



All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

To be uploaded in Website: www.aiimsbhubaneswar.nic.in (Tender)

Reference No: **J-11054(035)/2020-21/S&P**

Dated: 21/05/2020

Sub: Procurement of “Surgical Hyper thermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) & Smoke Evacuator” (Make: RAND S.p.A, Italy) for the Department of Surgical Oncology at AIIMS, Bhubaneswar on Proprietary basis - Inviting Comments thereon.

The Department of Surgical Oncology of AIIMS, Bhubaneswar has requested for Procurement of **Surgical Hyper thermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) & Smoke Evacuator** (Make: RAND S.p.A) through **M/s Regency Lifesciences India Pvt. Ltd., Bangalore**, Authorised distributor of RAND S.p.A., Italy.

The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.

In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.

The objections/comments/proposal should be sent in sealed cover to the Office of Sr. Procurement Cum Stores Officer, AIIMS, Bhubaneswar (Odisha) – 751019 or through E-mail to aso@aiimsbhubaneswar.edu.in, aso.jkbiswal@aiimsbhubaneswar.edu.in, spo@aiimsbhubaneswar.edu.in, so as to reach on or before **date: 10-06-2020** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The ref. no. – **J-11054(035)/2020-21/S&P** dt:21-05-2020, due on dated:10-06-2020 should be superscripted on sealed envelope.

Enclosure:

1. Proprietary Article Certificate from Indenting Officer of Department of Surgical Oncology, AIIMS, Bhubaneswar. **Annexure-I.**
2. PAC of **M/s RAND S.p.A, Italy** for the Surgical Hyper thermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) & Smoke Evacuator (Make: RAND S.p.A, Italy) **Annexure-II.**
3. Certificate of Authorization, Price quotation with CMC and Consumables for Surgical Hyper thermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) & Smoke Evacuator (Make: RAND S.p.A, Italy) **Annexure-III.**
4. Technical Boucher of the items (**Annexure-IV**).

Copy to:

- | | |
|--|--------------------------------|
| 1. Indenting Officer, Department of Surgical Oncology: | for information please |
| 2. PS to DDA | : for kind information please. |
| 3. Accounts Officer | : for information please |
| 4. IT Cell | : for hoisting in the website. |

Sd/-

Sr. Procurement-cum-Stores Officer
AIIMS, Bhubaneswar

AIIMS, BHUBANESWAR



Proprietary Article Certificate

Valid for the Current Financial Year

File No. and Date Reference :		
1	Description of article	Surgical Hyperthermic Chemotherapy Perfusion system for Isolated limb perfusion and Intra-peritoneal Chemotherapy (HIPEC) & Smoke evacuator
2	Forecast of quantity /annual requirement	01 set
3	Approximate estimated value for above quantity	Rs. 1,20,000,00/-
4	Maker's name and address	M/s Rand s.r.l Via Statale 112, n.62, 41036, Medolla (MO), Italy
5	Name(s) of authorized dealers/ stockist	M/s Regency Lifesciences India Pvt. Ltd, 84 th A Cross, 5 th Main, HRBR 2 nd Block, Kalyan Nagar, Bangalore -560043 (Indian Agent)
6	I approve the above purchase on PAC basis and certify that : Note- Tick to retain only one out of (b), C-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.	
6 (a)	This is the only firm who is manufacturing / stocking this item. AND	☒
6 (b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	☒
6 (c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.) : OR	
6 (c-2)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources) : OR	
7	Reference of concurrence of finance wing to the proposal :	
History of PAC Purchase of this item for past three years may be given below :		
Name of the Supplier		
Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)
		Adverse Performance Reported if Any

Signature of the Indenting Officer

Signature of Approving Authority.....

Date..... Designation of Officer.....

Dr. Madhabananda Kar
Professor & Head
Department of Surgical Oncology
AIIMS, Bhubaneswar-751019

INNOVATION IN MEDICAL TECHNOLOGY

To:

8TH MAY, 2020

Sr. Procurement-cum Store Officer
All India Institute of Medical Sciences,
Bhubaneswar

Dear Sir,

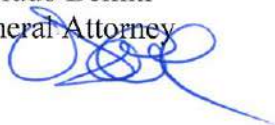
**Sub: Proprietary Article Certificate for RAND Performer HT HIPEC System
For treating stage III and IV advanced Peritoneal Carcinomatosis (Cancer)**

We, RAND S.p.A, Italy hereby confirm that Performer HT HIPEC System, Hyperthermic Intraperitoneal Chemotherapy System manufactured by us is a proprietary item. This is the only system which has got capabilities as follows:

- **US FDA approved for Hypertermia Perfusion**
- 2 Peristaltic Pumps
- Automatic Therapy Management Software
- 12.1" Colour Touch Screen
- Multifunctional Software
- Up to 8" Temperature Probes
- Online Trouble shooting
- Automatic Electroclamps
- 6 Pressure Sensors
- Patient –Balance Systems
- Built-in printer
- 7 Litre Reservoir
- 3 graduated filters
- **US FDA and CE marked**

Thanking you

For RAND S.p.A
Corrado Bellini
General Attorney



Annexure-III**Manufacturers' Authorisation Form**

Date of Bid Submission: 08/05/2020

Tender No.: E -Tender No. **11054/035/AIIMSBBBSR/SO/2019-
20/134**To The Director
AIIMS Bhubaneswar
Sijua, Odisha, India

WHEREAS

We, Rand, SpA, Italy, who are official manufacturer in having factories at Via Statale 12, n.62 41036, Medolla (MO), Italy, do hereby authorise Messrs. Regency Lifesciences India Pvt. Ltd., Ist Cross, No 118/5, Hennur Main Road, Kacharakanahalli, St Thomas Town Post, Bangalore 560084 to submit a bid the purpose of which is to provide the following equipment, manufactured by us Surgical Hyperthermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) and to subsequently negotiate and sign the contract.

We accept the Warranty / Guarantee condition mentioned in the tender documents of AIIMS Bhubaneswar.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent including availability of spare parts & consumables for the period of 10 years for supplied equipment to AIIMS Bhubaneswar.

Signed (*insert signature of authorised representative of the manufacturer*)Name: (*insert complete name of authorised representative of the manufacturer*)Duly authorised to sign this authorisation of behalf of: (**insert complete name of Bidder**)

Rand S.p.A.

General Attorney

Corrado bellini

Date on 08/05/2020





Financial Bid
(with Break-up)

Sl. No	Name of Equipment	Qty	Rate Per Unit	GST (%)	Amount (including GST)	Total
	Surgical Hyperthermic chemotherapy perfusion system for Isolated limb perfusion and Intra- peritoneal chemotherapy (HIPEC) & Smoke Evacuator	1				
	<u>Consists of :</u>					
1)	Performer HT - HIPEC System	1	72,08,267.00	8,64,992.04	80,73,259.04	80,73,259.04
	<u>Consumables for Performer HT</u>					
1)	1) Hang & Go Kit for HIPEC	10	1,15,623.00	13,874.76	1,29,497.76	12,94,977.60
2)	2) ILP KIT	10	1,63,508.00	19,620.96	1,83,128.96	18,31,289.60
3)	3) Disposable Needle probe (Pack of 10 Nos. (Minimum Purchase Quantity 1 pac)	2	1,14,455.00	13,734.60	1,28,189.60	2,56,379.20
	per case 3 - 4 Nos. Needle Probe required for ILP cases					
4)	4) Disposable Temperature Probe (Pack of 100)	1 pack	2,70,753.00	32,490.36	3,03,243.36	3,03,243.36
	<u>Atmos Medizintechnik, Germany</u>					
1	Smoke Evacuator FUMOVAC 700 Reference no: HM57525420	1	4,50,518.25	54,062.19	5,04,580.44	5,04,580.44
	<u>Consumables For Smoke Evacuator FUMOVAC 700</u>					
1	Smoke Evacuation Filter for Fumovac 700 Reference no: HM5752423 (Twin pack consisting of two filters) Minimum ordering quantity : 1 pack	2	47,527.20	5,703.26	53,230.46	1,06,460.93
2	Smoke Evacuation Tubing Set for Open Surgeries (Pack of 24 Nos) Reference no: HM57525328	24	2,227.84	267.34	2,495.18	59,884.27
					Total :	1,24,30,074.44
Special one time Discount 5% is offered					5%	6,21,503.72
TOTAL						1,18,08,570.72

5 years warranty and 5 years CMC

**** Warranty not applicable for consumables**

REGENCY LIFESCIENCES INDIA PVT LTD



Signature of the bidder with seal.

