Performer HT

Hyperthermic Perfusion System

RAND

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

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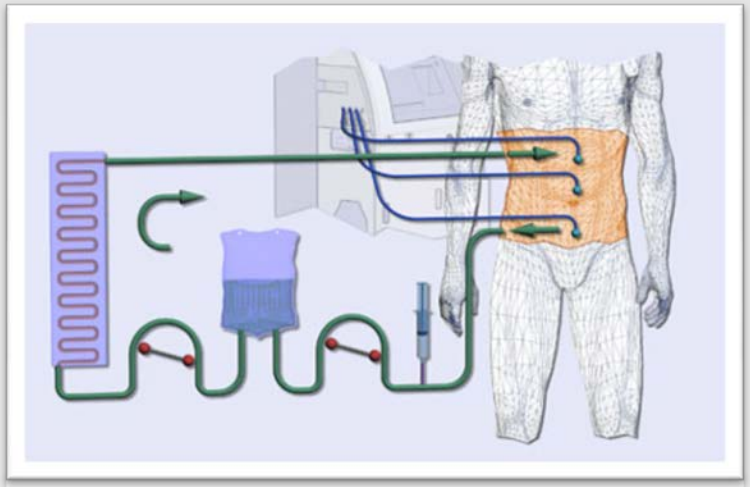
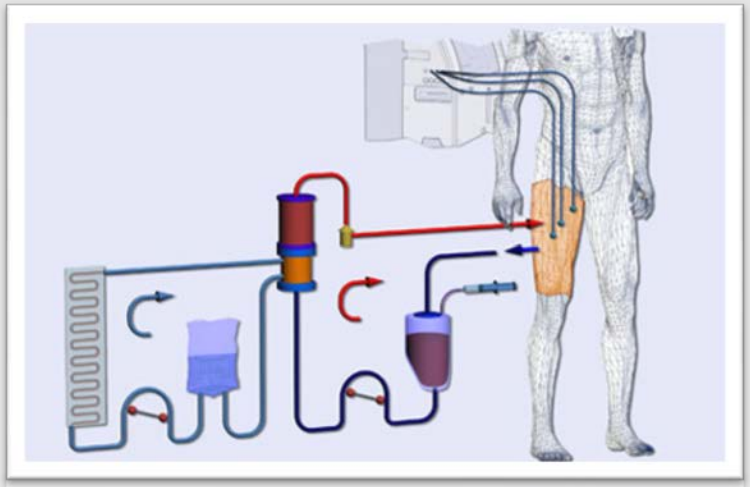
REGIONAL CANCER THERAPIES

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

Hyperthermic Intraperitoneal and Intrapleural Perfusion



Isolated Limb or Organ Perfusion



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HYPERTERMIC INTRAPERITONEAL AND INTRAPLEURAL PERFUSION

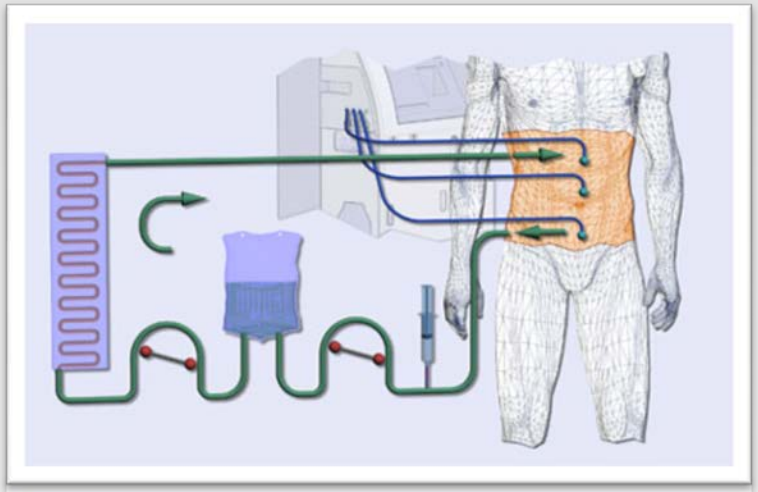
INDICATIONS

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 chemoterapeutic 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



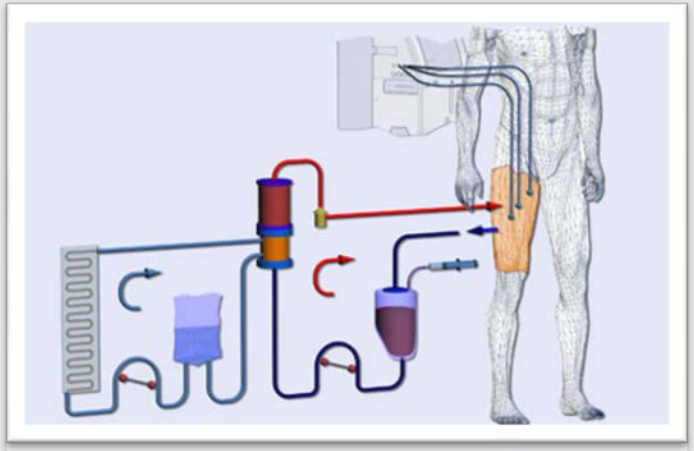
ISOLATED LIMB PERFUSION

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.



