TECHNICAL MANUAL

OPTIMA
PT/ST/VS

Fresenius Vial
Infusion Technology

TABLE OF CHANGES

The information contained in this document only concerns :

- OPTIMA PT/ST/VS type,
- MCM 440 PT/OT type,
- MCM550 ST type.

Technical Manual reference :.....: NT 1789

Revision date :.....: 27 May 2003

Applicable from serial no :.....: 18180100

Date	Revision no.	Pages concerned	Changes
27/05/2003	A0	All	First release

TABLE OF CONTENT

1. OVERVIEW

1.1. General

The OPTIMA Pump is a new volumetric pump based on the same mechanical pumping mechanism as the MVP pump.

The battery is automatically recharged when the pump is connected to the mains..

A choice of easily accessible configurations ensures optimum use of functions according to the needs of each department.

3 types of OPTIMA exist : VS / PT/ ST

- OPTIMA VS / MCM 440 OT: PVC Type Volumetric pump with standard PVC Set. The Drip sensors is optional. An automatic control of the occlusivity of the pump (OCS –Occlusivity Control System) is implemented.
- OPTIMA PT / MCM 440 PT :PVC Type Volumetric with standard PVC Set. The Drip sensors is compulsory.
- OPTIMA ST / MCM 550 ST Silicone Type Volumetric with standard Silicone Set. The Drip sensors is compulsory
- Mains differences between the types :

Description	VS / OT	PT	ST
Functional differences			
Tube	Standard PVC	Standard PVC	Standard Silicone
Drip Sensor	Optional	Standard	Standard
OCS Test (Occlusivity Control System)	Yes	No	No
Tube Clamping	A mechanical clamp on the device assure the clamping of the tube when the door is opened.	A mechanical clamp on the device assure the clamping of the tube when the door is opened.	A mechanical clamp on the device assure the clamping of the tube when the door is opened.
Maximum Rate	1000 ml/h	1000 ml/h	1500 ml/h
OCS	A dc motor assure the clamping of the tube during OCS	NO OCS -> no DC motor	
Tube clamping during door opening	A mechanical clamp on the device assure the clamping of the tube when the door is opened.		

1.2. Bloc diagrams

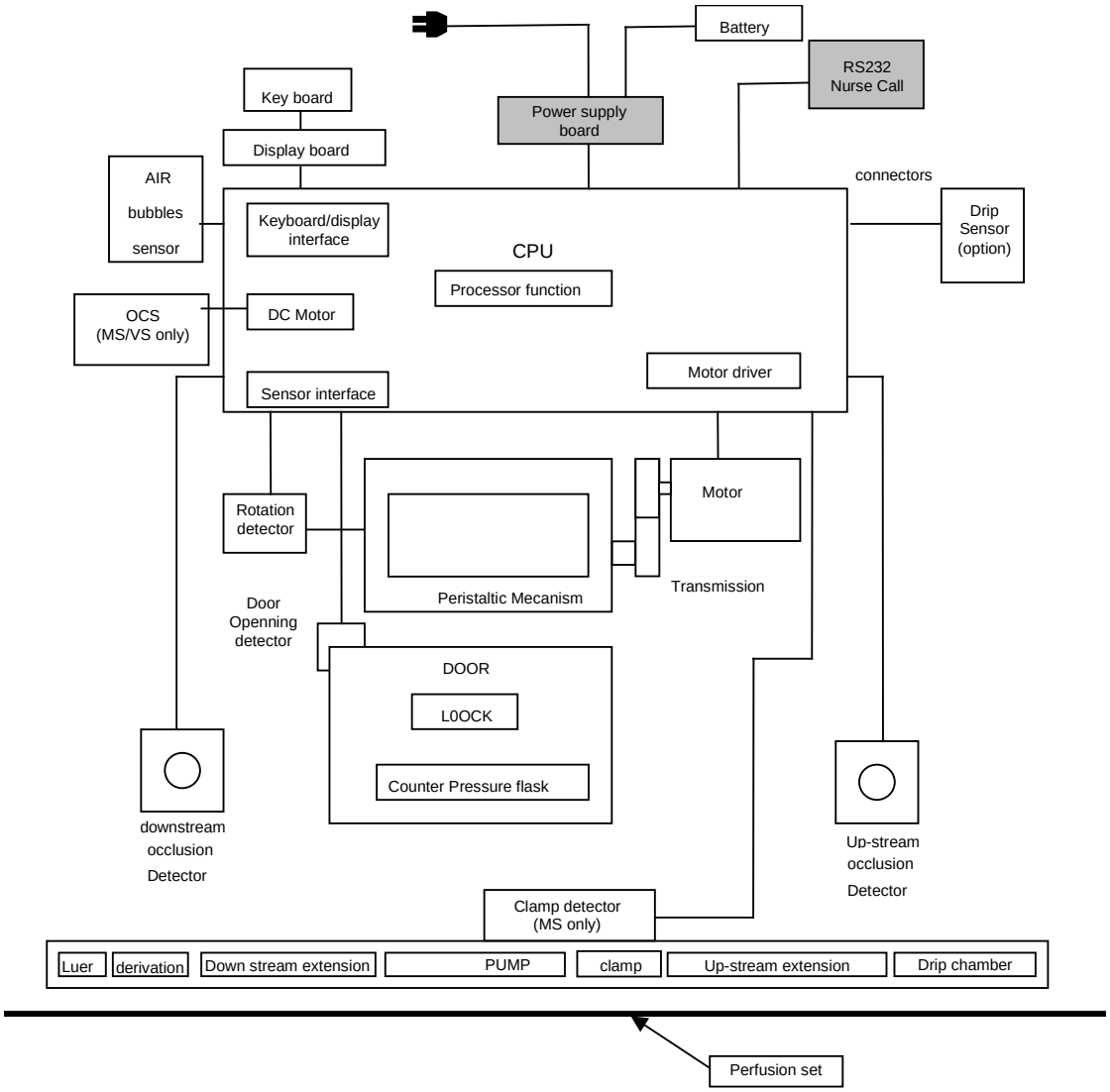


Figure 1. General diagram of the OPTIMA

1.3. Precautions to be taken before use

Please consult the user guide.

1.4. Internal safety features

The pump has a continuous functions inspection system as soon as the pump is ON. . Nevertheless, the qualified personnel in your establishment or our Maintenance Department should always be notified of any abnormal functioning when no specific cause can be found. (See useful addresses, chapter 9)

For any mains failure the pump is powered automatically from its internal battery.

Opening the pump or the battery cover must only be carried out by qualified staff with all the necessary technical precautions. Non-compliance with these procedures may be dangerous for the staff and may damage the Module.

1.5. Technical characteristics

1.5.1. Biological characteristics

The infusion liquid is only in contact with the infusion set.

1.5.2. Mechanical characteristics

The OPTIMA Pump operates with a linear peristaltic system.

1.5.3. Dimensions / Weight

- ❑ H x L x D ..... 135 x 175 x 145 mm
- ❑ Weight ..... 2.9 kg approximately

1.5.4. Electrical characteristics

- ❑ External power supply..... 100 – 240 Vac
- ❑ Power..... 50 VA
- ❑ Battery..... 6V – 2.7/ 3 Ah NiMH.
- ❑ Fuse ..... 2 x 630 mA T IEC 127

1.5.5. Electronic characteristics

The Device contains 4 PCB's:

- CPU PCB.
- Display / keyboard PCB.
- Power Supply PCB.
- Air detection PCB

1.5.6. Operator's guide

The operator's guide is available upon request to our Maintenance Department (see useful addresses at the end of this document)

1.5.7. Registration cards

Registration information is available upon request to our Maintenance Department.

1.5.8. Material used to build the OPTIMA / MCM

- ❑ Top and bottom housing ..... Polycarbonate / ABS
- ❑ Keyboard..... Polyester
- ❑ Stickers ..... Polyester
- ❑ Pump membrane ..... Elastomer (latex free)
- ❑ Drip sensor..... Polycarbonate / ABS or polyamide
- ❑ Rear housing handle..... PC + 10%

1.5.9. Conformity and -symbols

- ❑ Conform EN60 601-1 and EN60 601-2-24.standards

CE0459 marking in compliance with EEC 93/42 Medical Device directive.

IP 31 Liquid projections protected.

CF type device

Battery.

CLASS I device

- ❑ Each symbol shows below is visible on the device or in this document.

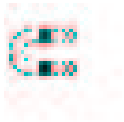
Refer to accompanied documents.

Equipotentiality

Protective earth

RS 232 RS232 Communication Interface 4000V insulation

Nurse Call 4000V insulation / 24Vdc-1A



Permanent magnet allowing the fixing of drops sensor

2. ELECTRONIC BOARDS

2.1. CPU board

2.1.1. Functional description.

2.1.1.1 CPU

Main Microprocessor ..... T80c5112 / 512 Ko of Flash / 8Ko of RAM

External RAM ..... 32 Ko

EEPROM ..... 16 Ko

Secondary Microprocessor MSP430

Control frequency of the main microprocessor, time keeper function, ON/OFF function and control the charge of the battery.

