Chapter 15: Alarms and Troubleshooting

15.1 Alarm System

The machine has been designed to recognize and control various types of malfunctions and faults. There are three ways in which the operator is advised of an alarm condition:

- An **Audible alarm signal**;
- A **Visual alarm signal** with a flashing light at the top of the machine;
- An **Alarm Message**, displayed in the Alarm Area on the left bottom side of the Touch Screen. The alarms are referenced by number, located on the left side of the alarm message.

NOTE

If more than one alarm occurs at the same time, they are automatically prioritized by the system.

The machine will restart the interrupted action only after all the alarms have been solved.

15.2 Alarm Classification

15.2.1 Classes of alarms

The alarms are classified according to their triggering cause, the part of the machine affected and the type of intervention required from the operator. Each alarm class is characterized by a specific visual and audible alarm signal. The classes of Alarms will be described in decreasing order of importance, i.e. the first is the most serious type of alarm.

Class A: Alarms related to the safety of the patient, caused by internal machine processes, requiring operator intervention to remove the cause, returning the process data to the operating limits. They may be identified by:

- A **Visual** alarm signal with a flashing Red light of 4-4 modulation (one flash of 4/8 second, followed by a 4/8 second pause).
- An **Audible** alarm signal with a 4-4 modulation.
- An **Alarm Message** on the top of the **Alarm Area**.

Class B: Alarms not related to the safety of the patient, caused directly by an operator error on the machine controls or caused by machine conditions requiring operator intervention. These require operator intervention. They may be recognized by:

- A **Visual** alarm signal with a flashing Yellow light of 1-7 modulation (a flash of 1/8 of a second, followed by a pause of 7/8 second).
- An **Audible** alarm signal with a 1-7 modulation.
- An **Alarm Message** on the top of the **Alarm Area**.

Class E: Alarms not related to the safety of the patient, caused by control errors that may revert to normal without the need for operator intervention. They usually require the intervention of a Service technician. They may be identified by:

- A **Visual** alarm signal with a flashing Yellow light of 1-7 modulation (a flash of 1/8 second, followed by a pause of 7/8 second).
- An **Audible** alarm signal with a 1-7 modulation.
- An **Alarm Message** on the top of the **Alarm Area**.

Class D: Alarms not related to the safety of the patient or to an error condition, caused by machine state requiring the attention of the operator. They may be identified by:

- A **Visual** alarm signal with a flashing Yellow light of 1-7 modulation (a flash of 1/8 second, followed by a pause of 7/8 second).
- An **Audible** alarm signal with a 1-7 modulation.
- An **Alarm Message** on the top of the **Alarm Area**.

Class C: Alarms not related to the safety of the patient, caused due to transitory control errors which usually revert to normal without operator intervention. If these errors persist, the machine is probably not functioning properly and a Service technician must be notified. They may be identified by:

- A **Visual** alarm signal with a flashing Yellow light of 1-7 modulation (a flash of 1/8 second, followed by a pause of 7/8 second).
- An **Alarm Message** on the top of the **Alarm Area**.

The operator can therefore identify the class of alarm with the aid of the three types of indicators available and then take an appropriate action.

15.3 Levels of operator intervention

When an alarm condition occurs, the operator may be able to manually deal with the problem, depending on its class.

The specific actions to take are described for each individual alarm. Four types of intervention are possible:

- MUTE
- CONFIRM
- OVERRIDE
- RESET

15.3.1 Mute

It is possible to temporarily (for about 2 minutes) deactivate the audible alarm signal, by pressing the ***MUTE*** key on the Hard Key Panel.

It is important to consider that during the MUTE status:

- The LED on the MUTE key switches ON.
- The Audible alarm is deactivated.
- The Visual alarm remains.
- The Alarm Message remains in the Alarm Area with the description of each alarm.

It is possible to remove the MUTE status:

- Automatically: when the time has elapsed.
- Manually: by pressing the MUTE key.

NOTE

If a new alarm is triggered, different from the previous one, during a MUTE status, the MUTE status will be automatically removed.

15.3.1.1 Confirm

The ***CONFIRM*** operation forces a removing of the alarm, it clears the audible and visible feedbacks as well as the time counters used to generate the alarm. Therefore, the Confirm condition restores the functionalities which has been previously stopped, bringing back the machine as before the alarm generation.

After having solved the alarm causes, the operator can confirm the alarm by pressing the ***CONFIRM*** button, displayed on the right top side of the Alarm Area.

When the fault has been removed and the ***CONFIRM*** button pressed, the conditions that have generated the alarm will be cleared and the previous process will be resumed. However, if the safety conditions aren't still satisfied, the alarm will reappear again.

⚠WARNING

Press the ***CONFIRM*** button to clear the alarm only after having removed the causes of the alarm, as described on the message displayed on the Alarm Area.

15.3.2 Override

The Artis Dialysis System allows to ***OVERRIDE*** only the alarm related to a Blood Leak Detection.

The ***OVERRIDE*** of this alarm can be performed to give the possibility to ignore it and to continue the treatment. *It is useful every time a recovery of a dangerous situation requires the machine working, to reactivate some functionality that was stopped due to the alarm presence.*

To override the alarm, press the **OVERRIDE** button displayed in the Alarm Area when the Blood in Dialysate alarm is triggered.

It is important to consider that during an override period:

- Some of the safety mechanisms are disabled for a limited period of time (about 2 minutes);
- The Audible and the Visual alarm signals are maintained;
- The Alarm Message is still displayed in the Alarm Area.

If one or more additional faults cause an alarm during the OVERRIDE state, the description relative to each fault is displayed in the Alarm Area.

⚠WARNING

During an **OVERRIDE** status, the operator is responsible for monitoring of the parameters that have been overridden.

15.3.3 Reset

Some alarms can be automatically ***RESET*** by the machine when there are no more failures. In this cases, the *confirm* option is not available.

The ***RESET*** operation foresees an automatic removing of the alarm after that the conditions that weren't previously satisfied and that consequently have generated an alarm, are satisfied again for a specified time interval, dependent on the alarm itself.

After an automatic alarm reset, the audible and visible feedbacks are cleared and the functionalities, which have been stopped by the machine at the start of the alarm, are restored again.

15.4 Guidelines to respond to an alarm situation

In case of an alarm condition, the operator should perform the following actions:

1. Press the ***MUTE*** key to silence the Audible Alarm, if desired.

2. Observe the Alarm Message in the Alarm Area on the left bottom of the Touch Screen.

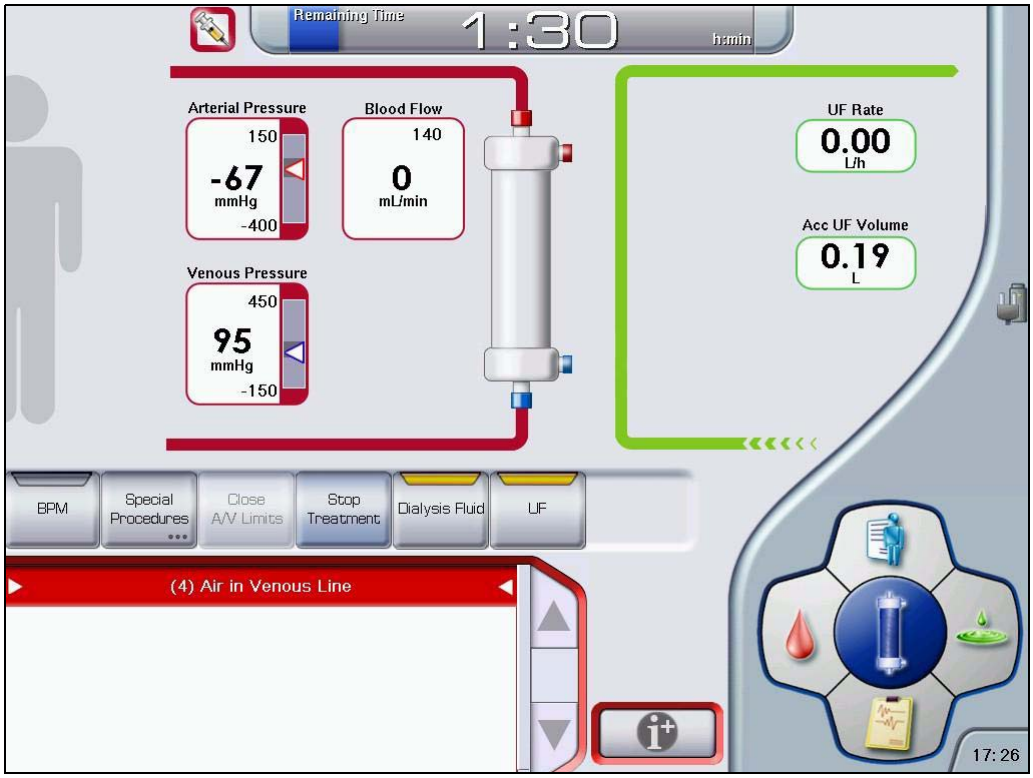

Figure 15-1. Alarm Area

NOTE

The alarm message can be marked in:
- blue, if the alarm is intended to notify or remind the operator about specific machine condition/end of procedures.
- red, in all the other conditions.

3. If more than five alarms are triggered, it is possible to scroll the Alarm window up and down using the Scroll Buttons.

4. Determine the cause of the alarm. If uncertain about the cause or the appropriate response to the alarm, refer to the “15.6 Alarm

Troubleshooting" Section in this Chapter, for possible causes and solutions. If a Help window is available, the "I+" button is displayed.

5. Correct the cause of the alarm as described in "15.6 Alarm Troubleshooting".

15.5 Alphabetic List of Alarms

The table below contains a list of all the alarms in alphabetical order, indicating:

- The message that appears on the Touch Screen;
- The Technical Code;
- The Class;
- The possibility or not to CONFIRM the alarm.

ALARM MESSAGE	CODE	CLASS	CONFIRM
<< GENERAL SYSTEM FAILURE>>	XXX	A	NO
80% Maximum Substitution Volume Reached	551	E	YES
90% Maximum Substitution Volume Reached	552	E	YES
Acid/Acetate Concentrate Container Empty	1	A	YES
Acid/Acetate Concentrate Error	369	A	NO
Air Detector Cleaning Required	583	A	YES
Air Detector Inspection Required	584	A	YES
Air in Blood T0 Failure	385	A	YES
Air in Hydraulic Pathway (LD1)	33	E	NO
Air in Hydraulic Pathway (LD2)	35	E	NO
Air in Venous Line	4	A	NO
Arterial Infusion Line Open	519	E	YES
Arterial Line Clamped	517	E	YES
Arterial Pressure Below Treatment Min. Limit	306	A	YES
Arterial pressure high	305	A	YES
Arterial pressure high	457	A	YES
Arterial pressure low	384	A	YES
Arterial pressure out of range	11	A	YES
Arterial Pump Segment Not Correctly Loaded	586	E	YES
Autoscheduled Disinfection/Rinse Program not Performed	562	A	YES

ALARM MESSAGE	CODE	CLASS	CONFIRM
Backup battery failure	183	E	YES
Bicarbonate Concentrate Error	370	A	NO
BiCart cartridge empty	21	A	YES
Bioslave Subsystem Communication Error	296	E	NO
BLD Sensitivity Loss	170	E	YES
Blood Cassette presence required	507	A	NO
Blood in Dialysate	28	A	NO
Blood Lines Clamped	509	A	YES
Blood pump cover open	8	B	NO
Blood pump rotor error	13	B	YES
Blood Pump Rotor Error	363	A	YES
Blood pump speed error	12	B	YES
Blue Dialysis Fluid Tube Incorrect Position	330	B	NO
BPM Diastolic pressure alarm	46	A	YES
BPM failure	30	A	YES
BPM Heart rate alarm	66	A	YES
BPM Measurement failure	31	A	YES
BPM Systolic pressure alarm	132	A	YES
Cassette Repositioning Failed	557	E	YES
CDF1 Ultrafilter Lower Switch Error	61	E	NO
CDF2 Ultrafilter Lower Switch Error	563	E	NO
Chemical Process Not Properly Performed: Disinfectant Tank Empty	533	A	YES
Communication Protective Cond. Cell Stopped	449	A	YES
Communication Select Cond. Cell Stopped	450	A	YES
Conductivity too high	463	A	NO
Conductivity too low	462	A	NO
Dialysate pH high	40	A	NO

ALARM MESSAGE	CODE	CLASS	CONFIRM
Dialysate pH low	368	A	NO
Dialysate Pressure High	146	B	YES
Dialysate Pressure Low	540	B	YES
Dialysis fluid flow high	44	A	NO
Dialysis fluid flow low	373	A	NO
Dialysis fluid flow too low	425	A	YES
Dialysis fluid temp high	134	A	NO
Dialysis fluid temp low	377	A	NO
Dialysis fluid temp too high	460	A	NO
Dialysis fluid temp too low	461	A	NO
Dialyzer Inlet Pressure High	87	A	YES
Dialyzer Inlet Pressure Low	94	A	YES
Dialyzer Outlet Pressure High	88	A	YES
Dialyzer Outlet Pressure Low	95	A	YES
Dialyzer Pressure Maximum	114	A	NO
Dialyzer Pressure Minimum	115	A	NO
Diascan measurement error	536	A	YES
Diascan: Autocalibration Failure	528	B	NO
Diascan: Low Clearance	530	D	YES
Diascan: Low Kt/V	531	D	YES
Diascan: Measurement Failure	529	B	YES
Disinfection not Properly Performed	534	B	YES
Flowmeter Alignment Failed	506	A	YES
Fluid path obstruction	206	A	YES
Fluid Removal Complete	53	B	YES
Hemoconcentration Risk	524	E	YES
Hemocontrol Error	554	A	YES
Hemocontrol: BV% not available	234	B	YES
Hemocontrol: Early on Prescription	230	B	YES
Hemocontrol: High Na Concentration	231	B	YES

ALARM MESSAGE	CODE	CLASS	CONFIRM
Hemocontrol: Late On Prescription	229	B	YES
Hemocontrol: Low Na Concentration	232	B	YES
HEMOSCAN Autocalibration Failure	473	B	NO
HEMOSCAN: DARK Out of Range	223	C	NO
HEMOSCAN: L/H Out of Range	226	C	NO
HEMOSCAN: Minimum Blood Volume	191	E	NO
HEMOSCAN: TEST Out of Range	225	C	NO
Heparin infusion complete	58	B	YES
Heparin pump lower limit reached	69	E	NO
Heparin pump overload	55	A	NO
Heparin pump speed error	70	B	YES
Heparinization Not Initiated	71	B	YES
Hydraulic Centralise Acetate Connector Type One	565	E	NO
Hydraulic Centralise Acetate Connector Type Two	566	E	NO
Hydraulic Sensor Dirty (LP)	34	E	NO
Incorrect bicarbonate concentrate	18	B	NO
Incorrect bicarbonate concentration	23	A	NO
Incorrect bicarbonate concentration	366	A	NO
Incorrect bicarbonate concentration	464	A	NO
Incorrect bicarbonate concentration	465	A	NO
Incorrect BiCart Holder Arms Position	22	B	NO
Incorrect Cassette line connections or clamps status	542	A	YES
Incorrect concentrate connector	2	B	NO
Incorrect conductivity measured	62	A	NO
Incorrect conductivity measured	375	A	NO
Incorrect fluid conductivity detected	496	A	NO
Incorrect venous or arterial line position in clamp	205	A	NO
Insert the HEMOSCAN cuvette	454	B	NO

ALARM MESSAGE	CODE	CLASS	CONFIRM
Insufficient water supply	100	A	NO
Isolated UF Completed	570	D	YES
Isolated UF target loss will not be achieved	581	E	NO
Leakages H	548	E	YES
Leakages I	549	E	YES
Leakages Test (A) Failure	467	E	YES
Leakages Test (B) Failure	468	E	YES
Leakages Test (C) Failure	469	E	YES
Leakages Test (D) Failure	470	E	YES
Leakages Test (E) Failure	498	E	YES
Leakages Test (F) Failure	499	E	YES
Leakages Test (G) Failure	500	E	YES
Left Blue EvaClean door incorrect position	416	B	NO
Line Not Connected in EvaClean Port or Access Line Open	518	E	YES
Low blood pump speed	204	A	YES
Low Disinfectant Level in last Clean Cart Process	504	E	YES
Low Heparinization	573	A	YES
Low Temperature	81	D	NO
Maximum Substitution Volume reached	546	A	YES
Maximum Substitution Volume reached	553	E	YES
MAXIMUM TEMPERATURE LIMIT	90	A	NO
Na or Bic Settings result in conductivity out of range	401	E	NO
New Ultra Scan is suggested	545	E	YES
No power - Using battery backup	353	A	NO
No Power - Using Battery Backup	415	A	YES
Not Performing UF	443	E	YES

ALARM MESSAGE	CODE	CLASS	CONFIRM
On line blood restitution: wrong Ultra Cassette configuration	579	A	YES
On line Prime - Incorrect Ultra or Blood cassette configuration	580	A	YES
On-line door incorrect position	423	E	NO
Patient Venous Line Incorrect Position	547	E	YES
PDr Pressure High	452	A	YES
PDr Pressure Low	453	A	YES
Power Failure: Check Power Supply	550	E	YES
Pre Filter Pressure High	541	A	YES
Preparation can not proceed until dressing is complete	576	E	NO
Preparation Completed	559	E	YES
Preparation not Completed - Incorrect Condition on Acetate Distribution	476	A	YES
Preparation not Completed - Incorrect Condition on Bicarbonate Distribution	477	A	YES
Preparation not Completed - Incorrect Condition on D1 Flow Rate	474	A	YES
Preparation not Completed - Incorrect Condition on TcA	475	A	YES
Pressure Alarm Limits Still Expanded	525	E	NO
Priming Completed *(See **NOTE 1**)*	560	E	YES
Pump speed too high	10	A	YES
Pump speed too low	362	A	YES
Red Dialysis Fluid Tube Incorrect Position	331	B	NO
Reminder - HDF Substitution Still Disabled	526	E	YES
Reminder - Still In Isolated UF	479	E	YES
Reminder - Still in Pause Therapy	329	E	YES
Reminder - Wrong Dip Switches	502	E	YES
Reminder:	558	E	YES

ALARM MESSAGE	CODE	CLASS	CONFIRM
Residual Check Reminder	582	E	YES
Right Red EvaClean door incorrect position	417	A	NO
Saline Bag Not Connected	515	E	YES
Saline Bag Empty	585	E	YES
Select Bag Holder Incorrect Position	411	D	NO
Select Cart Holder Arms Incorrect Position	3	B	NO
Sensor Bar Door Open	424	E	NO
Smart Scan - High QD	514	D	YES
Smart Scan - Low QB	512	D	YES
Smart Scan - Low QD	513	D	YES
Smart Scan – Low Real QB	577	D	YES
Still in bypass	302	E	YES
SUPPLY VOLTAGE INCORRECT	187	E	NO
System Pressure out of range	522	A	YES
T1 Test Arterial Pressure	447	E	YES
T1 Test Arterial Pump/ABD	419	E	YES
T1 Test Conductivity Cells Failed	445	E	YES
T1 Test Flow Meters	422	E	YES
T1 Test Pre Filter Pressure	418	E	YES
T1 Test Temperature Failed	444	E	YES
T1 Test Venous Pressure	446	E	YES
Timeout on Data Reception	532	D	YES
TMP High	68	A	YES
TMP Low	142	A	YES
TMP Set too Low	567	E	NO
TMP Maximum Limit	527	E	NO
Tool not Connected	561	E	YES
Treatment can not begin until the ultrafilters have been replaced	571	A	NO

ALARM MESSAGE	CODE	CLASS	CONFIRM
Treatment Time Complete	51	B	YES
UF Deviation	505	A	NO
UF rate higher than expected	145	A	YES
UF rate lower than expected	379	A	YES
UF target will not be achieved	60	B	NO
Ultra Inlet Tube Clamped	556	A	YES
Ultra Scan aborted: TMP Set and Upper Limit Updated	543	E	YES
Ultra Scan completed: TMP Set and Upper Limit Updated	544	E	YES
Ultrafilter Cover Error	564	E	NO
Ultrafilter Replacement Reminder	402	D	YES
Venous Flow Maximum	413	A	YES
Venous Flow Minimum	412	A	YES
Venous Infusion Line Open	587	A	YES
Venous Line Clamped	516	E	YES
Venous line not in patient sensor	364	A	NO
Venous Pressure Below Treatment Min. Limit	459	A	YES
Venous pressure high	155	A	YES
Venous pressure low	382	A	YES
Venous Pressure Not Decreasing	472	A	YES
Venous Pressure Not Increasing	351	A	YES
Venous pressure out of range	153	A	YES
Venous pressure too high	154	A	YES
Venous pump cover is open	149	B	NO
Venous pump rotor error	158	B	YES
Venous pump rotor error	521	A	YES
Venous pump speed error	157	B	YES
Water Leakage	539	A	NO
Wrong A/V or System Pressure Offset	319	E	YES

ALARM MESSAGE	CODE	CLASS	CONFIRM
Wrong Acid/Acetate Connector	568	E	NO
Wrong Arterial and Venous Treatment Limits	503	A	YES
Wrong Bicarbonate Connector	569	E	NO
Wrong Disinfectant used in Chemical Disinf.	578	A	YES
Wrong disposable configuration on Ultra Cassette holder	508	A	NO
Wrong Single Needle Clamps Position	574	A	YES

WARNING

The use of Remote Alarm device does not release the operator from the responsibility to observe the alarms triggered by the machine.

NOTE 1

For this alarm, the audible signal is not triggered.

15.6 Alarm Troubleshooting

The Alarm Area gives all the necessary instructions to respond to most of the alarm situations. Under certain circumstances, however, the alarm system could not give detailed information.

Therefore, additional information are provided in this section for each of the alarms listed in the previous table.

The alarms below are listed according to their technical code number.

ACID/ACETATE CONCENTRATE CONTAINER EMPTY 1

Reason for Alarm	The Acid Pump cannot reach the set conductivity value.
Machine Actions	• The dialysis fluid goes into Bypass; • The Acid Pump (PA) is stopped.

Possible Cause	**Suggested Action**
1. The Acid concentrate canister is empty.	1. Replace the empty Acid canister with a new one. Refer to the "Section 7.6: Change Acid" of this Operator's Manual for detailed information on the special procedure. Press the ***CONFIRM*** button to continue.
2. Massive air leak from the Acid concentrate canister.	2. Check and if necessary replace the Acid concentrate canister with a new one. Refer to the "Section 7.6: Change Acid" of this Operator's Manual for detailed information on the special procedure. Press the ***CONFIRM*** button to continue.
3. The Acid pick-up tube connector is not connected to the concentrate canister.	3. Verify that the Acid pick-up tube connector is properly connected to the concentrate canister. Press the ***CONFIRM*** button to continue.
	Call for Service if the alarm persists.

INCORRECT CONCENTRATE CONNECTOR 2

Reason for Alarm	The Acid Concentrate Connector is not in the proper position, or it is not fully inserted into its Concentrate Connector Port.
Machine Actions	In DIALYSIS: • The phase currently running stops; • The concentrate pump PA is stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Acid Concentrate Connector is in the wrong position, or not fully inserted into its Concentrate Connector port.	1. Verify the right connector position in relation to the machine phase.
	Call for Service if the alarm persists.

SELECT CART HOLDER ARMS INCORRECT POSITION 3

Reason for Alarm	The Select Cart Holder Arms are in the wrong position or not closed securely.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Select Cart Holder Arms are in the wrong position, or not closed securely.	1. Verify the correct position of the Select Cart Holder Arms in relation to the machine phase. In Dialysis, Rinsing and Disinfection: Position the connector correctly.
	Call for Service if the alarm persists.

AIR IN VENOUS LINE 4	
Reason for Alarm	Air has been detected in the Venous Patient Line.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. Air in the Venous Patient Line.	1. Clamp the Venous Patient Line under the Venous Line Clamp; 2. Clamp the venous dialyzer line; 3. Attach a sterile luer-lock syringe to the venous infusion line; 4. Unclamp the venous infusion line and create a negative venous pressure (*-50 mmHg*) with the syringe *(See **NOTE 1**)*; 5. When the machine opens the Venous Line Clamp, clamp the venous infusion line, unclamp the Venous Patient Line and unclamp the venous dialyzer line *(See **NOTE 2**)*; 6. If bubbles are still present, repeat the procedure; 7. Start the Arterial pump by pressing the “Blood Pump On/Off” key on the hard key panel; 8. If needed, adjust the chamber levels *(See **NOTE 3**)*.
	Call for service if the alarm persists.

NOTE 1

Do not allow the venous pressure inside the venous chamber to decrease below -150 mmHg.

NOTE 2

After unclamping the venous dialyzer line, the Venous Line Clamp will close again if:

- *The venous pressure reaches 60 mmHg*
- *The venous pressure exceeds 40 mmHg for more than 5 seconds.*

NOTE 3

Refer to "Chapter 7: Special Procedures" for better explanations on the adjust chamber levels procedure.

BLOOD PUMP COVER OPEN 8

Reason for Alarm	The Arterial pump cover is open.
Machine Actions	• The Arterial Pump is stopped; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The Arterial pump cover is open.	1. Close the Arterial pump cover. Be sure the Arterial pump cover is securely latched.
2. The magnet is dirty.	2. Carefully clean the magnet placed behind the Arterial pump cover with a cloth dipped in a disinfectant solution.
	Call for Service if the alarm persists.

PUMP SPEED TOO HIGH 10

Reason for Alarm	The Blood flow is higher than the Pump speed set value or than the maximum permitted value.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero.