RanD

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 O_2 and Hct: connection for measurement device of Sat O_2 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

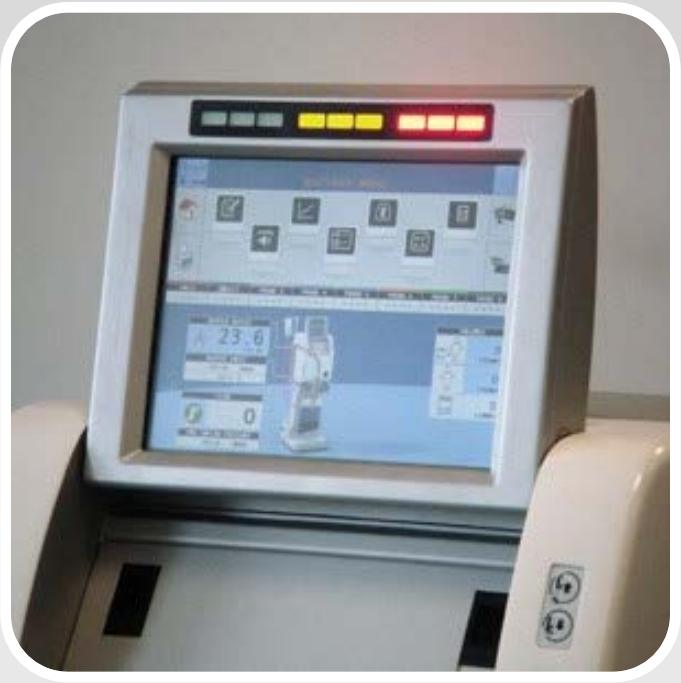
Safety: pressure monitoring allows to advise any overpressure condition potentially dangerous to the patient and/or to the medical personnel.
Reference labels on the disposable sensors allow to minimize the risk of making wrong connections during the kit assembly

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

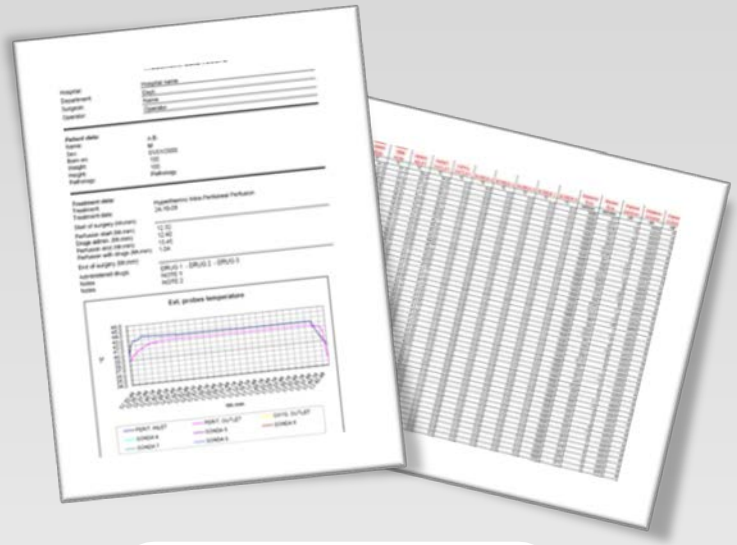
Safety: the equipment data (software version and calibration data) and all the treatment events logs are stored into a file

RanD

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.