2.1.1.2 Stepper motor control

The motor is powered with 12 or 20 volts according to the flow rate.
The signal command is performed either by ½ step or ¼ step according to the requested flow rate.

2.1.1.3 Rotation control

An optical sensor verifies the rotation of the came shaft.
This sensor generates an alarm for any difference higher than ± 5 % with the programmed value

2.1.1.4 Door detector

A Hall effect sensor placed in the Module and a magnet located in the door
This sensor detects door opening and set missing when door is closed.

2.1.1.5 Drip sensor (optional on Optima MS and VS or MCM 440 OT)

The drip detection is performed by an optical sensor.
An infra-red filter avoids interference due to external light.
This sensor generates an alarm for any flow rate difference higher than ± 40% of the programmed value

2.1.1.6 Downstream pressure sensor

This sensor detects downstream occlusion on the infusion line.
It also detects the right positioning of the infusion set when the door is closed.
It generates an alarm in both cases.

2.1.1.7 Up-stream pressure sensor

This sensor detects up-stream occlusion on the infusion line when the drip sensor is absent.
This sensor detects the right positioning of the infusion set when the door is closed.
It generates an alarm in both cases.

2.1.1.8 Buzzer

The device is equipped with 2 buzzers triggered by the microprocessor.

2.1.1.9 On/Off function

When the device is connected to the mains, it is in **"stand by"** mode.

Switching ON is performed

- Either by pressing the ON/OFF key
- Or by opening the door, according to the software configuration.

Switching OFF is performed :

- Either manually by pressing the ON/OFF key
- Or automatically when battery is low.

The On/off function is performed by the secondary microprocessor

2.1.1.10 Battery charge management

The battery charge is managed by both primary and secondary microprocessors.

2.1.1.11 Air detector

An ultra- sound sensor allows to detect air bubbles in the infusion set.
It generates an alarm if air bubbles are larger than programmed value.

2.1.1.12 Automatic OCS clamp

The OPTIMA MS and VS or MCM MS and OT are equipped with a DC motor actuated clamp. After each infusion start or door closing, the infusion set is clamped by this system and the device checks then pumping mechanism occlusivity.

2.1.1.13 Nurse Call / RS232

The RS232 and Nurse Call have both 4000 V dielectric strenght. The Nurse call relay is rated 24 VDC/1A.

2.1.2. Connectors description

2.1.2.1 General

Connector	Pin number	Function
J7	2x17	For development purpose
J3	2x7	For manufacturing
J9	1x4	Air Sensor
J1	1x20	CPU/Display interconnection
J12	1 x 4	Drip Sensor
J4	1 x 4	Stepper Motor
J6	1 x 3	Power Supply
J8	1 x 4	Battery
J5	1 x 6	Not Used
J11	1 x 8	RS232 / NURSE CALL
J10	1 x 2	DC motor
J2	1 x 20	Sensors

2.1.2.2 J9 – Air Sensor

Pin	Description	
1	/TST	Sensor check
2	5V	Power Supply
3	GND	Ground
4	/DETECT	Air output signal

2.1.2.3 J1 – CPU/Display board interconnection

Pin	Description	
1	5V	Power Supply
2	VBAT	Battery voltage
3	GND	
4	MOSI-AFF	Serial output
5	GND	
6	MISO_AFF	Serial Input
7	GND	
8	CLK-AFF	Serial clock
9	GND	
10	CSLCD	Chip Select LCD
11	GND	
12	CSAFCL	Chip Select Display

Pin	Description	
13	GND	
14	A0AFF	LCD Adress
15	GND	
16	RESET/	
17	GND	
18	TON/OFF	ON/OFF signal
19	VBAT	Battery Voltage
20	5V	Power supply

2.1.2.4 Drip Sensor

Pin	Description	
1	CDLED-goutte	Led command 5V / 40 mA
2	GND	
3	GND	
4	Pulse-goutte	Output drop signal

2.1.2.5 J4 - Stepper motor

Pin	Description	
1	+ Bobine A	+ Coil A
2	- Bobine A	- Coil A
3	+ Bobine B	+ Coil B
4	- Bobine B	- Coil B

2.1.2.6 J6 – Power Supply

Pin	Description	
1	ALIM EXT	Not Used
2	GND	
3	ALIM SECT	Power Supply 9V / 1.3A

2.1.2.7 J8 Battery

Pin	Description	
1	VBATNC	+ Battery
2	ANA-CTN	Temperature sensor output
3	GND	
4	VBATNP	+ Battery before thermal fuse (fuse breakdown detection)

2.1.2.8 J11 RS232/Nurse Call

Pin	Description	
1	TxD-PC	Data Reception from PC
2	RTS-PC	Request to send from PC (Should be positioned at high state)
3	DTR-PC	Data Terminal Ready of PC (Should be positioned at high state)
4	RXD-PC	Data Transmission to PC
5	GND	
6	Nurse Call	Normally Opened Contact
7	Nurse Call	Common Contact

8	Nurce Call	Normally closed Contact

2.1.2.9 J10 - D.C. motor

Pin	Description
1	+ DC motor.
2	- DC motor.

2.1.2.10 J2 – Sensors

Pin	Description	
1	GND	
2	Pres-Clamp	Switch clamp output
3	CD-Clamp	Switch clamp power supply
4	Up-Force Sensor	Upstream force sensor output
5	Up-Force Sensor	Upstream force sensor – input
6	Up-Force Sensor	Upstream force sensor output
7	Up-Force Sensor	Upstream force sensor + input
8	GND	
9	Hall effect sensor	Hall effect power supply
10	Hall effect sensor	GND
11	Hall effect sensor	Hall effect output
12	Dw-Force Sensor	Downstream force sensor output
13	Dw-Force Sensor	Downstream force sensor – input
14	Dw-Force Sensor	Downstream force sensor output
15	Dw-Force Sensor	Downstream force sensor + input
16	GND	
17	ET-OPTO	Outlet opto signal
18	CD-LED	LED driver
19	GND	Opto ground
20	5V	LED Power supply

2.1.3. Electronic drawings

On request at Fresenius Vial After Sales Service department

2.1.4. Components layout

On request at Fresenius Vial After Sales Service department

2.2. Display board

2.2.1. Functional description

The display board is considered as a peripheral board of the CPU board.

- The keyboard matrix is connected to this board.

- Display description

Function	Display
Flow rate m/l	4 green 7-segment LED display
Alarm	1 red LED
Pre-alarm	1 orange LED
Perfusion signal LED's	4 green LED
Drop LED's	1 green LED
Battery LED's	1 green LED
Mains LED's	1 orange LED
Perfusion start LED's	1 green LED
LCD	33x100 points LCD display

2.2.2. Connector description

2.2.2.1 General

J1	1 x 20 Pins	CPU/Display boards Interconnection
J2	18 Pins	LCD connector
J3	10 Pins	Keyboard connector

2.2.2.2 J1 - CPU/Display Board interconnection

Pin	Description	
1	5V	Power Supply
2	VBAT	Battery voltage
3	GND	
4	MOSI-AFF	Serial output
5	GND	
6	MISO_AFF	Serial Input
7	GND	
8	CLK-AFF	Serial clock
9	GND	
10	CSLCD	Chip Select LCD
11	GND	
12	CSAFCL	Chip Select Display
13	GND	
14	A0AFF	LCD Address
15	GND	
16	RESET/	
17	GND	
18	TON/OFF	ON/OFF signal
19	VBAT	Battery Voltage
20	5V	Power supply

2.2.2.3 J2 LCD Connector

Pin	Description	
1	VBAT	+ back light
2	-led	- back light
3	+5V	
4	/RESET	
5	VSS	Gnd
6	LD0	Data Write
7	GND	Write Select
8	LD6	Data Write
9	A0AFF	LCD Address
10	LD5	Data Write
11	LD4	Data Write
12	LD3	Data Write
13	LD2	Data Write
14	LD1	Data Write
15	LD0	Data Write
16	-	Enable
17	LCDCS2	Chip select
18	LCDCS1	Chip select

2.2.2.4 J3 keyboard Connector

Pin	Description	
1	COL2	Keyboard Column
2	COL1	Keyboard Column
3	COL0	Keyboard Column
4	Ligne 3	Keyboard Line
5	Ligne 2	Keyboard Line
6	Ligne 1	Keyboard Line
7	Ligne 0	Keyboard Line
8	TON/OFF	On / Off
9	CONTRÔLE	Keyboard Control line
10	GND	

2.2.3. Electronic drawings

On request to Fresenius Vial After Sales Service department

2.2.4. Components layout

On request to Fresenius Vial After Sales service department

2.3. POWER SUPPLY BOARD

2.3.1. Functional description

An AC / DC 12W Module convertor (switching mode power supply) convert the mains input voltage (100 – 240 Vac) to 9Vdc 1.3A. This voltage is used to charge the battery and power the device.