Possible Cause	Suggested Action
1. The Blood Pump speed is different from the set value.	1. Press the ***CONFIRM*** button to restart the Blood Pump.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE OUT OF RANGE 11

Reason for Alarm	The arterial pressure is beyond the upper or lower limit of the sensor.
Machine Actions	• The Blood Pump is stopped; • The UF Rate is automatically set to minimum.

Possible Cause	**Suggested Action**
1. Restriction of blood flow from the Patient's Vascular Access or in the Arterial Patient Line.	1. Check for restriction of blood flow in the Arterial Patient Line, i.e. kinks, clamps, clotted arterial needle, poor flow from the Patient's Vascular Access; The alarm clears when the arterial pressure is in the proper range. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
2. Arterial pressure decreased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient and a resulting pressure drop increase for a given needle at a fixed blood flow rate.	2. Attention should be given to revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

BLOOD PUMP SPEED ERROR 12

Reason for Alarm	The Blood Pump is not turning at the requested speed.
Machine Actions	• The Blood Pump is stopped; • The UF Rate is automatically set to zero.

Possible Cause	Suggested Action
1. The pump segment is jamming the rotor of the blood pump.	1. Verify the correct placement of the pump segment into the rotor. Press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

BLOOD PUMP ROTOR ERROR 13

Reason for Alarm	The arterial hall sensor is not detected properly.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Arterial pump segment is not correctly inserted into the rotor.	1. Verify that the Arterial pump segment is correctly inserted into the rotor. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

INCORRECT BICARBONATE CONCENTRATE 18

Reason for Alarm	The Bicarbonate Concentrate Connector is in the wrong position or not fully inserted into its Concentrate Connector Port.
Machine Actions	In DIALYSIS: • The concentrate pumps (PA, PB, PSel) shall be stopped; • The phase currently running stops; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Bicarbonate Concentrate Connector is in the wrong position.	1. Dialysis: verify that the Bicarbonate Concentrate Connector is connected to its Concentrate Connector Port (BiCart Treatment only), the Concentrate Canister or the Central Bicarbonate Port.
2. The Bicarbonate Concentrate Connector is not fully inserted into its Concentrate Connector Port.	2. ADR: verify that the Bicarbonate Connector is connected securely to its Concentrate Connector Port.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

BICART CARTRIDGE EMPTY 21

Reason for Alarm	The BiCart Cartridge is either empty or not connected properly; as a result the Bicarbonate Pump cannot reach the set conductivity value.
Machine Actions	• The Bicarbonate Concentrate Pump (PB) is stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The BiCart Cartridge is almost empty.	1. Replace the BiCart according to the BiCart Change procedure.
2. The Bicarbonate powder is not well distributed in the BiCart Cartridge.	2. Tap the bottom of the BiCart Cartridge to evenly distribute the powder.
3. The BiCart Cartridge is in the wrong position.	3. Verify the correct position of the BiCart into its holder. Repeat the BiCart Change procedure.
	Call for Service if the alarm persists.

INCORRECT BICART HOLDER ARMS POSITION 22

Reason for Alarm	The BiCart Holder Arms are in the wrong position or not closed securely.
Machine Actions	In DIALYSIS: During the dialysis fluid preparation phase: • The phase currently running stops; • The concentrate pump PB is stopped. During treatment: • The phase currently running stops; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The BiCart Holder Arms are in the wrong position, or not closed securely.	1. Verify the correct position of the BiCart Holder Arms in relation to the machine phase.
	Call for Service if alarm persists.

INCORRECT BICARBONATE CONCENTRATION 23

Reason for Alarm	The Bicarbonate Conductivity is beyond the set or permitted range.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Bicarbonate pick-up tube connector is not well fitted to the Concentrate Canister.	1. Verify that the Bicarbonate pick-up tube connector is properly connected to the concentrate canister.
2. Massive air leak from the Bicarbonate Concentrate Canister.	2. Replace the Bicarbonate Concentrate Canister.
3. The BiCart is not well positioned in its holder.	3. Ensure the BiCart is securely placed in its holder.
	Call for Service if alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

BLOOD IN DIALYSATE 28

Reason for Alarm	Blood has been detected in the dialysate by the Blood Leakage Detector.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. A break in the dialyzer membrane caused a blood leakage into the hydraulic circuit.	1. Press the ***OVERRIDE*** button. Some of the safety mechanisms shall be disabled for the subsequent 2 minutes. Visually check the dialysate for blood presence. If the results are positive, replace the dialyzer and the Blood Cassette. Follow the correct procedure to replace the extracorporeal circuit.
2. The blood leak sensor is dirty.	2. Press the ***OVERRIDE*** button. Some of the safety mechanisms shall be disabled for the subsequent 2 minutes. Visually check the dialysate for blood presence. If the results are negative and the alarm persists, stop the treatment. As soon as possible perform a chemical disinfection to clean the blood leak sensor.

Possible Cause (Continued)	Suggested Action (Continued)
3. Massive air leak from the Red/Blue dialysis fluid tube connectors, as the BLD sensor could confuse air with blood.	3. Press the ***OVERRIDE*** button. Some of the safety mechanisms shall be disabled for the subsequent 2 minutes. Deactivate the dialysis fluid flow by pressing the “Dialysis fluid” action button. • the dialysis fluid goes into bypass; • the “Dialysis fluid” action indicator switches to grey. Verify that the Red/Blue dialysis fluid tube connectors do not leak and are securely fitted to the dialyzer. Activate again the dialysis fluid flow by pressing the deactivated “Dialysis fluid” action button. • the “Dialysis fluid” action indicator switches to green.
	Call for Service if the alarm persists.

BPM FAILURE 30

Reason for Alarm	The BPM System was calibrated incorrectly, is malfunctioning or is disconnected.
Machine Actions	• The Blood Pressure Monitoring system is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. Temporary blockage of the device.	1. Press the ***CONFIRM*** button to remove the alarm. Do not perform any other Blood Pressure measurements. If the BPM Mode parameter is set to Auto, set it to Manual. At the end of the treatment: • switch the machine OFF, wait a few seconds and then switch the machine back ON; • take a Blood Pressure to verify if the BPM device is functioning correctly: if the result is negative, a service technician assistance is required.
	Call for Service if the alarm persists.

BPM: MEASUREMENT FAILURE 31

Reason for Alarm	• The BPM System may have been unable to record a blood pressure measurement because of patient and/or Cuff conditions; • The BPM Tubing may be kinked or disconnected; • The BPM System may be leaking; • There may be a Hardware/Communication failure on the BPM System.
Machine Actions	• The Blood Pressure Monitoring System is stopped and the measurement is not available.

Possible Cause	**Suggested Action**
1. The tubing of the BPM cuff is kinked or disconnected.	1. Verify that the external tubing of the BPM cuff is connected and that there are no leaks or kinks. Press the ***CONFIRM*** button and retry the measurement.
2. The patient moved his arm too many times during the measurement. The BPM was unable to measure the blood pressure.	2. Press the ***CONFIRM*** button and retry the measurement.
3. The external tubing of the BPM cuff or the BPM cuff itself is leaking.	3. Replace the tubing of the BPM cuff and the BPM cuff with a new one.
4. There is a communication problem between the BPM cuff and the machine.	4. Repeat the blood pressure measurement.
	Call for Service if the alarm persists.

AIR IN HYDRAULIC PATHWAY (LD1) 33

Reason for Alarm	LD1 Level Sensor failed its test during dialysis preparation or an ADR process. The level sensor may have detected air, failed or needs to be cleaned.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into bypass; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Massive air leak from an empty concentrate canister.	1. Check for empty Acid, BiCart or Bicarbonate canister. The alarm clears before patient connection.
2. Dirty LD1 level detector.	2. Perform a RINSE or a Chemical Disinfection to clean the sensor from deposits.
3. The concentrate tube is not in the proper position for the current phase of the machine.	3. Verify the proper placement of the concentrate tube for the current phase of the machine.
4. The BiCart holder arms are not in the fully closed position.	4. Place the BiCart holder arms in the closed position.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

HYDRAULIC SENSOR DIRTY (LP) 34

Reason for Alarm	The LP Level Sensor failed its test during dialysis preparation or an ADR process. The level sensor may have detected air, failed or needs to be cleaned.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into bypass; • All the pumps are stopped.

Possible Cause	Suggested Action
1. Dirty LP level detector.	1. Perform a RINSE or a Chemical Disinfection to clean the sensor from deposits.
	Call for Service if the alarm persists.

AIR IN HYDRAULIC PATHWAY (LD2) 35

Reason for Alarm	The LD2 Level Sensor failed its test during dialysis preparation or a cleaning process. The Level Sensor may have detected air, failed or needs to be cleaned.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into bypass; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Massive air leak from an empty concentrate canister.	1. Check for empty Acid, BiCart or Bicarbonate canister.
2. Dirty LD2 level detector.	2. Perform a RINSE or a Chemical Disinfection to clean the sensor of deposits.
3. The Concentrate tube is not in the proper position for the current phase of the machine.	3. Verify that the concentrate tubes are in the proper position for the current phase of the machine.
4. The BiCart holder arms are not in the fully closed position.	4. Move the BiCart holder arms to the closed position to remove the alarm and to allow cleaning of the complete circuit.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

DIALYSATE PH HIGH 40

Reason for Alarm	The dialysis fluid pH value exceeds the alarm threshold.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The machine has run out of concentrates.	1. Replace the empty canister, then wait a few seconds for the machine to stabilize.
2. There is an air leak from the Acid or Bicarbonate Pick-up tube connector/ BiCart.	2. Verify there are no air leaks from the the Acid and Bicarbonate Pick-up tube connectors/BiCart.
3. The Acid or Bicarbonate Pick-up tube connector has accumulated debris or salt crystals.	3. Rinse the accumulated debris from the Acid and Bicarbonate Pick-up tube connector.
4. The Acid or Bicarbonate Pick-up tube is not properly connected to the concentrate canister.	4. Verify that the Acid and Bicarbonate Pick-up tubes are securely connected and that no air bubbles are being drawn into the tube.
5. The solution in the concentrate canister is not a solution correct for hemodialysis treatments (Refer to the "Chapter 16: Specifications", in this Operator's Manual).	5. Stop the dialysis preparation and replace the Blood Cassette and the dialyzer with a new Blood Cassette and a new dialyzer. Run a complete RINSE procedure. Replace the solution with the correct solution and then restart the dialysis preparation.
6. The solution in the concentrate canister is not correct or diluted.	6. Verify that the solution concentration is correct and if needed replace it with a correct solution.
7. The Acid Pick-up tube connector is not securely connected to its concentrate connector port (if using concentrate from a central delivery system).	7. Verify that the Acid Pick-up tube connector is securely connected to its concentrate connector port.
8. An incorrect type of dialysis fluid concentrate could be selected on the *Fluid Settings* sub-screen.	8. Verify that the correct type of dialysis fluid concentrate has been selected on the *Fluid Settings* sub-screen, otherwise select the correct concentrate combination.
	Call for Service if the alarm persists.

DIALYSIS FLUID FLOW HIGH 44

Reason for Alarm	The dialysis fluid flow is higher than the set value or than the maximum permitted flow.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. Unstable dialysis fluid flow has been detected by the machine.	1. Wait for a while, if the problem persists call for service for recalibration of the flowmeter.
2. There are deposits or debris inside the flowmeters of the machine.	2. Perform a Descaling or a Chemical Disinfection.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

BPM: DIASTOLIC PRESSURE ALARM 46

Reason for Alarm	The diastolic pressure measurement made by the BPM device is outside the configured limits.
Machine Actions	• The Blood Pressure Monitoring system is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. The diastolic pressure measurement, made by the BPM device, is outside the alarm limits set by the operator in *BPM Settings* sub-screen.	1. Press the ***CONFIRM*** button to remove the alarm message. Check in the *BPM Settings* sub-screen that the *"Diastolic upper" and "Diastolic lower"* pressure limits are not too much restrictive.
	Call for Service if the alarm persists.

TREATMENT TIME COMPLETE 51

Reason for Alarm	Notification: the entered TREATMENT TIME has elapsed.
Machine Actions	• The UF Rate is automatically set to zero.

Possible Cause	Suggested Action
1. The TREATMENT TIME is complete.	1. Disconnect the patient.
2. Additional TREATMENT TIME may be needed.	2. Increase the set TREATMENT TIME to lengthen the treatment. Press the ***CONFIRM*** button to continue.
	Call for Service if the alarm persists.

FLUID REMOVAL COMPLETE 53

Reason for Alarm	Notification: the patient's weight removal is complete.
Machine Actions	• The UF Rate is automatically set to minimum.

Possible Cause	Suggested Action
1. The programmed “TARGET UF VOLUME” has been reached.	1. Disconnect the patient or increase the set “TARGET UF VOLUME”, then select the UF button.
	Call for Service if the alarm persists.

HEPARIN PUMP OVERLOAD 55

Reason for Alarm	The heparin syringe has reached the upper limit or the Heparin Line is clamped.
Machine Actions	• The Heparin Pump is stopped.

Possible Cause	**Suggested Action**
1. The syringe holder has reached the upper hardware limit while the heparin program is active.	1. Disable the heparin program and use the down arrow key to exit from the error situation.
2. The syringe holder has reached the upper hardware limit while the heparin program is not active.	2. Use the down arrow key to exit from the error situation.
3. The syringe holder has reached the upper hardware limit and the Heparin syringe is empty.	3. Disable the heparin delivery program, use the down arrow key to exit from the error situation. Pull out the syringe from the holder, refill the syringe and place it back on the holder. Restart the program.
4. Blocked heparin line.	4. Disable the heparin program, verify if the heparin line is blocked and remove the possible obstruction. Enable the heparin delivery program.
5. The syringe is defective.	5. Disable the heparin delivery program, pull out the defective syringe, prepare a new filled one, place it back on the holder. Restart the program.
6. Incorrect position of the syringe.	6. Ensure that the syringe is properly placed into the syringe holder.
	Call for Service if the alarm persists.

HEPARIN INFUSION COMPLETE 58

Reason for Alarm	The programmed heparin “Stop Time” has been reached.
Machine Actions	• The Heparin Pump is stopped.

Possible Cause	**Suggested Action**
1. The Heparin delivery program is complete.	1. Enter the *Heparin Settings* sub-screen. Deactivate the heparin delivery program to remove the alarm or in case the patient needs more heparin, set a new value for the heparin “Stop Time”, lower than the previous one.
2. The programmed heparin “Stop Time” is greater than the programmed “Treatment Time”.	2. Set a new value either for the heparin “Stop Time” or for the “Treatment Time”, lower than the previous one.
	Call for Service if the alarm persists.

UF TARGET WILL NOT BE ACHIEVED 60

Reason for Alarm	The remaining treatment time is not enough to reach the programmed "Isolated UF Volume".
Machine Actions	• None.

Possible Cause	Suggested Action
1. The programmed Isolated UF volume has not been achieved due to many bypass conditions.	1. Press the "Isolated UF Settings" button on the *Fluid* screen. From the *Isolated UF Settings* sub-screen, change the "Isolated UF Time" and/or "Isolated UF Volume" parameters.
2. The "UF" action button has been deactivated for too long time, therefore the time left after its activation is not sufficient for the achievement of the set "Isolated UF Volume".	2. Press the "Isolated UF Settings" button on the *Fluid* screen. From the *Isolated UF Settings* sub-screen, change the "Isolated UF Time" and/or "Isolated UF Volume" parameters. Then select the "Isolated UF" action button.
	Call for Service if the alarm persists.

CDF1 ULTRAFILTER LOWER SWITCH ERROR 61

Reason for Alarm	The CDF1 first ultrafilter lower connector microswitch (SWLOWUF1) is indicating an error condition.
Machine Actions	• In ADR: The phase currently running stops; • In Dialysis fluid preparation: The machine will not continue until the microprocessor receives the correct signal from the switch; • In DIALYSIS: The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The CDF1 ultrafilter lower connector microswitch is indicating an error condition.	1. Check the correct position of the ultrafilter.
	Call for Service if the alarm persists.

INCORRECT CONDUCTIVITY MEASURED 62

Reason for Alarm	The conductivity of the dialysis fluid is above the allowed limit.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Acid or Bicarbonate concentrate canister is empty.	1. Supply appropriate concentrate to the relevant inlet connector. Wait for stability of the dialysis fluid flow.
2. The Acid or Bicarbonate pick-up tube connector(s) are not properly positioned into the concentrate canister(s).	2. Verify that the connector(s) are properly positioned into the proper canister(s). Wait for stability of the dialysis fluid flow.
3. Massive air leak from a concentrate canister.	3. Check and replace the concentrate canister. Wait for stability of the dialysis fluid flow.
4. The Acid or Bicarbonate pick-up tube connector(s) has accumulated debris or salt crystals.	4. Rinse the accumulated debris from the connector(s).
5. Inappropriate solution in the Acid concentrate canister.	5. Verify that appropriate concentrate has been used.
6. When using acid central delivery, the Acid or Bicarbonate pick-up tube connector is not securely connected to its concentrate connector port.	6. Verify that the Acid or Bicarbonate pick-up tube connector is properly positioned in its concentrate connector port.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

BPM HEART RATE ALARM 66

Reason for Alarm	The BPM heart rate measurement is outside the established limits.
Machine Actions	The Blood Pressure Monitoring system is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. The BPM heart rate measurement is outside the established limits.	1. Press the ***CONFIRM*** button to remove the alarm message. Check in the *BPM Settings* sub-screen that the *"Max Heart Rate"* and *"Min Heart Rate"* alarm limits are not too much restrictive.
	Call for Service if the alarm persists.

TMP HIGH 68

Reason for Alarm	The TMP Upper Limit value has been exceeded.
Machine Actions	• The UF Rate is automatically set to zero; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The TMP Upper Limit value is incorrect for the dialyzer used.	1. From the *Fluid Settings* sub-screen, verify that the correct TMP Upper Limit value was entered for the dialyzer used.
2. The blood flow rate is too high for the dialyzer used in the current operating condition.	2. Verify the correctness of the patient prescription (ultrafiltration rate). Decrease the blood flow, using the blood flow decrease key, if this operation is not in disagreement with the patient prescription (to decrease the venous pressure and avoid hemoconcentration).
3. The ultrafiltration value is too high for the dialyzer used in the current operating condition.	3. Verify the correctness of the patient prescription (ultrafiltration rate).
4. The transmembrane pressure is too high.	4. Consider increasing the dialysis fluid flow to increase the dialysis fluid pressure.
5. The extracorporeal circuit is clotting.	5. Check the extracorporeal circuit for clotting. Refer to your internal policy.
	Call for Service if the alarm persists.

HEPARIN PUMP LOWER LIMIT REACHED 69

Reason for Alarm	The heparin pump has reached the lower limit.
Machine Actions	• The Heparin Pump is stopped.

Possible Cause	Suggested Action
1. The syringe holder has reached the lower hardware limit.	1. Use the up arrow key to exit from the error situation.
	Call for Service if the alarm persists.

HEPARIN PUMP SPEED ERROR 70

Reason for Alarm	The Heparin Infusion Rate is different from the expected one.
Machine Actions	• The Heparin Pump is stopped.

Possible Cause	**Suggested Action**
1. The actual heparin pump infusion rate is incorrect.	1. Press the ***CONFIRM*** button to restart the heparin pump. If the problem does not occur anymore, the heparin infusion will proceed according to the settings.
2. The actual heparin pump infusion rate is incorrect.	2. Press the ***CONFIRM*** button to restart the heparin pump. If the problem persists, the alarm will be displayed and the pump will be stopped again. To proceed with the infusion, deactivate the heparin program and infuse the heparin manually or using the "Heparin Syringe Positioning Keys".
	Call for Service if the alarm persists.

HEPARINIZATION NOT INITIATED 71

Reason for Alarm	The Heparin Delivery Program has not been activated.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The heparin infusion was not enabled by the operator.	1. In *Heparin settings* sub-screen: • Press the “Heparin” action button to enable the heparin delivery program and • Press the ***CONFIRM*** button to remove the alarm.
2. No heparin delivery program is needed.	2. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

LOW TEMPERATURE 81

Reason for Alarm	This alarm appears if, in Chemical Disinfection with heating, the hydraulic circuit temperature falls below 35,5°C.
Machine Actions	• The process time will stop until the temperature measured in the hydraulic circuit reaches 36°C.

Possible Cause	Suggested Action
1. Temporary drop of the temperature.	1. No Action is required. The machine should heat automatically.
	Call for Service if the alarm persists.

DIALYZER INLET PRESSURE HIGH 87

Reason for Alarm	Pressure higher than what is allowed has been detected at the Dialyzer Inlet Connector.
Machine Actions	• The phase currently running stops; • The P1 and P2 pumps are stopped; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Red and Blue dialysis fluid tube connectors are in the wrong position.	1. Verify that the Red and Blue dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the ***CONFIRM*** button.
2. The Red and Blue dialysis fluid tube connectors are in the proper position, but not well inserted.	2. Verify that the Red and Blue dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the ***CONFIRM*** button.
3. The external dialysis fluid tubes are kinked.	3. Verify that the external dialysis fluid tubes are not kinked, then press the ***CONFIRM*** button.
4. Massive presence of air inside the hydraulic circuit.	4. Verify the presence of air in the external dialysis fluid tubes.
5. The blood flow is too high, producing an overpressure within the hydraulic circuit.	5. Verify the correctness of the patient prescription (ultrafiltration rate). Decrease the blood flow, using the blood flow decrease key, if this operation is not in disagreement with the patient prescription.
6. Clotting or clogging in the blood side of the dialyzer.	6. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary.
7. The dialysis fluid flow rate is not correct for the current dialyzer.	7. From the *Fluid Settings* sub-screen, reduce the dialysis fluid flow rate.
8. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	8. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 7: Special Procedures", in this Operator's Manual).
	Call for Service if the alarm persists.

DIALYZER OUTLET PRESSURE HIGH 88

Reason for Alarm	Pressure higher than what is allowed has been detected at the Dialyzer Outlet Connector.
Machine Actions	In DIALYSIS: • If the pressure is greater than 450 mmHg, the UF pump is driven at the current value and the phase currently running stops; • If the pressure is greater than 500 mmHg, the UF pump is driven at the current value and the phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The dialysis fluid tube connectors are in the wrong position.	1. Verify that the dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the ***CONFIRM*** button.
2. The dialysis fluid tube connectors are in the proper position, but not well inserted.	2. Verify that the dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the ***CONFIRM*** button.
3. The external dialysis fluid tubes are kinked.	3. Verify that the external dialysis fluid tubes are not kinked, then press the ***CONFIRM*** button.
4. The blood flow is too high, producing an overpressure on the hydraulic side of the machine.	4. Verify the correctness of the patient prescription (ultrafiltration rate). Consider reducing the blood flow if this operation is not in disagreement with the patient prescription.
5. Clotting or clogging in the blood side of the dialyzer.	5. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary.
6. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	6. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 7: Special Procedures", in this Operator's Manual).
	Call for Service if the alarm persists.

MAXIMUM TEMPERATURE LIMIT 90

Reason for Alarm	The temperature measured by TP is greater than the following maximum values: • In DIALYSIS: 60°C (114.8°F) • In Chemical Disinfection: 42°C (107.6°F) • In Heat or Heat Citric Disinfection: 110°C (230 °F)
Machine Actions	• The heater is turned off; • The phase currently running stops; • All the hydraulic pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The machine had a temporaneous unstable condition.	1. Verify the patient safety. Wait for the temperature to drop; the heater is automatically turned on.
2. The machine has malfunctioned.	2. Discontinue the dialysis treatment and call for Service.
3. The incoming water temperature is too high.	3. Check the incoming water temperature (Refer to the "Chapter 16: Specifications" in this Operator's Manual).
	Call for Service if the alarm persists.

DIALYZER INLET PRESSURE LOW 94

Reason for Alarm	Pressure lower than what is allowed has been detected at the Dialyzer Inlet Connector.
Machine Actions	In DIALYSIS: • The P1 and P2 pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Dialysis fluid tube connectors in the wrong position.	1. Verify the dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the ***CONFIRM*** button.
2. Dialysis fluid tube connectors in the proper position, but not well inserted.	2. Verify the dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the ***CONFIRM*** button.
3. The external dialysis fluid tubes are kinked.	3. Verify the external dialysis fluid tubes are not kinked, then press the ***CONFIRM*** button.
4. The UF Rate is too high for the dialyzer used.	4. Check the proper UF Rate for the dialyzer used. Consider reducing the blood flow if this operation is not in disagreement with the patient prescription, then press the ***CONFIRM*** button.
5. Clotting or clogging in the blood side of the dialyzer.	5. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary.
6. The dialysis fluid flow is not correct for the current dialyzer.	6. Consider reducing the dialysis fluid flow rate.
	Call for Service if the alarm persists.

DIALYZER OUTLET PRESSURE LOW 95

Reason for Alarm	Pressure lower than what is allowed has been detected at the Dialyzer Outlet Connector.
Machine Actions	In DIALYSIS: • If the pressure is lower than -350 mmHg, the UF Pump is stopped; • If the pressure is lower than -450 mmHg, the UF Pump is stopped; • All the pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The dialysis fluid tube connectors are in the wrong position.	1. Verify that the dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the ***CONFIRM*** button.
2. The dialysis fluid tube connectors are in the proper position, but not well inserted.	2. Verify that the dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the ***CONFIRM*** button.
3. The external dialysis fluid tubes are kinked.	3. Verify that the external dialysis fluid tubes are not kinked, then press the ***CONFIRM*** button.
4. The blood flow is too high, producing an overpressure on the hydraulic side of the machine.	4. Verify the correctness of the patient prescription (ultrafiltration rate). Consider reducing the blood flow if this operation is not in disagreement with the patient prescription.
5. Clotting or clogging in the blood side of the dialyzer.	5. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary.
6. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	6. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 7: Special Procedures", in this Operator's Manual).
	Call for Service if the alarm persists.