RanD

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

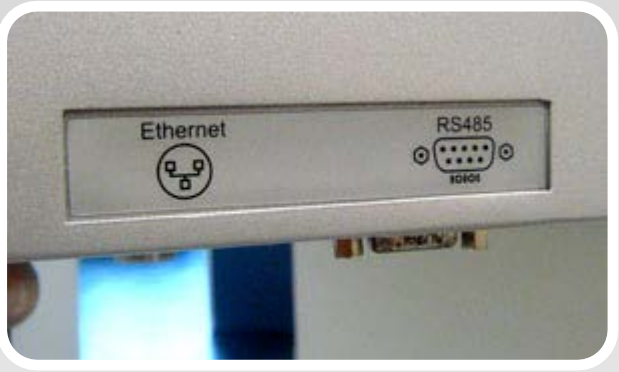
HEIGHT CONTROL DEVICE

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

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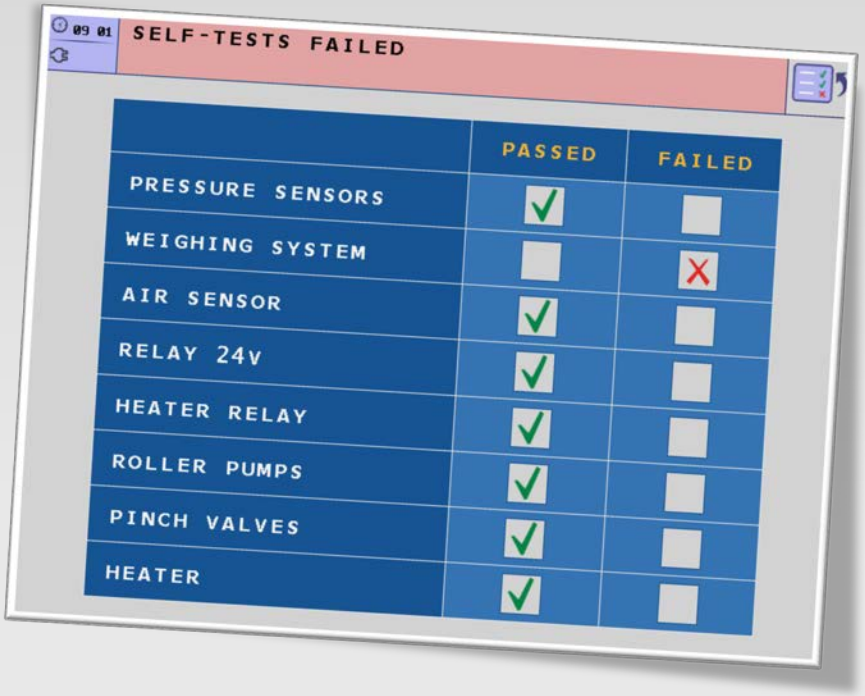
User interface

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



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

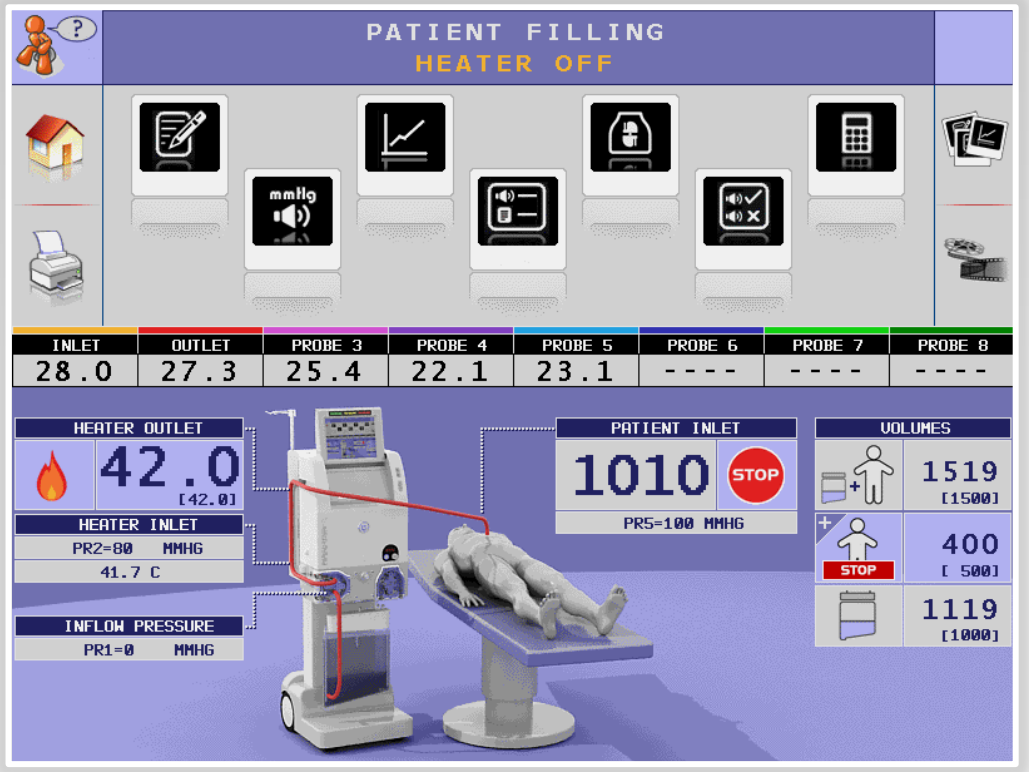
SERVICE SCREENS

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.

