7 Alarms

8.1 Alarm Display and Resetting

8.1.1 Alarm Display and Resetting during Priming / Self-test

During Priming and Self-test phases, some alarms may occur that stop the test in progress. These alarms can frequently be the consequence of incorrect operations or tubing line assembling.

In case of an alarm, the acoustic signal is activated, the AQ push-button led lightens, and the running test alarm is displayed in the dedicated area on the screen.

The acoustic signal can be muted by pressing AQ push-button once.

After the cause of the alarm has been removed, the failed test can be repeated by pressing AQ push-button again.

Alarm conditions that may occur during the sequence of the tests are listed below. The causes and the suggested remedies are also given.

DPC (DPS) self-test failed	Possible cause	Suggested remedy action
Device hardware test:		
Power relay test	accidental trouble	Switch OFF and ON the equipment to try again
	technical failure	call service
SAD reference test	accidental trouble	Switch OFF and ON the equipment to try again
	technical failure	call service
SAD counter test	accidental trouble	Switch OFF and ON the equipment to try again
	technical failure	call service
Zero pressure test	deviation of value > 20 mmHg between two sensors	new calibration is necessary
	disposable connected	remove disposable (transducer protector only)
	technical failure	call service

DPC (DPS) self-test failed (902) / (904)	Possible cause	Suggested remedy action
Test during Preparation:		
Load cell test	disposable setup configuration	check setup configuration
	saline bag closed	open the saline bag clamps
	blood pump segment occluded	check the occlusion
	technical failure	call service
Air detector test	disposable setup configuration	check setup configuration
	saline bag closed	open the saline bag clamps
	tubing line not empty at test start	empty the tubing line
	dialysate / solution pump seg- ment obstructed	remove the obstruction
	technical failure	call service
Dialysate / Solution /	disposable setup configuration	check setup configuration
UF pump test	pump segment size according to the selected therapy	check therapy mode
	pump segment obstructed	remove the obstruction
	technical failure	call service
Heater test	accidental trouble	repeat the test
	technical failure	call service
BLD calibration / test	accidental trouble	check tubing insertion and repeat the test
	technical failure	call service
Disposable leakage test	disposable setup configuration	check setup configuration including connections
	blood pump segment occluded	check pump segment
	safety clamp obstructed	check safety clamp for obstruction
Level adjustment test	level adjustment pump segment	repeat the test and/or call service

8.1.2 Alarm Display and Resetting during Therapy

The alarms and warnings that may occur during Therapy are displayed in the dedicated field on the screen.

An acoustic signal is activated and AQ push-button led lightens when a problem occurs.

Press AQ push-button once to stop the acoustic signal.

The acoustic signal is reactivated after 60 seconds if the trouble has not been shot.

When the cause of alarm has been identified and removed, the acoustic signal can be silenced by pushing AQ push-button again. The red led turns off and the system starts again.

Alarms and warnings that may occur in all therapies are listed here below so to help the user identify and remove them. The causes and the suggested remedies are also given.