INSUFFICIENT WATER SUPPLY 100

Reason for Alarm	The Inlet Water pressure is low.
Machine Actions	• All the Hydraulic Pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. Pressure drop in the water distribution system.	1. Verify that there is adequate water pressure in the water distribution system.
2. The water inlet tube is disconnected.	2. Connect the water inlet tube to the proper water valve.
3. The water valve is closed.	3. Verify the water valve is open.
4. The incoming water filter is clogging.	4. Check the water filter in the machine for clogging. A clogged filter will decrease the amount of water flowing through the system.
	Call for Service if the alarm persists.

DIALYZER PRESSURE MAXIMUM 114

Reason for Alarm	The dialyzer inlet pressure, measured by the PI pressure sensor, OR the dialyzer outlet pressure, measured by the PO pressure sensor, has exceeded the maximum limit.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The dialysis fluid tube connectors are not in the proper position or are not well inserted.	1. Verify that the dialysis fluid tube connectors are in the proper position and are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time.
2. The external dialysis fluid tubes are kinked.	2. Verify that the external dialysis fluid tubes are not kinked.
3. Massive presence of air inside the hydraulic circuit.	3. Verify the presence of air into the external dialysis fluid tube. Verify the dialysis fluid connectors are well fitted to the dialyzer or to the machine.
4. The UF Rate is too low.	4. Verify the correctness of the patient prescription (ultrafiltration rate). Consider reducing the Blood Pump speed if this operation is not in disagreement with the patient prescription.
5. Clotting or clogging in the dialyzer and/ or Blood Cassette.	5. Check for clotting or clogging in the blood side of the dialyzer or in the Blood Cassette. Replace the dialyzer and the Blood Cassette if necessary.
6. The dialysis fluid flow rate is not correct for the current dialyzer.	6. Consider reducing the dialysis fluid flow rate.
7. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	7. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 7: Special Procedures", in this Operator’s Manual).
	Call for Service if the alarm persists.

DIALYZER PRESSURE MINIMUM 115

Reason for Alarm	The dialyzer inlet pressure, measured by PI sensor, OR the dialyzer outlet pressure, measured by PO sensor, are below the minimum limit.
Machine Actions	• The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The dialysis fluid tube connectors not in the proper position or are not inserted well.	1. Verify that the dialysis fluid tube connectors are in the proper position and are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time.
2. The external dialysis fluid tubes are kinked.	2. Verify that the external dialysis fluid tubes are not kinked.
3. Massive presence of air inside the hydraulic circuit.	3. Verify the presence of air in the external dialysis fluid tubes. Verify the dialysis fluid connectors are well fitted to the dialyzer or to the machine.
4. The UF Rate is too high for the dialyzer used.	4. Verify the correctness of the patient prescription (ultrafiltration rate). Consider increasing the Blood Pump speed if this operation is not in disagreement with the patient prescription.
5. Clotting or clogging in the dialyzer or the Blood Cassette.	5. Check for clotting or clogging in the blood side of the dialyzer or in the Blood Cassette. Replace if necessary.
6. The dialysis fluid flow rate is not correct for the current dialyzer.	6. Consider increasing the dialysis fluid flow rate.
	Call for Service if the alarm persists.

BPM SYSTOLIC PRESSURE ALARM 132

Reason for Alarm	The systolic pressure measurement made by the BPM device is outside the configured limits.
Machine Actions	• The Blood Pressure Monitoring System is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. The systolic pressure measurement made by the BPM device is outside the configured limits.	1. Press the ***CONFIRM*** button to remove the alarm message. Check in the *BPM settings* sub-screen that the *("Systolic upper"/"Systolic lower")* pressure limits are not too much restrictive.
	Call for Service if the alarm persists.

DIALYSIS FLUID TEMP HIGH 134

Reason for Alarm	The temperature of the dialysis fluid is 2°C above the value set by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. A temporary instability of the dialysis fluid flow.	1. Wait for stability of the system.
2. The temperature of the dialysis fluid has exceeded the safety limits.	2. Check the incoming water temperature (Refer to the "Chapter 16: Specifications" in this Operator's Manual).
3. The machine has recently been turned on and has not yet reached the operating temperature.	3. If the machine temperature remains high or low for more than 10 minutes, discontinue the dialysis treatment.
4. The machine has an internal malfunction.	4. Discontinue the dialysis treatment.
	Call for Service if the alarm persists.

TMP LOW 142

Reason for Alarm	The current TMP value is below the lowest TMP safety limit.
Machine Actions	• The UF Rate is automatically set to zero; • The Venous pump is stopped.

Possible Cause	Suggested Action
1. The dialyzer used is not correct for the current treatment.	1. Verify the correctness of the patient prescription (ultrafiltration rate). Increase the blood flow, using the blood flow increase key, if this operation is not in disagreement with the patient prescription. Comply with the specifications of the dialyzer.
2. The Blood Pump is stopped.	2. Correct the action which caused the Blood Pump to stop and restart the Blood Pump.
3. The Red and Blue dialysis fluid tubes are blocked.	3. Check that the Red and Blue dialysis fluid tubes are not kinked or clamped.
4. The Blood Cassette is not well positioned or a pressure pod diaphragm has collapsed. The Pressure Sensor cannot read properly.	4. If the alarm condition persists, verify the Blood Cassette position. Verify that the pressure pod diaphragm is not collapsed. If required, perform a Cassette Repositioning Procedure (Refer to the "Chapter 7: Special Procedures", of this Operator's Manual).
	Call for Service if the alarm persists.

UF RATE HIGHER THAN EXPECTED 145

Reason for Alarm	The ultrafiltration rate (UFR) is above the value confirmed by the operator or the maximum permitted value.
Machine Actions	• The Venous Pump is stopped; • The dialysis fluid goes into Bypass; • Calibration request.

Possible Cause	**Suggested Action**
1. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect valves control.	1. Press the ***CONFIRM*** button and continue the treatment.
2. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect flowmeter reading.	2. Press the ***CONFIRM*** button and continue the treatment.
3. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect P2 pump flow or P2 reading.	3. Press the ***CONFIRM*** button and continue the treatment.
4. The machine could not perform an alignment of the D2 flowmeter during the treatment and the Ultrafiltration Mass Balance could be incorrect.	4. Press the ***CONFIRM*** button and continue the treatment.
	Call for Service if the alarm persists.

DIALYSATE PRESSURE HIGH 146

Reason for Alarm	The pressure in the Ultrafilter is higher than the permitted limit.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into Bypass; • All the pumps are stopped.

Possible Causes	**Suggested Action**
1. The Ultrafilter is clogged.	1. During treatment: from the *Fluid Settings* sub-screen, decrease the dialysis fluid flow rate to continue with the dialysis process in progress. When the treatment is complete, replace the Ultrafilter according to the procedure.
2. The Red and Blue dialysis fluid tube connectors are not properly positioned.	2. Verify that the Red and Blue dialysis fluid tube connectors are properly positioned to the dialyzer or to the machine, depending upon the current machine phase. Press the ***CONFIRM*** button to restart the current operation of the machine.
	Call for Service if the alarm persists.

VENOUS PUMP COVER IS OPEN 149

Reason for Alarm	The Venous Pump Cover is open.
Machine Actions	• The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Venous Pump Cover is open.	1. Close the Venous Pump Cover. Be sure the Venous Pump Cover is securely latched.
2. The magnet is dirty.	2. Carefully clean the magnet placed behind the blood pump cover with a cloth dipped in a disinfectant solution.
	Call for Service if the alarm persists.

VENOUS PRESSURE OUT OF RANGE 153

Reason for Alarm	The measured venous pressure is outside the permitted range.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to minimum; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. Restriction of blood flow to the Patient's Vascular Access or in the Venous Patient Line.	1. Check for restriction of blood flow in the Venous Patient Line, i.e. kinks, clamps, clotted venous needle, poor flow to the Patient's Vascular Access; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump. The alarm clears when the venous pressure is in the proper range.
2. Venous pressure has increased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a pressure increase for a given needle at a fixed blood flow rate.	2. Attention should be given to revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

VENOUS PRESSURE TOO HIGH 154

Reason for Alarm	The measured venous pressure is above the maximum venous treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero (typical value 100 ml/h); • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	Suggested Action
1. Restriction of blood flow to the Patient's Vascular Access or in the Venous Patient Line.	1. Carefully check the Blood Cassette connections and assess the Patient's Vascular Access. Check for restrictions, such as: • kinks in the Venous Patient Line; • closed clamps; • clotted venous needle. If necessary decrease the blood flow per clinical policy. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump. 2. If the alarm persists: • attach a sterile syringe to the Venous Infusion Line; • open the clamp on the Venous Infusion Line to decrease the pressure; • when the pressure stabilizes, close the clamp on the Venous Infusion Line and remove the syringe; • select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.

Possible Cause (Continued)	Suggested Action (Continued)
2. The venous pressure has increased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a pressure increase for a given needle at a fixed blood flow rate.	1. Attention should be given to the revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump. 2. If the alarm persists: • attach a sterile syringe to the Venous Infusion Line; • open the clamp on the Venous Infusion Line to decrease the pressure; • when the pressure stabilizes, close the clamp on the Venous Infusion Line and remove the syringe; • select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

VENOUS PRESSURE HIGH 155

Reason for Alarm	The venous pressure is above the Venous Pressure Threshold as displayed in the Venous Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The venous pressure is above the allowed limit.	1. Carefully check the Patient's Vascular Access, the Cassette connections and inspect for kinking of the Venous Patient Line. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the treatment. Press the "Close A/V Limits" button when the arterial and venous pressures are stable. 2. If the alarm persists: • attach a sterile syringe to the Venous Infusion Line; • open the clamp on the Venous Infusion Line to decrease the pressure; • when the pressure stabilizes, close the clamp on the Venous Infusion Line and remove the syringe; • select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

VENOUS PUMP SPEED ERROR 157

Reason for Alarm	The Venous Pump is not turning at the requested speed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The pump segment is jamming the rotor of the venous pump.	1. Verify the correct placement of the pump segment into the rotor. Press the ***CONFIRM*** button to restart the venous pump.
	Call for Service if the alarm persists.

VENOUS PUMP ROTOR ERROR 158

Reason for Alarm	The venous hall sensor is not detected properly.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Venous pump segment is not correctly inserted into the rotor.	1. Verify that the Venous pump segment is correctly inserted into the rotor.
	Call for Service if the alarm persists.

BLD SENSITIVITY LOSS 170

Reason for Alarm	Deposits and/or debris collected on the Blood Leak Detector (BLD) are causing a loss of sensitivity.
Machine Actions	None.

Possible Cause	Suggested Action
1. An excessively high value is present at the receiver of the Optical Sensor, due to deposits on the detector.	1. Press the ***CONFIRM*** button to remove the alarm. Perform a Chemical Disinfection procedure to clean the Sensor.
	Call for Service if the alarm persists.

⚠WARNING

After a “BLD Sensitivity Loss (#170)” alarm perform a Chemical Disinfection program before starting a new treatment.

BACKUP BATTERY FAILURE 183

Reason for Alarm	The T1 test performed by the machine on the Backup Battery has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The battery in the Battery Backup Kit needs to be replaced.	1. Press the ***CONFIRM*** button and continue with the treatment if the Battery Backup Kit is not required for this dialysis treatment. Replace the Battery when appropriate.
	Call for Service if the alarm persists.

SUPPLY VOLTAGE INCORRECT 187

Reason for Alarm	The Protection Module detects a difference between the reference values and the Power Supply voltages after the Patient Connection.
Machine Actions	• GENERAL SAFE STATE.

Possible Cause	Suggested Action
1. Power supply failure during preparation.	1. If the alarm persists until the end of the function check/preparation phase, do not start the dialysis treatment.
	Call for Service if the alarm persists.

HEMOSCAN: MINIMUM BLOOD VOLUME 191

Reason for Alarm	The Hemoscan sensor detects blood volume lower than the "Alarm Limit" set value.
Machine Actions	• The dialysis process continues *(See **NOTE**)*;

Possible Cause	**Suggested Action**
1. Great increase of the Hemoglobin concentration in the patient's blood since the start of the treatment.	1. Take the appropriate clinical action.
2. The Hemoscan "Alarm Limit" value is incorrect for this patient.	2. Change the "Alarm Limit" value in the *Hemoscan Settings* sub-screen.
	Call for Service if the alarm persists.

NOTE

This alarm occurs in order to signal to the operator possible patient's health risk.

LOW BLOOD PUMP SPEED 204

Reason for Alarm	The Blood Pump has been running at less than 50 ml/min for more than 30 sec.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Blood pump speed is less than 50 ml/min for more than 30 sec.	1. Press the ***CONFIRM*** button to remove the alarm. Increase the blood pump speed to more than 50 ml/min.
	Call for Service if the alarm persists.

INCORRECT VENOUS OR ARTERIAL LINE POSITION IN CLAMP 205

Reason for Alarm	The Venous/Arterial Patient Line has been incorrectly inserted into the Venous/Arterial Line Clamp.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is not correctly inserted into the Venous Line Clamp.	1. Remove and correctly re-insert the Venous Patient Line into the Venous Line Clamp.
2. The Arterial Patient Line is not correctly inserted into the Arterial Line Clamp.	2. Remove and correctly re-insert the Arterial Patient Line into the Arterial Line Clamp.
	Call for Service if the alarm persists.

FLUID PATH OBSTRUCTION 206

Reason for Alarm	There is an excessive pressure in the Drain Tube. (Due to Drain Tube kinking/obstruction or bad connection)
Machine Actions	• The dialysis fluid goes into Bypass; • The heater is turned off; • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Obstruction or kinking in the Drain Tube.	1. Verify that the Drain Tube is not kinked or obstructed in any way.
	Call for Service if the alarm persists.

HEMOSCAN: DARK OUT OF RANGE 223

Reason for Alarm	Electronic malfunctioning of the Hemoscan Monitoring System.
Machine Actions	• None. • Hemoscan Monitoring disabled.

Possible Cause	Suggested Action
1. Internal malfunctioning of the Hemoscan Monitoring System.	1. From the *Hemoscan Settings* sub-screen, deactivate the Hemoscan function.
	Call for Service if the alarm persists.

HEMOSCAN: TEST OUT OF RANGE 225

Reason for Alarm	Electronic malfunctioning of the Hemoscan Monitoring System.
Machine Actions	• None. • Hemoscan Monitoring disabled.

Possible Cause	Suggested Action
1. Internal malfunctioning of the Hemoscan Monitoring System.	1. From the *Hemoscan Settings* sub-screen, deactivate the Hemoscan function.
	Call for Service if the alarm persists.

HEMOSCAN: L/H OUT OF RANGE 226

Reason for Alarm	Electronic malfunctioning of the Hemoscan Monitoring System.
Machine Actions	• None. • Hemoscan Monitoring disabled.

Possible Cause	Suggested Action
1. Internal malfunctioning of the Hemoscan Monitoring System.	1. From the *Hemoscan Settings* sub-screen, deactivate the Hemoscan function.
	Call for Service if the alarm persists.

HEMOCONTROL: LATE ON PRESCRIPTION 229

Reason for Alarm	A reduction in BV% has occurred, lower than expected and thus a lower Accumulated UF volume (weight loss) is reached.
Machine Actions	• None.

Possible Causes	**Suggested Action**
1. A reduction in BV% has occurred, lower than expected and thus a lower Accumulated UF volume (weight loss) is reached.	1. Press the ***CONFIRM*** button to remove the alarm message. If the alarm persists, set a lower Final BV value and/or a lower UF Volume value.
	Call for Service if the alarm persists.

HEMOCONTROL: EARLY ON PRESCRIPTION 230

Reason for Alarm	A reduction in BV% has occurred, lower than expected and thus a higher Accumulated UF volume (weight loss) is reached.
Machine Actions	• None.

Possible Causes	Suggested Action
1. A reduction in BV% has occurred, lower than expected and thus a higher Accumulated UF volume (weight loss) is reached.	1. Press the ***CONFIRM*** button to remove the alarm message. If the alarm persists, set a greater Final BV value and/or a greater UF Volume value.
	Call for Service if the alarm persists.

HEMOCONTROL: HIGH NA CONCENTRATION 231

Reason for Alarm	The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity higher than the Na tolerance set.
Machine Actions	• None.

Possible Causes	**Suggested Action**
1. The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity higher than the Na limits set.	1. Press the ***CONFIRM*** button to clear the alarm. If the alarm persists, correct the Final Na value in the *Hemocontrol Settings* sub-screen, as suggested by the indications displayed.
	Call for Service if the alarm persists.

HEMOCONTROL: LOW NA CONCENTRATION 232

Reason for Alarm	The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity lower than the Na tolerance set.
Machine Actions	• None.

Possible Causes	**Suggested Action**
1. The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity lower than the Na limits set.	1. Press the ***CONFIRM*** button to clear the alarm. If the alarm persists, correct the Final Na value in the *Hemocontrol Settings* sub-screen, as suggested by the indications displayed.
	Call for Service if the alarm persists.

HEMOCONTROL: BV% NOT AVAILABLE 234

Reason for Alarm	The HEMOSCAN™ is unable to supply a reliable Blood Volume.
Machine Actions	• None.

Possible Causes	Suggested Action
1. The HEMOSCAN™ is unable to supply a reliable Blood Volume.	1. Remove the causes which have stopped the measuring of the Blood Volume by the HEMOSCAN™ or wait.
	Call for Service if the alarm persists.

BIOSLAVE SUBSYSTEM COMMUNICATION ERROR 296

Reason for Alarm	An internal communication problem between the Master Module and the Bio Module occurred.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. Temporary communication problem.	1. Wait a few seconds for the alarm to be cleared.
2. If the alarm persists and the machine stops functioning.	2. Perform a Fast Recovery procedure during a dialysis treatment as described in the "7.4 Fast Recovery" section of this Operator's Manual.
	Call for Service if the alarm persists.

STILL IN BYPASS 302

Reason for Alarm	The machine has been in BYPASS for more than 6 minutes, either because the operator has deselected the ”DIALYSIS FLUID” button, or due to an internal machine malfunction that is blocking the machine in bypass condition.
Machine Actions	• None. In DIALYSIS: The alarm is active when the machine is in FULL ACTIVITY with blood detected in the Venous Patient Line. The alarm will be displayed on the Touch Screen 6 minutes after the machine is in BYPASS.

Possible Cause	**Suggested Action**
1. Bypass has been selected and not cleared during the treatment.	1. Take the machine out of BYPASS by selecting the ”DIALYSIS FLUID” button.
2. The machine is stuck in bypass.	2. Perform a Fast Recovery procedure during a dialysis treatment as described in the “7.4 Fast Recovery” section of this Operator’s Manual.
3. The “Start Treatment” button has not been pressed.	3. Confirm the mandatory parameters (UF Volume and Treatment Time), if not already done, and then press the “Start Treatment” button.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE HIGH 305

Reason for Alarm	The measured arterial pressure is above the maximum arterial pressure threshold as displayed in the Arterial Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure

Possible Cause	**Suggested Action**
1. The Arterial Pressure Alarm Window needs to be set.	1. In the *A/V Limit Settings* sub-screen adjust the arterial pressure alarm limits; Press "Close A/V Limits" button: the machine automatically centralize the alarm window values around the current patient's arterial/venous pressures; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
2. The Arterial Patient Line may have become disconnected from the patient.	2. Carefully check the Cassette connections and the Patient's Vascular Access; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
3. Loss of diaphragm pressure between the Blood Cassette and the arterial pressure cone.	3. Perform a Cassette Repositioning Procedure, (Refer to the "Chapter 7: Special Procedures", in this Operator's Manual). When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE BELOW TREATMENT MIN. LIMIT 306

Reason for Alarm	The measured arterial pressure is below the minimum arterial treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The Arterial Pump speed is too fast.	1. Consider decreasing the blood flow if this operation is not in disagreement with the patient prescription. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
2. The Arterial Patient Line is kinked, clamped or restricted.	2. Check the Arterial Patient Line and the Patient's Vascular Access for restrictions, such as: • kinks in the Arterial Patient Line; • closed clamps; • clotted arterial needle; • poor flow from the Patient's Vascular Access. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
3. The arterial pressure decreased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a reduced pressure for a given needle at a fixed blood flow rate.	3. Attention should be given to the revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

WRONG A/V OR SYSTEM PRESSURE OFFSET 319

Reason for Alarm	The initial Arterial and Venous Pressure offset are out of range or they aren't yet been calculated.
Machine Actions	• The machine will stop at this point and will not proceed any further into the test.

Possible Cause	**Suggested Action**
1. If the Blood Cassette is filled with saline, it is possible to have a pressure different from 0 mmHg.	1. Clamp the prime line, the Arterial infusion line and the Venous infusion line. Open the Venous infusion line and the Arterial infusion line to the atmosphere. The pressures displayed on the Touch Screen should decrease toward 0 mmHg.
2. The Blood Cassette was installed incorrectly during the Venous/Arterial Pressure T1 Test.	2. The Venous Patient Line must be inserted into the Air Detector and the Sensor Bar door closed. The Blood Pump Cover must be closed. Reposition the Blood Cassette and restart the T1 test.
3. The Blood Pump Cover is open.	3. Close the Blood Pump Cover. Be sure the Blood Pump Cover is securely latched.
4. The magnet is dirty.	4. Carefully clean the magnet located behind the Blood Pump Cover, using a soft cloth dipped in Ethyl Alcohol (90°) or in Isopropyl Alcohol (70°).
	Call for Service if the alarm persists.

REMINDER - STILL IN PAUSE THERAPY 329

Reason for Alarm	The machine remains in PAUSE TREATMENT for more than 5 minutes.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The operator has maintained the selection of PAUSE TREATMENT for more than 5 minutes.	1. Press the ***CONFIRM*** button to remove the alarm. Interrupt the PAUSE TREATMENT procedure and continue the treatment.
	Call for Service if the alarm persists.

BLUE DIALYSIS FLUID TUBE INCORRECT POSITION 330

Reason for Alarm	The Blue Dialysis Fluid Tube Connector is not in the position required for the current operating phase.
Machine Actions	• All the hydraulic pumps are stopped; • Waits until the connector is in right position; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Blue Dialysis Fluid Tube Connector is not in the position required for the current operating phase.	1. Verify the correct position of the Blue Dialysis Fluid Tube Connector for the current operating phase.
	Call for Service if the alarm persists.

RED DIALYSIS FLUID TUBE INCORRECT POSITION 331

Reason for Alarm	The Red Dialysis Fluid Tube Connector is not in the position required for the current operating phase.
Machine Actions	• All the hydraulic pumps are stopped; • Waits until the connector is in right position; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. The Red Dialysis Fluid Tube Connector is not in the position required for the current operating phase.	1. Verify the correct position of the Red Dialysis Fluid Tube Connector for the current operating phase.
	Call for Service if the alarm persists.

VENOUS PRESSURE NOT INCREASING 351

Reason for Alarm	In Single Needle Single Pump mode, during the venous phase the venous pressure is not increasing as expected.
Machine Actions	• The Blood Pump is stopped.

Possible Cause	**Suggested Action**
1. The venous pressure is not increasing as expected.	1. Check if the Blood Cassette is properly loaded on the Cassette holder and if it is properly connected to the venous pressure pod. Press the ***CONFIRM*** button to restart the Blood Pump and remove the alarm.
2. The Venous/Arterial Patient Line could be kinked, clamped, restricted or have some leakages.	2. Check the Venous/Arterial Patient Line and the Patient's Vascular Access for kinks, clamps or other restrictions. Press the ***CONFIRM*** button to restart the Blood Pump and remove the alarm.
3. The Blood Cassette and/or the SNSP conversion kit could have some leakages.	3. Check the line connections to these devices and ensure that the related clamps are closed. Press the ***CONFIRM*** button to restart the Blood Pump and remove the alarm.
	Call for Service if the alarm persists.

NO POWER - USING BATTERY BACKUP 353

Reason for Alarm	The AC supply voltage has been interrupted in a machine equipped with the BATTERY BACKUP KIT.
Machine Actions	In RINSE: • The machine automatically switches OFF after 5 minutes. In DISINFECTION and in DIALYSIS: • The heater is turned off.

Possible Cause	**Suggested Action**
1. Interruption of the AC supply voltage in RINSE or DISINFECTION.	1. Switch OFF the machine.
2. Interruption of the AC supply voltage in DIALYSIS, during the Dialysis Fluid Preparation phase until Patient Connection.	2. Switch OFF the machine.
3. Interruption of the AC supply voltage in DIALYSIS, during the treatment phase.	3. Perform RINSEBACK to return the blood to the patient and then switch OFF the machine.
4. Interruption of the AC supply voltage in DIALYSIS, during EMPTYING or DESCALING.	4. Switch OFF the machine.
	Call for Service if the alarm persists.

PUMP SPEED TOO LOW 362

Reason for Alarm	The Blood pump speed is lower than the set value.
Machine Actions	• The Arterial and the Venous pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The Blood pump speed is incorrect.	1. Press the ***CONFIRM*** button to re-start the Blood Pump.
2. The Blood Pump speed is too high for the "SN Pressure Min" and "SN Pressure Max" parameter values set by the operator.	2. Decrease the Blood pump speed or consider changing the "SN Pressure Min" and "SN Pressure Max" parameter values. Press the ***CONFIRM*** button to re-start the Blood Pump.
	Call for Service if the alarm persists.

BLOOD PUMP ROTOR ERROR 363

Reason for Alarm	The Blood Pump is not functioning properly.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. If the alarm is displayed for the first time.	1. Press the ***CONFIRM*** button and continue the process.
2. If the alarm persists.	2. Perform a Fast Recovery procedure during a dialysis treatment as described in the “7.4 Fast Recovery” section of this Operator’s Manual. Then call for Service.