Date: 05.05.2020

Place : Bangalore

CMC CHARGES

Financial Bid (Part-II)

(Applicable only if participating for Equipment)

Name of the E-Tender: Supply, Installation & Commissioning Surgical Hyperthermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) & Smoke Evacuator at AIIMS, Bhubaneswar..

Tender Item No.	Name of the Equipment	Rates of CMC (for equipments only)					Total CMC Cost for 5 Years	TAXES (IF ANY)	Total CMC Cost for 5 Years including Taxes
		1 st yr	2 nd yr	3 rd Yr	4 th Yr	5 th yr		GST 18%	
1	Surgical Hyperthermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) & Smoke Evacuator Make : Model :	3,93,832.00	4,13,523.00	4,34,199.00	4,55,909.00	4,78,705.00	21,76,168.00	3,91,710.24	25,67,878.24
Total		3,93,832.00	4,13,523.00	4,34,199.00	4,55,909.00	4,78,705.00	21,76,168.00	3,91,710.24	25,67,878.24
(Rupees Twenty five lakhs sixty seven thousand eight hundred seventy eight only)									

Name(s) & Signature of the Bidder with rubber seal(s)



Name of the Firm **REGENCY LIFESCIENCES INDIA PVT LTD**

Date : 05.05.2020

Place : **Bangalore**



Regency Lifesciences

India Pvt. Ltd.

+91 80 - 2542 4415/2542 0851

regencylife.india@gmail.com

Financial Bid (Part –III)

Name of the E-Tender: Supply, Installation & Commissioning of Surgical Hyperthermic chemotherapy perfusion system for Isolated limb perfusion and Intra-peritoneal chemotherapy (HIPEC) & Smoke Evacuator at AIIMS, Bhubaneswar.

Details Consumables/Accessories require for HIPEC & Smoke Evacuator :

No of Items	Name of Consumables/ Accessories / Spare Parts	Pack Size	Quoted Rate		Amount (including
			(Per Unit)	GST (%)	GST)
	<u>CONSUMABLES</u>				
1	<u>For PERFOMER HT HIPEC SYSTEM</u>				
1)	1) Hang & Go Kit for HIPEC	1	1,15,623.00	13,874.76	1,29,497.76
2)	2) ILP KIT	1	1,63,508.00	19,620.96	1,83,128.96
3)	3) Disposable Needle probe (Pack of 10 Nos.	1 pac	1,14,455.00	13,734.60	1,28,189.60
	(Minimum Purchase Quantity 1 pac)				
	per case 3 - 4 Nos. Needle Probe required for ILP cases				
4)	Disposable Temperature Probe (Pack of 100)	1 pac	2,70,753.00	32,490.36	3,03,243.36
	<u>For Smoke Evacuator FUMOVAC 700</u>				
1	Smoke Evacuation Filter for Fumovac 700	1 pac	95,054.40	11,406.53	1,06,460.93
2	(Twin pack consisting of two filters)				
3	Tube, Ø 22 mm, 3.05 m, 24 pcs.	1 pac	53,468.16	6,416.18	59,884.34
4	Adapter reusable electrosurgical pencil, 10 pcs.	1 pac	31,521.00	3,782.52	35,303.52
5	Speculum tube set, 2.44 m, sterile, 5 pcs.	1 pac	9,427.00	1,131.24	10,558.24
6	Laparoscopic tube set SEO, 12 pcs.	1 pac	43,670.00	5,240.40	48,910.40
7	Disposable smoke evacuation pencil with 3 electrodes(70/100/152 mm), 40 pcs.	1 pac	1,46,830.00	17,619.60	1,64,449.60
8	Air suction handle for smoke-evacuation, 25 pcs.	1 pac	71,962.00	8,635.44	80,597.44

9	Air hose Ø 22 mm, L = 2.10 m, disposable, not autoclavable	1 pac	1,348.00	161.76	1,509.76
10	Air hose Ø 22 mm, L = 2.10 m, reusable	1	5,342.00	641.04	5,983.04
11	Air hose Ø 22 mm, L = 2.70 m, reusable	1	8,376.00	1,005.12	9,381.12
12	Air hose, internal Ø = 10 mm, L = 1.8 m, reusable	1	6,120.00	734.40	6,854.40
Recommended Accessories for FUMOVAC 700					
1	Remote switch activator		51,189.00	6,142.68	57,331.68

REGENCY LIFESCIENCES INDIA PVT LTD



Signature of the bidder with seal.

Date: 05.05.2020

Place : Bangalore

1st Cross, No 118/5, Hennur Main Road, Kacharakanahalli, St Thomas Town Post, Bangalore 560084.

Performer HT

Hyperthermic Perfusion System

Hyperthermic Perfusion System
PERFORMER HT



INNOVATION IN MEDICAL
TECHNOLOGY



Intended use

Equipment

Software

Disposable kit

Safety standards

PERFORMER HT SYSTEM

Performer HT is an electromechanical device based on the extracorporeal circulation of fluids. It is used during hyperthermic perfusion therapies, and in particular for the following therapies:

Hyperthermic Intra-Peritoneal or Intra-Pleural Perfusion with the aim of providing localized hyperthermia by circulating warmed fluids, that may contain chemotherapeutic drugs, in the peritoneal or pleural cavity for a 30 to 90 minutes time period. The treatment can be performed in conditions of open or closed abdomen, upon prior introduction and positioning of temperature monitoring probes and catheters to be connected to the extracorporeal circulation circuit.

Isolated Limb / Organ Perfusion, consisting in the isolation of an anatomical district followed by intra-arterial hyperthermic perfusion of chemotherapeutic drugs, in conditions of hyperoxia/hypoxia.

PERFORMER HT SYSTEM

The “**Performer HT System**” consists of:

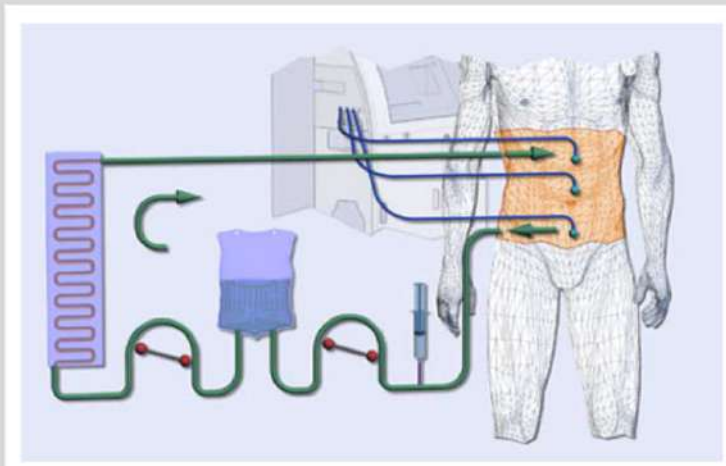
- Equipment (Hardware & Software)
- Disposable Kit



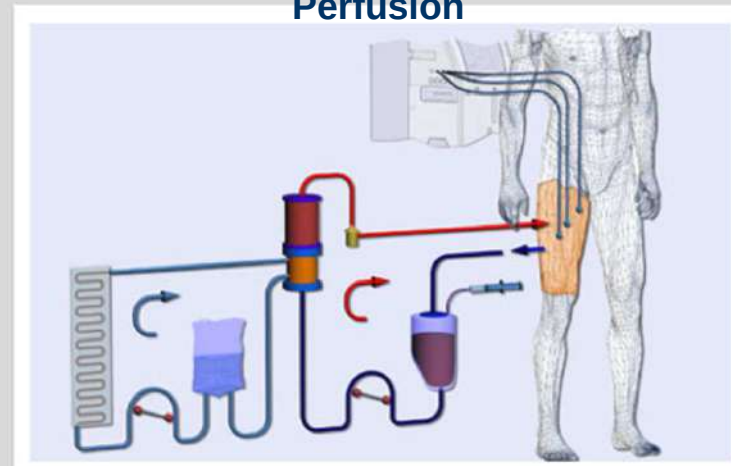
REGIONAL CANCER THERAPIES

Series of innovative techniques involving the **direct perfusion of the tumor**, or anatomical region invaded by the tumor with **high doses of chemotherapeutic drugs**.