PA lower limit (812) PA upper limit (810) PBE upper limit (814)	blood pump speed too fast value setting wrong limit catheter or fistula needle incorrectly positioned or obstructed technical failure no blood flow catheter or fistula needle are not connected blood flow too high tubing line kinking	adapt blood flow to the patient adjust low limit value check catheter or fistula needle call service check blood flow check catheter or fistula needle positioning adapt blood flow to the filter size	
PA upper limit (810) PBE upper limit	catheter or fistula needle incorrectly positioned or obstructed technical failure no blood flow catheter or fistula needle are not connected blood flow too high tubing line kinking	check catheter or fistula needle call service check blood flow check catheter or fistula needle positioning	
(810) PBE upper limit	tioned or obstructed technical failure no blood flow catheter or fistula needle are not connected blood flow too high tubing line kinking	call service check blood flow check catheter or fistula needle positioning	
(810) PBE upper limit	no blood flow catheter or fistula needle are not connected blood flow too high tubing line kinking	check blood flow check catheter or fistula needle positioning	
(810) PBE upper limit	catheter or fistula needle are not connected blood flow too high tubing line kinking	check catheter or fistula needle positioning	
PBE upper limit	not connected blood flow too high tubing line kinking	positioning	
	tubing line kinking	adapt blood flow to the filter size	
(814)	1		
		check tubing connection	
	anticoagulation rate	check anticoagulant flow rate	
PBE lower limit	tubing line kinking	check line	
(816)	UF Rate to high	adapt UF Rate	
	filter efficiency	check filter	
PV upper limit	blood pump speed too high	reduce blood flow	
(806)	high limit of window control	set new window limit	
	catheter or fistula needle in wrong positi-	check catheter of fistula needle	
	on or obstructed		
	technical failure	call service	
PV lower limit	blood pump speed too low	increase the blood flow	
(808)	low limit of window control	set new window limit	
	catheter or fistula needle disconnected or out of shunt	check catheter or fistula needle	
	leakage in the transducer protector or in the level adjustment system	check transducer protector and level adjustment system by a syringe	
	technical failure	call service	
PFD upper limit	decreasing of filter efficiency	flush filter	
(822)	anticoagulation rate		
	filter clogging	replace filter	
Air in the blood return line	blood level below the chamber	readjust blood level (follow special	
(802)		procedure, par. 8.2)	
	blood flow too fast (turbulence)	adapt blood flow to the system	
	tube deformed due to long squeezing	turn the tube into the device	
	SAD cover not properly closed	check the cover is properly closed	
	technical failure	call service	
Long time blood pump stop	blood pump stop command	start blood pump	
(830)	technical failure	call service	
Blood pump cover open (824)	the blood pump cover is open technical failure		
High removable ratio of blood	Ratio total- UF / bloodflow	decrease Sub flow and / or increase	
(832) > 25% in Dialysis therapies blood flow		·	
	> 35% in Plasma therapies		



Alarm/Warning	Possible cause	Suggested remedy action
Blood leak sensor failure (836)	Selftest disturbed	repeat the test and / or call service
PD1 upper limit	tubing kinking or warming bag occlusion	check tubing connection and warming bag
(848)	blood side high pressure	check blood side pressure
PD1 lower limit (850)	disconnection of the green Subline	Check connection
PD2 upper limit	tubing kinking	check tubing connection
(852)	UF rate too high	adapt the UF rate to the filter size
	filter efficiency	check filter condition
PD2 lower limit (854)	disconnection of the yellow filtrat line	Check connection
TMP upper limit	UF rate too high	adapt UF rate to the filter size
(856)	filter efficiency	check filter condition
Solution pump cover is open	pump cover open	check if the cover is properly closed
(882) / (884)	technical failure	call service
UF pump cover open	pump cover open	check if the cover is properly closed
(880)	technical failure	call service
High temperature of solution (858)	solution flow not regular	reduce the set value or reduce fluid flow rate
	variation value too high	make variation in steps of 2 °C max
	technical failure	call service
Temperature too low	solution flow not regular	check fluid temperature
(860)		reduce fluid flow rate
	variation value too high	set variation in steps of 2 °C max
	technical failure	call service
Air in solution line: bag(s) empty	air in the tubing, bags are empty	replace the bags
(844)	tubing deformed due to long sqeezing	turn the tubing into the device
	A.D. cover not properly closed	check the cover is properly closed
	technical failure	call service
Blood leakage	filter is damaged	check filter
(prebable filter damage) (838)	air in the tubing	check if there is air in the tubing and remove it
	balance	make new self-balance
	technical failure	call service
Weighing system overload	too much weight on the system	check total weight
(868)	technical failure	call service
Weighing system empty	no weight on the system	hang fluid bags to the system
(870)	technical failure	call service
Safety 12 V failed (888)	Safety 12 V failure	Switch OFF and ON the Diapact® CRRT and / or call the service
24 V failed (890)	24 V failure	Switch OFF and ON the Diapact® CRRT and / or call the service
Supervisor failed (896)	Controller recognize Supervisor failure	Switch OFF and ON the Diapact® CRRT and / or call the service