User interface

PERFUSION MODE

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



Message Bar

Secondary Screen

Temperature Bar

Main area

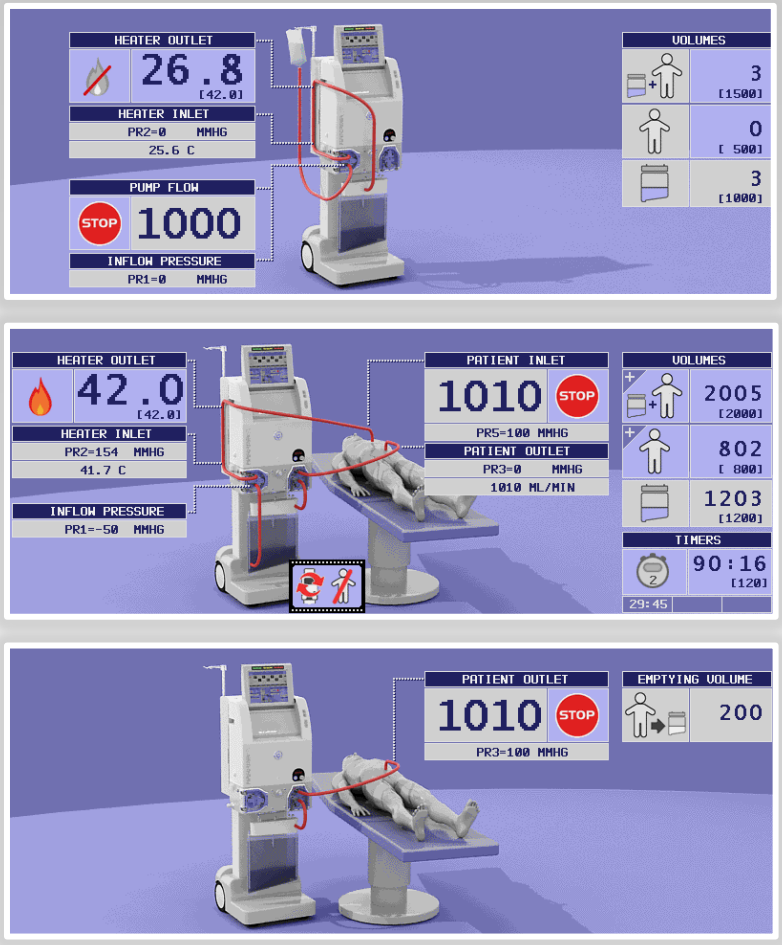
Main screen

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

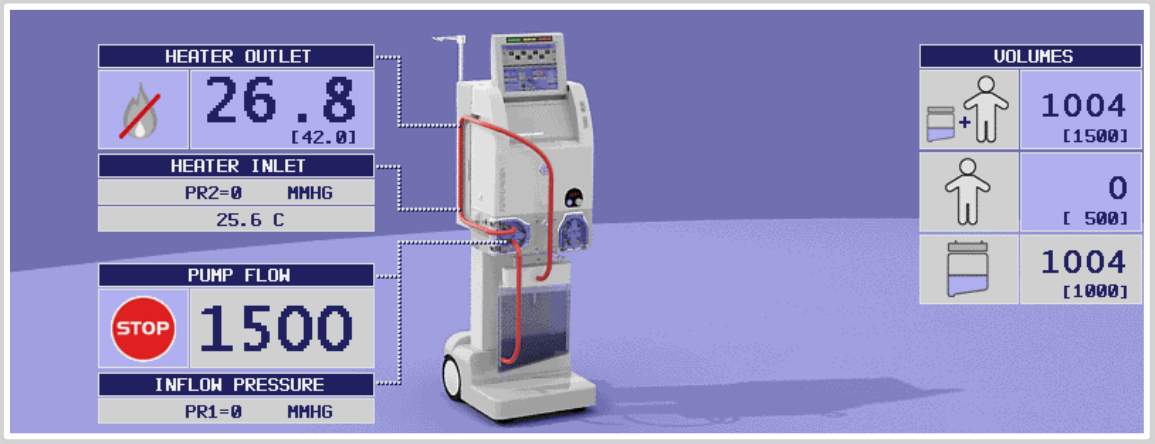
The content of the main screen is contextual to the active phase (Preparation, Circulation and Emptying phase): in each phase the displayed information refers to the current phase (circuit diagram, parameters and commands), thus enabling the operator to identify the different functions