Hyperthermic Intraperitoneal and
Intrapleural Perfusion



Isolated Limb or Organ
Perfusion



HYPERTHERMIC INTRAPERITONEAL AND INTRAPLEURAL PERFUSION

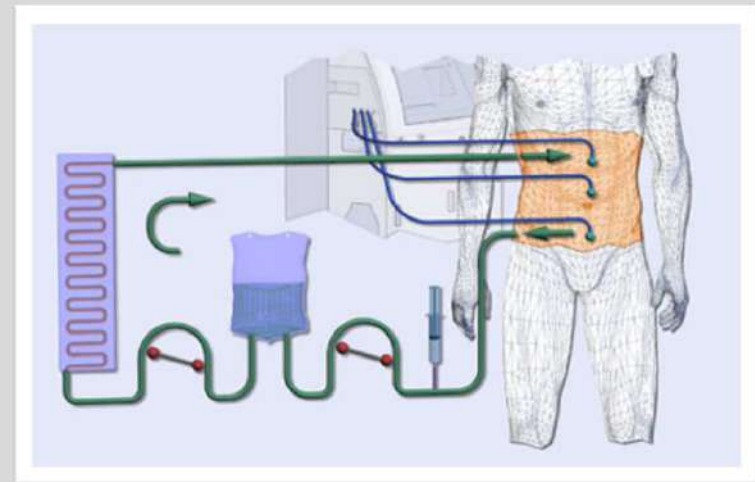
INDICATIONS

The treatment is indicated after cytoreductive surgery for carcinoma, peritoneal and gastrointestinal sarcomatosis, ovarian carcinoma, pseudomyxoma peritonei, peritoneal mesothelioma and pleural mesothelioma

PROCEDURE

Perfusion of the cavity with hyperthermic solution containing chemotherapeutic drugs:

- Hyperthermia: 41.0/42.0 °C
- Flow: from 600 to 2.000 ml/min
- Volume: from 3 to 8 Liters
- Time: 30/90 min
- Technique: open/closed abdomen



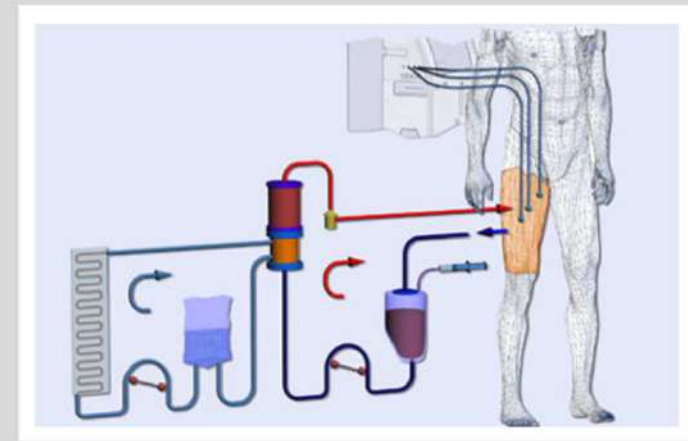
ISOLATED LIMB PERFUSION

INDICATIONS

- melanoma of the limb with in-transit metastases (Stage IIIA, according to MD Anderson Cancer Center staging system)
- melanoma of the limb with in-transit metastases to regional lymph nodes (Stage IIIB)
- association of the two above mentioned stages (Stage IIIAB)
- primary, locally advanced and not resectable soft tissue sarcomas of the limb

PROCEDURE

Perfusion of Isolation of an anatomic district, typically a limb, followed by intra-arterial hyperthermic perfusion of chemotherapeutic drugs, in hyperoxya/hypoxya conditions.



Integrated devices

The Performer HT equipment includes **all the devices necessary** for the treatment execution, in particular:

- Heating device
- Temperature monitoring system
- Peristaltic pumps for flow control
- Weighing system for volume control
- Pressure monitoring sensors
- Touch-screen display for monitoring and parameter setting

Intended use

Equipment

Software

Disposable kit

Safety standards

Heating device

Temperature control of the solution perfused to the patient

Settable Temperature: from 28°C to 46 °C

Accuracy: ± 0.3 °C

Safety: 4 integrated temperature sensors for monitoring inlet, outlet and heater plate temperature.



Temperature control

Monitoring up to 8 temperatures in the body cavity.

Probes: esophageal, needle and generic purpose use medical probes, disposable or re-usable.

Safety: monitoring system independent from heater, that signals potentially dangerous temperatures in the peritoneal cavity.

Sat O₂ and Hct: connection for measurement device of Sat O₂ and Hct (for ILP).



Flow control

PERISTALTIC PUMPS

2 pumps with settable flow rate up to 2 L/min.

Safety: open-cover sensor, revolution sensor, digital encoder.

Flow setting: through dedicated panel or display.



Volume control

WEIGHING SYSTEM

Monitoring of dilution total volume and volume in the patient's body cavity.

Safety: the volume monitoring enables the user to control exactly the volume in which drugs are diluted and signals anomalous conditions like a failed volume return to the patient.



Pressure control

PRESSURE SENSORS

Control of pressure in different points of the circuit (up to 6) and in particular in the inlet and outlet lines of the patient

Safety: pressure monitoring allows to advise any overpressure condition potentially dangerous to the patient and/or to the medical personnel.

Reference labels on the disposable sensors allow to minimize the risk of making wrong connections during the kit assembly



Monitoring and parameters setup

MONITOR

The Performer HT user interface consists of a colour graphic display with a touch-screen system that allows to control and monitor all the functions

Safety: the user is able to manage in a simple and immediate way all anomalous situations signaled through the message bar and other visual/acoustic indications



Data management

ELECTRONIC FORMAT

All treatment data are stored on the file system memory (with a sampling interval from 2 to 600 seconds) and with the possibility to copy them to the external memory card (Compact Flash or USB stick) for an automatic elaboration on a PC.



Stored Data:

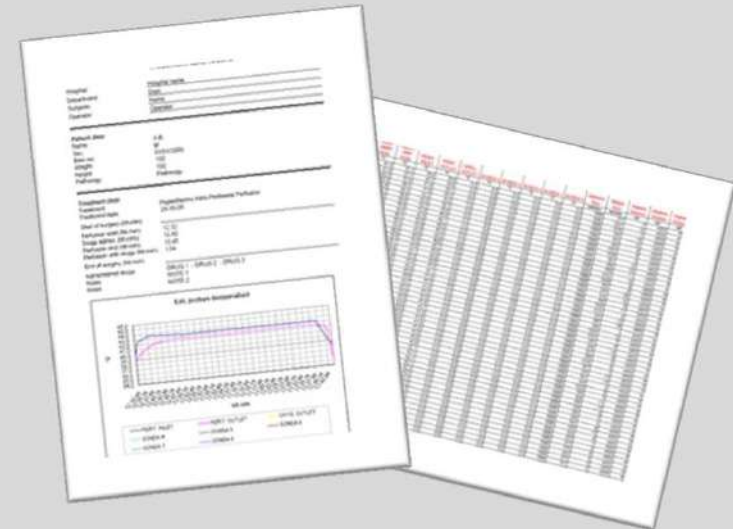
- Treatment parameters (temperatures, flows, pressures, volumes, ...)
- Patient data

Safety: the equipment data (software version and calibration data) and all the treatment events logs are stored into a file

Data management

PAPER FORMAT

Using a MS Excel based software, a report is automatically created containing all the treatment data both in table and graphic format



Integrated Printer

Straight after the end of the therapy, by using the integrated printer it is possible to get a report containing patient and medical staff's data and a list of the main treatment parameters, sampled every 5 minutes.