Alarm/Warning	Possible cause	Suggested remedy action	
DPD Selftest failed (900)	test failed during priming	check test, confirm with AQ	
Clotting danger (914)	PD 2 < PD2 min - 50 mmHg (high flux filter)	follow the display check filter Condition	
Removal not achievable (915)	PD 2 < PD2 min - 50 mmHg (low flux filter)	follow the display check filter Condition	
Weighing system empty (870)	no weight on the system technical failure	hang fluid bags to the system	
Bag is moving (866)	bag/s is / are moving	stop bag movement	
unespected weight change (872)	weight chance 200g	confirm reason with EQ	
unespected weight change (940)	bag chance without active bag chance funktion	confirm reason with AQ after bag changing and start therapy	
bag movement (864)	weight variation to high (bag change)	confirm with AQ after bag changing and start therapy	
Less UF removal (878)	wrong in/out fluid balance delivery pump speed delivery tubing kinking technical failure	check weighing system check delivery pump check tubing connection call service	
More UF removal (876)	wrong in/out fluid balance return pump speed return tube kinking, leakage technical failure	check weighing system check delivery pump check tube connection call service	
Cycle time is over (834)	the preset cycle time is over	start new cycle by striking START THERAPY or strike END OF THERAPY	
Cyclical weight preamphilier test failed (862)	occasional unbalance technical failure	reset with AQ call service	
Air detector failure (846)	Selftest of AD is disturbed	switch off and on the mashine or call service	



7.1.3 Protective System Alarms

Diapact CRRT is equipped with a protective system (DPS board) that can intervene indipendently of the system control (DPC board), thus allowing a total safety condition for the patient.

If protective system alarms occur, there are three possible alternatives.

- **Resettable alarm:** This kind of alarm can be reset just like the control system ones by pressing AQ push-button. In this case the therapy can normally restart after the
- **Removable alarm:** These alarms can be temporarily switched off by pressing EQ push-button.

WARNING! In this case the operator may decide to go

- **Non resettable alarm:** The unit is in a critical condition. The alarm cannot be reset nor switched off. The therapy must be interrupted and the patient disconnected.



Supervisor Alarm	Conditions	Suggested Action
DPD-DPS COMMUNICATION ERROR	not resettable	accidental trouble. Switch OFF and ON the equipment. technical failure. Disconnect the patient and call service
SAD SENSOR ERROR	not resettable	accidental trouble. Switch OFF and ON the equipment. technical failure. Disconnect the patient and call service
SAD FUNCTION ERROR	not resettable	accidental trouble. Switch OFF and ON the equipment. technical failure. Disconnect the patient and call service
SAD REF. ERROR	not resettable	accidental trouble. Switch OFF and ON the equipment. technical failure. Disconnect the patient and call service
BLD TEST ERROR	resettable	start new self-test and calibration by switching OFF and ON the equipment.
SAD SHOWS AIR	resettable during Therapy	technical failure. Call service follow air removal procedure
JAD SHOWS AIN	removable during End of Therapy	the operator can exclude the alarm, under his/her own responsibility, for about 20 secs, following a special procedure after checking visually, the operator can decide whether to reset or start a new automatical self-test and calibration
BLOOD LEAK RECALIBR.	resettable during Therapy	remove the cause
VENOUS PRESSURE HIGH	resettable	remove the cause
VENOUS PRESSURE LOW	resettable	remove the cause
PA HIGH	resettable	remove the cause
PA LOW	resettable	remove the cause
BLOOD PUMP STOP	resettable	start blood pump
PD2 HIGH	resettable	remove the cause
PD2 LOW	resettable	remove the cause
TEMPERATURE HIGH	resettable during Therapy	alarm reset allows to continue the Therapy without the heater. If the trouble is occasional, the heater function can be restored by switching OFF and ON the equipment. The oper tor can decide whether to continue with or without the heater
UF VOLUME HIGH	resettable	verify the total fluids weight and configuration
UF VOLUME LOW	resettable	verify the total fluids weight and configuration
UF RATE HIGH	resettable	verify the total fluid weight an configuration
UF RATE LOW	resettable	verify the total fluid weight an configuration
SUB FLOW HIGH	resettable	verify the total fluids weight and configuration
SUB FLOW LOW	resettable	verify the total fluids weight and configuration
WEIGHT-TEST ERROR	resettable	reset with AQ
LOAD CELL DISTURBED	resettable	check bags on the weighing system. Strike AQ button to reset