VENOUS LINE NOT IN PATIENT SENSOR 364

Reason for Alarm	The machine is not detecting that the Venous Patient Line is present into the Air Detector housing or into the Venous Line Clamp (ONLY after Patient Connection).
Machine Actions	• The Blood Pump is stopped; • The UF Rate is automatically set to minimum; • The Venous Line Clamp is closed.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is not properly inserted into the Air Detector housing or into the Venous Line Clamp.	1. Verify that the Venous Patient Line has been inserted correctly into the Air Detector housing and into the Venous Line Clamp.
	Call for Service if the alarm persists.

INCORRECT BICARBONATE CONCENTRATION 366

Reason for Alarm	The Bicarbonate conductivity is below the set or permitted range.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Bicarbonate concentrate canister. or the BiCart are almost empty.	1. Verify adequate levels of concentrates. If BiCart, replace as described in the related section of the "Chapter 7: Special Procedures", in this Operator's Manual.
2. The Bicarbonate pick-up tube connector is not well fitted to the concentrate canister.	2. Verify that the Bicarbonate pick-up tube connector is well fitted to the proper concentrate canister.
3. Massive air leak from the Bicarbonate concentrate canister.	3. Replace the Bicarbonate concentrate canister.
4. The BiCart is not well positioned into its holder.	4. Ensure the BiCart is securely placed into its holder.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

DIALYSATE PH LOW 368

Reason for Alarm	The dialysis fluid pH value is below the alarm threshold.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous pump is stopped.

Possible Cause	Suggested Action
1. The concentrate canisters are empty.	1. Verify that none of the concentrate canisters are empty.
2. The solution in the concentrate canister is not correct or diluted.	2. Verify that concentrates are being used and are of the appropriate formulation for the selected treatment type. If using dialysis fluid concentrate solutions, replace the concentrates as needed, then wait a few seconds for the machine to stabilize. If using solutions other than concentrates during the dialysis fluid preparation: • Stop the dialysis preparation; • Replace the Blood Cassette and the Dialyzer; • Run a complete RINSE procedure; • Replace solutions; • Restart the dialysis fluid preparation.
3. Air leak from the Red/Blue pick-up tube connectors or the Red/Blue pick-up tube is not connected to the Concentrate Canister or the Red/Blue pick-up tube connector has accumulated debris or salt crystals.	3. If the alarm persists, verify that: • the Red and Blue pick-up tube connectors and Red and Blue pick-up tubes are free of leaks/holes and debris. • the Red/Blue pick-up tube connectors are securely connected to the appropriate concentrate connector port/ canister. If necessary, rinse the accumulated debris from the Connector(s).
	Call for Service if the alarm persists.

ACID/ACETATE CONCENTRATE ERROR 369

Reason for Alarm	A discrepancy is indicated between the conductivity of the dialysis fluid both for the dialysis fluid flow and the rotation speed of the associated Pump(s). The actual Pump(s) speed does not match with the actual concentrate(s) used.
Machine Actions	• The dialysis fluid goes into Bypass. • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The type/dilution of the Acid Concentrate used is incorrect.	1. Verify that the correct type/dilution of Acid Concentrate is being used. Replace the Acid Concentrate as needed, press the ***CONFIRM*** button, then wait a few seconds for the machine to stabilize.
2. The concentrate Connector is not securely connected to its port/canister.	2. Verify that the Connector is securely connected to the appropriate port/ canister.
3. The Acid Pump speed is incorrect.	3. If the machine does not stabilize, or if the machine has been switched from the Central Concentrate to an individual Concentrate Canister, then perform an Acid Pump Auto-calibration procedure.
	Call for Service if the alarm persists.

BICARBONATE CONCENTRATE ERROR 370

Reason for Alarm	A discrepancy is indicated between the conductivity of the dialysis fluid both for the dialysis fluid flow and the rotation speed of the associated Pump/Pumps. The actual Pump(s) speed does not match with the actual concentrate(s) used.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The type/dilution of Bicarbonate Concentrate used is incorrect.	1. Verify that the correct type/dilution of Bicarbonate Concentrate is being used. Replace the Bicarbonate Concentrate as needed, press the ***CONFIRM*** button, then wait a few seconds for the machine to stabilize.
2. The Concentrate Connector is not securely connected to its port/canister.	2. Verify that the Connector is securely connected to the appropriate port/ canister.
3. The dialysis fluid type selected in the "Fluid Settings" subscreen is incorrect.	3. Ensure that the correct type of dialysis fluid has been selected on the "Fluid Settings" subscreen.
4. The Bicarbonate Pump speed is incorrect.	4. If the machine does not stabilize, or if the machine has been switched from the Central Concentrate to an individual Concentrate Canister, then perform a Bicarbonate Pump Auto-calibration procedure.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

DIALYSIS FLUID FLOW LOW 373

Reason for Alarm	The dialysis fluid flow is lower than the set value or than the minimum permitted flow.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous pump is stopped.

Possible Cause	Suggested Action
1. There are deposits or debris inside the flowmeters of the machine.	1. Perform a Chemical Disinfection.
	Call for Service if the alarm persists.

INCORRECT CONDUCTIVITY MEASURED 375

Reason for Alarm	The conductivity of the dialysis fluid is below the allowed limit.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. Inappropriate solution in the Acid Concentrate Canister.	1. Verify that appropriate concentrate has been used for the selected treatment type.
2. Massive air leak from Concentrate Canisters/Connectors/Tubes or the Connectors are not securely connected to their Canisters/Ports or the Canisters/Connectors have accumulated debris or salt crystals.	2. If the alarm persists: • verify that Concentrate Canisters, Connectors and Tubes are free of leaks/holes and debris; • verify that the Connectors are securely connected to the appropriate Canisters/ Ports; • if necessary, rinse the accumulated debris from the Canister(s)/ Connector(s); • massive air leaks affect conductivity readings.
3. Inadequate Concentrates are being used.	3. If using dialysis fluid concentrate solutions, replace concentrates as needed then wait a few seconds for the machine to stabilize. If using solutions other than concentrates during dialysis fluid preparation: • stop the dialysis fluid preparation; • replace the Blood Cassette and the dialyzer; • run a complete ADR: RINSE procedure; • replace the solutions; • re-start the dialysis fluid preparation.
4. The Acid or Bicarbonate Connector is not properly positioned into the Central Concentrate port.	4. Verify that the Acid or Bicarbonate Connector is properly positioned into the Central Concentrate port on the front panel.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

DIALYSIS FLUID TEMPERATURE LOW 377

Reason for Alarm	The temperature of the dialysis fluid is 2°C below the value set by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous pump is stopped.

Possible Cause	**Suggested Action**
1. A temporary instability of dialysis fluid flow.	1. Wait a few seconds for the system to stabilize.
2. The temperature of the dialysis fluid has exceeded the safe limits.	2. Verify that the incoming water temperature is between 5.0°C - 32.2°C (41-90 degrees F). If the incoming water temperature exceeds the specified range, then adjust the temperature of the water source per clinical policy. If this alarm persists, then discontinue the dialysis treatment.
	Call for Service if the alarm persists.

UF RATE LOWER THAN EXPECTED 379

Reason for Alarm	The ultrafiltration rate (UFR) is below the value confirmed by the operator or the minimum permitted value.
Machine Actions	• The Venous Pump is stopped; • The dialysis fluid goes into Bypass; • Calibration request.

Possible Cause	**Suggested Action**
1. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect valves control.	1. Press the ***CONFIRM*** button and continue the treatment.
2. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect flowmeter reading.	2. Press the ***CONFIRM*** button and continue the treatment.
3. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect P2 pump flow or P2 reading.	3. Press the ***CONFIRM*** button and continue the treatment.
4. The machine could not perform an alignment of the D2 flowmeter during the treatment and the Ultrafiltration Mass Balance could be incorrect.	4. Press the ***CONFIRM*** button and continue the treatment.
	Call for Service if the alarm persists.

VENOUS PRESSURE LOW 382

Reason for Alarm	The measured venous pressure is either below +10 mmHg or below the venous pressure threshold as displayed in the Venous Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. If <10 mmHg, the Venous Patient Line may have become disconnected from the patient.	1. Carefully check the Patient's Vascular Access, the Cassette connections and inspect for kinking of the Venous Patient Line. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE LOW 384

Reason for Alarm	The measured arterial pressure is below the minimum arterial pressure threshold, as displayed in the Arterial Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The Arterial pressure alarm window needs to be set.	1. In the *A/V Limit Settings* sub-screen adjust the arterial pressure alarm limits; Press “Close A/V Limits” button: the machine automatically centralize the alarm window values around the current patient’s arterial/venous pressures. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
2. The Arterial Patient Line may have become disconnected from the patient.	2. Carefully check the Cassette connections and the Patient's Vascular Access. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
3. The Arterial Patient Line is kinked, clamped or restricted.	3. Check the Arterial Patient Line and the Patient's Vascular Access for restrictions, such as: • kinks in the Arterial Patient Line; • closed clamps; • clotted arterial needle; • poor flow from the Patient’s Vascular Access. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.

Possible Cause (Continued)	**Suggested Action (Continued)**
4. Loss of diaphragm pressure between the Blood Cassette and the arterial pressure cone.	4. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 7: Special Procedures", in this Operator's Manual). When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

AIR IN BLOOD T0 FAILURE 385

Reason for Alarm	The T0 Test, related to the Air Detector sensor, has failed.
Machine Actions	• The Blood Pump is stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to minimum.

Possible Cause	Suggested Action
1. The T0 Test failed.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

NA OR BIC SETTINGS RESULT IN CONDUCTIVITY OUT OF RANGE 401

Reason for Alarm	The Sodium or Bicarbonate Settings result in conductivity out of range.
Machine Actions	• The machine continues the treatment with the previous conductivity set; • The new set conductivity is not stored in the machine memory.

Possible Cause	Suggested Action
1. One of the formula input (Na set, HCO3 set, Concentrate set) causes the results out of range.	1. Change the value of the formula input.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

ULTRAFILTER REPLACEMENT REMINDER 402

Reason for Alarm	The machine notifies that the ultrafilters should be replaced.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The ultrafilters should be replaced.	1. Press the ***CONFIRM*** button to remove the alarm. If needed, replace the ultrafilters with new ones (Refer to the “7.18 Ultrafilter Change Procedure” section of this Operator’s Manual).
	Call for Service if the alarm persists.

SELECT BAG HOLDER INCORRECT POSITION 411

Reason for Alarm	The Select Bag holder is in the wrong position.
Machine Actions	In DIALYSIS: • All hydraulic module pumps are stopped; • The dialysis fluid goes into Bypass; • Waits until the connector is in right position. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Select Bag holder is in the wrong position.	1. Check the position of the Select Bag holder.
	Call for Service if the alarm persists.

VENOUS FLOW MINIMUM 412

Reason for Alarm	The venous blood flow is lower than the expected set value.
Machine Actions	• The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Venous Pump speed is different from the set value.	1. Press the ***CONFIRM*** button to restart the Blood Pump.
	Call for Service if the alarm persists.

VENOUS FLOW MAXIMUM 413

Reason for Alarm	The venous blood flow is greater than the expected set value.
Machine Actions	• The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Venous Pump speed is different from the set value.	1. Press the ***CONFIRM*** button to restart the Blood Pump.
	Call for Service if the alarm persists.

NO POWER - USING BATTERY BACKUP 415

Reason for Alarm	A power failure occurred and therefore the battery back-up is used.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Interruption of the AC supply voltage in DIALYSIS, during the Dialysis fluid Preparation phase until Patient Connection.	1. Switch OFF the machine.
2. Interruption of the AC supply voltage in DIALYSIS, during the treatment phase.	2. Perform RINSEBACK to return the blood to the patient and then switch OFF the machine.
3. Interruption of the AC supply voltage in DIALYSIS, before the patient connection or after the patient disconnection.	3. Switch OFF the machine.
	Call for Service if the alarm persists.

LEFT BLUE EVACLEAN DOOR INCORRECT POSITION 416

Reason for Alarm	The Left Blue EvaClean door position is wrong.
Machine Actions	The machine waits until the EvaClean Door is closed, in the meantime: In DIALYSIS: • All hydraulic module pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Left Blue EvaClean door is open when it should be closed.	1. Verify that the door is closed.
2. The Left Blue EvaClean door is closed when it should be opened.	2. Verify that the door is opened.
	Call for Service if the alarm persists.

RIGHT RED EVACLEAN DOOR INCORRECT POSITION 417

Reason for Alarm	The Right Red EvaClean door position is wrong.
Machine Actions	• The machine stops and waits for the EvaClean Door to be closed.

Possible Cause	Suggested Action
1. The Right Red EvaClean door is open when it should be closed.	1. Verify that the door is closed.
2. The Right Red EvaClean door is closed when it should be opened.	2. Verify that the door is opened.
	Call for Service if the alarm persists.

T1 TEST PRE FILTER PRESSURE 418

Reason for Alarm	The acquired inlet pressure value is out of range respect to the set point.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The T1 test failed during preparation.	1. Verify that the dialysis fluid connectors are properly positioned to their bypass ports. Repeat the dialysis fluid preparation.
	Call for Service if the alarm persists.

T1 TEST ARTERIAL PUMP/ABD 419

Reason for Alarm	The acquired flow value is out of range respect to the set point.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	Suggested Action
1. The T1 test failed during preparation.	1. Press the ***CONFIRM*** button to remove the alarm. Perform an Extra Priming procedure.
	Call for Service if the alarm persists.

NOTE

This alarm appears also in case the Arterial Pump cover is opened and then closed while the machine is performing the T1 Arterial Pump/ABD test. In this case, pressing the ***CONFIRM*** button, the alarm message is removed but if the “Reset Prime” button is pressed, the priming procedure gets stuck.

To restore the priming procedure, proceed as follows:

1. Open the Arterial Pump Cover;
2. Close the Arterial Pump Cover;
3. Press the “Auto-Prime” button to start again the priming procedure.

T1 TEST FLOW METERS 422

Reason for Alarm	The T1 test performed by the machine on the T1 Test Flow Meters has failed or it has exceeded the maximum allowed time for the execution.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	**Suggested Action**
4. The T1 test Flowmeter failed.	1. Press the ***CONFIRM*** button and wait for the new flowmeter test.
	Call for Service if the alarm persists.

ON-LINE DOOR INCORRECT POSITION 423

Reason for Alarm	The Ultra Door position is wrong.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Ultra Door is open when it should be closed.	1. Verify that the door is closed.
2. The Ultra Door is closed when it should be opened.	2. Verify that the door is opened.
	Call for Service if the alarm persists.

SENSOR BAR DOOR OPEN 424

Reason for Alarm	The sensor detected that the Sensor Bar Door is open.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Sensor Bar Door is open when it should be closed.	1. Verify that the door is closed.
	Call for Service if the alarm persists.

DIALYSIS FLUID FLOW TOO LOW 425

Reason for Alarm	The dialysis fluid flow is lower than the set value or than the minimum permitted flow.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. There are deposits or debris inside the flowmeters of the machine.	1. Perform a Chemical Disinfection.
	Call for Service if the alarm persists.

NOT PERFORMING UF 443

Reason for Alarm	The UF button has been deselected during treatment.
Machine Actions	• None.

Possible Cause	Suggested Action
1. During treatment the operator has deselected the UF button (the machine doesn't apply UF for six consecutive minutes, so an alarm message will be displayed).	1. Press the ***CONFIRM*** button to remove the alarm message (pay attention that UF doesn't restart automatically).
	Call for Service if the alarm persists.

T1 TEST TEMPERATURE FAILED 444

Reason for Alarm	The T1 test performed by the machine on the Temperature has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	Suggested Action
1. The T1 test Temperature failed.	1. Press the ***CONFIRM*** button and wait the machine to perform another Temperature test.
	Call for Service if the alarm persists.

T1 TEST CONDUCTIVITY CELL FAILED 445

Reason for Alarm	The T1 test performed by the machine on the Conductivity cells has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	**Suggested Action**
1. The T1 test Conductivity failed.	1. Press the ***CONFIRM*** button and wait the machine to perform another Conductivity test. If the alarm persists, call for service.
	Call for Service if the alarm persists.

T1 TEST VENOUS PRESSURE 446

Reason for Alarm	The T1 test performed by the machine on the Venous pressure has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	Suggested Action
1. The T1 test Venous pressure failed.	1. Press the ***CONFIRM*** button and perform unload/load cassette for a new Venous pressure test.
	Call for Service if the alarm persists.

T1 TEST ARTERIAL PRESSURE 447

Reason for Alarm	The T1 test performed by the machine on the Arterial pressure has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	**Suggested Action**
1. The T1 test Arterial pressure failed.	1. Press the ***CONFIRM*** button and perform unload/load cassette for a new Arterial pressure test.
	Call for Service if the alarm persists.

COMMUNICATION PROTECTIVE COND. CELL STOPPED 449

Reason for Alarm	The communication between the Protective System and the conductivity cell Γp has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the ***CONFIRM*** button to remove the alarm. If the problem persists, disconnect the patient.
	Call for Service if the alarm persists.

COMMUNICATION SELECT COND. CELL STOPPED 450

Reason for Alarm	The communication between the Protective System and the conductivity cell ΓcP has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the ***CONFIRM*** button to remove the alarm. If the problem persists, disconnect the patient.
	Call for Service if the alarm persists.

PDR PRESSURE HIGH 452

Reason for Alarm	The pressure of the dialysis fluid that is going to the drain, measured by the PD pressure sensor, is higher than the permitted value.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

PDR PRESSURE LOW 453

Reason for Alarm	The pressure of the dialysis fluid that is going to the drain, measured by the PD pressure sensor, is lower than the permitted value.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

INSERT THE HEMOSCAN CUVETTE 454

Reason for Alarm	The Hemoscan Cuvette is not inserted into the Sensor Bar door.
Machine Actions	• The appearance of the Auto-Prime Action button has been delayed. • None.

Possible Cause	Suggested Action
1. The cassette is loaded and the cover is open and/or the cuvette is not present.	1. Insert the Arterial Patient Line with the Hemoscan cuvette into the Sensor Bar. Firmly close the Sensor Bar door.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE HIGH 457

Reason for Alarm	The measured arterial pressure is above the maximum arterial treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The Arterial Patient Line may have become disconnected from the patient.	1. Carefully check the Cassette connections and the Patient's Vascular Access. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
2. The Arterial Pump speed is too low.	2. Consider increasing the blood flow if this operation is not in disagreement with the patient prescription. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

VENOUS PRESSURE BELOW TREATMENT MIN. LIMIT 459

Reason for Alarm	The measured venous pressure is below the minimum venous treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero (typical value 100 ml/h); • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. Restriction of blood flow to the Patient's Vascular Access or in the Venous Patient Line.	1. Carefully check the Blood Cassette connections and assess the Patient's Vascular Access. Check for restrictions, such as: • kinks in the Venous Patient Line; • closed clamps; • clotted venous needle. If necessary decrease the blood flow per clinical policy. When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
2. The venous pressure has decreased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a pressure decrease for a given needle at a fixed blood flow rate.	2. Attention should be given to the revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm Area and press the ***CONFIRM*** button to restart the blood pump.
	Call for Service if the alarm persists.

DIALYSIS FLUID TEMP TOO HIGH 460

Reason for Alarm	The temperature of the dialysis fluid measured by the ΓP conductivity cell is greater than 41°C.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. A temporary instability of dialysis fluid flow.	1. Wait for stability of the system.
2. The temperature of the dialysis fluid has exceeded the safe limits.	2. Check the incoming water temperature (Refer to the "Chapter 16: Specifications" in this Operator's Manual).
3. The machine has recently been turned on and has not yet reached the operating temperature.	3. If the machine temperature remains high or low for more than 10 minutes, discontinue the DIALYSIS.
4. The machine has an internal malfunction.	4. Discontinue the DIALYSIS.
	Call for Service if the alarm persists.

DIALYSIS FLUID TEMP TOO LOW 461

Reason for Alarm	The temperature of the dialysis fluid measured by the ΓP conductivity cell is lower than 32°C
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. There are deposits or debris inside the flowmeters of the machine.	1. Perform a Chemical Disinfection.
	Call for Service if the alarm persists.

CONDUCTIVITY TOO LOW 462

Reason for Alarm	The measured conductivity is below the desired set point.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. Inappropriate solution in the Acid Concentrate Canister.	1. Verify that concentrates are being used and are of the appropriate formulation for the selected treatment type.
2. Massive air leak from Concentrate Canisters/Connectors/Tubes or the Connectors are not securely connected to their Canisters/Ports or the Canisters/Connectors have accumulated debris or salt crystals.	2. If the alarm persists: • verify that Concentrate Canisters, Connectors and Tubes are free of leaks/holes and debris; • verify that the Connectors are securely connected to the appropriate Canisters/Ports; • If necessary, rinse the accumulated debris from the Canister(s)/ Connector(s); • massive air leaks affect the conductivity readings.
3. Inadequate Concentrates are being used.	3. If using dialysis fluid concentrate solutions, replace the concentrates as needed, then wait a few seconds for the machine to stabilize. If using solutions other than concentrates during the dialysis fluid preparation: • stop the dialysis fluid preparation; • replace the Blood Cassette and the dialyzer; • run a complete ADR: RINSE procedure; • replace the solutions; • re-start the dialysis fluid preparation.
4. The Acid or Bicarbonate pick-up tube connector is not properly positioned into the Central Concentrate port.	4. Verify that the Acid or Bicarbonate pick-up tube connector is properly positioned into the Central Concentrate port on the front panel.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

CONDUCTIVITY TOO HIGH 463

Reason for Alarm	The measured conductivity is above the desired set point.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Acid or Bicarbonate Concentrate canister is empty.	1. Supply appropriate concentrate to the relevant inlet connector. Wait for stability of the dialysis fluid flow.
2. The Acid or Bicarbonate pick-up tube connector(s) are not properly positioned to the concentrate Canister(s).	2. Verify the connector(s) are properly positioned to the proper Canister(s). Wait for stability of the dialysis fluid flow.
3. Massive air leak from the concentrate canister.	3. Replace the concentrate canister. Wait for stability of the dialysis fluid flow.
4. The Acid or Bicarbonate pick-up tube connector(s) has accumulated debris or salt crystals.	4. Rinse the accumulated debris from the connector(s).
5. Inappropriate solution in the Acid concentrate canister.	5. Verify that appropriate concentrate has been used.
6. When using central delivery acid, the Acid or Bicarbonate pick-up tube connector is not securely connected into its concentrate connector port.	6. Verify that the Acid or Bicarbonate pick-up tube connector is properly positioned in its concentrate connector port.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

INCORRECT BICARBONATE CONCENTRATION 464

Reason for Alarm	The conductivity of the solution after the mixing of the bicarbonate and the select bag is below the setpoint fixed by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Bicarbonate Concentrate Canister or BiCart are almost empty.	1. Verify adequate levels of concentrates. If BiCart, replace as described in the related section of the "Chapter 7: Special Procedures", in this Operator's Manual.
2. The Bicarbonate pick-up tube connector is not well fitted to the Concentrate Canister.	2. Verify the Bicarbonate pick-up tube connector is well fitted to the proper Canister.
3. Massive air leak from the Bicarbonate Concentrate Canister.	3. Replace the Bicarbonate Concentrate Canister.
4. The BiCart is not well positioned into its holder.	4. Ensure the BiCart is securely placed into its holder.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

INCORRECT BICARBONATE CONCENTRATION 465

Reason for Alarm	The conductivity of the solution after the mixing of bicarbonate and select bag is above the setpoint fixed by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Bicarbonate pick-up tube connector is not well fitted to the Concentrate Canister.	1. Verify the Bicarbonate pick-up tube connector is well fitted to the proper Canister.
2. Massive air leak from the Bicarbonate Concentrate Canister.	2. Replace the Bicarbonate Concentrate Canister.
3. The BiCart is not well positioned into its holder.	3. Ensure the BiCart is securely placed into its holder.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

LEAKAGES TEST (A) FAILURE 467

Reason for Alarm	Failure of the leakages test on the PO, PFS, PD pressure sensors: pressure sensor out of calibration.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
	Call for Service if the alarm persists.

LEAKAGES TEST (B) FAILURE 468

Reason for Alarm	Failure of the leakages test on the R1 pressure regulator: pressure regulator out of calibration.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
	Call for Service if the alarm persists.

LEAKAGES TEST (C) FAILURE 469

Reason for Alarm	Failure of the leakages test on the PDrain, PFS or PO pressure sensors: pressure failure.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
	Call for Service if the alarm persists.

LEAKAGES TEST (D) FAILURE 470

Reason for Alarm	Failure of the leakages test on the PO, PFS and PD pressure sensors: negative calibration of pressure sensor.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
2. The Venous and Arterial Patient Lines are not properly connected to the EvaClean port.	2. Verify that the Venous and Arterial Patient Lines are properly connected. Press the ***CONFIRM*** button to repeat the current leakage test.
	Call for Service if the alarm persists.