ECG/EEG noise rejection filter : 2 Class X2 Capacitor and a 10Kohms resistance connected to a functional earth garanteed the EEG/EEG noise rejection

2.3.2. Connector description

2.3.2.1 General

Connector	Pin	Function
J1	1 x 1	Functional Earth
J2	1 x 2	Main supply connector
J3	1 x 3	Output power supply
J4	1 x 4	Battery Output
J5	2 x 5	Battery Input

2.3.2.2 J1 Functional Earth

Pin	Description	
1	-	Functional Earth

2.3.2.3 J2 Main Supply Connector

Pin	Description	
1	PH	Phase (100 – 240 Vac)
2	N	Neutral (100 – 240 Vac)

2.3.2.4 J3 Output Power supply

Pin	Description	
1	9V Sect	9V Output from AC/DC converter
2	GND	
3	9V Ext	9V From external power Supply (not used)

2.3.2.5 J4 Battery Output (this connector goes to the CPU board)

Pin	Description	
1	VBAT	+ Battery
2	+ Capteur Temp	Temperature Sensor output
3	Masse	GND
4	VBAT NP	+ Battery before thermal fuse (fuse breakdown detection)

2.3.2.6 J5 Battery Input (this connector comes from the battery pack)

Pin	Description	
1	VBAT	+ Battery
2	VBAT NP	+ Battery before thermal fuse (fuse breakdown detection)
3	+ Capteur Temp	Temperature Sensor output
4	- Capteur Temp	Temperature Sensor GND
5	Masse	Battery GND

2.3.3. Electronic drawings

On request to Fresenius Vial After Sales Service department

2.3.4. Components layout

On request to Fresenius Vial After Sales Service department

2.4. Air detector board

The air sensor is based on an ultrasonic sensor.

2.4.1. Electronic drawings and Components layout

The air sensor is based on an ultrasonic sensor.

3. Configuration, calibration and check

The configuration and calibration of the device are accessible :

- using the serial link (RS232) and the Fresenius Vial PC software to configure and calibrate the pump.
- Using the keyboard of the pump through a special encoded menu.

For further information, please contact our Maintenance Department (See addresses at the end of this document)
Any change, in the configuration leads to major changes in Module running, Staff trained on the software and devices are the only people authorised to performed theses operations.

3.1. Configuration

This mode is actived by pressing MODE key when switching ON the pump/
The main menu display :

- User setting
- Ward setting
- Maintenance

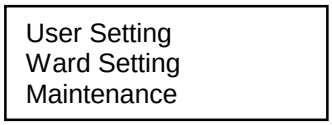
Each menu is composed with some sub-menu , press confirm key or “enter” to get through.
Some menu need a code to access to the sub-menu

The access code of “user setting” can be defined or disabled in the “ward setting”.
Once the access code is typed it is not necessary to type it again as long as the device is not switched off.
The 7 segments displays are off during the display of the main menu and codes typing.

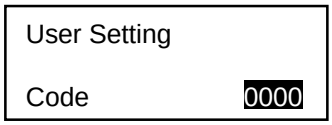
Main menu	Code Typing	Sub-menu	Sub-menu
Maintenance			
	This code will be given at the end of the maintenance staff training		
		Test	
			Maintenance test menu
		Maintenance configuration	
			Maintenance configuration menu
		Calibration	
			Maintenance calibration menu
User setting (see operator’s guide)			
	Code XXXX		
			User configuration menu
Ward setting (see operator’s guide)			
	Code 0200		
			Service configuration menu

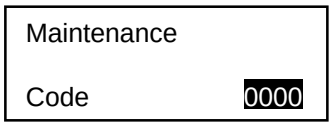
Maintenance	Test	tSt 1	Test1	Work duration display
		tSt2	Test2	LED's, LCD screen, 7- segment displays and buzzers test.
		tSt3	Test3	Keyboard test.
		tSt4	Test4	Battery voltage display
		tSt5	Test5	Last 10 alarms display.
		tSt6	Test6	Total work duration display.
		tSt9	Test9	Analog sensors value display.
		tStA	TestA	Software version number display.
		tStC	TestC	Clamp DC motor test.
		tStE	TestE	Calibration values display.
		tStF	TestF	Infusion stepper motor test.
		tStJ	TestJ	Before failure last 10 alarms codes display
	Configuration	SAU 1	SAV1	Preventive maintenance
		SAU2	SAV2	Tubing Set configuration
	Calibration	EtA 1	Etal1	Door calibration.
		EtA2	Etal2	Infusion correction coefficient configuration.
		EtA9	Etal9	Up-stream and down-stream pressure sensors calibration.

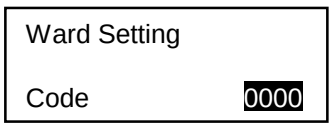
Main menu



Access code type

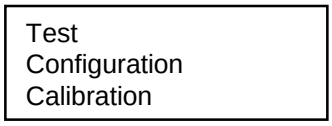






Code selection with Selection keys (or)
Proceed to sub-menus with confirm key or ENTER keys.
Code back to 0 if incorrect code validation, after 15 seconds non validation = beep.
STOP = back to main menu.

Maintenance sub-menu



3.2. Calibration

Calibration is possible on :

- Down-stream pressure sensor.
- Up-stream pressure sensor.
- Door Hall effect sensor..

Calibration is compulsory in the following cases

- Down-stream pressure sensor :
  After change of sensor, of its protective diaphragm, of the door or CPU board
- Up-stream pressure sensor :
  After change of sensor, of its protective diaphragm, of the door or CPU board
- Door Hall effect sensor :
  After change of sensor, of the door or CPU board

❑ The CPU board is configured with specific parameters for each Device, so it is forbidden to change CPU boards from a device to an other.

❑ For the same reasons, it is forbidden to change door from a device to another

3.2.1. Manual calibration menu

SELECTION keys = calibration choice

CONFIRM or ENTER keys = calibration procedure

STOP key = back to maintenance menu. Values are not memorised.

Calibration number is displayed on 7 segments display and simultaneously displayed in inverse video on LCD screen.

Etal1-Door
Etal2-Rate
Etal9-Pressure

Calibrations list :

Etal1 : door.

Etal2 : Infusion correcting coefficient configuration.

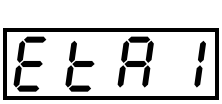
Etal9 : Up and Down-stream pressure sensor.

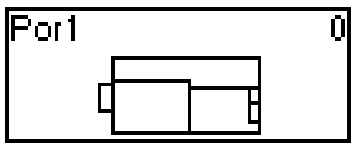
3.2.2. Door calibration (Etal1)

❑ 3 levels are calibrated

❑ Note : Pressing STOP allows to escape from the menu without memorisation.

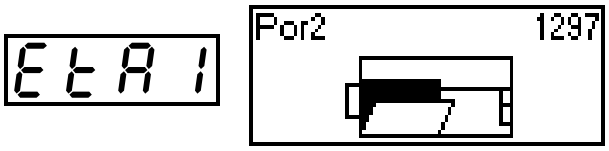
❑ Door closed without set :





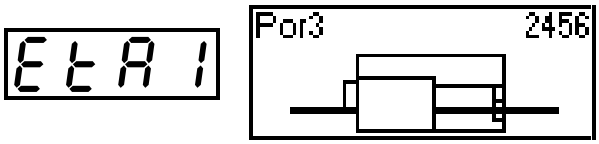
Close the door without set, record the value by pressing on or ENTER key.

❑ Door open without set :



Open the door without set, record the value by pressing on ⊙ or ⓩ ENTER key.

❑ Door closed with set :



Place a set with the clamp correctly positioned and close the door, record the value by pressing on ⊙ or ⓩ ENTER key.

Values :

Door closed without set :
1196 < X < 3750 mVolts

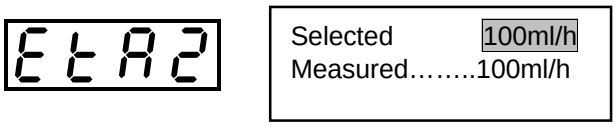
Door opened without set :
2197 < X < 2695 mVolts

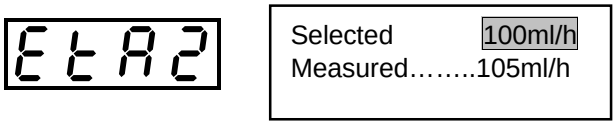
Door closed with set :
1699 < X < 3398 mVolts

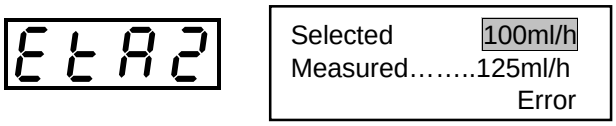
3.2.3. Correcting coefficient adjustment (Etal2)

This function allows to adjust the flow rate of the device according to the used set.
The adjustment range allows a correction up to –20% +10%
Measure the flow rate for a flow rate of 100 ml/h. Install the tube full with non mineral water, the container should be at 50cm above the device. Place a weight balance (0.01 g resolution and accuracy) at the same level as the device. Place a needle at the end of the tubing set. Collect on the balance the infused water. Select the rate and infuse for around 15 min. Press STOP on the device. Reset the balance (000g). Press START on the device (the pump infused at 100 ml/h). Infused for at least 15 min. Stop the infusion. Note the infused volume and time. Calculate the measured flow rate (volume collected on the balance / infusion time)

The Correcting coefficient adjustment is performed in Etal2.