7.2 SAD Alarm. How to Remove It

If a SAD alarm condition occurs, a special procedure must be followed to remove it:

- press AQ push-button once
- clamp the return venous line from the filter
- select the venous chamber of the Level Adjustment System (V push-button)
- press the upper key (the lower one is not enabled) in order to create a negative pressure inside the venous chamber and then in the tubing line
- check the value of the Venous Pressure on the display until
 -100 mmHg pressure is reached
- the safety clamp (SAC) opens. The air and, consequently, the alarm condition are removed



8

Installation and Technical Data

8.1 Notes on Installation

IMPORTANT!

After unpacking the equipment, check it for damage and completeness.

If any damage is detected that would endanger safe operation, the unit must not be started up. Inform the responsible service station.

The electrical fittings/installation of the room in which the unit is to be set up shall comply with the pertinent regulations (e.g. VDE 01017/VDE 0100 and/or IEC specification).

As Diapact® CRRT is a Class I equipment, special attention should be paid to the quality of the discharge earth.

Regulations specific to each country must be taken into account. If in doubt, consult a skilled electrician.

The unit may not be operated in explosion hazard areas.

Do not switch the unit on until it has reached room temperature

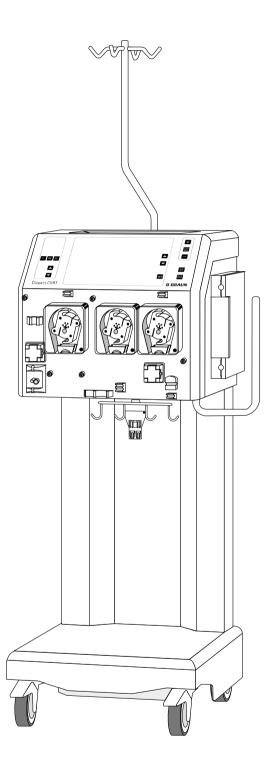
The available mains voltage must correspond to the voltage specified on the unit rating plate (e.g. 230 V AC, 50 Hz).

Do not use any adapter device or extension card on the main cable.

The unit is protected from the ingress of foreign bodies and dripping water according to IEC529: protection grade IP21.

Only the external surfaces of Diapact CRRT can be cleaned with neutral solutions. Do not use aggressive detergents or alcohol.





8.2 Electrical Installation

Mains connection specifications

(according to VDE 0107/VDE 0100 and /or IEC specifications)

Mains supply

Mains voltage: 110÷240 V AC
 Rated frequency: 50/60 Hz
 EL circuit breaker: 30 mA

Information for installation

Unit height: 1260 mmUnit width: 480 mmUnit length: 500 mm

Staff-call connection: max. 24 V/1 A/24 VA

(polarity as desired)

- Potential equalisation line connection (to DIN 42801)
- Interface connection with external PC (option, information available upon request)
- External pump connection, B|Braun type (information available upon request)

8.3 Important Notes

Manufacturer's responsibility

The manufacturer, assembler, fitter or instructor shall be considered responsible for the effects on the safety, reliability and performance of the unit if assembly, expansion, resetting, modifications or repairs have been performed by persons authorised by them, the electrical installation of the respective room corresponds to the requirements of VDE 0100/VDE 0107/IEC specifications, and the unit is used in accordance with the Operating Manual Instructions.

Maintenance

No special maintenance operations are required on the operator's side. Some interventions are carried out by the service.