VENOUS PRESSURE NOT DECREASING 472

Reason for Alarm	In Single Needle Single Pump mode, during the venous phase the venous pressure is not decreasing as expected.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The venous pressure is not decreasing as expected.	1. Check if the Blood Cassette is properly loaded on the Cassette holder and if it is properly connected to the venous pressure pod. Press the ***CONFIRM*** button to remove the alarm.
2. The Venous/Arterial Patient Line could be kinked, clamped, restricted or have some leakages.	2. Check the Venous/Arterial Patient line and the Patient's Vascular Access for kinks, clamps or other restrictions. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

HEMOSCAN AUTOCALIBRATION FAILURE 473

Reason for Alarm	Failure of the Hemoscan Autocalibration.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. Problem in the calculated coefficients in the autocalibration process of the Hemoscan.	1. Deactivate the Hemoscan.
	Call for Service if the alarm persists.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON D1 FLOW RATE 474

Reason for Alarm	During preparation, the flow of the D1Control Flowmeter is not stable.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Massive air in the hydraulic circuit.	1. Check that all the connectors are inserted in the machine. Then press the ***CONFIRM*** button.
2. Probable tubing popping upstream the D1 Control Flowmeter.	2. Switch off the machine.
	Call for Service if the alarm persists.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON TCA 475

Reason for Alarm	During preparation, the flow of the TcA Control Sensor is not stable.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Probable drift of the Tp or TcA temperature sensor.	1. Press the ***CONFIRM*** button. If the problem persist, switch off the machine and call for service.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON ACETATE DISTRIBUTION 476

Reason for Alarm	The dialysis fluid cannot reach the condition required on the acetate conductivity.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Massive air leak from the Acid Pick-up Tube.	1. Check the Acid Pick-up Tube. Then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON BICARBONATE DISTRIBUTION 477

Reason for Alarm	The dialysis fluid cannot reach the condition required on the bicarbonate conductivity.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Massive air leak from the Bicarbonate Pick-up Tube.	1. Check the Bicarbonate Pick-up Tube. Then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

REMINDER - STILL IN ISOLATED UF 479

Reason for Alarm	The simplified “Isolated UF” action button has been activated.
Machine Actions	• None.

Possible Cause	Suggested Action
1. More than 2 minutes have elapsed since the "Isolated UF" action button has been selected.	1. If the Isolated UF functionality is still desired press the ***CONFIRM*** button. Otherwise deactivate the function by pressing the activated "Isolated UF" action button.
	Call for Service if the alarm persists.

INCORRECT FLUID CONDUCTIVITY DETECTED 496

Reason for Alarm	The measured conductivity is outside the safety range limits.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. Acid concentrate not correctly supplied.	1. Supply appropriate concentrate to the relevant inlet connector. Wait for stable condition.
2. Massive air leak from the Acid Concentrate Canister.	2. Check and if necessary replace the Acid Concentrate Canister.
3. Acid pick-up tube connector not connected to the Concentrate Canister.	3. Verify the Acid pick-up tube connector is well fitted into the proper Canister.
4. Bicarbonate not correctly supplied.	4. Replace the BiCart according to the BiCart Change procedure.
5. The Bicarbonate powder is not well distributed in the BiCart Cartridge.	5. Tap the bottom of the BiCart Cartridge to evenly distribute the powder. Wait for stable condition.
6. The BiCart Cartridge is in the wrong position.	6. Ensure the BiCart is securely placed into its holder. Repeat the BiCart Change procedure.
	Call for Service if the alarm persists.

LEAKAGES TEST (E) FAILURE 498

Reason for Alarm	Failure of the leakages test on delivery of dialysis fluid in the hydraulic circuit and control of the patient weight loss.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
2. The Venous and Arterial Patient Lines are not properly connected to the EvaClean port.	2. Verify that the Venous and Arterial Patient Lines are properly connected. Press the ***CONFIRM*** button to repeat the current leakage test.
	Call for Service if the alarm persists.

LEAKAGES TEST (F) FAILURE 499

Reason for Alarm	Failure of the leakages test on delivery of dialysis fluid in the hydraulic circuit and control of the patient weight loss.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
	Call for Service if the alarm persists.

LEAKAGES TEST (G) FAILURE 500

Reason for Alarm	Failure of the leakages test on the PDrain, PFS or PO pressure sensors: negative pressure failure.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
	Call for Service if the alarm persists.

REMINDER - WRONG DIP SWITCHES 502

Reason for Alarm	The Dip Switch configuration detected by the machine is incorrect.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The machine is not properly configured.	1. Press the ***CONFIRM*** button. If the alarm persists, switch off the machine and call for service.

WRONG ARTERIAL AND VENOUS TREATMENT LIMITS 503

Reason for Alarm	This alarm occurs after that the alarm #525 has been triggered and not resolved within the due time (after 30 seconds in HD; 60 seconds in HDF). The arterial and venous pressure treatment limits are open for a long time interval.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The “Close A/V Limits” button has not been pressed within the due time.	1. Press the ***CONFIRM*** button to remove the alarm message.
2. The A/V pressure limits have not been automatically closed within the due time.	2. Carefully check the Patient’s Vascular Access and inspect the Arterial and Venous Patient Lines; Press the ***CONFIRM*** button to remove the alarm message.
3. The A/V pressures have exceeded the upper/lower intervals.	3. Carefully check the Patient’s Vascular Access and inspect the Arterial and Venous Patient Lines; Press the ***CONFIRM*** button to remove the alarm message.
	Call for Service if the alarm persists.

LOW DISINFECTANT LEVEL IN LAST CLEAN CART PROCESS 504

Reason for Alarm	The Clean Cart C dilution is not properly performed.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Clean Cart Holder Arms are in the wrong position or not securely closed.	1. Verify the correct position of the CleanCart Holder Arms in relation to the machine phase. Press the ***CONFIRM*** button. Switch the machine OFF, wait at least five seconds, switch it ON again and repeat the procedure to perform.
	Call for Service if the alarm persists.

UF DEVIATION 505

Reason for Alarm	The machine has detected an incorrect weight loss management.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped; • Calibration request.

Possible Cause	**Suggested Action**
1. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect valves control.	1. Press “Stop Treatment”; Perform a rinseback; Disconnect the patient.
2. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect flowmeter reading.	2. Press “Stop Treatment”; Perform a rinseback; Disconnect the patient.
3. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect P2 pump flow or P2 reading.	3. Press “Stop Treatment”; Perform a rinseback; Disconnect the patient.
4. The machine could not perform an alignment of the D2 flowmeter during the treatment and the Ultrafiltration Mass Balance could be incorrect.	4. Press “Stop Treatment”; Perform a rinseback; Disconnect the patient.
	Call for Service if the alarm persists.

FLOWMETER ALIGNMENT FAILED 506

Reason for Alarm	Error in the Ultrafiltration Mass Balance in the Hydraulic Module.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped; • Calibration request.

Possible Cause	**Suggested Action**
1. Temporary problem.	1. Press the ***CONFIRM*** button. If the problem persists disconnect the patient.
	Call for Service if the alarm persists.

BLOOD CASSETTE PRESENCE REQUIRED 507

Reason for Alarm	The Blood Cassette is not detected by the presence switch.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Blood Cassette was not loaded properly by the operator.	1. Load the Blood Cassette. If after the loading of the Blood Cassette the error persists, call for Service.
2. The Blood Cassette does not fit the pressure transducer.	2. Repeat the loading procedure for the Blood cassette.
	Call for Service if the alarm persists.

WRONG DISPOSABLE CONFIGURATION ON ULTRA CASSETTE HOLDER 508

Reason for Alarm	The Ultra Cassette is not detected by the presence switch.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Ultra Cassette was not loaded properly by the operator.	1. Load the Ultra Cassette. If after the loading of the Ultra Cassette the error persists, call for Service.
2. The Ultra Cassette does not fit the pressure transducer.	2. Repeat the loading procedure for the Ultra cassette.
	Call for Service if the alarm persists.

NOTE

This alarm can be triggered also if the following sequence is performed:

1. "Switch to HD" special procedure;
2. "Change Circuit" special procedure;
3. Blood Cassette priming;
4. Reset Priming.

In this case, the machine gets stuck and to solve the problem it is necessary to switch the machine OFF and then ON again.

BLOOD LINES CLAMPED 509

Reason for Alarm	The Blood lines are clamped or kinked.
Machine Actions	• The Arterial Pump is stopped; • The UF Rate is automatically set to zero; • The dialysis fluid goes into bypass.

Possible Cause	**Suggested Action**
1. The Blood lines are clamped or kinked.	1. Verify that the blood lines are not clamped or kinked, then press the ***CONFIRM*** button to continue the process.
	Call for Service if the alarm persists.

SMART SCAN - LOW QB 512

Reason for Alarm	The average blood flow rate (QB) value, measured during the last 5 minutes, is lower than 50 ml/min.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The QB value, measured during the last 5 minutes, is lower then 50 ml/min.	1. Verify that the set QB value is the desired one; then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SMART SCAN - LOW QD 513

Reason for Alarm	The ratio Dialysis fluid flow rate/Blood flow rate (QD/QB) has been lower than 1.5 during the last 10 minutes.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The ratio Dialysis fluid flow rate/Blood flow rate (QD/QB) has been lower than 1.5 during the last 10 minutes.	1. Increase the QD value in order to keep the ratio QD/QB between 1.5 and 3. Then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SMART SCAN - HIGH QD 514

Reason for Alarm	The ratio Dialysis fluid flow rate/Blood flow rate (QD/QB) has been higher than 3 during the last 10 minutes.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The ratio Dialysis fluid flow rate/Blood flow rate (QD/QB) has been higher than 3 during the last 10 minutes.	1. Decrease the QD value in order to keep the ratio QD/QB between 1.5 and 3. Then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SALINE BAG NOT CONNECTED 515

Reason for Alarm	The machine does not detect saline solution inside the Venous Patient Line during priming phase.
Machine Actions	• The phase currently running stops.

Possible Cause	Suggested Action
1. The machine does not detect saline inside the Venous Patient Line.	1. Check the Saline Bag clamp is open, then press the ***CONFIRM*** button.
2. The machine does not detect saline inside the Venous Patient Line.	2. Check that the Venous Line Clamp is open, then press the ***CONFIRM*** button.
3. The machine does not detect saline inside the Venous Patient Line.	3. Check that the pin of the Saline Bag is correctly broken.
	Call for Service if the alarm persists.

VENOUS LINE CLAMPED 516

Reason for Alarm	The Venous Patient Line is clamped or kinked.
Machine Actions	• The phase currently running stops.

Possible Cause	Suggested Action
1. The Venous Patient Line is clamped or kinked.	1. Check that the Venous Patient Line is not clamped or kinked, then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

ARTERIAL LINE CLAMPED 517

Reason for Alarm	The Arterial Patient Line is clamped or kinked.
Machine Actions	• The phase currently running stops.

Possible Cause	Suggested Action
1. The Arterial Patient Line is clamped or kinked.	1. Check that the Arterial Patient Line is not clamped or kinked, then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

LINE NOT CONNECTED IN EVACLEAN PORT OR ACCESS LINE OPEN 518

Reason for Alarm	Line not connected or not correctly connected to the EvaClean Ports.
Machine Actions	• The phase currently running stops.

Possible Cause	Suggested Action
1. Line Not Connected to the EvaClean Ports.	1. Check that the arterial and Venous Patient Lines are correctly connected to the EvaClean port, then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

ARTERIAL INFUSION LINE OPEN 519

Reason for Alarm	The clamp on the Arterial Infusion Line is open.
Machine Actions	• The phase currently running stops.

Possible Cause	Suggested Action
1. One of the clamps on the Arterial Infusion Lines is open.	1. Check that the clamps on the Arterial Infusion Lines are securely closed, then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

VENOUS PUMP ROTOR ERROR 521

Reason for Alarm	The Venous Pump is in failure.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Venous Pump is stopped.	1. Press the ***CONFIRM*** button to remove the alarm. .
	Call for Service if the alarm persists.

SYSTEM PRESSURE OUT OF RANGE 522

Reason for Alarm	The system pressure is beyond the upper or lower limit of the sensor.
Machine Actions	• None.

Possible Cause	Suggested Action
1. A safety condition has not been satisfied when an alarm occurred.	1. Perform a Fast Recovery procedure during dialysis treatment (Refer to the “7.4 Fast Recovery” section of this Operator’s Manual).
	Call for Service if the alarm persists.

HEMOCONCENTRATION RISK 524

Reason for Alarm	The filtration ratio exceeds the allowed range.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. Filtration Ratio Out of Range.	1. Increase the Arterial pump speed.
2. Filtration Ratio Out of Range.	2. Decrease the Venous pump speed.
	Call for Service if the alarm persists.

PRESSURE ALARM LIMITS STILL EXPANDED 525

Reason for Alarm	• The operator has not pressed the “Close A/V Limits” button to close the pressure alarm limits within the due time (30 seconds in HD; 120 second in HDF). • After a change of the blood flow rate, the machine was not able to automatically close the A/V pressure limits within the due time (30s in HD; 120s in HDF) because the new A/V pressure values set are not consistent with the change of the blood flow rate, compared to the previous A/V pressure values set.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The “Close A/V Limits” button has not been pressed within the due time.	1. Press the “Close A/V Limits” button: the machine automatically centralizes the alarm window values around the current patient’s arterial/venous pressures.
2. The A/V pressure limits have not been automatically closed within the due time.	2. Carefully check the Patient’s Vascular Access and inspect the Arterial and Venous Patient Lines; Press the “Close A/V Limits” button: the machine automatically centralizes the alarm window values around the current patient’s arterial/venous pressures.
3. The arterial or venous pump has been stopped by the operator or due to an alarm condition and restarted again. The A/V pressures have therefore exceeded the upper/lower intervals.	3. Carefully check the Patient’s Vascular Access and inspect the Arterial and Venous Patient Lines; Press the “Close A/V Limits” button: the machine automatically centralizes the alarm window values around the current patient’s arterial/venous pressures.
	Call for Service if the alarm persists.

REMINDER - HDF SUBSTITUTION STILL DISABLED 526

Reason for Alarm	During On Line treatment phases, the HDF Substitution button remains Off for more than 5 min.
Machine Actions	• None.

NOTE

This alarm is triggered in the following cases:
- At the beginning of the HDF Treatment, if the HDF Substitution button is not pressed within five minutes. When the alarm is confirmed the alarm disappears even if the HDF Substitution button is not activated.
- Each time the HDF Substitution button is activated and then deactivated if it remains deactivated for 5 minutes. The alarm disappears when the ***CONFIRM*** button is pressed to confirm the alarm.

Possible Cause	**Suggested Action**
1. HDF Substitution still disabled.	1. Press the ***CONFIRM*** button to confirm the alarm; Press the HDF Substitution button to restart the infusion of substitution fluid.
	Call for Service if the alarm persists.

TMP MAXIMUM LIMIT 527

Reason for Alarm	During On Line treatment phases, the TMP value exceeds the permitted max value.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The TMP value is beyond the permitted max value.	1. Stop the UF and wait the TMP to drop. Check the pre dialyzer pressure.
	Call for Service if the alarm persists.

DIASCAN: AUTOCALIBRATION FAILURE 528

Reason for Alarm	The DIASCAN autocalibration has failed: the autocalibration coefficient is out of the allowed range or the autocalibration has been interrupted because of prime start.
Machine Actions	• None.

Possible Cause	Suggested Action
1. There is a flowmeter instability.	1. Disable the Diascan deselecting the Diascan button.
	Call for Service if the alarm persists.

DIASCAN: MEASUREMENT FAILURE 529

Reason for Alarm	The DIASCAN has not been able to complete a measurement.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Diascan has not been able to complete a measurement.	1. To proceed with the Diascan measurement, press the ***CONFIRM*** button.
2. The Diascan has not been able to complete a measurement.	2. To stop the Diascan measurement, disable the Diascan deselecting the Diascan button.
	Call for Service if the alarm persists.

NOTE

The “Diascan: Measurement Failure (#529)“ alarm will be automatically reset if a Special Procedure is selected and confirmed.

DIASCAN: LOW CLEARANCE 530

Reason for Alarm	This alarm wil be triggered in the following conditions: • If the Clearance Low Limit alarm threshold is active, the alarm wil be triggered whenever the Clearance value is below its threshold value; • If the Clearance Low Limit alarm threshold is not active, the alarm wil be triggered whenever the Clearance value is lower than 55% of Blood Flow.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The clearance measured by the DIASCAN is below the threshold value set by the operator or the Clearance value is lower than 55% of Actual Blood Flow.	1. To proceed with the Diascan measurement, press the ***CONFIRM*** button.
2. The clearance measured by the DIASCAN is below the threshold value set by the operator or the Clearance value is lower than 55% of Actual Blood Flow.	2. To stop the Diascan measurement, disable the Diascan deselecting the Diascan button.
	Call for Service if the alarm persists.

NOTE

The "Diascan: Low Clearance (#530)" alarm will be automatically reset if a Special Procedure is selected and confirmed.

DIASCAN: LOW KT/V 531

Reason for Alarm	The Forecast KT/V value is below the “Target Kt/V” value set by the operator (This alarm can be activated only when the distribution volume has been set).
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Forecast KT/V value is below the “Target Kt/V” value set by the operator.	1. Check that: • The “Distribution Volume” value is properly set for the patient; • The current “Clearance” value is adequate to the treatment, according to the dialyzer used and to the patient’s vascular access; 2. Increase the “Treatment Time” in order to achieve the set “Target Kt/V” value or set a new value for “Target Kt/V” parameter. Then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

NOTE

The “Diascan: Low Kt/V (#531)“ alarm will be automatically reset if a Special Procedure is selected and confirmed.

TIMEOUT ON DATA RECEPTION 532

Reason for Alarm	Temporary problem with the network.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. Temporary problem with the network.	1. Reload the prescription, then press the ***CONFIRM*** button. If the alarm persists, switch off the machine.
	Call for Service if the alarm persists.

CHEMICAL PROCESS NOT PROPERLY PERFORMED: DISINFECTANT TANK EMPTY 533

Reason for Alarm	Chemical Disinfection process not correctly performed because the disinfectant tank is empty. Repeat the Chemical Disinfection process.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The disinfectant tank is empty.	1. Check the level of the disinfectant tank: • I*f the disinfectant tank is empty*, press the ***CONFIRM*** button and, at the and of the chemical disinfection procedure, replace the disinfectant tank with a new one. Repeat the disinfection procedure. • *If the disinfectant tank is full,* press the ***CONFIRM*** button and call for service.
	Call for Service if the alarm persists.

WARNING

When this alarm is triggered, the Chemical Disinfection process has not been correctly performed because the disinfectant tank is empty.
Repeat the Chemical Disinfection process using a tank containing enough disinfectant solution.

DISINFECTION NOT PROPERLY PERFORMED 534

Reason for Alarm	The programmed chemical process set by the operator has been interrupted before the process completion.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The disinfection process needs to be completed.	1. Press the ***CONFIRM*** button and start the process. If the alarm persists, call for service.
	Call for Service if the alarm persists.

DIASCAN MEASUREMENT ERROR 536

Reason for Alarm	The DIASCAN has not been able to complete a measurement.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The DIASCAN has not been able to complete a measurement.	1. Press the ***CONFIRM*** button and wait for the next Diascan measurement.
	Call for Service if the alarm persists.

WATER LEAKAGE 539

Reason for Alarm	A leakage was detected by the Water Leakage sensor in the hydraulic circuit.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. A water leakage was detected in the hydraulic circuit.	1. If possible, start with the Rinseback procedure, otherwise switch off the machine.
	Call for Service if the alarm persists.

DIALYSATE PRESSURE LOW 540

Reason for Alarm	The pressure in the Ultrafilter is lower than the permitted limit.
Machine Actions	• All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Ultrafilter is clogged.	1. If in treatment, the dialysis process in progress can be continued by decreasing the dialysis fluid flow rate and pressing the ***CONFIRM*** button to restart the current operation of the machine. When the treatment is complete, replace the Ultrafilter according to the procedure.
2. The Dialysis fluid connectors are not properly positioned.	2. Verify that the Dialysis fluid connectors are properly positioned to the dialyzer or to the machine, depending upon the phase of the machine at that time. Press the ***CONFIRM*** button to restart the current operation of the machine.
	Call for Service if the alarm persists.

PRE FILTER PRESSURE HIGH 541

Reason for Alarm	The Pre Filter Pressure is higher than the allowed limit.
Machine Actions	• The UF Rate is automatically set to zero; • The Arterial Pump is stopped; • The Venous Line Clamp is closed.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is clamped or kinked.	1. Check that the Venous Patient Line is not clamped or kinked. Carefully check the Venous Patient Line connections.
	Call for Service if the alarm persists.

INCORRECT CASSETTE LINE CONNECTIONS OR CLAMPS STATUS 542

Reason for Alarm	The Ultra/Blood Cassette Line connections or the Ultra/Blood Cassette Line Clamps status is incorrect.
Machine Actions	• All the pumps are stopped.

Possible Cause	Suggested Action
1. The Venous/Arterial Patient Lines have not been inserted in the EvaClean Ports.	1. Check that the Venous/Arterial Patient Lines are inserted in the EvaClean Ports. Then press the ***CONFIRM*** button to remove the alarm.
2. The Venous/Arterial Dialyzer Line is not securely connected to the dialyzer.	2. Check that the Venous/Arterial Dialyzer Lines are firmly connected to the dialyzer. Then press the ***CONFIRM*** button to remove the alarm.
3. The Ultra Inlet Line is not securely connected to the Ultra Port.	3. Check that the Ultra Inlet Line is firmly connected to the Ultra Port. Then press the ***CONFIRM*** button to remove the alarm.
4. A line on the Ultra/Blood Cassette (Ultra Service Line, Rinseback Service Line or Venous/Arterial Infusion Lines) may be unclamped.	4. Check that the clamps on the Ultra Service Line, Rinseback Service Line and Venous/Arterial Infusion Lines are securely closed. Then press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

ULTRA SCAN ABORTED: TMP SET AND UPPER LIMIT UPDATED 543

Reason for Alarm	The Ultra Scan has been aborted: the TMP Set and the Upper Limit have been consequently updated.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Ultra Scan has been aborted: the TMP set and the Upper Limit have been consequently up-dated.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

ULTRA SCAN COMPLETED: TMP SET AND UPPER LIMIT UPDATED 544

Reason for Alarm	The Ultra Scan has been completed: the TMP Set and the Upper Limit have been consequently updated.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Ultra Scan has been completed: the TMP set and the Upper Limit have been consequently up-dated.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

NEW ULTRA SCAN IS SUGGESTED 545

Reason for Alarm	Notification: the Ultra Scan has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Ultra Scan has been completed.	1. Perform a new scan and press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

MAXIMUM SUBSTITUTION VOLUME REACHED 546

Reason for Alarm	The Maximum Substitution Volume has been reached: one liter has been saved for performing on-line restitution.
Machine Actions	• The HDF button is locked.

Possible Cause	Suggested Action
1. The Maximum Substitution Volume has been reached: one liter has been saved for performing on-line restitution.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

PATIENT VENOUS LINE INCORRECT POSITION 547

Reason for Alarm	The position of the Venous Patient Line is incorrect. Probably during priming the Venous Patient Line has not been inserted under the Venous Line Clamp.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Venous Patient Line has not been inserted under the Venous Line Clamp.	1. Carefully check that the Venous Patient Line is under the Venous Line Clamp. Then press the ***CONFIRM*** button and continue the process.
	Call for Service if the alarm persists.

LEAKAGES H 548

Reason for Alarm	Failure of the leakages test on the PDrain, PFS or PO: negative pressure failure on the internal bypass circuit.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the CONFIRM button to repeat the current leakages test.
2. The Venous and Arterial Patient Lines are not properly connected to the EvaClean port.	2. Verify that the Venous and Arterial Patient Lines are properly connected. Press the ***CONFIRM*** button to repeat the current leakage test.
	Call for Service if the alarm persists.

LEAKAGES I 549

Reason for Alarm	Failure of the leakages test on delivery of dialysis fluid in the hydraulic circuit and control of the patient weight loss.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the ***CONFIRM*** button to repeat the current leakages test.
2. The Venous and Arterial Patient Lines are not properly connected to the EvaClean port.	2. Verify that the Venous and Arterial Patient Lines are properly connected. Press the ***CONFIRM*** button to repeat the current leakage test.
	Call for Service if the alarm persists.

POWER FAILURE: CHECK POWER SUPPLY 550

Reason for Alarm	A Power Failure occurred during on-line treatment.
Machine Actions	• None.

Possible Cause	Suggested Action
1. A Power Failure occurred during on-line treatment.	1. Check the power supply, in case no recovery is possible: • Press the ***CONFIRM*** button to remove the alarm. • Switch to HD treatment; • Perform a rinseback procedure; • Switch off the machine.
	Call for Service if the alarm persists.

80% MAXIMUM SUBSTITUTION VOLUME REACHED 551

Reason for Alarm	The maximum substitution volume has been reached (allowed by the U2000 ultrafilter): the actual value reaches 80% of the maximum limit (150L).
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The maximum substitution volume has been reached: the actual value reaches 80% of the maximum limit (150L).	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

90% MAXIMUM SUBSTITUTION VOLUME REACHED 552

Reason for Alarm	The maximum substitution volume has been reached (allowed by the U2000 ultrafilter): the actual value reaches 90% of the maximum limit (150L).
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The maximum substitution volume has been reached: the actual value reaches 90% of the maximum limit (150L).	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

MAXIMUM SUBSTITUTION VOLUME REACHED 553

Reason for Alarm	Notification: the machine has stopped the substitution process in order to save the remaining one liter for performing on-line restitution.
Machine Actions	• The HDF button is locked.

Possible Cause	Suggested Action
1. The machine has stopped the substitution process in order to save the remaining one liter for performing on-line restitution.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

HEMOCONTROL ERROR 554

Reason for Alarm	A failure on the Hemocontrol has been verified.
Machine Actions	The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. A failure on the Hemocontrol has been verified.	1. Deactivate the Hemocontrol, then press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

ULTRA INLET TUBE CLAMPED 556

Reason for Alarm	The Ultra Inlet Line is clamped when it should not be.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Ultra Inlet Line is clamped.	1. Check the Ultra Inlet Line and remove any clamps.
	Call for Service if the alarm persists.