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

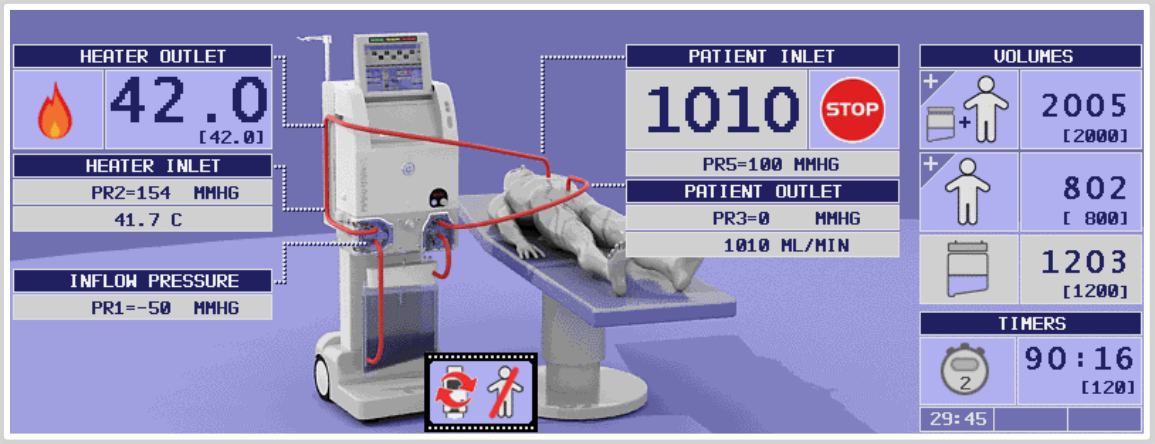


Main screen

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:

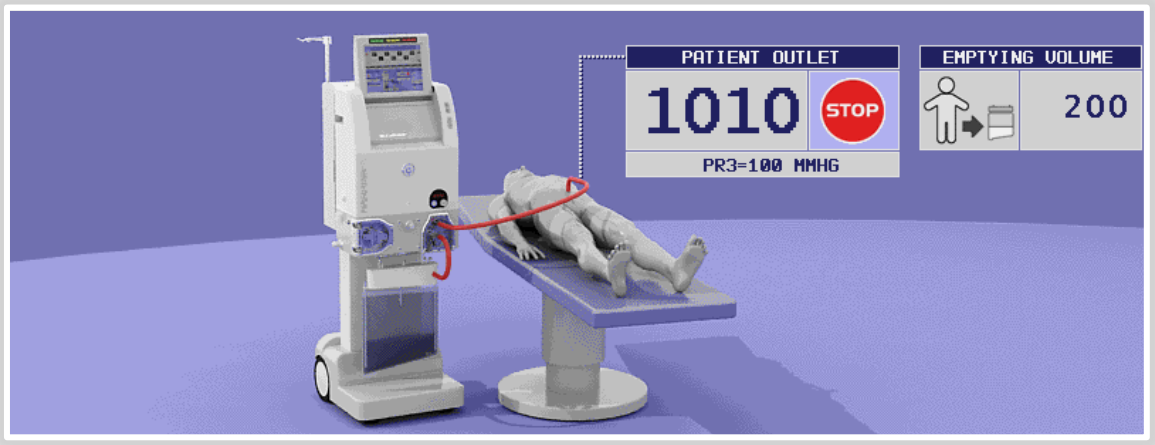
- Parameters display/set up
- By-pass phase activation
- Start of drug timers



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.