Disposable accessories

Only accessories, disposable articles and wearing parts may be used whose suitability for such use from the point of view of technical safety has been established by certification by a test agency authorised to test the ready-for-use unit.

Disposable accessories wasted

Disposable accessories used in each treatment must be disposed of according to local regulations.



Power failure

In the event of a mains power failure, an acoustic alarm lasting > 1 min is given out. This alarm can be muted by switching off the mains switch.

If the mains switch is turned on within < 30 min from the mains power failure, the treatment can be resumed.

Discharge currents

Note: increase the actual discharge current when connecting several additional units.

TMP calculation and control

The Trans-membrane Pressure is calculated with the formula:

$$TMP = \frac{(PBE + PV)}{2} - PD2$$

PBE = filter inlet pressure (blood side)

PV = venous pressure

PD2 = filter outlet pressure (fluid side)

Max TMP limits are not adjustable values. They are fixed by control system at + 400 mmHg for Dialysis therapies and + 150 mmHg for Plasma therapies respectively. If the above

limits are reached, the system automatically stops the fluid or plasma side, gives out an acoustic alarm and displays a message.

Calibration

The sensor calibration procedure is described in the Service Manual (load cell, temperature, pressure, blood leak, SAD, ect.) Calibration must be performed by authorized and trained people only.

Replacing fuses

Only the fuse values specified by the manufacturer can be used (see Service Manual).

Technical information

If required, the Service Manual can be provided in connection with technical training.

Electromagnetic disturbance

Diapact CRRT has been designed to comply with IEC 601.1.2 standards. However, the use of electromagnetic or other interfering devices (e.g. cellular phones) should be avoided where the unit works.

8.4 Technical Data

Extracorporeal Circuit

Blood pump:	Peristaltic pump roller with manual operating system. Motor stops with open cover condition.
Flow range:	10 ÷ 500 ml/min
Tolerance:	< ± 10%
Pressure range:	-180 ÷ +500 mmHg
Protective system:	Optocoupler and software control the status after therapy start.
Override time	120 secs
Arterial pressure (PA):	Electronically measured by means of a sensor and digitally displayed.
Range:	- 400 ÷ 100 mmHg
Tolerance:	+/- 10 mmHg
Operating limits:	- 150 mmHg (adjusble)
Protective system:	Pressure sensor, tested during the Preparation phase.
Protective sys. override time:	Cannot be excluded during therapy.
Acoustic alarm interval:	60 secs
Pre-filter pressure (PBE):	Electronically measured by means of a sensor and digitally displayed.
Range:	0 ÷ + 500 mmHg
Tolerance:	+/- 10 mmHg
Operating limits:	+ 200 mmHg (adjustable)
Acoustic alarm interval:	60 secs
Venous pressure (PV):	Electronically measured by means of a sensor and digitally displayed.
Range:	0 ÷ + 400 mmHg
Tolerance:	+/- 10 mmHg

Operating limits:	10 - 300 mmHg
Opreating limits:	5 - 380 mmHg
	-40 / + rest (adjustable window) on the actual value stored after 30 secs from the blood pump START command. A pressure variation due to a blood flow variation automatically modifies the position of these limits.
Protective system:	Pressure sensor, tested during the Preparation phase.
Protective sys. override time:	The upper limit cannot be excluded.
	The window and the lower limit can be excluded for 30 secs by pressing the START/STOP push-button of the blood pump.
Acoustic alarm interval:	60 secs
Safety Air Detector (SAD):	System with ultrasound sensors in the tubing below the venous drip chamber.
Sensitivity:	Alarm condition due to the presence of micro-bubbles or micro-foam or when the blood level in the tubing drops below the sensor level.
Protective system:	Automatic, cyclical check during therapy (0.11 ml of air).
	Counter of the integrated time/volume (limit 2.0 ml).
Protective sys. override time:	It cannot be excluded during therapy. Exclusion is possible during 20 secs in "End of therapy" phase only by following the safety procedure.
Acoustic alarm interval:	60 secs
Safety clamp:	On the reinfusion bloodline to the patient the safety clamp closes the line in case of alarm from the Safety Air Detector and in all blood pump stop conditions (redundant function).
Solution pump:	Peristaltic pump roller with manual operating system. The motor stops if the cover is open.