Battery supply sytem (UPS)

BATTERY

The rechargeable battery integrated in the base allows to continue to use the equipment for a period of about 2 hours in case of power failure

If the equipment setup is performed out of the surgery (lines connection and preheating of the solution to be perfused), the battery can be used for the subsequent transfer into the surgery without need of interruption



Procedure automation

AUTOMATIC ELECTROCLAMPS

The various phases of the procedure are automatically activated by 2 two-ways electroclamps without the operator's intervention, thus simplifying the treatment execution and minimizing possible human errors



Air detection

Air Sensor

The air sensor located at the entry of the heater allows to advise the conditions of an empty reservoir or the presence of air in the circuit, and automatically activates the security status for the patient



Height regulation

HEIGHT CONTROL DEVICE

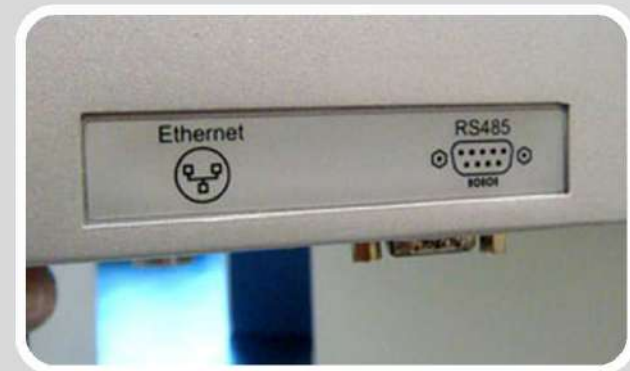
The machine is equipped with an electro-mechanical system that allows to reduce the height of 140 cm (operating condition) to a minimum of 90 cm, facilitating the transportation inside and outside the hospital.



Output connection

ETHERNET CONNECTION & RS232/485

Performer HT can be connected to an external PC or a net through Ethernet connection (interface RJ45) or serial port (standard RS232/485)



Intended use

Equipment

Software

Disposable kit

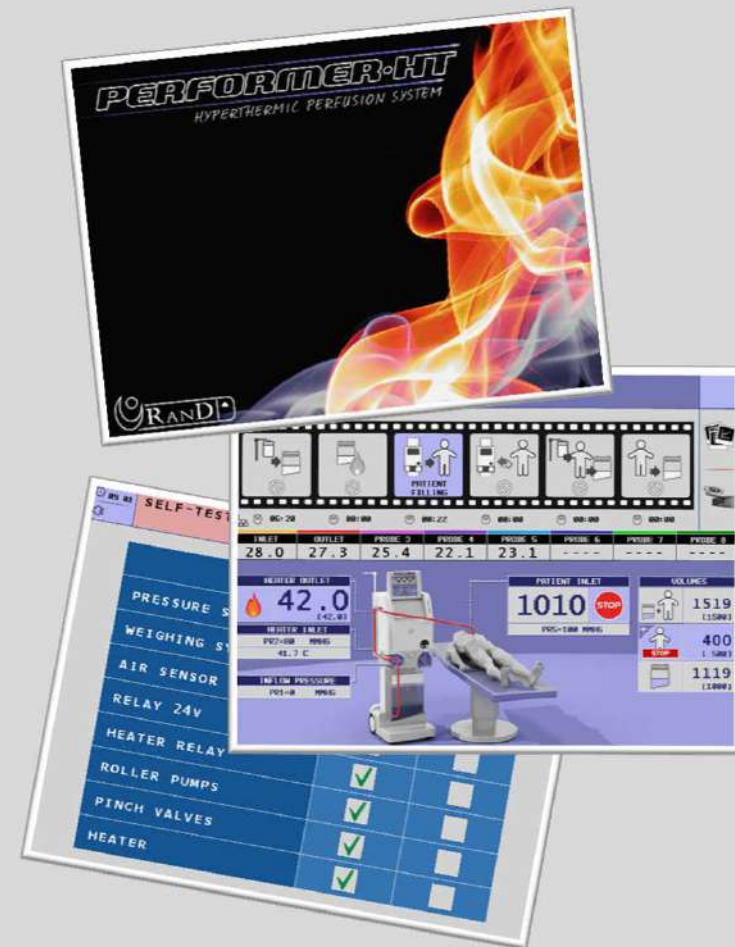
Safety standards

User interface

USER INTERFACE

The performer HT equipment is provided with an extremely simple user interface, allowing the user to learn easily and immediately all the available functions for treatment execution.

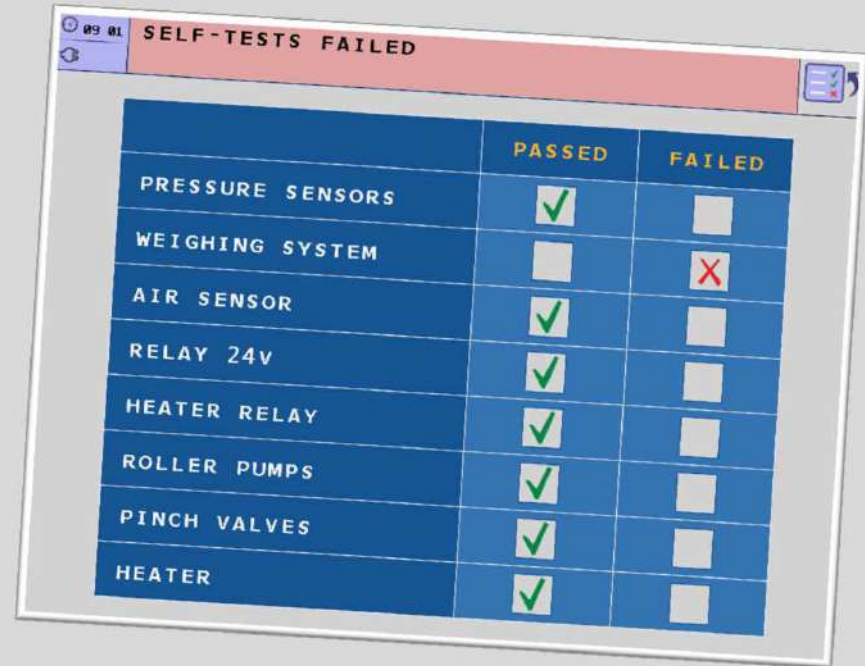
The activation of automatic procedures of treatment restore in case of problems, as well as the presence of an on-line-Help system, allow the operator to quickly and effectively manage anomalous situations, in full safety conditions and with a minimal manual intervention



User interface

INITIAL SELFTEST

At switch-on, the equipment performs a set of automatic self tests in order to verify the correct functionality of the different devices and to guarantee the utmost safety during the treatment execution

A screenshot of a user interface window titled "SELF-TESTS FAILED". The window contains a table with two columns: "PASSED" and "FAILED". The table lists eight components: PRESSURE SENSORS, WEIGHING SYSTEM, AIR SENSOR, RELAY 24V, HEATER RELAY, ROLLER PUMPS, PINCH VALVES, and HEATER. The "PASSED" column shows green checkmarks for all components except the WEIGHING SYSTEM, which shows a red 'X' in the "FAILED" column. The "FAILED" column shows empty checkboxes for all other components.

	PASSED	FAILED
PRESSURE SENSORS	✓	☐
WEIGHING SYSTEM	☐	✗
AIR SENSOR	✓	☐
RELAY 24V	✓	☐
HEATER RELAY	✓	☐
ROLLER PUMPS	✓	☐
PINCH VALVES	✓	☐
HEATER	✓	☐

User interface

MAIN MENU

After the correct execution of the self tests, the equipment automatically activates the main menu screen, from which it is possible to enter the Perfusion mode or to select one of the available options in the option menu:

- copy file in a USB memory stick
- copy file in a Compact Flash memory card
- activation of service screens



User interface

SERVICE SCREENS

The service screens allow to execute all the monitoring, system set up and calibration procedures directly on the equipment, without the need of an external PC connection.