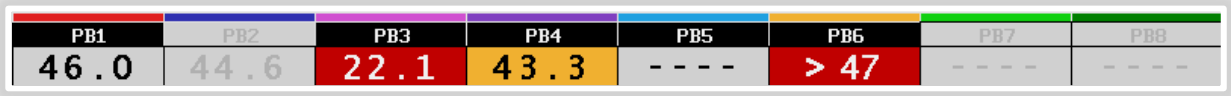


Temperature bar

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



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

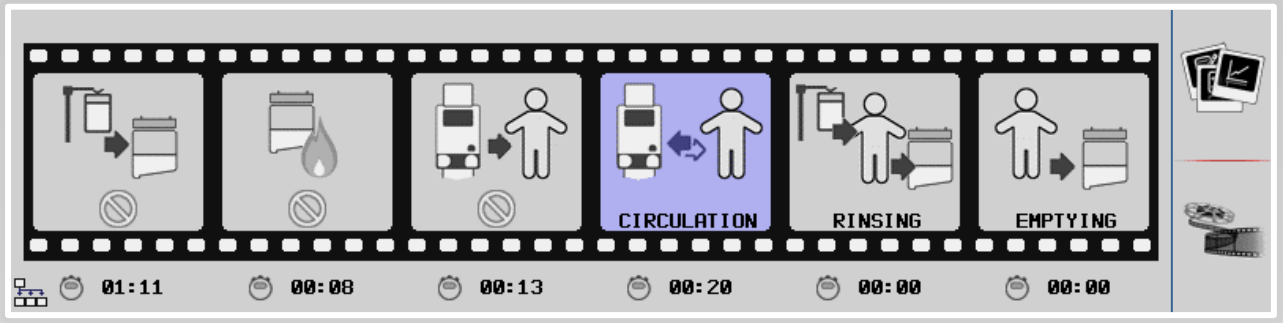
SECONDARY SCREEN

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

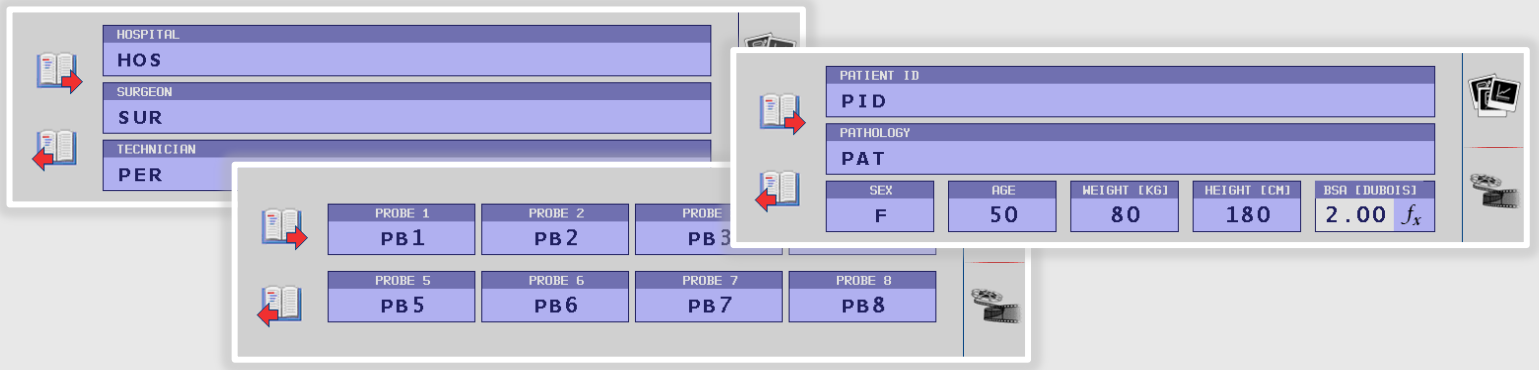
- Selection of different treatment phases
- Filling of treatment/patient data
- Display real time external probes diagrams
- Parameters set up
- Management of safety system

Secondary screens

TREATMENT PHASE SELECTION

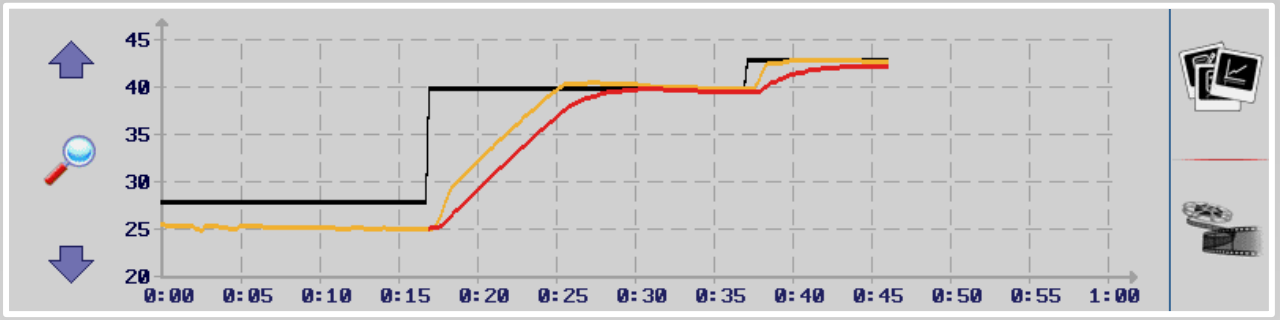


ENTERING OF PATIENT/TREATMENT DATA



Secondary screens

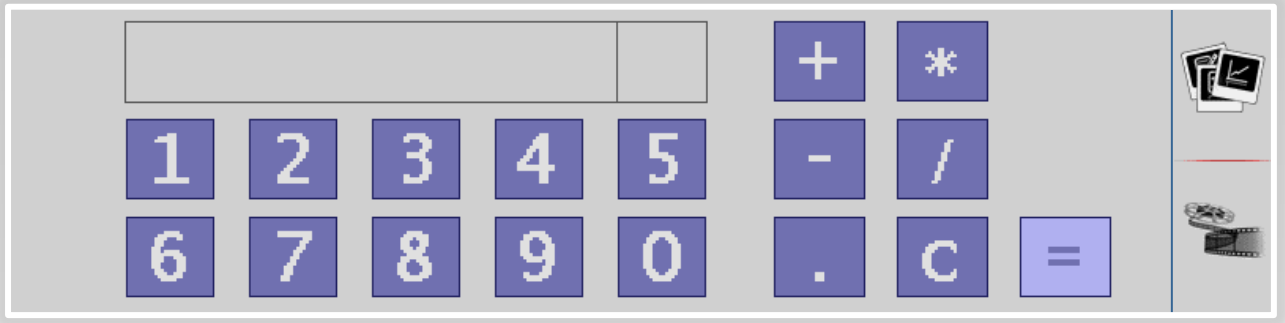
TEMPERATURE PROBE DIAGRAMS



PARAMETER SET UP

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.