CASSETTE REPOSITIONING FAILED 557

Reason for Alarm	In HDF mode, the Ultra Cassette Repositioning Procedure has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. In HDF mode, the Ultra Cassette Repositioning Procedure has failed.	1. Press the ***CONFIRM*** button to remove the alarm and to restart the Arterial Pump.
	Call for Service if the alarm persists.

REMINDER: 558

Reason for Alarm	Notification: the set time has elapsed for the note entered on the keyboard window.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The set time has elapsed for the note entered on the keyboard window.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

PREPARATION COMPLETED 559

Reason for Alarm	Notification: the preparation process has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The preparation process has been completed.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

PRIMING COMPLETED 560

Reason for Alarm	Notification: the Priming sub-process has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Priming sub-process has been completed.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

AUTOSCHEDULED DISINFECTION/RINSE PROGRAM NOT PERFORMED 562

Reason for Alarm	The autoscheduled disinfection/rinse program has not been performed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The autoscheduled disinfection/rinse program has not been performed.	1. Press the ***CONFIRM*** button to remove the alarm message. Make sure that a Disinfection/Rinse program has been performed before starting a new treatment.
2. Following a Bacteriostatic Chemical disinfection, the scheduled Disinfection/ Rinse program has not been performed because the machine has automatically performed a Rinse process instead of the program scheduled.	2. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

This alarm will be triggered each time the machine is switched on during the day in which the scheduled process has not been performed (although the alarm message has been confirmed). The alarm will be definitely removed the day after the one the process has been scheduled, only if the alarm message has been confirmed, otherwise it will continue to be triggered also in the subsequent days.

CDF2 ULTRAFILTER LOWER SWITCH ERROR 563

Reason for Alarm	The CDF2 second ultrafilter lower connector microswitch (SWLOWUF2) is indicating an error condition.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	**Suggested Action**
1. The CDF2 ultrafilter lower connector microswitch is indicating an error condition.	1. Check the correct position of the ultrafilter.
	Call for Service if the alarm persists.

ULTRAFILTER COVER ERROR 564

Reason for Alarm	The ultrafilter cover is not placed correctly.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
1. The ultrafilter cover is not placed correctly.	1. Check the correct position of the ultrafilter cover.
	Call for Service if the alarm persists.

HYDRAULIC CENTRALISE ACETATE CONNECTOR TYPE ONE 565

Reason for Alarm	The Hydraulic Centralise Acetate Connector Type One is not placed correctly.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
The Hydraulic Centralise Acetate Connector Type One is not placed correctly.	1. Check the correct position of the Hydraulic Centralise Acetate Connector Type One.
	Call for Service if the alarm persists.

HYDRAULIC CENTRALISE ACETATE CONNECTOR TYPE TWO 566

Reason for Alarm	The Hydraulic Centralise Acetate Connector Type Two is not placed correctly.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
1. The Hydraulic Centralise Acetate Connector Type Two is not placed correctly.	1. Check the correct position of the Hydraulic Centralise Acetate Connector Type Two.
	Call for Service if the alarm persists.

TMP SET TOO LOW 567

Reason for Alarm	During dialysis, the TMP set is lower than the actual TMP measured.
Machine Actions	• The Venous Pump is stopped. • If the machine is performing UC scan, the procedure fails.

Possible Cause	Suggested Action
1. The TMP set is lower than the actual TMP measured.	1. Increase the TMP set value.
	Call for Service if the alarm persists.

WRONG ACID/ACETATE CONNECTOR 568

Reason for Alarm	The position of the Acid Pick-up Tube Connector detected by the Protective Subsystem is wrong (probably there is a misalignment with the Hydraulic Subsystem).
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
1. The Acid Pick-up Tube Connector is not placed correctly.	1. Check the correct position of the Acid Pick-up Tube Connector.
	Call for Service if the alarm persists.

WRONG BICARBONATE CONNECTOR 569

Reason for Alarm	The position of the Bicarbonate Pick-up Tube Connector is wrong.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
1. The Bicarbonate Pick-up Tube Connector is not placed correctly.	1. Check the correct position of the Bicarbonate Pick-up Tube Connector.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

ISOLATED UF COMPLETED 570

Reason for Alarm	The machine notifies that the Isolated UF process has been completed.
Machine Actions	• The machine remains in Isolated UF with deactivated “UF” button.

Possible Cause	Suggested Action
1. The Isolated UF process has been completed.	1. Press the ***CONFIRM*** button to proceed with the next phase.
	Call for Service if the alarm persists.

TREATMENT CAN NOT BEGIN UNTIL THE ULTRAFILTERS HAVE BEEN REPLACED 571

Reason for Alarm	The machine notifies that the ultrafilters have to be replaced, otherwise the treatment cannot be performed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The ultrafilters have to be replaced.	1. Replace the ultrafilters with new ones (Refer to the "7.18 Ultrafilter Change Procedure" section of this Operator's Manual).
	Call for Service if the alarm persists.

LOW HEPARINIZATION 573

Reason for Alarm	The volume of the Heparin infused is lower than the expected value.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The volume of the Heparin infused is lower than the expected value.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

WRONG SINGLE NEEDLE CLAMPS POSITION 574

Reason for Alarm	The Protective Subsystem has detected the Arterial and Venous line clamps open at the same time.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Protective Subsystem has detected the Arterial and Venous line clamps open at the same time.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

PREPARATION CAN NOT PROCEED UNTIL DRESSING IS COMPLETE 576

Reason for Alarm	The preparation can not proceed until the machine dressing procedure has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The machine dressing procedure is not been completed.	1. Complete the machine dressing procedure, then press the ***CONFIRM*** button on the *Confirm* window.
	Call for Service if the alarm persists.

SMART SCAN – LOW REAL QB 577

Reason for Alarm	The actual Blood Flow rate value is less than 90% of the Pump speed set value for more than three minutes.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The actual Blood Flow rate value is less than 90% of the Pump speed set value for more than three minutes.	1. Verify the set Arterial Pump speed and the arterial pressure. Decrease the arterial pressure or decrease the Arterial Pump speed. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

WRONG DISINFECTANT USED IN CHEMICAL DISINF. 578

Reason for Alarm	A wrong conductivity has been detected during a Chemical disinfection process with peracetic/low peracetic. The machine assumes that a disinfection with hypochlorite has been performed and the “Next Installation of Rear Ultrafilter”, “Date of Installation” and “Remaining Hypchlrt Disinfs” parameter values are reset.
Machine Actions	• When the machine is switched ON again, an “Ultrafilter Change” procedure will be forced.

Possible Cause	**Suggested Action**
1. A wrong conductivity has been detected during a Chemical disinfection program with peracetic/low peracetic.	1. Press the ***CONFIRM*** button to remove the alarm. and let the disinfection program end. When the machine is switched ON again, the “Treatment can not begin until the ultrafilters have been replaced (#571)” alarm will be displayed. Solve the alarm as described in the related troubleshooting of this chapter.
	Call for Service if the alarm persists.

ON LINE BLOOD RESTITUTION: WRONG ULTRA CASSETTE CONFIGURATION 579

Reason for Alarm	During the On Line Rinseback the Ultra or Blood cassette is not properly configured (Incorrect Ultra or Blood Cassette line connections or clamps status).
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. Incorrect Ultra or Blood Cassette line connections.	1. The Arterial patient line shall be connected to the Rinseback Service Line and the Clamp on the Rinseback Service Line shall be opened. Press the ***CONFIRM*** button.
2. Incorrect clamps status.	2. The clamps of the Arterial infusion lines shall be closed. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

ON LINE PRIME - INCORRECT ULTRA OR BLOOD CASSETTE CONFIGURATION 580

Reason for Alarm	During the On Line Priming the Ultra or Blood cassette is not properly configured (Incorrect Ultra or Blood Cassette line connections or clamps status).
Machine Actions	• The phase currently running stops.

Possible Cause	**Suggested Action**
1. During the On Line Priming the Ultra or Blood cassette is not properly configured.	1. Check that: • the Ultra Service Line clamp is closed and the cap is totally screwed; • the Rinseback Service Line clamp is closed and the cap is totally screwed; • the Venous and Arterial Infusion Line clamps are closed and the caps are totally screwed; • the Arterial and Venous Dialyzer Lines are properly connected to the dialyzer; • the Arterial and Venous Patient Lines are unclamped and properly connected to the EvaClean ports with the connector totally screwed; • the dialyzer, Ultra and Blood cassette are not re-used. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

ISOLATED UF TARGET LOSS WILL NOT BE ACHIEVED 581

Reason for Alarm	The remaining Isolated UF time is not sufficient in order to be reached the programmed Isolated UF target loss.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Isolated UF target loss will not be achieved.	1. Press the "Isolated UF" action button. 2. Reduce the Isolated UF parameter values: "Time" and/or "Volume".
	Call for Service if the alarm persists.

RESIDUAL CHECK REMINDER 582

Reason for Alarm	Notification: A test for residues of disinfectant has to be performed while setting up the machine for the next treatment.
Machine Actions	• None.

Possible Cause	Suggested Action
1. After chemical disinfection and before attaching the concentrates to the machine, a test for residues of disinfectant on the dialysis fluid has to be performed.	1. Perform a test for residues of disinfectant on the dialysis fluid (Refer to the “7.17 Residual Test after Chemical Disinfection” section of this Operator’s Manual).
	Call for Service if the alarm persists.

AIR DETECTOR CLEANING REQUIRED 583

Reason for Alarm	The Air Detector does not work with the maximum sensitivity because the Venous Patient line or the Air Detector is dirty.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is dirty or the Air Detector is defective.	1. Open the Sensor Bar door; 2. Remove the Venous Patient line from the air detector/patient sensor: an "Air in venous line (#4)" alarm will be triggered; 3. Carefully check that there is not air in the Venous Patient line; 4. Clean the Venous Patient line and the air detector/patient sensor; 5. Route again the Venous Patient line through the air detector/patient sensor; 6. Close the Sensor Bar door; 7. Press the ***CONFIRM*** button to clear the "Air Detector Cleaning Required (#583)" alarm; 8. Solve the "Air in Venous Line (#4)" alarm as described in the related troubleshooting of this chapter; 9. If the "Air Detector Cleaning Required (#583)" alarm persists, stop the treatment and perform a Manual Rinseback procedure.
	Call for Service if the alarm persists.

AIR DETECTOR INSPECTION REQUIRED 584

Reason for Alarm	The Air Detector does not work with the maximum sensitivity because the Venous Patient line or the Air Detector is dirty.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is dirty or the Air Detector is defective.	1. Open the Sensor Bar door; 2. Remove the Venous Patient line from the air detector/patient sensor: an “Air in venous line (#4)” alarm will be triggered; 3. Carefully check that there is not air in the Venous Patient line; 4. Clean the Venous Patient line and the air detector/patient sensor; 5. Route again the Venous Patient line through the air detector/patient sensor; 6. Close the Sensor Bar door; 7. Press the ***CONFIRM*** button to clear the “Air Detector Inspection Required (#584)” alarm; 8. Solve the “Air in Venous Line (#4)” alarm as described in the related troubleshooting of this chapter; 9. If the “Air Detector Inspection Required (#584)” alarm persists, stop the treatment and perform a Manual Rinseback procedure.
	Call for Service if the alarm persists.

SALINE BAG EMPTY 585

Reason for Alarm	The Saline Bag is empty or the Venous Infusion Line is clamped or the Prime Line is closed or obstructed.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Saline Bag is empty.	1. Change the Saline Bag; 2. Press the ***CONFIRM*** button to clear the alarm.
2. The Venous Infusion line is clamped or the clamp on the Prime Line is closed.	1. Open the clamp on the Venous Infusion line or on the Prime line; 2. Press the ***CONFIRM*** button to clear the alarm.
3. The Prime Line is obstructed.	1. Adjust the Prime Line position to avoid obstructions; 2. Press the ***CONFIRM*** button to clear the alarm.
	Call for Service if the alarm persists.

ARTERIAL PUMP SEGMENT NOT CORRECTLY LOADED 586

Reason for Alarm	The Arterial Pump Segment has not been properly loaded in the pump rotor or the clamp on the Arterial Infusion line is open.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Arterial Pump Segment has not been properly loaded in the pump rotor.	1. Press the ***CONFIRM*** button to clear the alarm; 2. Press the “Unload Cassette” button; 3. Press the ***CONFIRM*** button to start the unloading procedure; 4. Unload the cassette; 5. Perform again the loading cassette procedure.
2. The clamp on the Arterial Infusion line is open.	1. Close the clamp on the Arterial Infusion line; 2. Press the ***CONFIRM*** button to clear the alarm.
	Call for Service if the alarm persists.

VENOUS INFUSION LINE OPEN 587

Reason for Alarm	The clamp on the Venous Infusion line is open.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The clamp on the Venous Infusion line is open.	1. Close the clamp on the Venous Infusion line; 2. Press the ***CONFIRM*** button to clear the alarm.
	Call for Service if the alarm persists.

<< GENERAL SYSTEM FAILURE >>
System Blocking XXX

Reason for Alarm	This is a special alarm. The Main Board is blocked
Machine Actions	• GENERAL SAFE STATE • The Touch Screen is blocked

NOTE

In the alarm name, "xxx" means the internal code related to the alarm condition.

Possible Cause	Suggested Action
1. Main Board internal error.	1. If the alarm occurs during a disinfection/ rinse program, during the set-up or during the priming procedure, switch the machine OFF and after few seconds turn it ON again.
2. Main Board internal error.	2. If the alarm occurs during a tretament, perform a Fast Recovery procedure as described in the “7.4 Fast Recovery” section of this Operator’s Manual.
	Call for Service if the alarm persists.

15.7 Machine Malfunction Alarms

When a malfunction alarm occurs the following message is displayed in the Alarm Area

MALFUNCTION

together with the Numerical Code of the alarm.

If one of the malfunction alarm listed in the table below occurs:

- during a treatment: perform a Fast Recovery procedure as described in the "7.4 Fast Recovery" section of this Operator's Manual. If the alarm persists, take note of the alarm code, switch the machine OFF and call for Service.
- during a disinfection/rinse program: take note of the alarm code, switch the machine OFF and call for Service.

Below is a list of all the machine malfunction alarms in alphabetic order, indicating:

- The name of the alarm;
- The Numerical Code.

MALFUNCTION	CODE
ADR PROCESS NOT INITIATED	63
ADR Process Timed Out	190
Air compressor failure	466
ARTERIAL PRESSURE DATA ERROR	307
Arterial Pressure Negative Offset Data Error	430
Arterial Pressure Offset Data Error	431
ARTERIAL SENSOR ERROR	6
BIC CONC DATA ERROR	398
Bicarbonate pump failure	110
!BIO FLOW data error	25
Blood flow data error	27
BLOOD LEAK DETECTOR CALIBRATION ERROR	167
Blood leak detector data error	26
BLOOD SLAVE COMMUNICATION ERROR	295
BLOOD SLAVE ERROR	130
Bubble Trap T1 Test	493

MALFUNCTION	CODE
Concentrate pump failure	108
CONCENTRATION UM DATA ERROR	399
CONTROL DATA ERROR	327
Control Flowmeters Test Failed	497
CRC MESSAGE CHECK	471
D1 FLOWMETER FAILURE	300
D2 FLOWMETER FAILURE	301
DATA ERROR	43
Dialysate flow data error	45
Disinfection timeout error	67
EEPROM BLOOD ERROR	48
EEPROM CRC ERROR	173
EEPROM HYDRAULIC ERROR	49
Flow Meters Alignment Failure	535
Flowmeters alignment timeout	484
> GENERAL SAFE STATE <	64
HEATER PROTECTION ERROR *(See the **NOTE** below)*	59
Hydraulic slave error	131
Incorrect Arterial Clamp Position	7
Incorrect disinfectant	112
Incorrect disinfectant	113
Incorrect Rinsing or Disinfection	510
Incorrect Venous Clamp Position	148
Invalid Rinsing or Disinfection	511
Low Flow In Degasser	84
Maximum Arterial Pressure Data Error	432
MAXIMUM BLOOD FLOW DATA ERROR	312
Maximum Blood Volume Reached	481
Maximum Venous Pressure Data Error	458
Min UF rate data error	164

MALFUNCTION	CODE
Minimum Arterial Pressure Data Error	393
Minimum Venous Pressure Data Error	429
P1 Pump failure	104
P2 Pump failure	106
PAUSE THERAPY DATA ERROR	313
PC Pump failure	111
Pinch Calibration Edge Error	491
Pinch Calibration Out of Range	490
Pinch Calibration Time Out	492
Pinch Position Error	488
Pinch Position Out of Range	487
Pinch Position Time Out	489
Pinch valve wrong position optical sensor 1	494
Pinch valve wrong position optical sensor 2	495
PROTECTION MODULE DATA ERROR	185
PROTECTION MODULE SOFTWARE ERROR	182
PROTECTION SYSTEM FAILURE	120
PRSS Start Up Message Missing	480
Ps Out of Order	410
PWHO Out of Order	426
Select pump failure	486
Set value out of range	395
!S/N MAX PRESSURE Data Error	209
!S/N MIN PRESSURE Data Error	208
SODIUM CONC DATA ERROR	397
System Pressure Sensor Error	523
T1 Test BLD	434
T1 Test Cut 24 Volts Failed	440
T1 Test FPGA failed	485
T1 Test Pinch Valve	572
T1 Test Valves Command Failed	442

MALFUNCTION	CODE
T1 Test Venous Clamp	441
T1 Test Water Presence Sensor Failure	537
Temperature data error	135
Temperature mismatch between Tp and Tca	538
Timeout on messages acknowledge	396
Treatment time data error	239
UF data error	143
UF data error	240
ULTRAFILTER PRESSURE SENSOR ERROR	147
Venous pressure data error	150
Venous Pressure Negative Offset Data Error	427
Venous Pressure Positive Offset Data Error	428
VENOUS SENSOR ERROR	159

NOTE

If this alarm occurs during treatment:

1. Switch the machine OFF;
2. Perform a *Manual Rinseback* procedure as described in the "7.2 Manual Rinseback procedure in HD and HDF treatments" section of this Operator's Manual.

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Chapter 16: Specifications

Chemical Disinfection with hypochlorite is not currently available.

16.1 General Specifications

Following the main specifications related to Artis Dialysis System general characteristics are reported.

16.1.1 Name

Artis Dialysis System.

⚠WARNING

The Artis Dialysis System must be used under the supervision of a physician.

16.1.2 Standards and Classifications

The Artis Dialysis System complies with the following classifications and standards.

Equipment Classifications

- Class IIb (MDD 93/42/EEC)
- Class I, Applied Part Type B (EN 60601-1)
- Protection Class: IP21 (IEC 60529)
- Not suitable for use in the presence of flammable anesthetics, or anesthetic mixtures with air or with oxygen or nitrous oxide. (EN 60601-1)
- Continuous Operation (EN 60601-1)

⚠WARNING

Do not use the Artis Dialysis System near flammable gas or flammable anesthetic mixtures with air, with oxygen or with nitrous oxide.

CE Marking

- European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
  Notified body: British Standards Institution (BSI) with the notified body number 0086.

NOTE

- The CE marking by the manufacturer GAMBRO S.p.A. covers the equipment.
- The compatibility of the Artis Dialysis System with the other accessories and disposables listed in this operator's manual has been verified during product validation.
- The CE-marking of this manual is only valid if the device which it describes is CE-marked.

International Standards

Medical Equipment Standards[a]	
IEC 60601-1	• MEDICAL ELECTRICAL EQUIPMENT - Part 1: General Requirements for safety (Equivalent to EN 60601-1)
IEC 60601-1-2	• MEDICAL ELECTRICAL EQUIPMENT - Part 1-2: General Requirements for safety - Collateral standard: Electromagnetic Compatibility - Requirements and tests (Equivalent to EN 60601-1-2)
IEC 60601-1-4	• MEDICAL ELECTRICAL EQUIPMENT - Part 1-4: General Requirements for safety - Collateral standard: Programmable electrical medical systems (Equivalent to EN 60601-1-4)
IEC 60601-1-6	• MEDICAL ELECTRICAL EQUIPMENT - Part 1-6: General Requirements for safety - Collateral standard: Usability (Equivalent to Harmonized standard EN 60601-1-6)
IEC 60601-2-16	• MEDICAL ELECTRICAL EQUIPMENT - Part 2-16: Particular Requirements for the safety of hemodialysis, haemodiafiltration and haemofiltration equipment (Equivalent to EN 60601-2-16)
IEC 60601-2-30	• MEDICAL ELECTRICAL EQUIPMENT - Part 2-30: Particular Requirements for safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment. (Equivalent to Harmonized standard EN 60601-2-30)
EN 980	• Graphical Symbols for Use in the Labelling of Medical Devices

Medical Equipment Standards[a] (Continued)	
EN ISO 10993-1	• Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-4	• Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	• Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10	• Biological evaluation of medical devices - Part 10: Tests for irritation and delayed type hypersensitivity.
EN ISO 10993-11	• Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
ANSI/AAMI SP10	• Electronic or automated sphygmomanometers.

a. Independent internationally recognized experts have rigorously checked conformity with these standards.

Radio Frequency Interference and Electromagnetic Environment Requirements

The Artis Dialysis System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix A, of this operator's manual.

FCC / Canada Radio Certification

The Artis Dialysis System has embedded a module approved with FCC ID: XD3-RFMOD, IC: 8313A-RFMOD.

These devices comply with part 15 of the FCC rules.

Changes or modifications not expressly approved by the party responsible for compliance could void user's authority to operate the equipment.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

16.1.3 Power Supply

Main Characteristics

Parameter	*Values*
Mains Voltage	• 230/240 VAC (±10%) • 115 VAC (±10%)
Frequency	• 50/60 Hz (±5 Hz)

Parameter	***Values***
Power Consumption	• Max. 10 A at 230/240 VAC • Max. 16 A at 115 VAC
Power Supply Cord	• Max. length 3 m.
Mains Connector	• Certified to IEC 60320/C19
Mains Plug	• Earthed plug, 250 V AC (10-16 A), • Earthed plug 125 VAC (20 A)
Dielectric Strength	• Complying with clause 20 of IEC 60601-1
Battery Back-up	• Voltage 24 volt, 7.2 Ah • Fuse: T 12 A

⚠WARNING

Possible hazards may arise from equipment (other than the accessories listed below) being connected to the machine, which may cause the permitted leakage current to be exceeded.

⚠WARNING

Wait at least 5 seconds after switching OFF the machine before turning it ON again.

⚠WARNING

The correct installation of a MEDICAL ELECTRICAL SYSTEM requires that each SYSTEM component be individually connected to the main power.
It is strongly recommended: **NOT TO USE MULTIPLE PORTABLE SOCKET-OUTLETS.**
However, if using multiple portable socket-outlets, they must comply with the IEC 60601-1-1 Standard and must **NOT BE PLACED ON THE FLOOR**.

⚠WARNING

- Check that the Artis Dialysis System is properly grounded.
- Do not remove the panels. If necessary, ask qualified staff to open panels.
- Disconnect the machine from the main power supply before every cleaning, checking or maintenance operation.

⚠WARNING

The Artis Dialysis System is provided with energy cells (batteries). When replacing these components, follow local regulations for proper disposal.

Power failure

In case of a mains power failure, an audible alarm is triggered and the red lamp is illuminated.

16.1.4 Physical Data

The physical data reported below must be considered approximated.

Parameter	***Dimensions***
Height (without Infusion Pole)	• 1550 mm
Infusion Pole Height	• 1500 to 2000 mm. Max. load 10 Kg
Width	• 500 mm (excluded the EvaClean connector and dialyzer holder) • 660 mm (when the dialyzer holder is turned in the position used for transportation)
Width of the base	• 700 mm (included back-tray)
Depth	• 600 mm
Depth of the base	• 900 mm (included back-tray) • 700 mm (excluded back-tray)
Floor Area	• 0.405231 m^2
Dry Weight	• < 130 Kg
Transportation	• in horizontal position

Wheels and Portability

The Artis Dialysis System is provided with 4 double wheels: two lockable wheels on the front side and two wheels without brake on the rear side.

The locks are foot-operated:

- to brake the machine, press the two locks completely down;
- to release the brake, pull the two locks completely up.

⚠WARNING

Before moving the Artis Dialysis System, check that the two locks are released and remove infusion bags or any other weights or hanging objects from the Infusion Pole or from the concentrate container tray.

⚠WARNING

To avoid jolting, carefully move the Artis Dialysis System by using the handles on the rear panel.
The machine could be damaged if handled in an improper way.

16.1.5 Environmental Data

Operational Mode

Parameter	***Values***
Ambient Temperature Range	• +18°C to +35°C (65°F to 94°F).
Relative Humidity Range	• 30 to 85 % rh
Air Pressure Range	• 795 to 1060 HPa

Storage and Transportation

Parameter	***Values***
Ambient Temperature Range	• -20°C to +70°C[a]
Relative Humidity Range	• 10 to 95% rh (non-condensing)
Air Pressure Range	• 500 to 1060 HPa

a. Temperatures above +50° C are allowed ONLY for maximum 12 hours

⚠WARNING

If condensation of Artis Dialysis System occurs when moving it between locations with different temperatures and high relative humidity (e.g. outdoor and indoor locations), the inside of the machine shall be allowed to dry before switching it on.

⚠WARNING

During transportation and storage the Artis Dialysis System has to be kept in its original packing.

16.1.6 Software revision

This operator's manual revision is related to the 6.04.11 software revision.

16.1.7 Connection of external equipment

⚠WARNING

- All external equipments connected to the Artis Dialysis System must be compliant with IEC 60950 or IEC 60601 series. Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in the standard.
- Any person who connects external equipments to signal input, signal output or other connectors has formed a Medical Electrical system and is therefore responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, contact qualified technician or your local representative.