The image displays three overlapping screenshots of the service screens, showing various monitoring and calibration settings.

SENSORS Screen: This screen displays various sensor parameters. It includes fields for CONTROL, PROTECTIVE, WEIGHT, PRESSURES, AIR SENSOR, AIR MODULE, and TEMPERATURES. The bottom navigation bar shows EXIT, MONITORING, SETTING, and CALIBRATION.

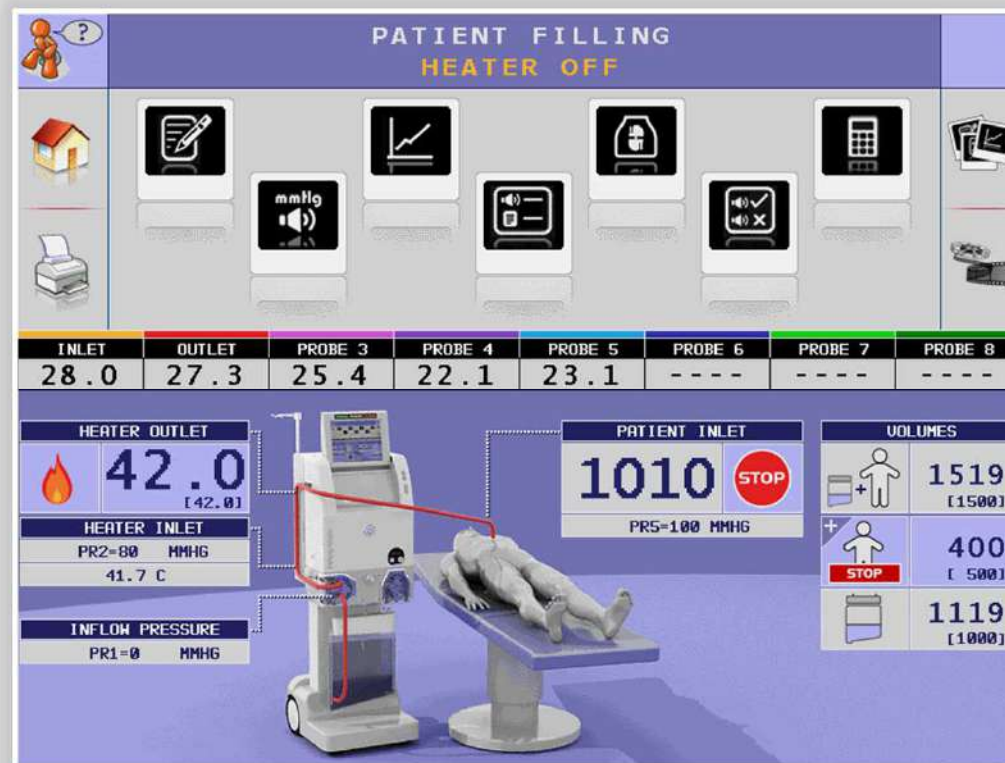
CALIBRATION Screen: This screen displays calibration data for various sensors. It includes a table with columns for CONTROL, OFFSET, GAIN, and T-SET. The bottom navigation bar shows EXIT, MONITORING, SETTING, and CALIBRATION.

TEMPERATURES Screen: This screen displays temperature calibration steps. It includes a table with columns for INLET, OUTLET, and TEMPERATURE. The bottom navigation bar shows EXIT, MONITORING, SETTING, and CALIBRATION.

User interface

PERFUSION MODE

In the Perfusion mode the screen is divided into 4 areas:



Message Bar

Secondary Screen

Temperature Bar

Main area

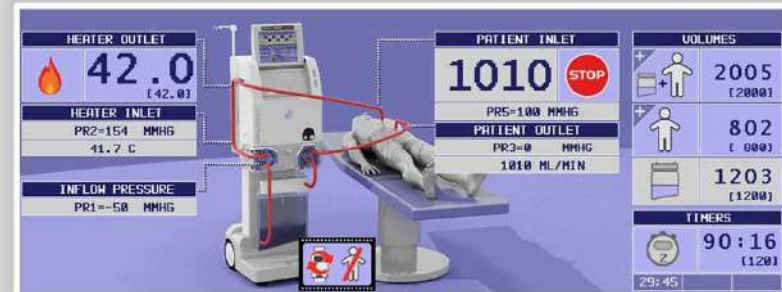
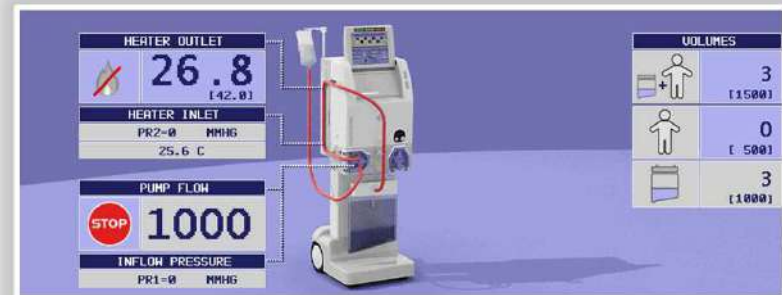
Main screen

CONTROL CENTER

The main area is the screen section from which it is possible to access immediately to all information and necessary commands of the treatment

Dynamic information

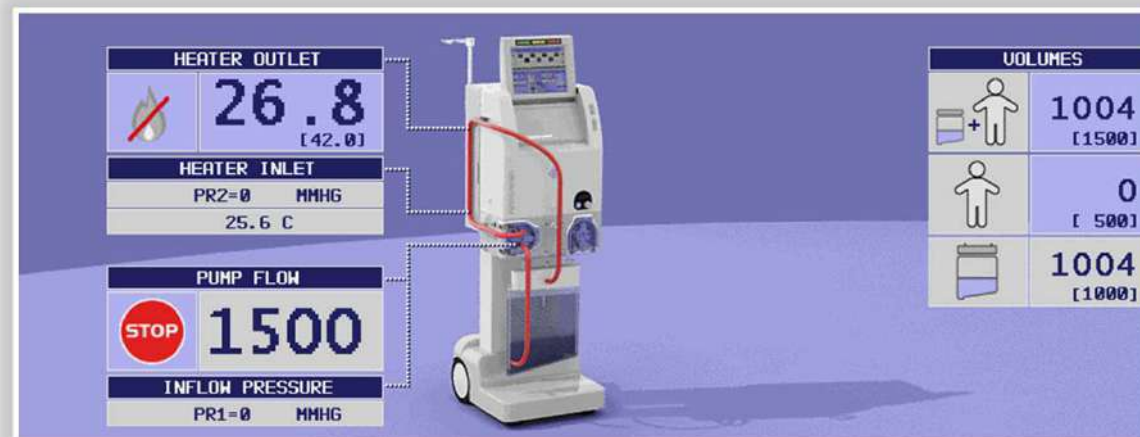
The content of the main screen is contextual to the active phase (Preparation, Circulation and Emptying phase): in each phase the displayed information refers to the current phase (circuit diagram, parameters and commands), thus enabling the operator to identify the different functions



Main screen

PHASE 1 – PREPARATION

The Preparation phase (Circuit filling and Pre-heating) is **fully automatic**: the only operator's tasks are the dilution of volume setting and the phase starting through the dedicated pushbutton