Fluid Circuit

Flow range:	0 ÷ 400 ml/min		
Tolerance:	< 10%		
Pressure range:	20 ÷ 500 mmHg		
Plate warmer:	Heating system based on temperature transfer between the plate and the plastic bag.		
Temperature range:	30 ÷39°C (max set value may not be achieved in Single Pass mode with flow > 150 ml/min)		
Tolerance:	Tolerance 0.5 °C 2 °C 3 °C 3° C	Flow range < 50 ml/min > 50 < 100 ml/min > 100 < 150 ml/min > 150 < 250 ml/min	<i>Note</i> Recirculation mode only
	Solutions should be stored at room temperature.		
Operating limits:	+1 °C / -3 °C of the set value		
Protective system:	A temperature sensor constantly checks plate temperature, tested during the preparation phase. Limits are fixed as the follow:		
	- flow rate < 100 ml/min 40.5 °C - flow rate ≥ 250 ml/min 43.5 °C		
	flow rate 100 < < 250 ml/min $40.5 + \Delta$ °C $\Delta = [(flow rate -100) / 150] \times 3$		
Protective sys. override time:	The upper limit cannot be excluded during therapy.		
Acoustic alarm interval:	60 secs		

Filter outlet pressure:	Electronically measured by means of a sensor and digitally displayed.
(switching chamber pressure in Single Needle mode)	
Range:	-500 ÷ +500 mmHg
Tolerance:	+/- 10 mmHg
Operating limits:	The negative limit induces an acoustic alarm without interrupting the treatment (warning).
Acoustic alarm interval:	60 secs
Protective system:	Pressure sensor, tested during Preparation phase.
Ultrafiltration pump:	Automatic volumetric control of the fluids coming out of the filter by means of an electronic weighing system.
	The integration of the continuously measured data determines the ultrafil tration pump speed control.
	The motor stops if the cover is open.
Flow range:	0 ÷ 300 ml/min
Tolerance:	<10%
Pressure range:	-200 ÷ +500 mmHg
Air Detector (AD):	System with ultrasound sensor checks the tubing below the solution pump.
Sensitivity:	Alarm condition due to the presence of bubbles or when the tube is empty.
Acoustic alarm interval:	60 secs
Blood Leak Detector (BLD):	Integrated photometric system as a slave device.
Sensitivity:	Dialysis therapies > 0.5ml/200 ml flow rate, tested with bovine blood HTK 32%
	Plasma therapies > 0.5 ml/100 ml flow rate, tested with bovine blood HTK 32%
Time of intervention	About 20 secs
Protective system:	Self-test / calibration (balancing) during Preparation phase, with possibility of new calibration / self-test during therapy.
Acoustic alarm interval:	60 secs

Weighing System

Load cell:	Loading capacity 27 kg Resolution 1 g Linearity 0.015 % f.s.
Operating range:	0.05 - 27.00 kg
Overload protection:	Electronic at 27.0 kg
	Mechanical at 27.0 kg
Control system:	Close loop on UF pump.
	Limits \pm 120/150/180 g on set weight.
	Tolerance ± 30 g.
Protective system:	Continuous comparison during the treatment of the actual measured weight with the theoretical weight by means of a software routine.
	Self-test after power-on and during the Preparation phase.
	Limit \pm 300 g of the expected value.
	Cyclical weight-test (± 6% UF rate).
Protective sys. override time:	Cannot be excluded during therapy.



8.5 General Data

Other technical data

Rated voltage: 110 ÷ 240 V AC

230 V AC with BPS option

Rated frequency: 50/60 Hz

50 Hz with BPS option

Rated current: max. 3.5 A

Classification: Type B

Earth discharge current: $< 500 \mu A$ Patient discharge current: $< 100 \mu A$

Protection class:

Potential equalisation: Conditions for connection available upon request.