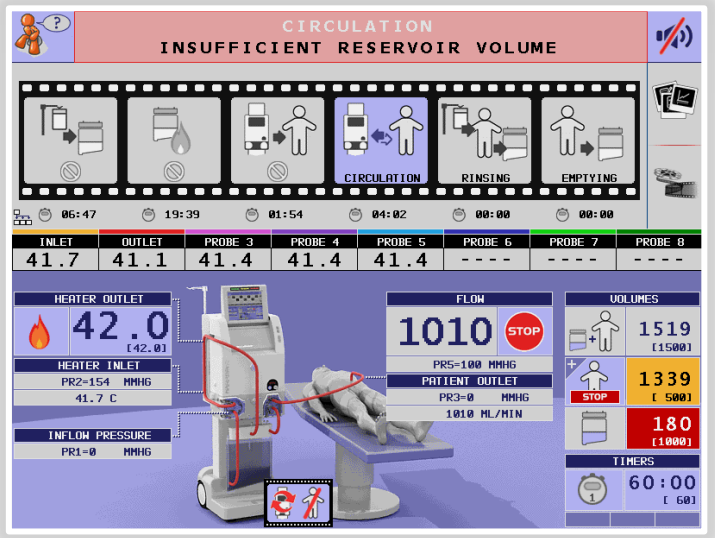
Main functions concerning safety features for the patient and the user:

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

Software: safety

ALARMS/ALERTS

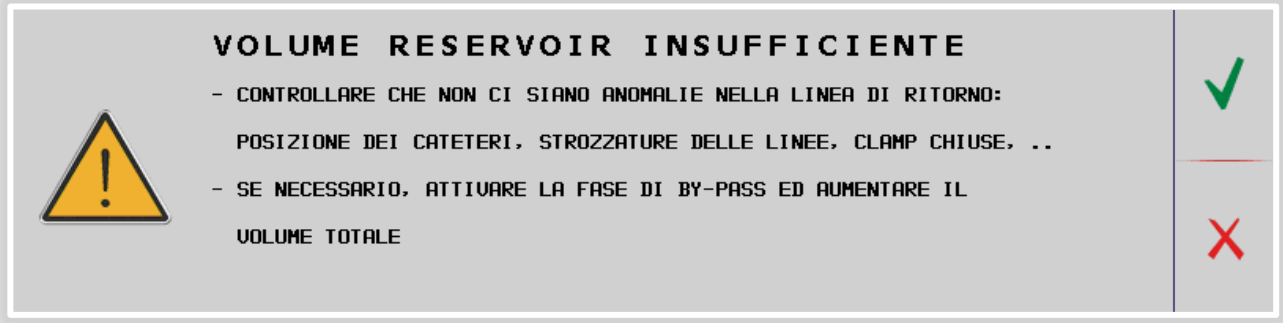
Every fault or potential risk is signaled to the operator through an alarm/alert system including visual and acoustic buzzer, which allows to activate automatically the patient full safety status (heater switch off, pumps stop, by-pass phase activation), while the problem is identified and solved



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.