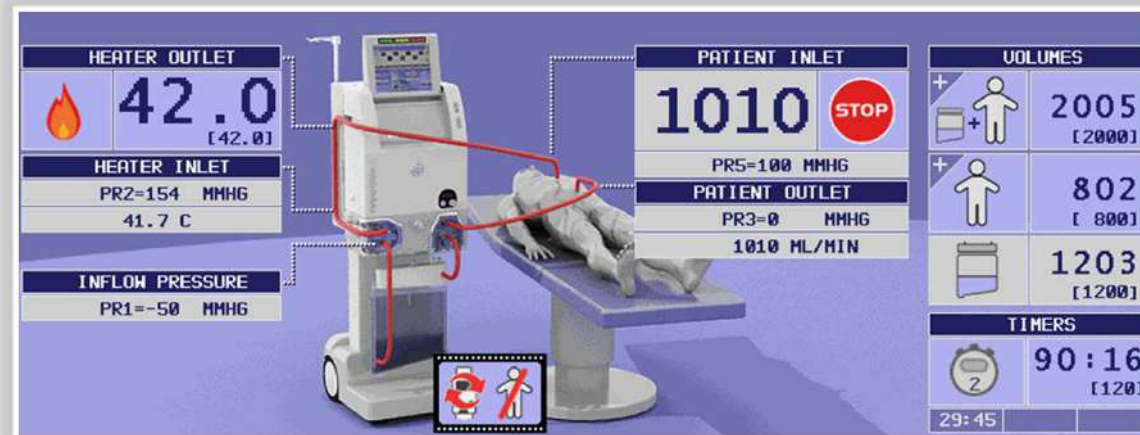


Main screen

PHASE 2 – DRUG CIRCULATION

During Circulation phase, the equipment automatically monitors the solution temperature and the patient volume. The operator can access all the available functions through the Main area:

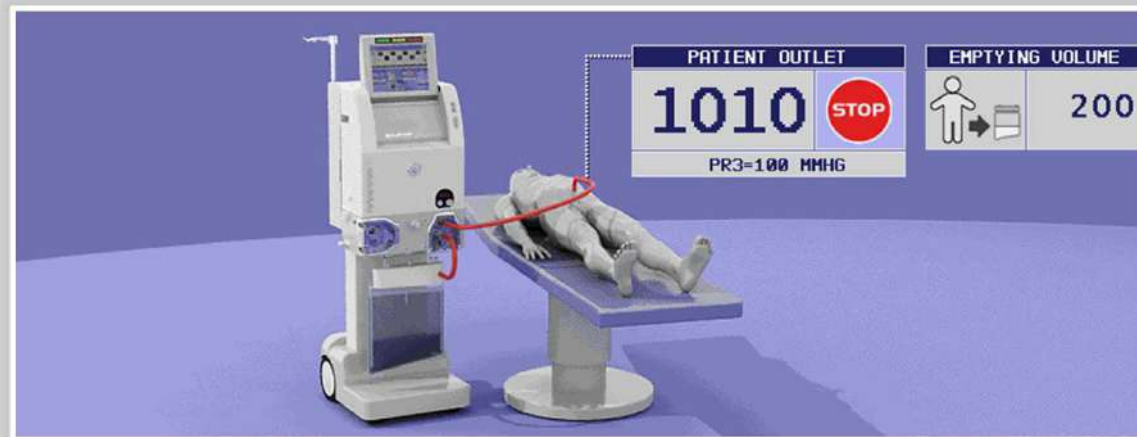
- Parameters display/set up
- By-pass phase activation
- Start of drug timers



Main screen

PHASE 3 – RINSING/EMPTYING

Once the drug circulation phase is completed, the operator can proceed with the emptying phase of the peritoneal cavity, that can be preceded or followed by a rinsing phase. In both phases, the main screen displays the corresponding value of Rinsing or Emptying volume.



Temperature bar

TEMPERATURE BAR

The temperature bar allows to:

- Display temperature values detected by the 8 probes located into the peritoneal cavity
- Instantly identify conditions of high temperature of one or more probes (yellow/red box)
- Hide/show selectively the temperature probes diagrams

PB1	PB2	PB3	PB4	PB5	PB6	PB7	PB8
46.0	44.6	22.1	43.3	----	> 47	----	----

Message bar

MESSAGE BAR

The message bar is used to:

- Display the current phase
- Display/confirm alert/alarm messages
- Activate troubleshooting screen
- Display the current time and the battery charge status



Secondary screens

SECONDARY SCREEN

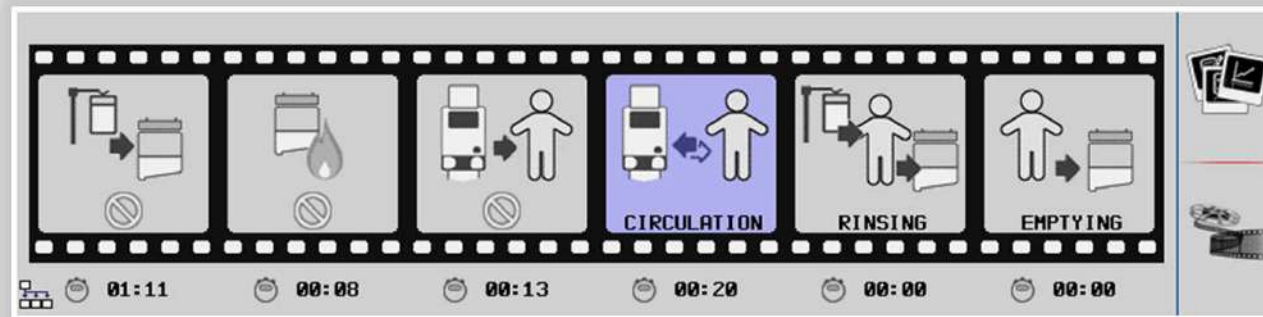
In this screen area, a series of pages are displayed, selectable by the operator, allowing to perform different operations, such as:

- Selection of different treatment phases
- Filling of treatment/patient data
- Display real time external probes diagrams
- Parameters set up
- Management of safety system