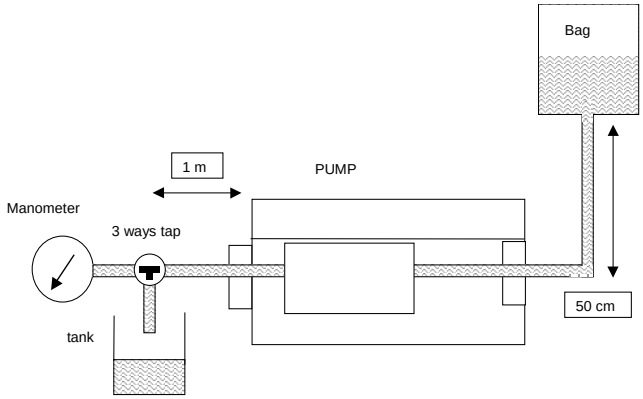
SELECTION key (⌃ or ⌄) : selects the programmed flowrate(100, increment 1 ml/h) and actual flow rate (80 à 120 ml/h).
ENTER key : to select a field value.
confirm key : calculate record the new coefficient if included between 0.8 and 1.1 times the programmed one, back to the configuration menu otherwise Error is displayed.

STOP key : back to the menu without calculation of the coefficient.

Note : After flowrate adjustment a control of the flowrate should be done

3.2.4. Up and Down stream pressure sensors calibration (Etal9)

This calibration should be done with the set selected on the pump in SAV2. sea §3.4.3, Set number Configuration (SAV2)
The set has a relaxation time when the door is closed, so follow precisely the following procedure to guarantee the occlusion alarm level.



Test set

The manometer and the device should be placed at the same level

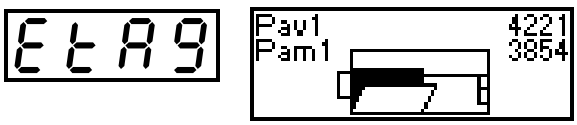
❑ Calibration

RAZ Presure calibration NO

Complete calibration choice YES or NO through the selection key . If Yes, the force sensor calibration values are set to zero for all the tubes
YES choice is mandatory for any replacement of the force sensor door or CPU board
NO choice does not set to zero the force sensor calibration value for the other tubes, only the one selected on the pump is set to zero. See §3.4.3, Set number Configuration (SAV2)
The following procedure allows to carry out the calibration of the active tube.

3.2.4.1 Door open

1. Open the door of the device without disposable set.
2. Record the values " door open down-stream pressure" and "door open up-stream pressure by pressing on ENTER ⏎



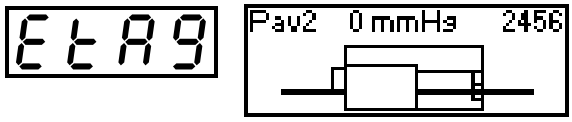
Values :

door open down-stream pressure threshold :
1997 < X < 4453 mVolts

door open up-stream pressure threshold :
1997 < X < 4297 mVolts

3.2.4.2 Calibration of the down-stream pressure sensor at pressure zero (0 mmHg), Door closed.

1. Place a disposable infusion set as described here above and open the 3 ways tap between the pump and the manometer.
2. To relax the infusion set, press on the confirm key -> the pump run at 200 ml/h.
3. When the pressure reaches about 750 mmHg, open the 3 way tap to release the pressure.
4. Let infuse at zero pressure for about 5 minutes.
5. Stop the device by pressing on STOP.
6. Record the pressure by pressing ENTER;

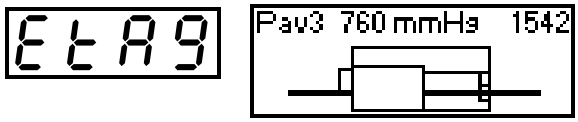


Values :

down-stream pressure sensor at pressure zero (0 mmHg), Door closed :
1499 < X < 3696 mVolts

3.2.4.3 Calibration of the down stream pressure sensor at 750 mmHg, Door closed;

1. Close the tap between the pump and the manometer.
2. Start the pump by pressing confirm key.
3. Open and close the tap until the manometer pressure reaches 750 mmHg ± 30 mmHg
4. Stop the pump by pressing on STOP key.
5. Record the pressure by pressing on ENTER key.

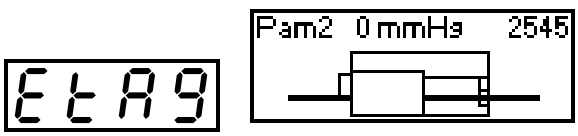


Values :

down stream pressure sensor at 760 mmHg, Door closed
898 < X < 2998 mVolts

3.2.4.4 Calibration of the up stream pressure sensor at 0 mmHg

1. Open the tap between the pump, the manometer and tank.
2. Wait until the pressure set to zero.
3. Infusion set still in place and door closed, press ENTER key to record the value.



Values :

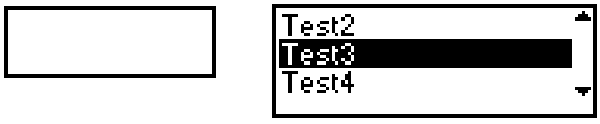
up stream pressure sensor at 0 mmHg
1499 < X < 3696 mVolts

3.3. Tests : Maintenance tests

3.3.1. Manual Service test menu

Choice with SELECTION keys
Proceed with confirm or ENTER keys.
Back to maintenance menu with STOP. (no parameter stored)
Test number is displayed on 7 segments display and simultaneously on LCD screen.

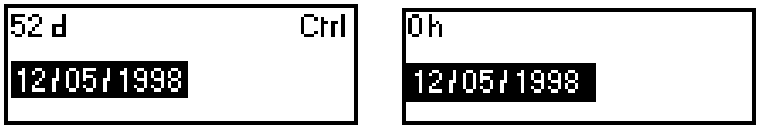
3.3.2. Maintenance tests list :



Test1 : Display of working duration and number of switching on.
Test2 : LED's, LCD screen, 7 segments display and buzzers test.
Test3 : Keyboard test .
Test4 : Battery voltage display.
Test5 : Last 10 alarms codes display.
Test6 : Total working duration and total number of switching on.
Test9 : Analog sensor value display.
TestA: Software version number display.
TestC : Clamp dc motor test.
TestE : Calibration values display.
Test F: Infusion motor test.
TestJ : Last 10 alarms before fail codes display.

3.3.3. Working duration (Test1)

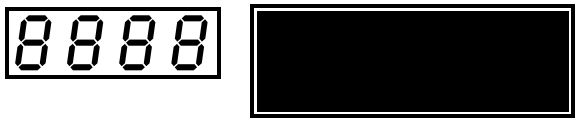
Display the cumulated pump working time in hours (<72 hours) in days (<120 days) or in months and the maintenance date.
Flashing display Ctr 1, if pump working time is ≥ time before maintenance (see SAV1) or if actual date ≥ maintenance date (SAV1).



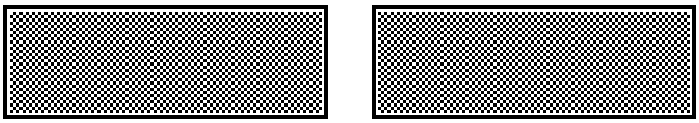
ENTER : selects date
SELECTION : changes maintenance date in actual date or restores configured maintenance date.
(if maintenance date = actual date then display = 0 h and Ctrl = erasing)
Confirm and ENTER : saves changes and goes back to test menu.
STOP : goes back to test menu with erasing of change of maintenance date.
If date of maintenance is changed then working duration is set to zero.

3.3.4. LED's, LCD screen, 7 segments display and Buzzers Test (Test2)

Lighting of all the LED's, display of 8 plus decimal point on the 7 segments display, LCD screen completely black; wait for pressing on ON or ENTER.



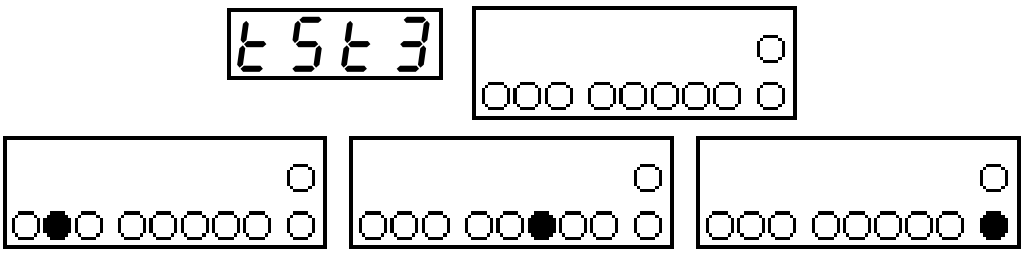
Scrolling of LED, one by one, scrolling of segments one by one on all the display then scrolling of 8 and decimal point on each display. Scrolling of LCD screen image.



Back to test menu (manual test).