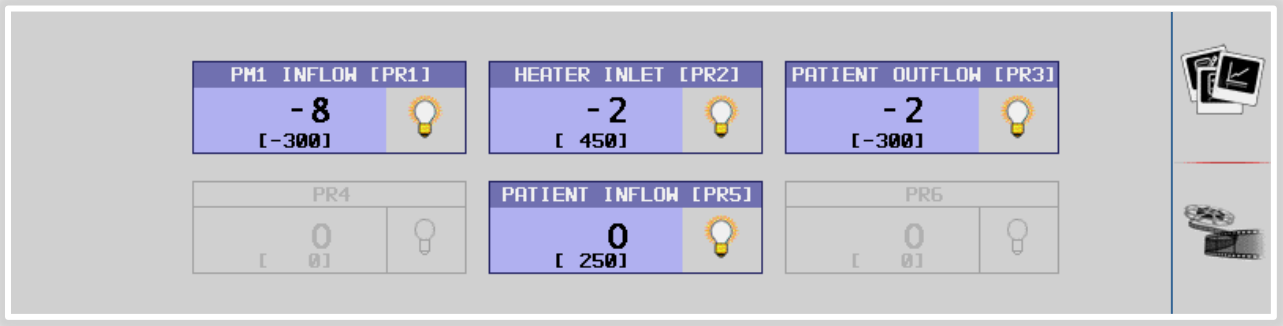
Software: safety

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

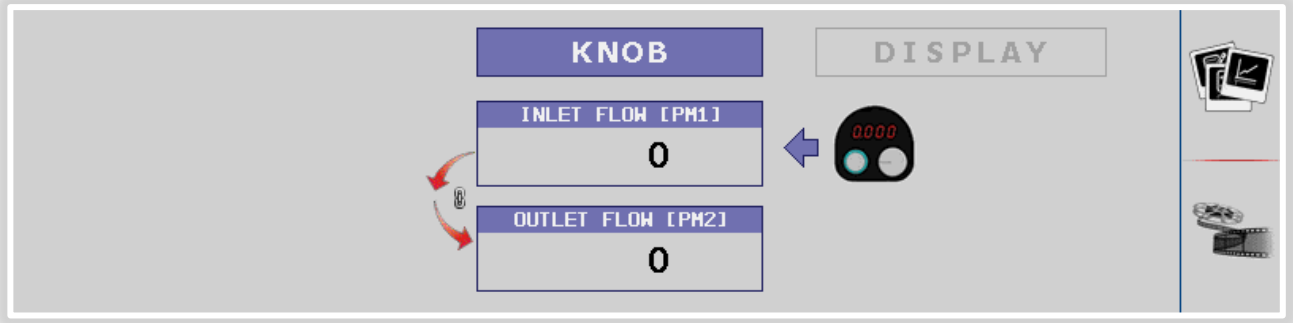


Software: safety

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

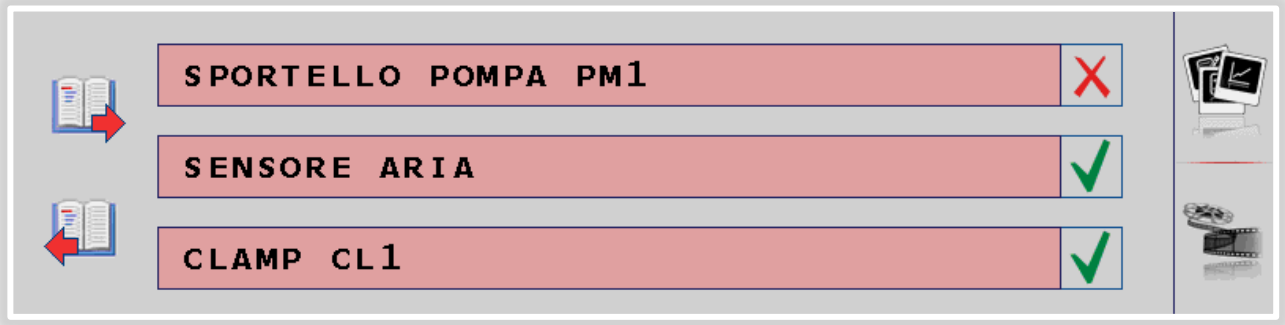


Software: safety

DEVICES FAILURE MANAGEMENT

3. Clamps, air sensor, lid sensors

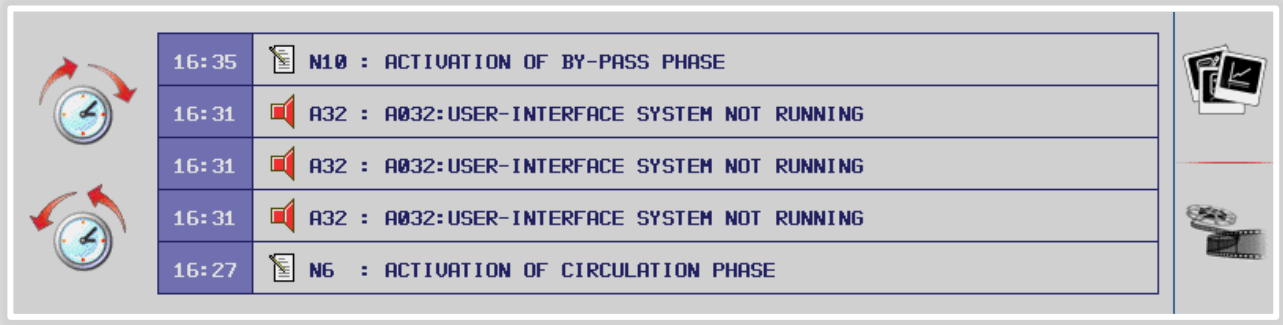
In case of failure of devices which are not essential for the treatment execution, it is possible to exclude them temporarily by means of the dedicated secondary screen, in order to complete the treatment



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.



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

RanD

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

RanD

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:

- H_2O circuit
- Blood circuit
- Temperature probes
- Clave connectors

RanD

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.

RanD

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

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RAND

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)

RanD

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 medical devices - Microbiological methods

- ASTM F1980-07 — Standard Guide for Accelerated Aging of Sterile Medical Device Packages

- ISO 11607-1/2 — Packaging for terminally sterilized medical devices