Water protection grade: | IP 21

Acoustic alarm volume: | > 65 dBA (1m from loud speaker and buzzer)

Dimensions: 480 x 500 x 1260 mm

 $(W \times D \times H)$

Housing material: | Aluminium, corrosion-resistant.

Empty weight: | 45 kg (about 75 Kg with BPS full-option)

Ambient conditions

a) Operation

Temperature: + 15 to + 40 ° C Rel. Humidity: 30% to 90% Atmos. Air press. 700 - 1 060 mbar

b) Transport and storage

Temperature: $-20 \text{ to } +55 ^{\circ} \text{ C}$ Rel. Humidity: 10% to 90%Atmos. Air press. 700 - 1060 mbar

Safety standards

Constructional, including electrical: IEC 513

IEC529 EN 60601-1

EN 60601-1-1

Functional: prEN 1441

IEC 601-1-4
IEC 601-2-16

Electromagnetic compatibility: EN 60601-1-2

Clinical data: EN 540

Connection options for peripheral units:

Optional connection to an external Personal Computer.

Information available from manufacturer upon request.

8.6 Function Check and Commissioning

	heck and Commissioning for the machine D	·				
Art. No Un	it NoYear of Purch	ase:User:				
Manufactu	rer: B. Braun Melsungen AG, Medical Techno	ology Division				
	ION CHECK according to the specified check manual/intructions for use and subject to te	list must be carried out and documented before setting into service, with chnical amendments.	reference to the service manual and			
Check I	List (Note: calibrated measurement equipr	nent must be used).				
1. Visual I	nspection					
1.1	Cleanliness, completeness, damages, mois	ture influences, roller moveability				
1.2	Type plate, stickers and inscriptions					
1.3	Mains supply (power supply line and mains terminal device)					
1.4	Battery power supply (option), connection	with the main supply				
2. Functio	n Inspection (document measurement va	ulues)				
2.1	Pay attention to the starting procedur	c of the unit in order to check the mains components!				
	Switch on machine:	Check the character sets that appear on the screen, then confirm v Check that no weight is hanged on the weighing system, then con Select CWH therapy	,			
2.2	LCD display	Function, image display, alarm signal, keys function				
2.3	Blood pump	Delivery rate 100 (±10%) larm cover switch	[ml/min]			
2.4	Ultrafiltration pump	Retum rate 50 (±10%) Alarm cover switch	[ml/min]			
2.5	Substitution pump	Return rate 50 (\pm 10%) Alarm cover switch	[ml/min]			
2.6	Venous tubing clamp:	Function and accuracy				
		Gap 1.5 (+0.1) mm	[mm]			
2.7	Arterial pressure PA: (permissible tolerance ±12 [mmHg])	Comparison measurement at	$\begin{array}{ccc} - 400 = & [mmHg] \\ 0 = & [mmHg] \end{array}$			
2.8	Inlet pressure PBE: permissible tolerance ±12 [mmHg])	Comparison measurement at	$\begin{array}{ccc} 0 = & & [mmHg] \\ + 400 = & & [mmHg] \end{array}$			
2.9	Venous pressure PV: (permissible tolerance ±12 [mmHg])	Comparison measurement at	0 =			
2.10	Pressure PD1: (permissible tolerance ±12 [mmHg])	Comparison measurement at	0 = [mmHg] + 400 = [mmHg]			
2.11	Pressure PD2 / PSC: (permissible tolerance ±12 [mmHg])	Comparison measurement at	0 =			
3. Setting	into service (monitor) according to serv	ice manual				
3.1	Temperature:	Comparison measurement at 37 (-1.5 +0.5) °C	[°C]			
3.2	Weight:	Comparison measurement at 10,000g (±50g)	[g]			
3.4	Pressures:	Comparison measurement PA/PV (tolerance \pm 20 mmHg)	[mmHg]			
3.5	Blood leak detector:	Soft-Balance, Alarm function				
3.6	Safety air detector (SAD):	Alarm function				
4. Electric	al safety check according to EN 60601-	-1/IEC 601-1				
4.1	Measure mains voltage		[V~]			
4.2	Protective earth conductor resistance < 0	.2 [W]:- Potential equalization bolt	[W]			
	(Machine incl.power supply cord)	Screw connection of heater body	[W]			
4.3	Earth leakage current £ 0.5 [mA]:	During heat-up phase	[mA]			
4.4	Patient leakage current:	Under normal conditions < 0.1				
Documenta	ation with exception of check list (e.g. mach	ine record book)				
The FUNCT	ION CHECK was carried out on:	Machine was handed over on:	to:			
	P. Proup Melcungen Ad					