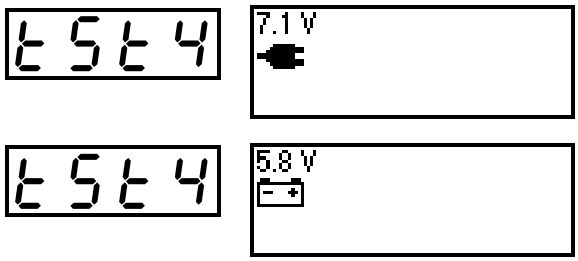
STOP : quick return to test menu (manual test).

3.3.5. Keyboard test (Test3)



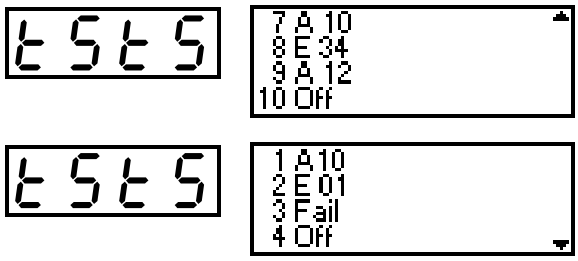
Display of pressed keys in inverse video.
Confirm or ENTER : back to test menu.

3.3.6. Battery voltage display (Test4)



Confirm or ENTER : back to test menu.

3.3.7. Display of the last 10 alarms codes (Test5)

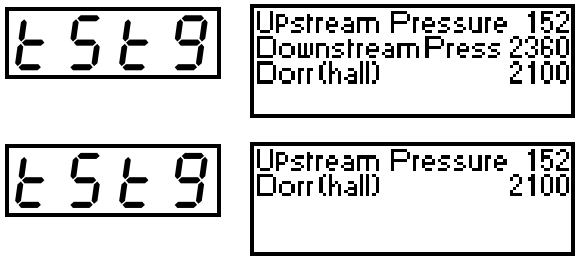


SELECTION : Codes scrolling.
Confirm or ENTER : back to test menu.

3.3.8. Total working duration (Test6)

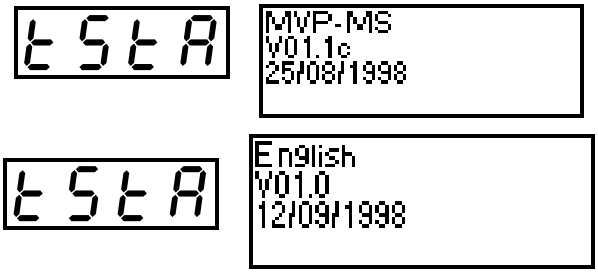
Display the Total pump working duration independent of Test 1. The Display duration can't be set to zero.

3.3.9. Display analog values of sensors (Test9)



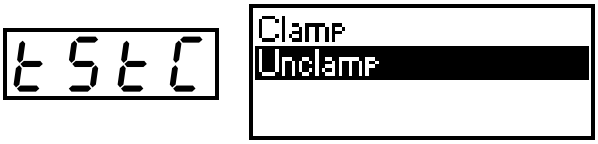
Display of analog input values in form 0-5000 for 0-1024 Lsb.
No display for up-stream sensor if not used.
Confirm or ENTER: back to test menu

3.3.10. Display of software version number (TestA)



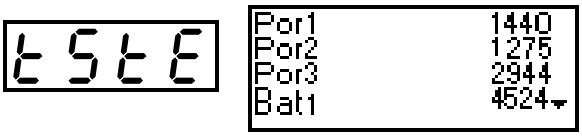
Confirm or ENTER : proceeds to language version then back to test menu.
SELECTION : language scrolling.

3.3.11. Motor clamp Test (TestC)



SELECTION : function choice.
Confirm or ENTER : Run clamp or unclamp.
STOP : stops motor and return to test menu if motor already stopped.
Clamp: the dc motor turns forward to clamp.
Unclamp : the dc motor turns backward to unclamp.
If problem on clamp motor driver then LCD screen black and “Er31” displayed on 7 segment display.
STOP : to return to test menu.

3.3.12. Calibration values display (TestE)

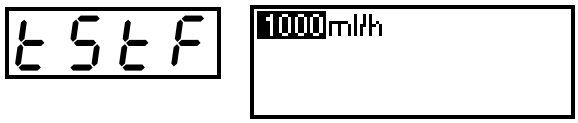


SELECTION : scrolling of calibration values.
Confirm or ENTER : back to test menu
Display of calibration values in form 0-5000 for 0-1024 Lsb.
The calibration values list is as following:
Por1 : Hall effect sensor, door closed, without set.
Por2 : Hall effect sensor, door opened.
Por3 : Hall effect sensor maximum value , door closed, with set.
Pam1 : Upstream pressure, door open.
Pam2 : Upstream pressure, 0 mmHg.
Pav1 : Downstream pressure, door open.
Pav2 : Downstream pressure, 0 mmHg.
Pav3 : Downstream pressure, 750 mmHg.

The value between brackets gives the number of calibrations done.
Display of upstream and downstream pressure calibration values in accordance with active set number.

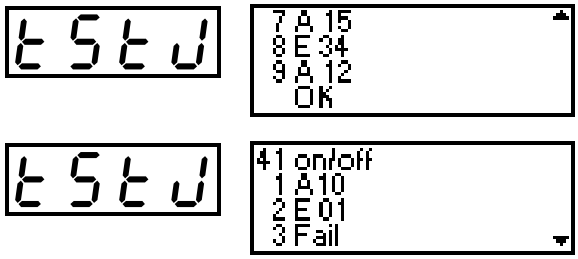
3.3.13. Infusion motor Test (TestF)

This test allows to set the motor running without alarm management.



SELECTION : selection of infusion flow rate (0.1 ml/h à 1000 ml/h).
ENTER : flow rate validation.
STOP : stops motor and return to test menu if motor already stopped
If motor problem then LCD screen blank and “Er01, Er11, or Er21 ” displayed on 7 segment display.
STOP : to return to test menu.

3.3.14. Display of last 10 alarms before a failure occurs (TestJ)



SELECTION : scrolling number of switching on then error and codes.
Confirm or ENTER: back to test menu.

3.4. Maintenance Service Configuration.

3.4.1. Service configuration Menu.

Display of configuration number on 7 segments display and coloured inverse on the LCD screen at the same time.

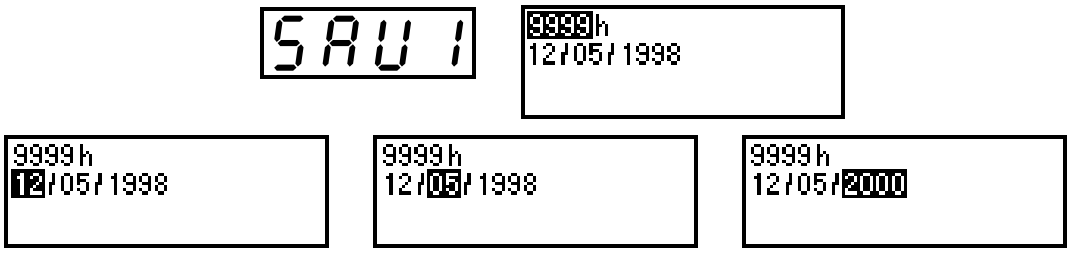
SELECTION : configuration selection.
Confirm or ENTER: configuration execution.
STOP : return to test menu.

Service configurations list :

- SAV1 : preventive maintenance.
- SAV2 : set number configuration.

Display of configuration number on 7 segments display and coloured inverse on the LCD screen at the same time.

3.4.2. Preventive maintenance (SAV1)



SELECTION : number of hours before maintenance or date of maintenance selection.
ENTER : changes one field to another.
Confirm : back to Service configuration menu with recording of new duration and date.
STOP : erases the last changes and goes back to Service configuration menu.
Choice of number of hours before maintenance between 1 and 9999 hours.
0 inhibits the request of preventive check with the working duration.
Choice of the date between 01/01/1990 and 31/12/2079.
One of the three numbers = 0, inhibits the request of preventive check with the date.

3.4.3. Set number Configuration (SAV2)

Display of different sets available for the pump type.
A check mark shows the sets already calibrated.
SELECTION : moves up or down in the set list.
Confirm or ENTER: saves the set selection (coloured inverse selection)
STOP : cancel the last selection and return to calibration menu.
If a non-calibrated set is selected, at the next switching on, the device is locked in occlusion and/or upstream pressure alarm, requiring calibration.

3.5. Technical failures messages.

Any technical fail use initiates an error code as well as a continuous sound alarm.
An error code is displayed on the 7 segments display.

Error codes Err xx	Description
10	Internal RAM problem
20	External RAM problem
30	Incoherent EPROM check sum
40	EEPROM problem
50	ADC problem
60	Incoherent infusion set parameter
70	Motor frequency incompatibility.
80	Keyboard problem.
01	Motor rotation error.
11	Motor rotation error.
21	Motor rotation error.
31	DC Motor.
41	Motor rotation error.
03	Serial link transmission error
14	Error on motor period calculation parameters verification
24	Motor rotary direction incompatibility.
44	Quartz frequency incompatibility.
54	display board missing.
74	No battery connection.
84	Battery charge error
56	Software problem.
28	Non compatible language file.
55	clock failure
94	Battery temperature error
55	Secondary microprocessor error
85	Secondary microprocessor error
16	Date / time check error

Alarm codes A xx	Description
10	Battery
12	End of infusion
16	Downstream Occlusion
17	Air detection
18	Air detection
19	Upstream Occlusion
20	No tubing set
21	No clamp

Alarm codes A xx	Description
22	Door
23	No drip sensor
24	Drip sensor : low flowrate
25	Drip sensor : high flowrate
26	Free flow
27	Occlusion control

4. REPLACING SUB-ASSEMBLIES

4.1. Module opening.

When opening the OPTIMA, anti-static precautions must be strictly applied.
The use of anti-static carpet and grounded bracelets is highly recommended.
Disconnect battery as soon as the Module is opened.