The Artis Dialysis System is provided with a Connectivity Panel (see "Figure 16-1. Connectivity Panel") for connection of external equipments, including the following ports:

Connectivity Panel	
10/100 Base T Ethernet Port	• Used for connecting the machine to a Personal Computer to interface with the Communication System
RS232 Serial Port *(Not currently available)*	• Used for connecting the machine to a bed scale, WRO300 or WRO300H
USB Port	• Used for flash memories *(only for service interventions)*
BPM Port	• Used for connecting the BPM device
Remote Alarm	• Max voltage: 24 V AC • Max current: 500 mA
External Water Valve *(Not currently available)*	• Max voltage: 24 V DC • Max current: 500 mA

Connectivity Panel (Continued)	
Hour Meter	• Displays the cumulative hours of machine operation (total time that power to the machine has been on)
Potential Equalization Connector	• Used for connecting a Potential Equalization Conductor to the machine

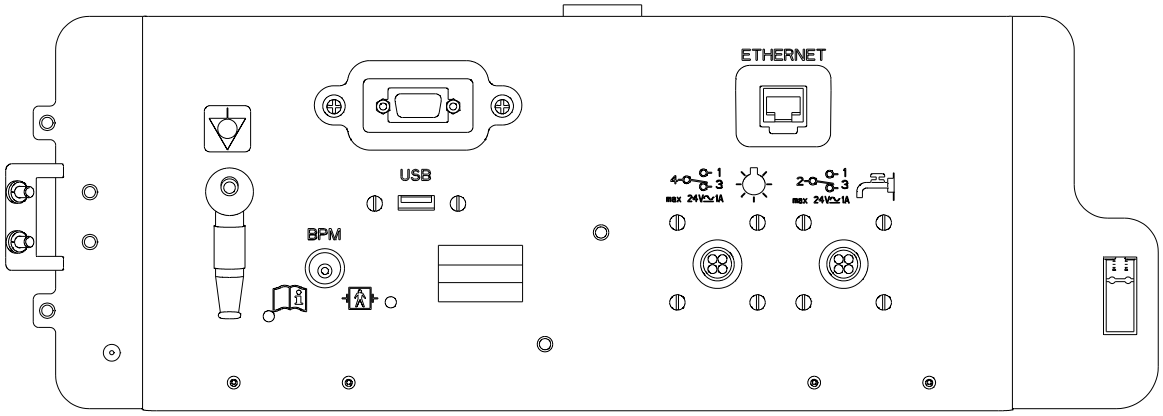

Figure 16-1. Connectivity Panel

16.1.8 Shipping List

The machine packaging contains the following components:

- Artis Dialysis System
- CD ROM of Artis operator's manual
- Installation Checklist
- Water Inlet and Drain Tubes
- Infusion pole (maximum load: 10 Kg or 22 lb)

NOTE

Adjustement of the infusion pole height must be done without bags on the hooks.

- Concentrate Wand
- pH probe assembly
- BPM Cuff
- Top Tray
- Chemical Container Shelf

- BPM (Blood Pressure Monitoring)
- Central Concentrate Supply Kit

Accessories

- SNSP Expansion Chamber Holder
- CWP Adapter Kit

⚠WARNING

Do not assemble, install or use the Artis Dialysis System before having carefully read this operator's manual.

16.2 Hydraulic Circuit Specifications

16.2.1 Water Supply

The quality of the incoming water used by the Artis Dialysis System must comply with local standards and ISO 13959 standard.

Main Requirements

Parameter	***Value***	***Conditions***
Pressure	• 150 to 800 kPa	/
Inlet Water Demand (Flow Rate)	• < 1 l/min	/
Inlet Water Conductivity	• 0 to 0.5 mS/cm	/
Temperature (Treatment)	• +5°C to +35°C • +10°C to +35°C • +16°C to +35°C	• Dialysis Fluid Flow Rate: 300 to 800 ml/min (230V) • Dialysis Fluid Flow Rate: 300 to 750 ml/min (115V) • Dialysis Fluid Flow Rate: 750 to 800 ml/min (115V)
Temperature (Heat Disinfection)	• +5°C to +93°C	/
Inlet Tube	• Length: 5 m • Internal diameter: 8 mm	/

Drain

Parameter	***Value***
Drain Flow Rate	• Max. 1.2 l/min
Drain Fluid Temperature	• Max. 90°C
Pressure	• 0 to 13 kPa
Drain Tube Length	• Max. 5 m
Drain Outlet Height	• Max. 1.3 m above floor level

Make the connection of the drain, as described in applicable local and international standards, with an external pressure connector to avoid back flow. Mantain an air clearance between the drain connector of the machine and the drain itself.

16.2.2 Concentrate Connectors

The concentrate and disinfectant connectors on the Artis Dialysis System are colour-coded as follows:

Connector	***Colour***
Acid Tube Connector	• Red, located on the machine front side
Disinfectant Tubes	• Yellow and Clear, located on the machine rear side

16.2.3 Dialysis Fluid

⚠WARNING

It is recommended to use concentrates which conform to the requirements of the European Pharmacological Standards.
The control of alarm threshold and dialysis fluid conductivity precision is of major medical importance in ensuring a safe dialysis treatment.

⚠WARNING

Attention must be given to the safety hazards related to incorrect choice of dialysis fluid concentrates.

Dialysis Fluid Temperature

Parameter	***Values***
Range	• +35.5°C (or +2°C above the inlet water temperature, whichever is greater) to +39.5°C
Accuracy	• +0.5°C/-1.8°C of the set value
Alarm Limits	• ±2 °C (±0.5°C) of the set value • Min. +34.5 °C (±0.5°C) • Max. +41 °C (±0.5°C)
Protection system type	• Monitoring of the dialysis fluid temperature

⚠WARNING

When the temperature of the dialysis fluid exceeds the alarm threshold, the audible and visual alarms are triggered.

Dialysis Fluid Flow

Parameter	***Values***
Dialysis Fluid Flow Rate	• 300 to 800 ml/min, in steps of 50 ml/min
Accuracy	• ± 2% of the set value
Alarm Limits	• ±10% (accuracy ±1%) of the set value • Min. 250 ml/min (±10 ml/min) • Max. 900 ml/min (±10 ml/min)

⚠WARNING

When the dialysis fluid flow exceeds the alarm threshold, the audible and visual alarms are triggered.

Dialysis Fluid Pressure

Parameter	***Values***
Permitted Values	• -350 to +480 mmHg
Accuracy	• ± 25 mmHg
Alarm Limits	• -350 to +480 mmHg

⚠WARNING

When the dialysis fluid pressure exceeds the alarm threshold, the audible and visual alarms are triggered.

Degassing

Parameter	***Values***
Method of Degassing	• Heating in combination with vacuum pumping.
Pressure	• < 150 mmHg (±10 mmHg) or dissolved gas in dialysis fluid < 7.0 mg/l .

pH Supervision

Parameter	***Values***
Range	• 1.0 to 13.0 ph units
Accuracy	• ±0.2 ph units

Parameter	Values
Alarm Limits	• 6.5 to 7.6 ph units (±0.1 ph units)

WARNING

When the pH of the dialysis fluid exceeds the alarm threshold, the audible and visual alarms are triggered.

Supported Concentrates

Parameter	Values
Liquid concentrates	• Acidic (A) concentrate for preparation of 8.4% bicarbonate dialysis fluid
Dry concentrates	• BiCart® Cartridge: Sodium Bicarbonate 8.4% concentrate for preparation of 8.4 % bicarbonate dialysis fluid
Ions Concentration	
Na+ (Sodium)	• 138 to 140 mmol/l (±2.5%)
HCO3- (Bicarbonate)	• 24 to 38 mmol/l (± 5%)
K^+	• 0 to 4 mmol/l (± 5%)
Ca^{2+}	• 1 to 1,75 mmol/l (± 5%)
Mg^{2+}	• 0,375 to 0,75 mmol/l (± 5%)
Cl^-	• 103,80 to 110,5 mmol/l (± 5%)
$CH3COO^-$	• 2 to 3 mmol/l (± 5%)
Glucose	• 0 to 5,55 g/l (± 5%)

Ions Concentration

Parameter	Values
Na+ (Sodium)[a]	• 130 to 160 mmol/l (±2.5%)
HCO3- (Bicarbonate)[a]	• 24 to 38 mmol/l (± 5%)

a.Can be set by the operator

Concentrate Supply Pressure

Parameter	Values
Range	• -20 kPa to +50 kPa

Total Conductivity

Parameter	***Values***
Conductivity measurings	• 13.3 to 15.7 mS/cm
Accuracy	• ± 0.2 mS/cm
Alarm Limits	• 13.1 to 15.9 mS/cm

⚠WARNING

It is responsibility of the user to determine the correspondence between the dialysis fluid conductivity, displayed by the machine and the dialysis fluid solute content, verified by clinical laboratory results, for each concentrate used for dialysis treatment.
This can be done by taking dialysis fluid samples at different conductivity values (e.g. 13, 14, 15 mS/cm) and sending them to a laboratory for analysis.

Conductivity of the Bicarbonate Solution

BiCart Cartridges (sodium bicarbonate cartridge - see specific instruction sheet) can be used with the Artis Dialysis System.

⚠WARNING

Carefully read the BiCart Cartridge Instructions for Use before using the device. BiCart Cartridge may only be used by staff, who are specially trained for hemodialysis treatments, using the Artis Operator's Manual.

BiCart Solution Conductivity Monitor	
Parameter	***Value***
Conductivity values allowed	• 2.2 to 3.8 mS/cm
Average accuracy	• ±0.1 mS/cm
Alarms	• ±5% of the conductivity value

Dialysis Fluid Pump Monitoring for Concentrate Exchange

The reference values for the speed of the acid/acetate and bicarbonate ceramic pumps are defined during the corresponding calibration processes and represent the 0% functioning point.

A safety system is present to prevent concentrate exchange errors, by generating an alarm in case the pump speeds are measured outside a range of ±10% to ±17% of the reference value.

16.2.4 Substitution Fluid

Parameter	***Value***
Substitution Fluid Flow Rate	• 1.2 to 19.8 l/h
Online Produced Substitution Fluid	• Max. 100 litres, in post-dilution (99L for treatment, 1L for restitution)
Alarm Limits	• 10% of the set substitution fluid flow rate or ±5 mL/min, whichever is greater
OnLine Bolus *(default)*	• 50 mL to 1000 mL, in steps of 10 mL (*default 150 mL*)
OnLine Bolus Rate *(default)* *Preset*	• 20 mL/min to 330 mL/min, in steps of 5 mL/ min *(150 mL/min)*
Q_F/Q_B (in Post-dilution) *Preset*	• 30% to 50%, in steps of 1%, in Volume Control Mode. Default:40% • 30% to 60%, in steps of 1%, in Pressure Control Mode. Default:40%
Q_F/Q_B (in Pre-dilution) *Preset* *(not currently available)*	• 80% to 120%, in steps of 1%

NOTE

The On-line Substitution Fluid, prepared with inlet water conforming to ISO 13959 and concentrates conforming to European Pharmacopea, will have a microbiological fluid quality of:
• Bacterial content less than 10E-6 CFU/ml,
• Endotoxin content < 0.03 IU/ml measured with an LAL assay.

Volume Control Mode

Hemodiafiltration treatments performed by the Artis Dialysis System can be controllable in Volume Control Mode (Post dilution): the total weight loss, the Substitution Fluid Flow Rate and Treatment Time are set by the user while the TMP pressure varies accordingly to the total Ultra-filtration rate (weight loss rate + substitution fluid flow rate).

In online volume control treatments, the following ratios will always be displayed:

- Ratio between the total Ultra-filtration rate (weight loss rate + substitution fluid flow rate) and the Real Blood Flow Rate (Q_F/Q_B) in POST dilution mode
- Ratio between the Substitution Fluid Flow Rate and the Real Blood Flow Rate (Qi/Qb) in PRE dilution mode

TMP in Volume Control Mode

The operator will be able to set the maximum alarm limit for the TMP, during an Online treatment in volume control mode, in the following range:

- 0 mmHg to Absolute Maximum TMP, in steps of 10 mmHg

where the Absolute Maximum TMP is a pre-defined value set by a Service technician in the following range:

- 0 mmHg to +500 mmHg in steps of 10 mmHg

Pressure Control Mode

Hemodiafiltration treatments performed by the Artis Dialysis System can be controllable in Pressure Control Mode (Post dilution): the Total Weight Loss, the TMP and the Treatment Time are set by the user while the Substitution Pump Fluid Flow Rate varies accordingly to the TMP.

In online pressure control treatments, the following ratios will always be displayed:

- Ratio between the total Ultra-filtration rate (weight loss rate + substitution fluid flow rate) and the Real Blood Flow Rate (QF/QB) in POST dilution mode
- Ratio between the Substitution Fluid Flow Rate and the Real Blood Flow Rate (Qi/Qb) in PRE dilution mode

Pressure Control Mode with Ultra Control

Hemodiafiltration treatments performed by the Artis Dialysis System can be controllable in Pressure Control Mode (Post dilution) with Ultra Control: if the related functionality has been selected in the Preset, then during the treatment, the machine allows manual Ultra Scans or automatic Ultra scans. During an Ultra Scan, the machine automatically increases the TMP from the initial value to the value that maximizes the total Ultra-filtration.

In case of manual Ultra Scans, the Ultra Scan process is activated by the user and automatically stopped by the machine as the optimum TMP is reached. A manual Ultra Scan can also be stopped by the user.

In case of automatic Ultra Scans, three Ultra Scan processes are automatically activated by the machine with a fixed timing and automatically stopped by the machine as the optimum TMP is reached. An automatic Ultra Scan can also be stopped by the user.

TMP in Pressure Control Mode

The operator will be able to set the maximum alarm limit for the TMP, during an Online treatment in volume control mode, in the following range:

- 0 mmHg to Absolute Maximum TMP, in steps of 10 mmHg

where the Absolute Maximum TMP is a pre-defined value set by a Service technician in the following range:

- 0 mmHg to +350 mmHg in steps of 10 mmHg

16.2.5 Ultrafiltration system

The accuracy of the Ultrafiltration system will be guaranteed in the following operating ranges:

Parameter	***Values***
Dialysis Fluid Flow	• 300 to 800 ml/min
UF Rate	• 0 to 3.0 l/h
UF Rate Accuracy	• ±50 ml/h
UF Volume	• 0 to 24 litres, in steps of 0.05 litres
UF Volume Accuracy	• ± 2.5% or ±50 ml/h * total treatment time, whichever is greater.
TMP	• -200 to +600 mmHg (±15 mmHg)
Treatment Time	• 00.30 to 08.00 (hour.minute), in steps of 5 minutes
Protein Content	• 0 to 120 mg/l
Protection System Type	• Monitoring of the ultrafiltration rate

⚠WARNING

If the difference between the accumulated weight loss rate measured by the Ultrafiltration System and the accumulated weight loss rate measured by the Protective System of the machine is greater than ±80 ml an audible and visual alarm is triggered.
When this alarm is activated the Venous Pump is stopped and the dialysis fluid goes into bypass.

NOTE

Besides the ultrafiltration, the patient's weight change during treatment is affected by other factors such as fluid and food intake, perspiration, drug administration, infusion priming and rinseback volumes, amongst others.
In addition, precise pre- and post-treatment weight are critical for the proper assesment of the ultrafiltration during the treatment. If these measurements are not accurate a discrepancy between the achieved ultrafiltration during treatment and the patient's weight changes will occur.

Ultrafiltration Supervision

Following the alarm limits for the Ultrafiltration System control:

Parameter	***Values***
UF Volume Supervision[a]	• < 540 ml
UF Rate Alarm Limits	• ±80 ml of the set value
Accumulated UF Volume Alarm limit	• ±0.10 -2.0 l or ±0.10 l/h*passed treatment time (h), can be preset
UF Rate Measurement	• 0 to +3.0 l/h • Accuracy: ±5 ml/min verified at the Start-up

a. It is defined as the difference between the Actual UF Volume and the UF Volume set by the operator.

16.2.6 Blood Leak Detection

Parameter	***Values***
Sensitivity	• > 0.35 ml/min (0.05 ml/min) , haematocrit 32%, ±2%
Alarm response time	• 5 seconds (±0.5 seconds)
Detection Method	• Optical Infrared System

⚠WARNING

A Safety Test of the Blood Leak Optical Sensor is automatically performed each time the machine enters the Preparation mode.
When the Blood Leak sensor test fails audible and visual alarms are triggered .

⚠WARNING

In the “Isolated UF” process or with the hydraulic circuit in bypass, the Blood Leak Alarm may be delayed, due to operating conditions and dialyzer characteristics.

16.2.7 Disinfection

⚠WARNING

Contact with cleaning and/or disinfection chemicals may pose a risk of burns, skin irritation or other adverse reactions. Always follow the chemical manufacturer's instructions when handling these products or cleaning spills.

NOTE

It is recommended to alternate the disinfection methods and/or the disinfectants, in order to optimize cleaning, descaling and disinfection of the machine.
For additional information contact your local representative.

16.2.7.1 Chemical Disinfectants

Following a list of the main chemical solutions that may be used with the Artis Dialysis System for chemical disinfection:

Active Ingredient	***Trade Names***
Sodium Hypochlorite	• Bleach® 5% • Amuchina™ 1.1%
Peracetic Acid	• Dialox™ 0,35% • Actril 0,06% • Renalin 4% • Oxagal 0,5%
Sodium Carbonate	• CleanCart A
Citric Acid	• CleanCart C

⚠WARNING

To prevent damaging the machine, do not leave disinfectant solutions in the machine for periods over the following limits:
- 20 min for Sodium Hypochlorite based solutions at Disinfectant strength (Max. 0.2% concentration)
- 20 min for Citric Acid based solutions at Disinfectant strength (Max. 2% concentration)
- 20 min for Sodium Carbonate based solution at Disinfectant strength (Max. 0.5% concentration)
- 72 hours for Peracetic Acid based solutions at Disinfectant strength (Max. 0.10% concentration)

16.2.7.2 Disinfection Programs

Following a list of the main disinfection programs allowable with the Artis Dialysis System.

The indicated "Total Time" parameter includes all the phases of the different disinfection processes (fill-up, circulation, drain and cooling).

Heat Disinfection

Parameter	***Values***
Temperature	• Max 99°C
Total Time	• 34 min

Heat Disinfection with CleanCarts

Parameter	***Values***
Heated Solution Concentration	• Max. 2%, CleanCart-C • Max. 0.5% CleanCart-A
Temperature	• Max. 99°C
Total Time	• 44 min

Central Heat Disinfection

Parameter	***Values***
Temperature	• Max 99° C
Total Time	• 34 min

Chemical Disinfection - Peracetic Acid

Parameter	*Values*
Disinfectant Solution Concentration after 1:35 dilution	• Max. 0.10%
Disinfection Time	• 16 min.
Rinse Time	• 38 min.

Chemical Disinfection - Low Peracetic Acid

Parameter	*Values*
Disinfectant Solution Concentration after 1:35 dilution	• Max. 0.01%
Disinfection Time	• 16 min.
Rinse Time	• 27 min.

Chemical Disinfection - Sodium Hypochlorite

(Not currently available)

Parameter	*Values*
Disinfectant Solution Concentration after 1:35 dilution	• Max. 0.2%
Disinfection Time	• 16 min.
Rinse Time	• 66 min.

16.2.7.3 Rinsing

The Artis Dialysis System will automatically perform a Rinse process after any Chemical Disinfection Program and a drain of the circuit after any Rinse process.

It is also possible to manually activate a rinsing process after a dialysis treatment.

The effectiveness of Rinsing (measured at a point in the hydraulic circuit just prior to the dialyzer connection) conforms to international standards for residual concentrations of disinfectant (European Pharmacological Standards and the ANSI - AAMI RD62):

- Peracetic maximum 1 ppm
- Sodium Hypochlorite maximum 0.1 ppm

NOTE

The test procedures for the measurement of disinfection and rinsing efficiency are available, upon request, from the manufacturer's quality control department.

WARNING

After a Chemical Disinfection program, a test for residues of disinfectant must be performed before attaching the concentrates to the machine to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

16.2.7.4 External Cleaning

It is possible to clean the Artis Dialysis System externally without affecting the original surface appearance using the following products:

- Isopropanol 60%
- Liquid soap
- Ethanol 70%
- Sodium Hypochlorite of 1.5% available chlorine

16.3 Extracorporeal Blood Circuit

16.3.1 ArtiSet Blood Tubing System

The Blood Cassettes will allow the bloodlines to be positioned in a way designed to ensure a simple and effective system.

The following Blood Cassettes are available for the Artis Dialysis System:

Code	Application	Prime Line	Patient Line Length
113201	Double Needle	NO	about 235 cm
107472	Prime Line	/	N/A
112559	HDF Online	NO	about 235 cm

NOTE

- Refer to the Blood Cassette labeling for priming volume data.
- Further information on suitable Blood Cassettes can be obtained by contacting your local representative.

WARNING

The use of the Blood Cassettes designed for Artis Dialysis System has been tested and validated to provide safe and proper functioning of the system.

WARNING

The appropriate Dialyzer and Blood cassette must be selected according to the patient's size and weight and to the treatment type.
The decision must be taken by a physician.
Before installing Gambro/Hospal Dialyzers and Blood Cassettes carefully read the related Instructions for Use.

⚠WARNING

This operator's manual contains a number of references to accessories and disposables for use with Artis Dialysis System. The Artis Dialysis System has been tested and validated for use with accessories and disposables listed in this manual. The manufacturer has not validated the use of accessories or disposables other than those specified in this manual. The Manufacturer does not accept responsibility or liability for use of accessories or disposables other than those specified in this manual. Depending on the circumstances, use of accessories or disposables other than those specified may also reduce the Manufacturer's warranties for the Artis Dialysis System.

⚠WARNING

The Manufacturer recommends the use of a dialyzer with dialysis fluid and blood connections that comply with ISO 8637.

NOTE

Do not use plate-type dialyzer.

16.3.2 Blood Pumps

The Artis Blood Module is made up of two peristaltic pumps designed for dialysis, with pump segment inserts of 6.36 x 9.54 mm (0.25x0.38 in).

To control the Blood Pumps, the Blood Module is provided with:

- An Electronic Speed Control System to keep the speed constant, independently of load variations;
- A light on the Hard Key Panel illuminated when the pumps are turning on (or when they are about to turn on, for example, after an automatic stop caused by an alarm);
- A Pump Direction Monitor;
- A system to automatically stop the Blood Pumps and close the Venous Line Clamp in case of air or foam detection;
- A Safety Control when the Blood Pump Covers are opened;
- Two cranks, one for each pump, for manual turning of the blood pumps;
- A Protective System to prevent overloads.

⚠WARNING

When using the Artis Dialysis System, stop the Blood Pumps before touching the Blood Pump Rotors.
Do not touch the blocking system.

Blood Pump Technical Characteristics

Parameter	*Value*	*Condition*
Speed of Pump Rotor	• 0 to 76 rpm approx.	/
Blood Flow Ramping Up *Can be preset*	• 25, 50 or 100 ml/min, per second	/
Max actual Blood Flow (at max rpm)	• 500 ml/min	• Arterial Pressure: 0 to -250 mmHg

16.3.3 Blood Flow

The Artis Dialysis System displays the following values related to the blood flow:

- The blood flow set value
- The blood flow actual value.

The blood flow set value represents the theoretical blood flow rate in the extra-corporeal circuit calculated from the speed of the blood pump rotor and the geometric characteristics of the pump segment.

The blood flow actual value is the actual blood flow rate in the extra-corporeal circuit. The actual value is usually lower than the set value due to the negative pressure in the access line at the inlet to the pump. The negative pressure is caused by the rotation of the pump itself and pressure drop linked to the motion of blood in the line. The actual value coincides with the set value when the pump inlet pressure (arterial pressure) is zero.

The accuracy on the estimate, using GAMBRO Blood Cassette, is typically within ±10% in the following conditions:

- the pressure before the pump, given by the pressure in the arterial chamber of the cassette, is higher (less negative) than –150 mmHg and in the Actual Blood Flow range from 100 ml/min to 500 ml/min.

The blood flow actual value is estimated by means of a mathematical algorithm taking into account the pump segment characteristics of GAMBRO Blood Cassette, the current pump speed and the pressure values in the extra-corporeal circuit.

NOTE

The Artis Dialysis System will be able to calculate and display the accumulated blood volume in the range 0 to 999 liters.

WARNING

A dedicated warning (Low Blood Pump Speed #204) exists in order to avoid blood loss due to coagulation resulting from interruption of blood flow.

Double Needle

Parameter	***Values***	***Conditions***
Adult Blood Cassette		
Actual Blood Flow	• 10 to 500 ml/min	• Arterial Pressure: 0 to -250 mmHg
Accuracy	• ±10% • ±20% or ±20 ml/min, whichever is greater	• Arterial Pressure: 0 to -150 mmHg • Total Treated Blood Volume: ≤120 liters • Actual Blood Flow: 100 to 500 ml/min • Arterial Pressure: 0 to -150 mmHg • Total Treated Blood Volume: 120 to 200 liters • Actual Blood Flow: 100 to 500 ml/min
Blood Pump Speed	• 10 to 580 ml/min, in steps of 10 ml/min	/
Accumulated Blood Volume	• 0 to 999 litres	/

Single Needle Single Pump

Parameter	*Values*	*Conditions*
Average Blood Flow	• 10 to 220 ml/min, in steps of 10 ml/min	/
Accuracy	• ±10 ml/min or ±20% whichever is greater	• Arterial Pressure: 0 to -150 • Treated Blood Volume: $\leq$ 120 L
SN Pressure Min	• 150 to 360 mmHg	/
SN Pressure Max	• 190 to 400 mmHg	/

NOTE

In Single Needle mode the stroke volume for each cycle is approximately 20 ml.