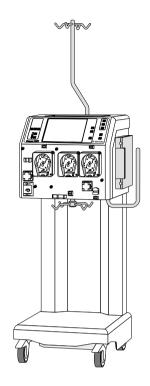


Date/Signature

NOTICE:	

9.

Accessoires



9.1 Diapact CRRT System and Relevant Disposable Products

Diapact® CRRT

Multifunctional system for continuous and intermittent renal replacement therapies and plasmapheresis.

Continuous therapies: CWH - CWHD - CWHFD - SCUF

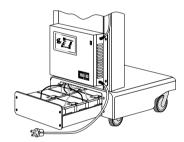
Intermittent therapies: HF - HD - HFD

Plasmapheresis: PEX - PAP

To perform treatments the machine needs:

- Tubing lines kit
- Hemofilter (plasmafilter/hemodialyzer)
- Solutions (dialysis or infusion)
- Filter/Cartridge (in plasma treatment)

Code: 07106505



Battery power supply (optional) not available jet

Internal battery pack + inverting device (230 V/12 V - 230 V) allow treatments to be performed even when the main power supply fails.

Code: 07106602



External syringe pump (optional)

Perfusor® Compact

Code and relevant disposable:

information available upon request

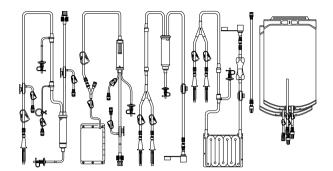


External infusion pump (optional)

Infusomat® fm

Code and relevant disposable:

information available upon request



Kit HEMOFILTRATION - HEMODIALYSIS

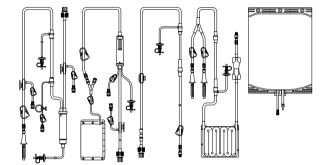
Therapies: CWH - CWHD - CWHFD - HF - HD - HFD

The kit includes:

- arterial line
- venous line
- dialysate/substitution line
- effluent/ultrafiltrate line
- connection line
- 2 collecting bag (7 lt)

Code: 07210349

Code: 07210429 (Pre-assembled Kit)

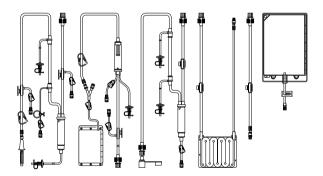


Kit SLOW CONTINUOUS ULTRAFILTRATION

Therapy: SCUF The kit includes:

- arterial line
- venous line
- ultrafiltrate line
- collecting bag (5 lt)

Code: 07210351



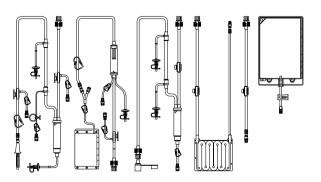
Kit PLASMAEXCHANGE

Therapies: PEX - PSE (Plasmaseparation)

The kit includes:

- arterial line
- venous line
- substitution line
- plasma line
- collecting bag (5 lt)

Code: 07210348



Kit PLASMA PERFUSION / ADSORPTION

Therapy: PAP

The kit includes:

- arterial line
- venous line
- plasma line
- treated plasma line
- adapter line
- collecting bag (3 lt)

Code: 07210352

(*) The marketing of the listed products has to be checked in all countries where different agreements may exist. Get in touch with the local distributor for further information.