4.2. Replacing CPU board.

In case of CPU board replacement, systematically perform configuration and calibration as described in chapter 3.

4.3. Dismounting pumping mechanism.

Retract the door axis and remove the door. Remove the sticker up to the pumping mechanism to unscrew axis holder.
Unscrew the 4 fixing screws of the pumping mechanism.

4.4. Replacement of pressure sensors.

In case of replacing pressure sensor, systematically perform configurations and calibrations described in chapter 3.
Be extremely careful within the direction of the sensor positioning (lead output).

4.5. Replacement of door or of Hall effect sensor

In case of replacing these elements, systematically perform configurations and calibrations described in chapter 3

5. MAINTENANCE

5.1. Recommendations

The qualified technicians in your establishment or our Maintenance Service should be notified of any abnormal operation of the device.

For further information concerning troubleshooting or usage procedure, please contact our Maintenance Department or our Sales Representative. (see Useful Addresses, chapter 9)

If the device has to be returned to our Maintenance Service, it must be disinfected and packed very carefully, if possible in its original packaging.

FRESENIUS VIAL INFUSION SYSTEMS is not liable for loss or damage to the device during transport to our Maintenance Service.

5.2. Cleaning and disinfecting

The Module DPS and the FRESENIUS VIAL Infusion Station form part of the patient's immediate environment. It is advisable to clean and disinfect the device's external surfaces on a daily basis in order to protect patient and staff.

- ❑ Disconnect the FRESENIUS VIAL OPTIMA Pump from the mains supply before starting to clean.
- ❑ Do not place in an AUTOCLAVE nor IMMERSE the device. Do not let liquids enter the device's casing.
- ❑ Use a cloth soaked in DETERGENT-DISINFECTANT, previously diluted with water if required.

  Avoid abrasive scrubbing which could scratch the casing

  Do not rinse or wipe surfaces.
- ❑ If the device is placed in a high contamination risk unit, it is advisable to leave it in the room during fumigation disinfecting, after having disinfected it with a moist cloth.
- ❑ Do not use:
  - ➢ TRICHLOROETHYLENE-DICHLOROETHYLENE,
  - ➢ AMMONIA,
  - ➢ AMMONIUM CHLORIDE,
  - ➢ CHLORINE and AROMATIC HYDROCARBON,
  - ➢ ETHYLENE DICHLORIDE-METHYLENE CHLORIDE,
  - ➢ CETONE

These aggressive agents could damage the plastic parts and cause device malfunction.

- ❑ Take care also with ALCOHOL BASED SPRAYS (20% - 40% alcohol). They lead to tarnishing and small cracks in the plastic, and do not provide the necessary cleaning prior to disinfecting.
- ❑ For further details, contact the service in charge of cleaning and disinfecting products of your establishment .

5.3. Storage

The device should be stored in a dry and cool place. In case of prolonged storage time, disconnect the battery through the battery door located on the rear panel . This operation should be made by qualified technician.

When storage a full recharge of the battery is recommended before restarting the pump, in order to avoid any risk caused by micro mains supply cuts and to insure maximum autonomy.

Storage place should be :

Temperature between -10°c and 60°c

Maximum relative humidity 90% no condensation.

5.4. Routine inspections

5.4.1. Checking before use

(Refer to operating instructions)

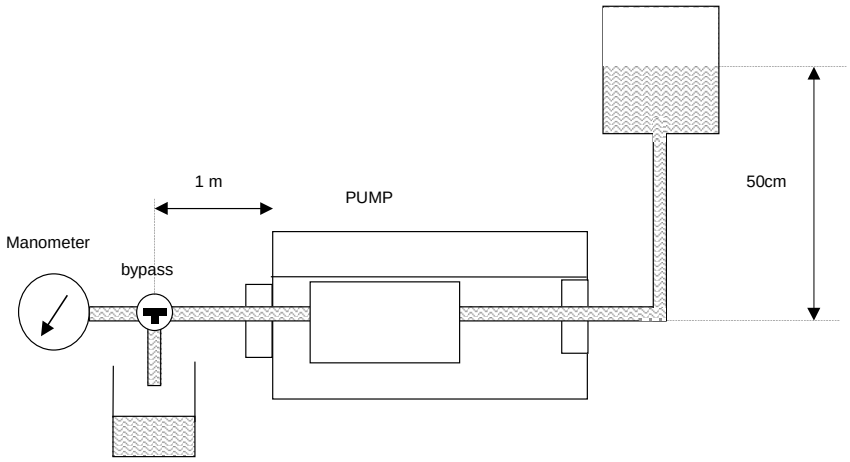
In order to ensure optimal work of the device, regular servicing inspections and tests are recommended.

A servicing check procedure should include the points listed below. These service checks are not covered by any contract or agreement with FRESENIUS VIAL INFUSION SYSTEMS and are the responsibility of the User's technical staff. For further information, please contact our Maintenance Service.

- ❑ Note: Failure to comply with these maintenance procedures could damage the device and lead to a functional failure.

5.4.2. Occlusion alarm checking

1. Make the following installation.



2. Program a 125 ml/h flow rate and a counter pressure alarm at 500 mmHg.
3. Start infusion with bypass closed between manometer and pump
4. After 5 minutes of infusion at 0 pressure, open bypass between the manometer and the pump.
5. When alarm goes, check the pressure P displayed by the manometer is correct :

   P= 500 mmHg ± 75 mmHg -> 0.65 ± 0.1 bar
6. Do the test again with a programmed counter pressure of 750 mmHg.

   P= 750 mmHg ± 110 mmHg -> 1 ± 0.15 bar

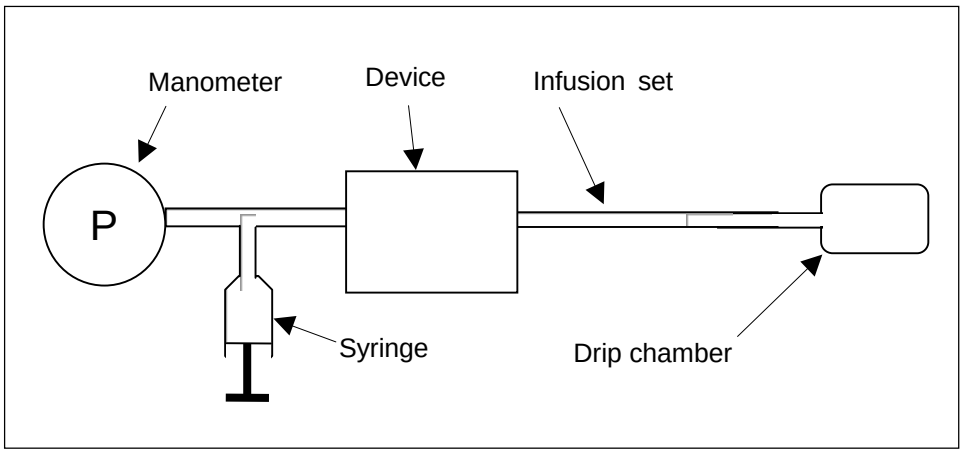
5.4.3. Battery autonomy test

1. The battery autonomy is minimum 4h for usual flow rates (< 125 ml/h).
2. The battery(when properly charged) pre alarm gives a warning to the user about 30 minutes before total stop of the device.

- ❑ Note : The battery charge duration is minimum 16 hours (100 % of its capacity) when the pump is ON.
- ❑ Note : The battery charge duration is minimum 5 hours (100 % of its capacity) when the pump is off.

5.4.4. Fix clamp checking (VS/PT and ST pumps)

1. Make the following installation.



2. Open the door of the device, the in line mechanical clamp should clamp the infusion set.

3. Apply a 0.5 bar pressure with the syringe and check no liquid goes in the drip chamber.

5.4.5. Air detector check

Note : Do the test with the tubing set displayed on the device. We recommend to do the test with the differents types of tubing sets used in the hostipal.

1. Place an infusion set full of water in the device.
2. For an air bubbles volume programmed at 0.20 ml.
3. Program a 60 ml/h flow rate.
4. Get drip chamber upside down for about 20 seconds (to infuse about 0.5 ml air bubble)
5. Check the air alarm goes when air bubbles pass through the air detector. The length passing through before alarm should approximately correspond to the size selected (1.3cm / 0.1ml).