NOTE

During a Single Needle Single Pump mode, the Artis Dialysis System will be able to automatically control the Arterial/Venous phase commutation according to pressure measurement in the Venous Patient Line (see "Single Needle Pressure Monitoring" section in this chapter).

NOTE

In Single Needle mode, the blood recirculation rate at the level of the patient's vascular access is influenced by the needle type or catheter used. The blood recirculation rate is not due to the single needle cassette characteristics.

Single Needle Double Pump

(Not currently available)

Parameter	***Values***	***Conditions***
Average Blood Flow	• 10 to 220 ml/min	/
Accuracy	• ±10 ml/min • ±10%	• Blood Flow ≤100 ml/min • Blood Flow >100 ml/min
Stroke Volume[a]	• 20 to 50 ml (±15%), in steps of 1 ml	• Cycle time: < 20 sec.
Accumulated Blood Volume	• 0 to 99.9 litres (+/-0.6 l * treatment time (h) or +/-15%)	/

a. The Stroke Volume value is calculated from Pump Flow Rate and Time.

NOTE

During a Single Needle Double Pump therapy, the Artis Dialysis System will be able to automatically control the Arterial/Venous phase commutation according to pressure measurement and stroke volume achieved.

16.3.4 Heparin Delivery

The Artis Dialysis System may be supplied with a syringe type infusion pump which delivers heparin with a standard 30 ml syringe.

Parameter	***Values***
Heparin Delivery Management	• Linear: bolus delivered at a constant flow • Intermittent: bolus delivery at a set interval of time • Manual: single bolus delivered when the button is pressed • Extra Bolus: a bolus is delivered when the "Extra Bolus" Action button is pressed.
Syringe Size	• 30 ml
Heparin Delivery Rate (Linear Mode)	• 0 ml/h or 1.5 ml/h to 10.0ml/h, in steps of 0.1 ml/h
Accuracy (on Accumulated Volume)	• ±1 ml or ±0.2 ml/h * heparinization time (h) or ±10% whichever is greater
Bolus Amounts *(default)*	• 0.5 to 10 ml, in steps of 0.5 mL *(0.5 mL)*

Parameter	*Values*
Bolus Delivery Rate	• 0.08 ml/s
Stop Time *(default)*	• 0 to total treatment time, in steps of 1 minute (30 min)
Max. Counter Pressure	• +900 mmHg
Heparin Delivery Alarm Limits	• Accumulated Heparin Volume: ±40% of the set Heparin Volume

NOTE

To prime the Heparin line, 0.6 ml of heparin will be injected into the Blood Cassette. This will happen regardless of the type of heparin delivery program selected.

Heparin Syringes

Following a list of the main syringes allowed on the Artis Dialysis System:

Syringe Name	*Volume (ml)*	*Internal Diameter*
TERUMO	30	23.1 mm (0.909 in)
BD 30 PLASTIPAK	30	21.6 mm (0.850 in)
PIC 30 LL	30	23.6 mm (0.929 in)
ICO GAMMA PLUS/ MONOSTERIL	30	23.9 mm (0.941 in)
PENTA 30	30	21.8 mm (0.858 in)

⚠WARNING

These diameters have been taken from samples from many countries and are correct at the time of printing. However, the manufacturer cannot be held responsible for changes in syringe dimensions that may occur. The user should periodically check the correlation between the stated and the actual diameters.

⚠WARNING

DO NOT USE syringes without luer lock connection.

⚠WARNING

The syringe infusion pump described above must be used **ONLY** for the infusion of heparin.

16.3.5 Hemoscan Sensor

The Artis Dialysis System provides a non-invasive mechanism to perform blood volume measurements, according to the following specifications:

Parameter	***Values***
Blood Flow Rate	• 180 to 500 ml/min
Blood Temperature	• 30 to 40°C
Relative Blood Volume	• -40% to +10%
Accuracy (standard error)	• ±3%
Resolution	• 0.1%
Hemoglobin Value Range	• 6 to 16 g/dl

16.3.6 Blood Pressure Monitor (BPM)

The Blood Pressure Monitor is a non-invasive system to read the patient's blood pressure during a treatment (refer to the "Chapter 8: BPM" of this operator's manual).

In the table below the main specifications related to the blood pressure monitor option are reported.

The alarm limits below can be preset. The value put in brackets and in italics is the default value.

Parameter	***Values***
Systolic pressure range[a]	• +60 to +255 mmHg
Low alarm limit	• 60-255 mmHg *(90 mmHg)*
High alarm limit	• 60-255 mmHg *(200 mmHg)*
Diastolic pressure range[a]	• +30 to +195 mmHg
Low alarm limit	• +30 to +195 mmHg *(50 mmHg)*
High alarm limit	• +30 to +195 mmHg *(100 mmHg)*
Heart rate range[b]	• 30 to 200 bpm
Low alarm limit	• 30 to 200 bpm *(40 bpm)*

Parameter	*Values*
High alarm limit	• 30 to 200 bpm *(120 bpm)*
Heart rate resolution	• 1 bpm
Cuff Pressure	• Max.: 300 mmHg
Cycle Time	• Typical cycle time: 35 s. • Max.: < 160 s.

a. Meets ANSI/AAMI SP-10. Mean error ±5 mmHg. Standard deviation 8 mmHg.
b. Heart Rate Accuracy: ±2% or ±3 bpm, whichever is greater

16.3.7 Automatic Functions

The following automatic functions are available with the Artis Dialysis System:

1. **Single Needle Single Pump:** arterial/venous cycles occur through automatic blood pump transition when preprogrammed venous pressure thresholds are reached.

2. **Linear or Intermittent *Heparin* Delivery:** through programming of the rate and timing of delivery.

3. **Heparin Bolus Injection Characteristics**

4. **Blood Sensor before Venous Line Clamp**: before blood detection by the Blood Sensor or before starting the dialysis treatment, some alarms are bypassed to allow easier filling of the extracorporeal and hydraulic circuits.

5. **Ultra Control:** in online treatments with Pressure control mode, it is possible to activate the Ultra Control functionality (ref to “16.2.4 Substitution Fluid” section of this chapter)

6. **Automatic Pump control:** in online treatments with Volume or Pressure control mode, each time that the substitution pump is stopped due to any reasons, the machine automatically decreases the blood pump speed in order to avoid venous pressure peaks.

16.3.8 Main Surveillance Devices

Following the specifications related to the main surveillance devices available with the Artis Dialysis System.

Ultrasonic Air Detector

The Blood Module has an Air Detector consisting of:

- An Ultrasonic Sensor located into the right Sensor Bar;
- A Transducer which carries out the auto-test every 250 ms;
- A Visual and Audible Alarm which is activated if air is detected.

Parameter	***Values***
Detection Method	• An ultrasonic wave band crosses the fluid in the blood line. When air is present in the line, the signal received by the detector is modified in proportion to the volume of air present. When the signal goes above a fixed threshold, the microprocessor triggers a signal, which causes the Venous Line Clamp to close and the Blood Pumps to stop.
Sensitivity	• Bubble volume ≥ 20 micro liters (±1 micro liter), at max. flow rate

Arterial Pressure Monitoring

The Arterial Pressure Sensor is used for measuring pre-pump arterial pressure in order to protect the patient from high negative arterial pressures between the patient and the Arterial pump.

During a treatment, an Arterial Pressure alarm will be triggered if the pressure measurements are not within the following ranges:

- Minimum and Maximum treatment limits;
- Minimum and Maximum Arterial pressure limits, calculated as:

  Max Arterial Limit = Operating value + Arterial Positive Offset

  Min Arterial Limit = Operating value - Arterial Negative Offset .

NOTE

In case of recovery procedures, the Artis Dialysis System will automatically set the Extreme Alarm limits as the Minimum and Maximum Arterial pressure limits.

Parameter	***Values***
Operating Range	• -400 to +150 mmHg
Accuracy	• ±10 mmHg or ±10%, whichever is greater (in the range -400 mmHg to +20 mmHg) • ±20 mmHg (in the range +20 mmHg to +150 mmHg)
Offset Values *(Default)*[a]	• Positive: 10 to 100 mmHg, in steps of 5 mmHg *(80 mmHg)* • Negative: 10 to 80 mmHg, in steps of 5 mmHg *(40 mmHg)*

Parameter	Values
Treatment Limits*(Default)*[a]	• Min: -300 to -100 mmHg, in steps of 10 mmHg *(-300 mmHg)* • Max: -100 to +150 mmHg, in steps of 10 mmHg *(0 mmHg)*
Extreme Alarm Limits (outside the treatment mode)	• Min: -500 mmHg • Max: +300 mmHg
Maximum Arterial Alarm Limit[a]	• -100 to +150 mmHg, in steps of 10 mmHg

a. Can be preset

⚠WARNING

Modification of the Blood Flow Rate causes a fluctuation in the Arterial Pressure and therefore an alarm may be triggered.
To prevent such an effect, following any start/stop of the Arterial pump or change in the Blood Flow Rate the Arterial pressure Alarm Window is automatically set wider for 30 seconds, in HD treatments, or for 120 seconds, in HDF treatments. Its lower value is set to -400 mmHg while the upper value is set to +150 mmHg.

Venous Pressure Monitoring (Double Needle Mode)

During a treatment, a Venous Pressure alarm will be triggered if the pressure measurements are not within the following ranges:

- Minimum and Maximum treatment limits;
- Minimum and Maximum Venous pressure limits, calculated as:

  Max Venous Limit = Operating value + Venous Positive Offset

  Min Venous Limit = Operating value - Venous Negative Offset

Parameter	Values
Operating Range	• -100 to +450 mmHg
Accuracy	• ±10 mmHg or ±10%, whichever is greater (in the range -20 mmHg to +450 mmHg) • ±20 mmHg (in the range -100 mmHg to -20 mmHg)
Offset Values *(Default)*[a]	• Positive: 10 to 70 mmHg in steps of 5 mmHg *(70 mmHg)* • Negative:10 to 40 mmHg in steps of 5 mmHg *(40 mmHg)*

Parameter	***Values***
Treatment Limits*(Default)*[a]	• Min: 10 to 100 mmHg, in steps of 10 mmHg *(10 mmHg)* • Max: 150 to 350 mmHg, in steps of 10 mmHg *(300 mmHg)*
Extreme Alarm Limits (outside the treatment mode)	• Min: -300 mmHg • Max: +450 mmHg
Maximum Venous Pressure Alarm Limit *(Default)*[a]	• +150 to +350 mmHg, in steps of 10 mmHg *(300 mmHg)*

a. Can be preset

NOTE

A Safety Test of the Venous Pressure Monitoring System is automatically performed each time the machine enters the Preparation mode.

WARNING

Modification of the Blood Flow Rate causes a fluctuation in the Venous Pressure and therefore an alarm may be triggered.
To prevent such an effect, following any start/stop of the Arterial pump or change in the Blood Flow Rate the Venous Pressure Alarm Window is automatically set wider for 30 seconds, in HD treatments, or for 120 seconds, in HDF treatments. Its lower value is set to -50 mmHg, while the upper limit is set to +450 mmHg.

⚠WARNING

Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's vascular access. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set.
To reduce the risk of needles disconnection:
- ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol;
- ensure that the patient's access is visible at all times during the dialysis treatment;
- inspect frequently the patient's access;
- adjust properly the venous pressure alarm window: the venous pressure alarm lower limit should be set as closely as practical to the actual patient's venous pressure value without generating excessive nuisance alarms.

Single Needle Pressure Monitoring

In Single Needle mode, the Venous Pressure Sensor is used for measuring the blood pressure in the Venous chamber for blood pump activation and deactivation, according to set venous pressure values:

Parameter	***Values***
Operating Range	• +150 to 400 mmHg, in steps of 10 mmHg
SN Pressure Min	• 150 to 360 mmHg
SN Pressure Max	• 190 to 400 mmHg
Alarm Limits	• +10 mmHg to +450 mmHg

⚠WARNING

The user must take precautions against the hazard of cross-contamination between patients by using only extracorporeal circuits that are not damaged.

Pre-Dialyzer Pressure

Parameter	***Values***
Operating Range	• -100 to +800 mmHg
Accuracy	• ±10 mmHg (in the Operating Range +300 mmHg to +800 mmHg) • ±20 mmHg or ±10%, whichever is greater (in the Operating Range -100 mmHg to +300 mmHg)
Alarm Limits	• 0 to +800 mmHg

16.3.9 Safety system actuators

The Artis Dialysis System is supplied with the following safety system actuators:

Arterial Line Clamp	• Used for Single Needle modes
Venous Line Clamp	• Automatic closure when required by an alarm as part of a specific safety state; • Closure in Single Needle modes to reduce recirculation; • The Venous Line Clamp is fitted with a position sensor to ensure proper functioning of the clamp, and to assure that the Arterial Pump is stopped.

16.4 Protective system

The Protection System controls fault conditions which may be dangerous for the patient, by placing the machine in a Safe State, as required by international regulations.

For each of these conditions, an independent safety chain is implemented. The conditions controlled are:

- Final Dialysis Fluid Conductivity
- Blood Pumps
- Bicarbonate Dialysis Fluid conductivity
- Degassing Pump Flow
- Presence of blood in the Hydraulic Circuit
- Concentrate Container Error
- Dialysis Fluid Flow
- Heparin Pump
- Error in the Single Needle Mode (optional)
- Maximum Dialyzer Pressure at the Dialyzer Inlet and Outlet
- Minimum Dialyzer Pressure at the Dialyzer Inlet and Outlet
- Heater Protection
- Voltage Drop of greater than 20 seconds and less than 4 minutes
- Voltage Drop of less than 20 seconds
- Presence of Air in the Venous Patient Line
- Profiling of Final Conductivity Activity
  (Not currently available)
- Profiling of Ultrafiltration Rate Activity
  (Not currently available)
- Temperature of the Dialysis Fluid
- Ultrafiltration Flow
- Ultrafiltrate Mass Balance
- Venous Pressure higher than the maximum permitted
- Venous Pressure outside the interval selected or less than the minimum permitted
- Arterial Pressure lower than the minimum permitted

- Arterial Pressure outside the interval selected or more than the maximum permitted
- Ultra Pure Water
- Incorrect Voltage
- Activity in Profiling Mode
  (Not currently available)
- Activity of Diascan System
- Control System Communication checking
- Correct Sequence of T1 Tests
- Power Failure
- Long Bypass

If, on encoutering a fault, the relevant safety state is not correctly configured, the protection system places the machine in a **General Safe State**:

1. The Venous Line Clamp is activated;
2. The Power Supply to all other actuators, except those for visual and audible alarms, is turned OFF.

16.5 Disposal of discarded equipment

Discarded electromedical equipment may not be disposed of together with municipal waste but must be collected separately in order to guarantee ecologically correct disposal to prevent dispersion of potential pollutants into the environment.

Pay attention to the fact that some components of the machine (display, batteries, circuit boards, etc.) may contain toxic substances which, if released into the environment, pose a risk to the health of living organisms and the environment itself.

When discarding electromedical equipment used at or through healthcare facilities, it may be returned directly to the local representative/distributor who has supplied it.

When discarding electromedical equipment used in private households, it may be:

- returned free of charge to the distributor at the time of purchasing new equipment
- sent to the specialized collection centres free of charge.

Users who return electromedical equipment to the subjects identified above actively contribute to reuse, recycling and recovery of potentially still useable materials and components and to reduction of the potential risks to the environment and human health.

Abusive disposal of discarded equipment may be punishable by law.

16.6 Preventive maintenance

To keep the machine in good and safe working order, a periodical preventive maintenance of the Artis Dialysis System must be performed both by the operator and by an authorized service technician.

The operator is responsible for a regular preventive maintenance of the solely machine external surface, whereas the machine internal components preventive maintenance must be performed exclusively by an authorized service technician.

16.6.1 Preventive Maintenance performed by the operator

Depending on the ambient conditions, the frequency and the average duration of daily use of the Artis Dialysis System, the operator is required to perform periodical preventive maintenance procedures on the machine external surface. In particular, the operator has to perform:

- External cleaning of the machine surface and outside components. Refer to the "12.9 External Cleaning" section of this Operator's Manual for the procedures and agents to be used.
- External disinfection of the water inlet tube. Refer to the "12.8 Water Inlet Tube disinfection" section of this Operator's Manual for the related procedure.
- External cleaning of the Touch Screen. Refer to the "12.9 External Cleaning" section of this Operator's Manual for the related procedure.
- Visual Inspection of the machine. Refer to the "12.11 Visual inspection" section of this Operator's Manual for the related procedure.
- Cassette Panel O-Rings Inspection and Greasing. Refer "12.12 Cassette Panel O-Rings Inspection and Greasing" section Inspection and Greasing" of this Operator's Manual for the related procedure.
- Replacement of the U9000 ultrafilters. Please refer to "7.18 Ultrafilter Change Procedure" section of the Operator's Manual.

⚠WARNING

No other maintenance procedures than those mentioned above will be performed by the operator of the machine. The machine panels must ***ONLY*** be opened by a fully trained service technician.

⚠WARNING

Stagnant water may contaminate the machine. If the machine is stored for more than 7 days, the water tube should be disinfected and rinsed before using it for treatment.

16.6.2 Preventive Maintenance performed by an authorized service technician

The ambient conditions, the frequency and the average duration of daily use of the Artis Dialysis System determine the maintenance frequency of the internal machine components; however when a maximum of 4,000 working hours has elapsed (or at least once a year) a technical preventive maintenance is required.

⚠WARNING

The manufacturer does not accept any responsibility for damages caused by any operation carried out on the machine by unauthorized staff.

⚠WARNING

Before replacing or checking any component in the Hydraulic Circuit, a Descaling procedure (i.e. a Heat with CleanCart-C disinfection) must be performed.

For a complete description of all the Technical Preventive Maintenance Procedures as well as the replacement frequency of the single components, refer to the “Preventive Maintenance” Section of the Artis Service Manual.

Please find below the list of the spare parts that have to be compulsorily replaced at least once a year:

Part/Assembly	***Sparepart code***	***SparePart Reference***	***Replacement Frequency***
Acid and Bicarbonate pick-up tube connectors (male and female)	6987762	“Acid/Bic Tube Conn AE”	Once a year
Air filter	6988430	“Filter 50 Micron AE”	Once a year
Blood Cassette pressure pods o-rings	6987747	“External O-ring kit”	Once a year
Electrovalves (EVC, EVD, EV1S)	6962468	“2 Way solenoid Valve Peek”	Once a year
EvaClean gasket	6987671	“EvaClean Assy AE”	Once a year
Filter (250u)	6988158	“Filter 250 Micron AE”	Once a year

Part/Assembly	***Sparepart code***	***SparePart Reference***	***Replacement Frequency***
Filter (50u)	6988430	"Filter 50 Micron AE"	Once a year
Heparin syringe plunger lock	6988869	"Syringe plung. lock AE"	Once a year
pH probe	6985089	"pH probe"	Once a year
PRV Pressure regulator	6987978	"PRV AE"	Once a year
Red and Blue dialysis fluid tube connectors (male and female)	6988950	"Dial. connectors male AE"	Once a year
	6988117	"Dial. connectors AE"	Once a year
Ultrafilter holder O-rings	6989537	"Ultrafilter back holder AE"	Once a year
	6987903	"Ultrafilter lower arms AE"	Once a year
	6988984	"Ultrafilter upper holder AE"	Once a year
BiCart Holder arms Lower O-ring BiCart	6988125	"BiCart Holder AE"	Once a year
Ultra Port gasket	6987366	"Sensor Bar Ultra Assy AE"	Once a year
Yellow and clear disinfectant connectors	6988026	"Yell/Clear Disinf Conn AE"	Once a year
SelectCart Holder arms *(not currently available)*	6988786	"SelectCart Holder AE"	Every two years

Periodic Safety Inspection

A safety inspection of the Artis Dialysis System is required at least once a year and according to the local policies. Only trained and qualified technicians are authorized to perform the safety inspection procedures. The inspection consists of the following tests:

Parameter	***Performance***	***Conditions***
Earth Leakage Current 230/240V version 230/240V version	 < 300 uA (typically = 250 uA) < 300 uA (typically = 180 uA)	Normal condition
Protective Earthing	0.2 ohm maximum	Between the protective earth pin in the mains plug and any accessible metal part that is protectively earthed.

16.7 Materials in contact with water, concentrates and dialysis fluid

AISI 303 steel
AISI 304 steel
AISI 904 L
Carbon
Ceramic, Aluminium oxide (Al2O3)
Ceramic, Steatite 221
Ceramic, Zirconium oxide (ZrO2)
Epoxy resin
Ethylene propylene
Ferrite (Barium-Strontium-Ferrit)
Fiberglas reinforced polyamide
Fiberglas reinforced polypropylene
Glass
Graphite
LCP
NBR
PEEK (Polyetherketone)
Peek + CF
Peek + GF
PPE + PS
PES (Polyetheresulphone)
PEX (Polyethylene)
Platinum
Polycarbonate
Polyurethane
PP (Polypropylene reinforced with talcum)
PP (Polypropylene)
PPS (Polyphenysulphide)
PSU (Polysulphone)
PTFE
PTFE (Polytetrafluoro ethylene)
PVC (Polyvinylchloride)
PVDF (Polyvinylidene fluoride)
Santroprene
Silicon rubber
Stainless steel SS2343
Stainless steel SS2353
Stainless steel SS2562
Titanium

16.8 Diascan

The Diascan™ system will be available in the following treatment modes:

- Hemodialysis (DN)
- Isolated UF

Following the main specifications related to this functionality:

Parameter	***Range***	***Accuracy***	***Resolution***	***Conductivity***
Ionic Dialysance	0 to 500 ml/ min	±7 ml/min[a]	1 ml/min	/
Plasma Sodium Concentration	130 to 160 mmol/l	±3 mmol/l[a]	1 mmol/l	/
Plasma Conduct.	13 to 16 mS/cm	± 0.05 mS/ cm[b]	0.01 mS/ cm	13 to 16 mS/ cm (0.05 mS/ cm)
Ionic Mass Bal	-800 to 800 mmol (HD)[b]	±25 mmol[a]	5 mmol	-
Depurated Vol	0 to 200 litres	±2 litres[a]	1.0 litres	/
KT/V	0 to 3	-	0.1	/

a.Accuracy Standard Error for a 4 hour dialysis.
b.Positive values correspond to solutes removed from the patient.

Accuracy is valid in HD double needle and on-line HDF postdilution, for blood flows 200 to 500 ml/min and dialysis fluid flows 500 to 800 ml/min.

The conductivity of the dialysis fluid can be measured by the DIASCAN™ system only if the following parameters fall in the indicated ranges:

Parameter	**Range**
Temperature Range	30-45 °C
Conductivity Range	13 to 16 mS/cm (0.05 mS/cm)

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Appendix A: Guidelines and Manufacturer's Declaration - Electromagnetic Emissions and Immunity

A.1 Guidance and manufacturer's declaration

A.1.1 Electromagnetic emissions

The Artis Dialysis System is intended for use in the electromagnetic environment specified in the table below.

The customer or the user of the Artis Dialysis System should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emission CISPR 11	Group 1	Artis Dialysis System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Artis Dialysis System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

A.1.2 Electromagnetic immunity

The Artis Dialysis System is intended for use in the electromagnetic environment specified in the table below.

The customer or the user of the Artis Dialysis System should assure that it is used in such an environment.

Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	• ±6 KV contact • ±8 KV air	• ±6 KV contact • ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	• ±2 KV for power supply lines • ±1 KV for input / output lines	• ±2 KV for power supply lines • ±1 KV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	• 1 KV line(s) to line(s) • 2 KV line(s) to earth	• 1 KV line(s) to line(s) • 2 KV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	• <5 % U_T (>95 % dip in U_T) for 0.5 cycles[a] • 40 % U_T (60 % dip in U_T) for 5 cycles[a] • 70 % U_T (30 % dip in U_T) for 25 cycles[a] • <5 % U_T (>95 % dip in U_T) for 5 s[a]	• <5 % U_T (>95 % dip in U_T) for 0.5 cycles[a] • 40 % U_T (60 % dip in U_T) for 5 cycles[a] • 70 % U_T (30 % dip in U_T) for 25 cycles[a] • <5 % U_T (>95 % dip in U_T) for 5 s[a]	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Artis Dialysis System requires continued operation during power mains interruptions, it is recommended that the Artis Dialysis System be powered from an uninterruptible power supply or a battery.

Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	• 3 A/m	• 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

a. U_T is the a.c. mains voltage prior to application of the test level.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	• 3 Vrms • 150 KHz to 80 MHz • 3 V/m • 80 MHz to 2.5 GHz	• 10 Vrms • 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Artis Dialysis System including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter. Recommended separation distance d = 0.35 $\sqrt{P}$ *d* = 0.35 $\sqrt{P}$ *80 MHz to 800 MHz* *d = 0.7* $\sqrt{P}$ *800 MHz to 2.5 GHz* where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Artis Dialysis System is used exceeds the applicable RF compliance level above, the Artis Dialysis System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Artis Dialysis System.
b. Over the frequency range 150 KHz to 80 MHz, field strength should be less than 10 V/m.

NOTE

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A.2 Recommended separation distances between portable and mobile RF communications equipment and Artis Dialysis System

Artis Dialysis System is intended for use in the electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of Artis Dialysis System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Artis Dialysis System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distances according to frequency of transmitter (m)**		
W	**150 KHz to 80 MHz** $d = 0.35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.7\sqrt{P}$
0,01	0.04	0.04	0.07
0,1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.21
100	3.50	3.50	7.00
For transmitters rated at maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

NOTE

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.