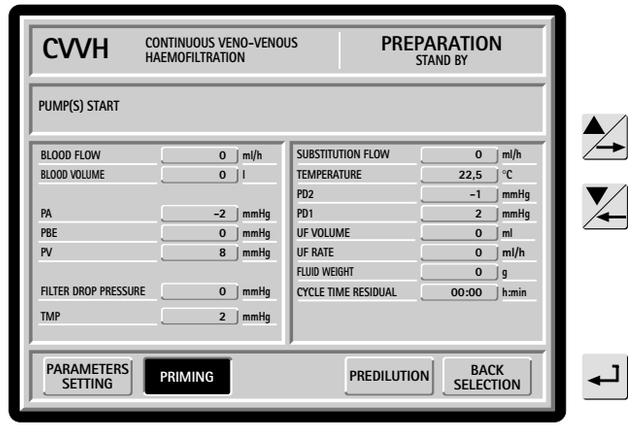
3.4 Preliminary Steps

Once the device test is over, the operator can do the following:

- activate the BACK-SELECTION function: e. g. select a different therapy in case of mistake. During this procedure, the Supervisor text (THERAPY SELECTION) appears. The user must confirm it by pushing the EQ button
- enable the PARAMETER SETTING function in order to set the parameters of the selected therapy
- enable the PRIMING function in order to start the priming or to stop it while running.

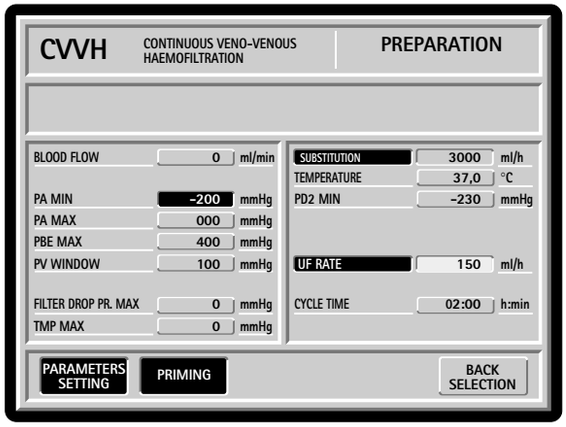
WARNING!

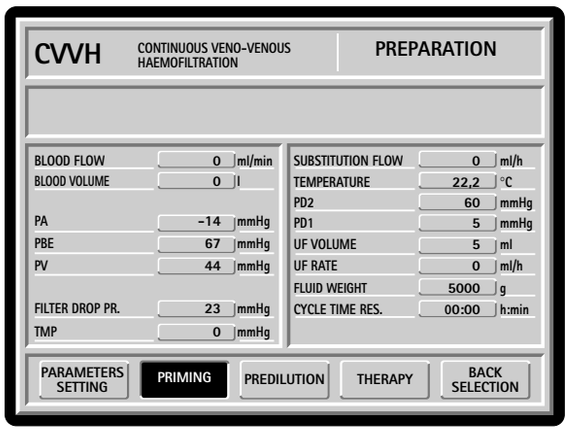
Before starting the priming phase, make sure that all clamps and snap-off connectors are open.

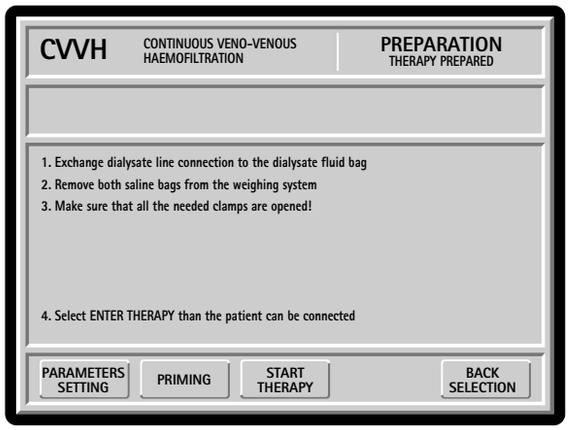


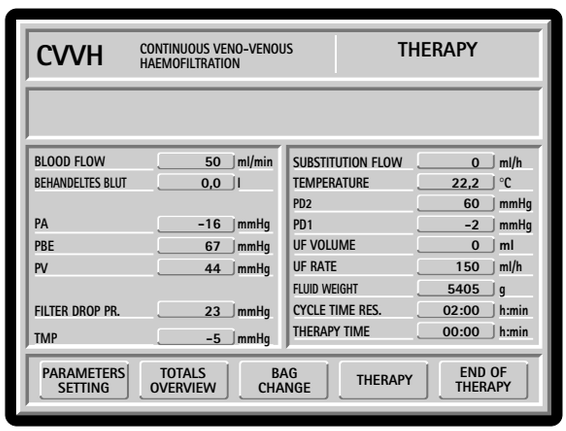
3.4.1 Priming

After the START-STOP PRIMING function activation, the system displays the message START PUMP(S)! In this situation it is necessary to push the blood pump relevant key. The machine starts the priming and performs a series of dynamic tests. If tests give negative results, the relevant warning message is displayed on the screen in order to identify the cause. The test can be repeated several times. If the fault condition persists, the Service must be contacted.









3.5 Parameter Setting and Adjustment

During the dinamic tests, the operator can select the parameter to be modified by means of cursors ↑ . and ↓ .

Once the parameter has been selected, push ↵ button.

Now the selected parameter can be increased or decreased by means of ↑ and ↓ buttons.

Once the Parameter Setting is completed, confirm it by means of ↵ .

Press ↵ once more to quit the Parameter Setting function.

3.6 End of Priming / Rinsing

At the end of the Preparation phase (filling and dynamic self-tests), the system performs a two minutes' final rinsing, then it stops.

START THERAPY function is displayed on the screen.

The operator can now activate the START THERAPY or, if necessary, continue the rinsing under his/her own control by enabling the RINSING function.

3.7 Therapy

After the rinsing phase, the START-THERAPY button is displayed at the bottom line of the screen. The START THERAPY function can be selected by the operator and therefore activated at any time.

The disposable setting-up shall be modified as per the guideline on the screen.

In order to switch from PREPARATION to THERAPY, the user must select START THERAPY, then press the EQ key while the string THERAPY is blinking at the supervisor position (safety procedure).

IMPORTANT NOTE!

In case the safety data have neither been modified nor confirmed during PARAMETER SETTING procedure, the system does not allow to switch to THERAPY. The operator must confirm the safety data , i.e. Substitution flow, Weight loss, Plasma volume...

Full information about Therapie and End of Therapie management in each treatment mode is given in the following chapters of this operating manual.

Ratio filtrate flow to blood flow

In case the ratio filtrate to blood flow will be exceeded in continuous/intermittent therapies 25 % and plasma therapies 35 % you will receive a warning. When exceeding the 50 % limit you will receive an alarm and the fluid side stop.

When selecting the function "PREDILUTION" the ratio hint/-alarm is not active.