5.4.6. Continuity test

1 Using a Ohmmeter, verify the presence of the electrical resistor higher than 10 M ohms between

Neutral and drip sensor plug (any pin)

Phase and drip sensor (any pin)

5.5. Technical check procedure

In order to ensure follow-up within the framework of a preventive maintenance, a routine inspection is recommended. It is recommended to use the technical manual as a complement, for correct run of the procedure.
A checking software allows to automatically perform the following tests.

IMPORTANT : recharge battery (16 hours) prior to the check procedure

Device : OPTIMA / MCM	Type :	Code:	Device serial N° :
Check date : ..... / ..... /		Depart :	Technician :

Check N°	Description	Con-form	YES NO	NA
1	FUNCTIONAL CHECK (see § 3.3.) ❑ Check general outside casing appearance, mains power cord and stickers. and pumping membrane			
2	❑ Display of working duration (test1) ……H/D/M			
3	❑ Last maintenance date (test1) ……..D/M/Y			
4	❑ Total working duration (test 6) ……H/D/M			
5	❑ Lights, buzzers and displays check (test2)			
6	❑ Keyboard check (test 3)			
7	❑ Door check Put on the pump without infusion set, door closed, connect drip sensor. Check the message on the alarm screen : Insert Tube Place an infusion set full of water in the device and closed the door: Check the absence of alarm. Open the door: Check the message : Door opened			
8	OCS Test (for pump OPTIMA MS and VS or MCM MS and OT) Install a tubing set and put on the device Check that the OCS test passes correctly Clamp Check (all pumps) Install a tubing set full of water (roller clamp opened) and bottle place at least 50 cm above the pump. Close the door and then open the door. Check the effective clamping of the tube (by the device for VS,PT,ST or by the clamp on the MS sets for the MS pump) :no drips at the end of the infusion sets. Detection of the clamp of the MS sets (for MS type pumps) Install the MS sets properly in the pump. Turn on the MS pump Check that there is no alarm display Open the door and move the clamp on the MS set outside the device. Close the door. Check that “no clamp”.			

Check N°	Description	Con-form	YES NO	NA
9	❑ Drip sensor check (if present) Check sensor integrity (chock marks, cleanliness of the detection zone, drip chamber maintaining spring, good condition of the cord) Connect the cord to the Module Install an infusion set full of water Start infusion Check that the green indicator flashes when a drop is detected. Disconnect the sensor: Check that the "drip sensor " alarm goes. ON Connect the drip detector , set the infusion at 60 ml/h remove the chamber from the drip detector . Verify the alarm should set : 40 sec < <2 min 30 sec			
10	❑ Air bubbles sensor check (see 5.4.6) When switching on, without infusion set: Check that the red indicator and the air sensor of LCD display flash Install an infusion set full of water Check that the red indicator and the air sensor of LCD display switch off. Select a 60-ml/h flow rate and start infusion. Keep drip chamber up side down for, at least 20 sec. to generate a > 0.25 ml air bubble for a device configured for a cumulated air detection of 0.25 in 15 min. Check the alarm **"air bubble"** goes on when bubble passes in the sensor.			
11	❑ Down-stream pressure detector. Install an infusion set full of water with a manometer at the end (see §5.4.2) Select a pressure threshold of 750 mmHg. Start infusion at 100 ml/h. Check that manometer indicates 750 mmHg ± 110 mmHg when alarm is triggered. Do it again for a pressure threshold of 500 mmHg (.± 75 mmHg)			
12	Average Flow rate check (can also be perform with a scale & ISDebit program test) Place the infusion set in a 100ml test tube. Select a 80ml/h flow rate and infuse for 1 hour Note the infused volume The flow rate can be adjusted (see 3.2.3) 76 ml < infused volume :……ml< 84 ml			
13	❑ Battery check Before checking, charge the battery for at least 16 hours Start an infusion at 125 ml/h, mains disconnected Check working autonomy is > 4h IMPORTANT : if autonomy < 3h30 , CHANGE battery.			
14	❑ Continuity test Neutral and Drip sensor connector (any pin) > 10Mohms Phase and drip sensor connector (any pin) > 10 Mohms Earth and equipotentiality < 0.1 Ohms Earth and screw below the device < 0.1 Ohms			

Checking result	*conform*	*no conform*
Visa :		

6. ANNEXE 1 : Illustrated parts lists

6.1. Subassemblies traceability table

6.1.1. Introduction

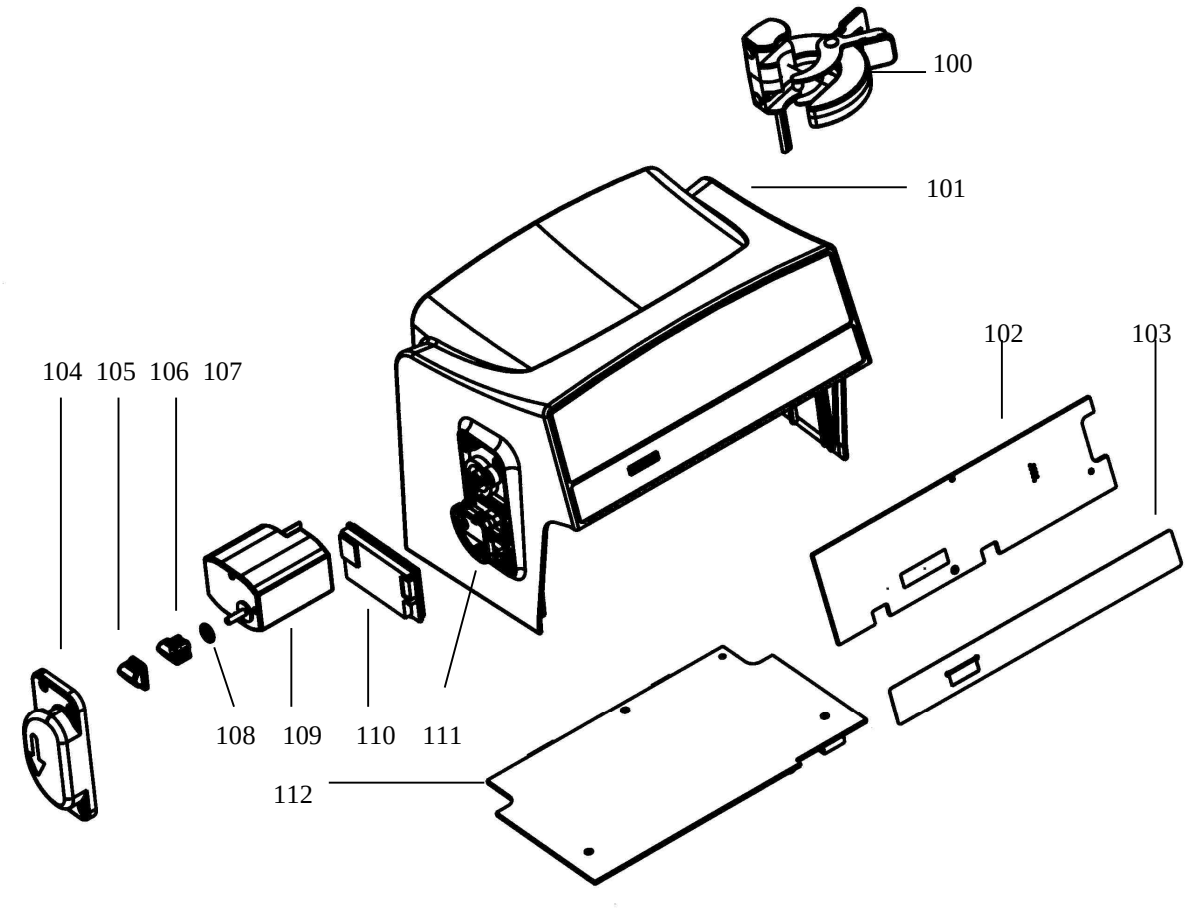
The aim of this chapter is to help the technician to find spare parts so that the module can be serviced.

6.1.2. Spare parts table

The table below lists the mains modifications made to improve the product. The module's serial number should be used when looking for components.