Secondary screens

TREATMENT PHASE SELECTION



ENTERING OF PATIENT/TREATMENT DATA

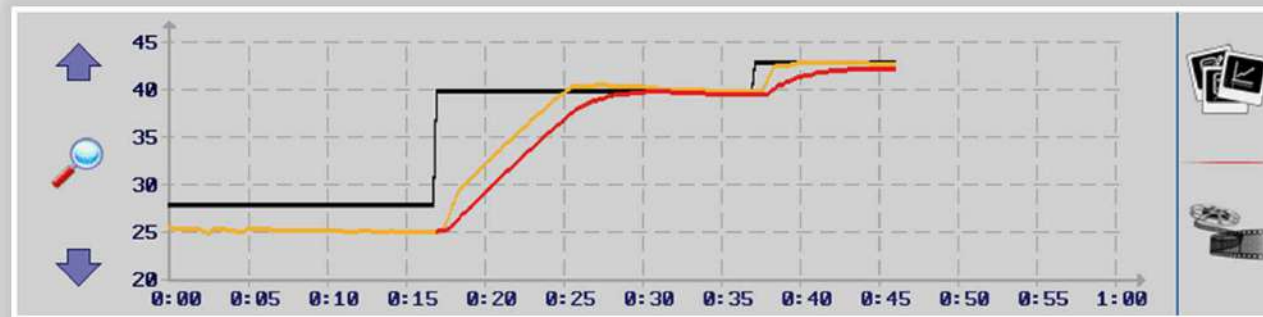
HOSPITAL					
HOS					
SURGEON					
SUR					
TECHNICIAN					
PER					

PATIENT ID					
PID					
PATHOLOGY					
PAT					
SEX	AGE	WEIGHT (KG)	HEIGHT (CM)	BSA (DUBOIS)	
F	50	80	180	2.00	f_x

PROBE 1	PROBE 2	PROBE 3	PROBE 4
PB1	PB2	PB3	PB4
PROBE 5	PROBE 6	PROBE 7	PROBE 8
PB5	PB6	PB7	PB8

Secondary screens

TEMPERATURE PROBE DIAGRAMS



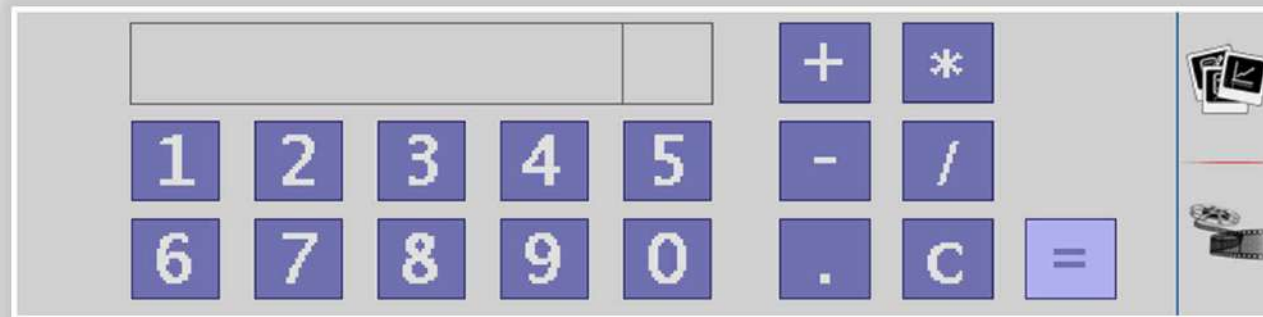
PARAMETER SET UP

A parameter set up screen for temperature. It features a numeric keypad (0-9) and a decimal point button. The current value is 28.0, and the range is 28.0 to 47.0. The unit is set to Celsius (C). A back arrow button is also present. The screen includes a magnifying glass icon on the left and a film strip icon on the right.

Parameter	Value
TEMPERATURE	28.0
Range	28.0 - 47.0
Unit	C

Secondary screens

CALCULATOR



Software: safety

SAFETY FUNCTIONS

Performer HT has been developed according to the most updated standards, paying attention to safety features and management of possible problems that could occur during the treatment execution.

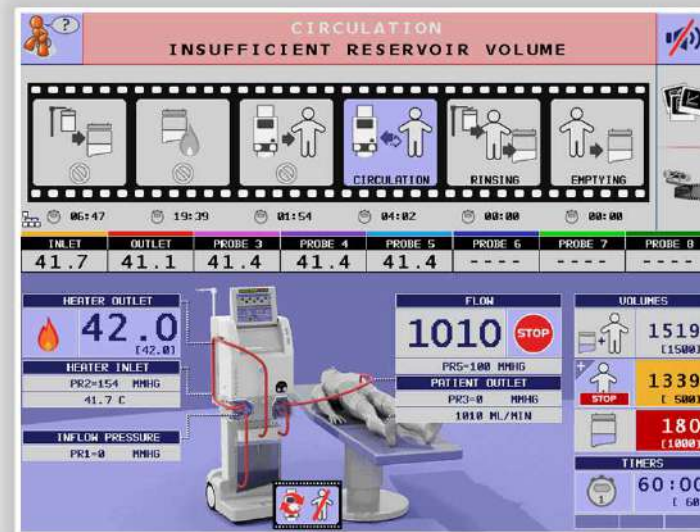
Main functions concerning safety features for the patient and the user:

- Alarms/Alerts
- Troubleshooting screen
- Devices failure management
- Event Log
- Confirmation screen
- Treatment re-establishment

Software: safety

ALARMS/ALERTS

Every fault or potential risk is signaled to the operator through an alarm/alert system including visual and acoustic buzzer, which allows to activate automatically the patient full safety status (heater switch off, pumps stop, by-pass phase activation), while the problem is identified and solved



Software: safety

TROUBLESHOOTING SCREEN

In case of alarm, the operator can activate the troubleshooting function, consisting in the displaying of current alarm screens where a series of suggestions are listed in order to identify and solve the failure.

	VOLUME RESERVOIR INSUFFICIENTE	✓
	- CONTROLLARE CHE NON CI SIANO ANOMALIE NELLA LINEA DI RITORNO: POSIZIONE DEI CATETERI, STROZZATURE DELLE LINEE, CLAMP CHIUSE, .. - SE NECESSARIO, ATTIVARE LA FASE DI BY-PASS ED AUMENTARE IL VOLUME TOTALE	✗

Software: safety

DEVICE FAILURE MANAGEMENT

In addition to the series of initial self tests performed at every start, Performer HT is provided with special functions able to solve possible problems which may occur during the treatment execution:

1. Pressure sensors

In case of failure of one of the 4 main pressure sensors, it is possible to disable it immediately and easily by means of the pressure monitoring/management screen and at the same time replace it with one of the 2 additional sensors

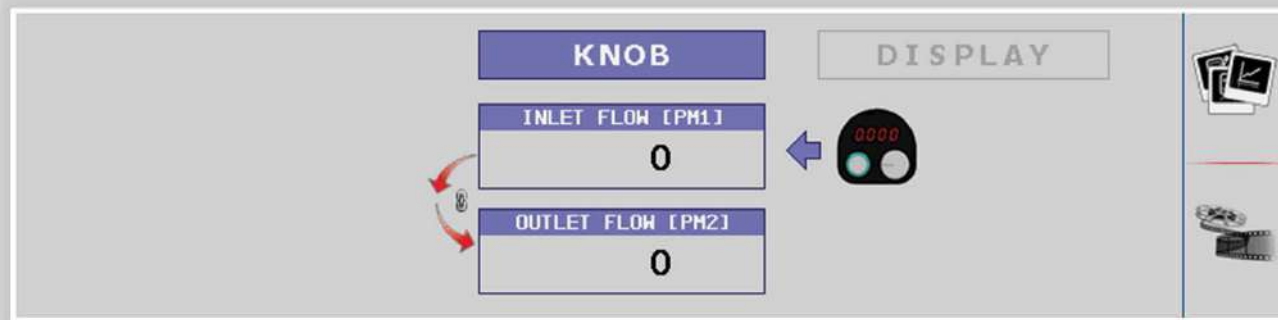


Software: safety

DEVICES FAILURE MANAGEMENT

2. Flow control knob

In case of flow control knob failure, it is possible to disable it by means of the dedicated secondary screen and activate the flow rate setting by means of the display

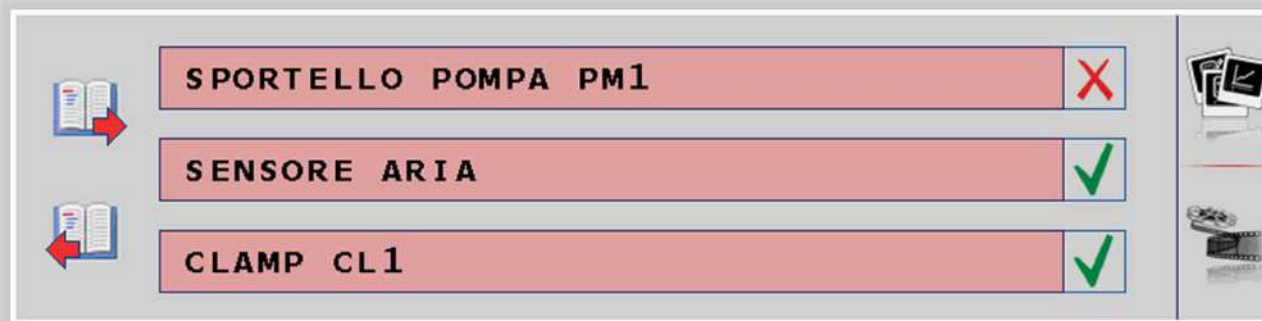


Software: safety

DEVICES FAILURE MANAGEMENT

3. Clamps, air sensor, lid sensors

In case of failure of devices which are not essential for the treatment execution, it is possible to exclude them temporarily by means of the dedicated secondary screen, in order to complete the treatment

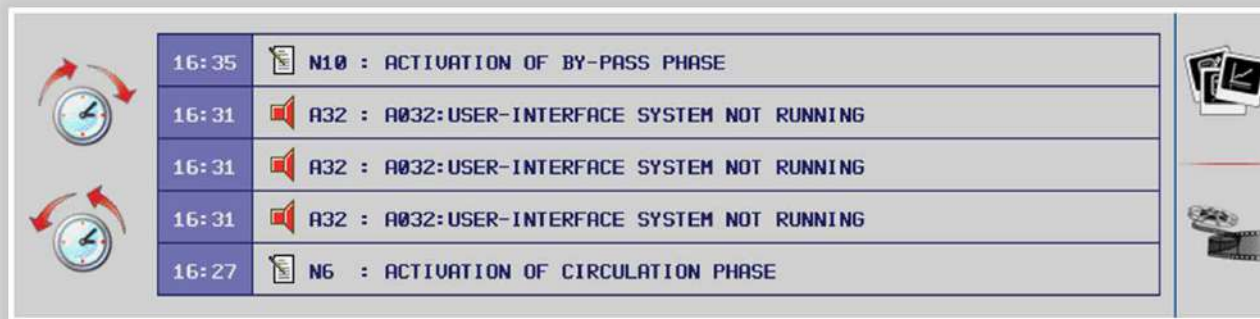


Software: safety

EVENT LOG

The Performer HT system stores all the treatment events, that are displayed in the dedicated secondary screen and stored into each treatment file.