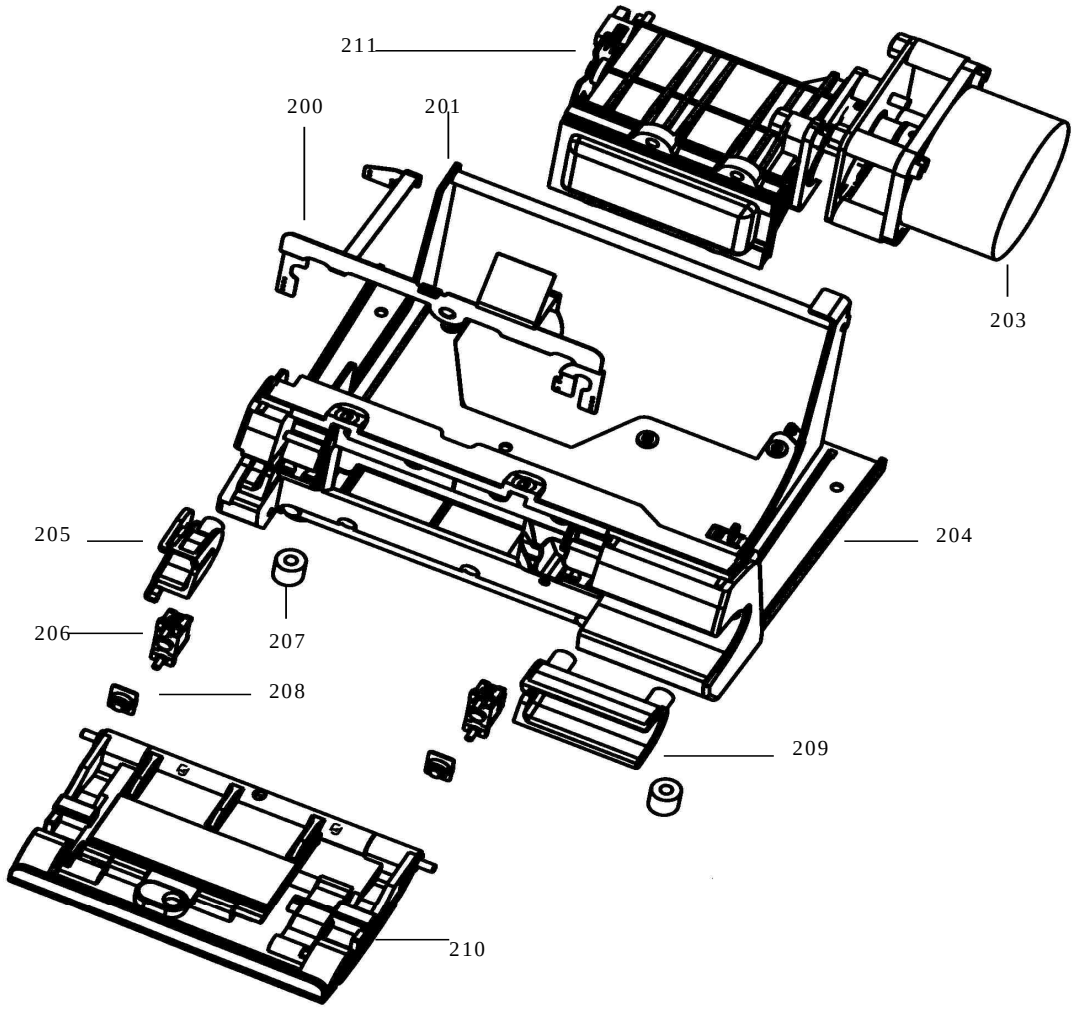
OPTIMA / MCM equivalence table	1
Instrument serial no.	From :18180100 To:
Display board	159602
CPU board	159601
Power Supply board	159603

6.1.3. Upper housing



Reference	Dig. ref	Quantity	Component
159611	101	1	Upper housing
159620	103	1	Keyboard
159602	102	1	Display board
159601	112	1	CPU board
159646	107	1	OCS motor
168402	110	1	PT / VS / OT air bubble board
168403	110	1	ST air bubble board
168938	111	1	Air sensor
174252	108	1	OCS foam ring
168442	104	1	Air sensor housing
159899	100	1	Drop detector

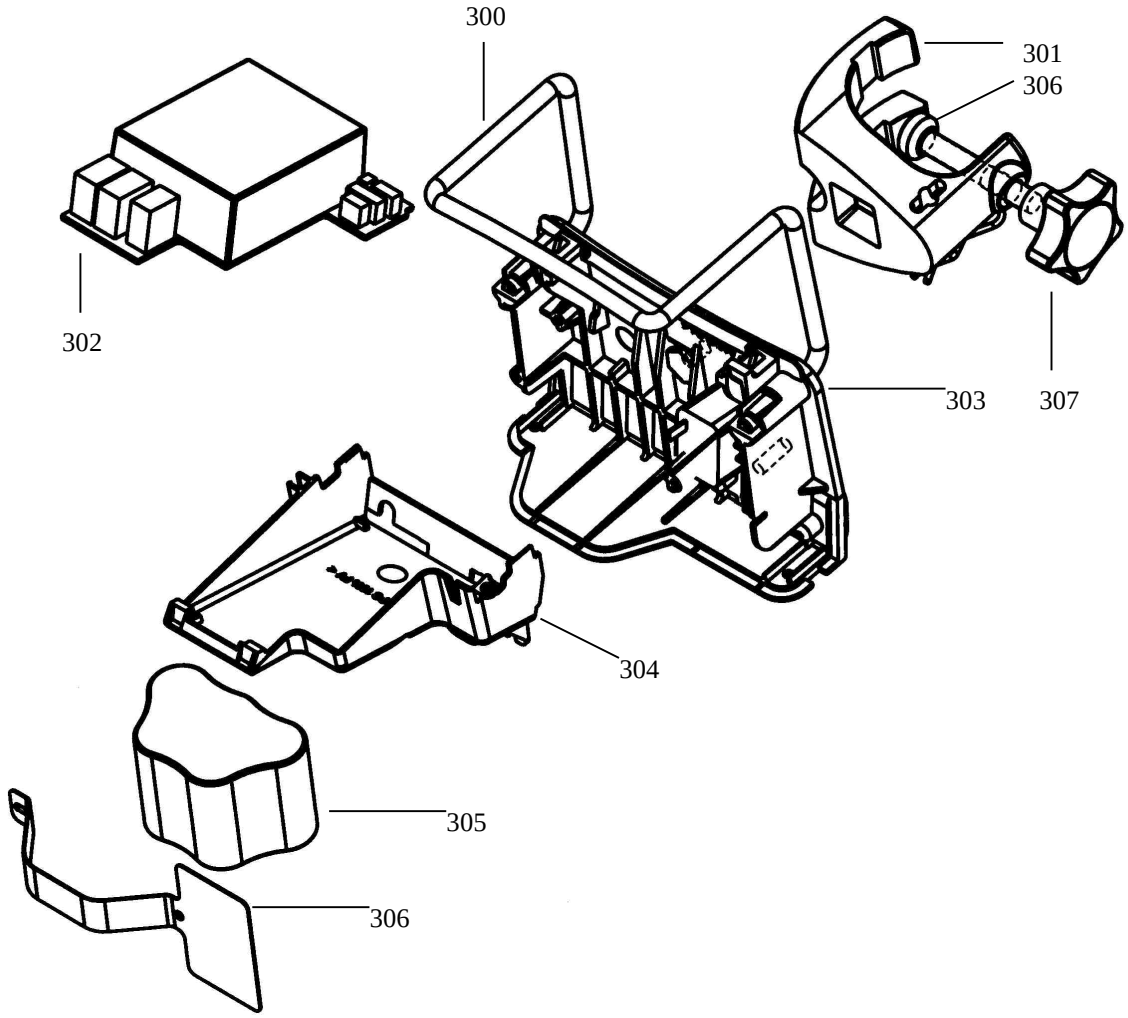
6.1.4. Base



Reference	Dig. Ref.	Quantity	Component
159895	204	1	Base
168480	206	2	Pressure sensor
168428		2	Sensor clip
168439	208	2	Sensor membrane
651211		1	Mechanical bloc membrane
159621	205	1	Left hook
168437	209	1	Right hook
159604	200	1	Flat cable
159648	203	1	Motor
168479	211	1	Mechanical bloc
168482		1	Belt
168483		1	Pump side gear
168489		1	Motor side gear
168485		3	Silent bloc 40 shores
159618	207	2	Feet
199261	210	1	PT / VS / OT door kit
199262	210	1	ST door kit

159632		1	Switch clamp holder

6.1.5. Brace



Reference	Dig. Ref.	Quantity	Component
159612	303	1	Brace Optima
159613	304	1	Shelf Optima
159603	302	1	Power supply board
159622	305	1	Battery pack
159642	301	1	Nut
182108	306	1	Screw cap
159643	307	1	M8 screw
159617	300	1	Handle

7. Circuit diagram

Cicuit daigrams are available nearby our service department, please refer to useful addresses chapter.

8. Addenda and information bulletins

9. Useful addresses

All request for information or documentation (technical file, tubing catalogue or commercial documentation) should be addressed to :

CUSTUMER SERVICE INTERNATIONAL

	Fresenius Vial Le Grand Chemin, 38590 Brézins FRANCE	Tel. : 33 (0)4 76 67 10 14 or 10 03 or 1067 Fax : 33 (0)4 76 67 11 12 E-mail : commercial.vial@fresenius-hemocare.com

MAINTENANCE SERVICES

INTERNATIONAL	Fresenius Vial Le Grand Chemin, 38590 Brézins FRANCE	Tel. : 33 (0)4 76 67 10 76 Fax : 33 (0)4 76 67 11 22
BELGIUM	Fresenius NV/SA Belgique DIVISION VIAL MEDICAL Molenberglei 7 2627 Schelle BELGIUM	Tel. : 32/388.07307 Fax : 32/388.05007
GERMANY	FRESENIUS MCM AM-NEUNEN BERG 8 63749 ALZENAU GERMANY	Tel. : 49/60 23 97 22-0 Fax : 49/60 23 43 06

Fresenius Vial SAS - Head Office: Le Grand Chemin - 38590 Brézins (FRANCE)
Capital: 13,744,520 EUR - SIREN Grenoble B 408 720 282.