Through this function, it is possible to track the history of the whole treatment and facilitate the cause analysis of possible occurred problems.



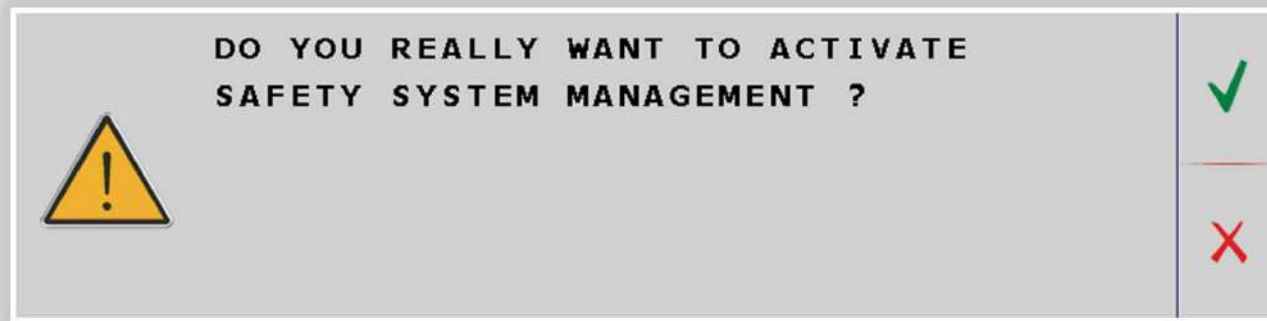
The image shows a screenshot of an event log interface. On the left, there are two circular icons with red arrows indicating a cycle. The main part of the interface is a table with five rows. The first row has a document icon, the second and third rows have speaker icons, the fourth row has a speaker icon, and the fifth row has a document icon. To the right of the table, there are two icons: a folder with a document and a film strip.

16:35		N10 : ACTIVATION OF BY-PASS PHASE
16:31		A32 : A032:USER-INTERFACE SYSTEM NOT RUNNING
16:31		A32 : A032:USER-INTERFACE SYSTEM NOT RUNNING
16:31		A32 : A032:USER-INTERFACE SYSTEM NOT RUNNING
16:27		N6 : ACTIVATION OF CIRCULATION PHASE

Software: safety

CONFIRMATION SCREEN

The execution of important procedures is protected by confirmation screens that avoid the unintentional activation by the user.



Software: safety

TREATMENT RESTORE

The unintentional switch-off of the equipment during the treatment execution is protected by a special restore function, that allows, within a few seconds, to bring the equipment back to the same status as before switching it off; in particular the following functions are restored:

- Previously active phase
- All parameters set-up
- Volume values
- Entered patient data

Intended use

Equipment

Software

Disposable kit

Safety standards

HIPEC Disposable Kit

PACKAGE CONTENTS

The Performer HT disposable kit includes all the material necessary to execute one treatment:

- Lines
- Reservoir
- Table pack
- Temperature probes
- Drainages
- Clave connectors



HIPEC Disposable Kit

SIMPLICITY AND SAFETY

The extracorporeal lines and reservoir are pre-assembled, thus making the equipment set-up extremely easy, quick and safe.

The following features contribute to simplify the kit connection:

- Identification labels on the lines to be inserted into the pump, clamps to be connected to pressure sensors
- Quick connectors on the lines to be connected to the table pack
- Colour code



HIPEC Disposable kit

RESERVOIR

In addition to the lines, the pre-assembled kit includes a solution filtration system consisting of:

Soft Reservoir

- Capacity: 7 lt
- Integrated filtration system

Rigid Reservoir

- Capacity: 1 lt
- 1.500 cm² double-stage filtration system for clusters and cell fragments
- 30 ppi pre-filter for macro filtration



HIPEC Disposable kit

Table pack

Table pack lines are provided with:

- Isolation thermal hoses to reduce heat loss towards environment
- Quick connection to the extracorporeal line
- 2 integrated temperature probes in infusion and withdrawal line
- 3 withdrawal lines
- 3 infusion lines

HIPEC Disposable Kit

TEMPERATURE PROBES

3 disposable probes for temperature monitoring into the peritoneal cavity, in addition to the 2 pre-assembled probes into infusion and withdrawal lines

DRAINAGES

5 pcs. 24Ch radiopaque silicone drainages

CLAVE CONNECTORS

The extracorporeal circuit is provided with 3 clave connectors (certified devices) for drug administration in different circuit points

ILP Disposable Kit

PACKAGE CONTENTS

The Performer HT disposable kit includes all the material necessary to execute the treatment except for the oxygenator:

- H₂O circuit
- Blood circuit
- Temperature probes
- Clave connectors



ILP Disposable kit

SAFETY AND SIMPLICITY

The water circuit is governed directly by Performer HT and is the unique entirely closed and fully sterile available in the market, making the set-up of the apparatus an operation extremely simple, rapid, safe and without the aid of additional heater-cooler.

With the aim to simplify the set-up of the circuit, there is the presence of:

- Identification labels on the lines inserted in the pumps, in the clamp and in the pressure sensors
- Quick connectors on the lines to the waste bag
- Color code



ILP Disposable kit

CIRCUIT CHARACTERISTICS

The combination of the Rand disposable kit with a pediatric oxygenator, allows to minimize extracorporeal volumes (maintaining a working volume in the venous reservoir of about 250ml).

In the blood circuit, a clave connector for the injection of chemotherapeutic drugs and a temperature probe to monitor the outgoing flow from the oxygenator are integrated.



ILP Disposable kit

TABLE PACK

The A/V table pack is provided with:

- Arterial and venous line
- Thermal insulation to reduce heat dispersion
- 1/4 "- 3 / 8" connections for cannulae
- 2 temperature sensors
- 1 arterial filter with integral bypass

Intended use

Equipment

Software

Disposable kit

Safety standards

Safety Standards

CE MARK

The Performer HT system complies with the essential requirements of the Directive on Medical Device 93/42 EEC (CE 0123).

FDA APPROVAL

510(k) clearance from the U.S. Food and Drugs Administration

Safety Standards

EQUIPMENT

- IEC 60601-1 3rd ed. General req.s for basic safety and essential performance
- IEC 60601-1-2 Electromagnetic compatibility
- IEC 60601-1-8 Alarm systems in medical electrical equipment
- ISO 14971 Application of risk management to medical devices
- IEC 62304 Software life-cycle processes
- IEC 62366 Application of usability engineering to medical Devices
- IEC 60529+A1 Degrees of protection provided by enclosures (IP Code)

Safety Standards

DISPOSABLE

- ISO 10993 series Biocompatibility - Biological evaluation of medical devices
- EN 556-1 Sterilization of medical devices
- ISO 11135-1 Sterilization of health care products - Ethylene oxide
- ISO 11138-1/2 Sterilization Of Health Care Products - Biological Indicators
- ISO 11737-1/2 Sterilization Of Health Care Products - Biological Indicators
- ASTM F1980-07 Sterilization of medical devices - Microbiological methods
- ISO 11607-1/2 Standard Guide for Accelerated Aging of Sterile Medical Device Packages



Packaging for terminally sterilized medical devices