PERFORMER 3

OPERATING MANUAL

RanD

Legend of symbols

Symbol	Description
CE	Conformité Européenne (European Conformity). This symbol means that the device fully complies with: - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices - Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
	Warning
	Follow instructions for use
MD	Medical device
REF	Catalogue Number
SN	Serial Number
	Quantity
	Date of Manufacture
	Manufacturer
	Fragile
	Handle with Care
	This Way Up
	Temperature Limitation
	Humidity Limitation

	Atmospheric pressure limitation
	Keep Dry
	Alternating Current
	Equipotentiality
	Fuse
	Warning, electricity
	Type BF Equipment
IP21	IP grade (as for IEC 60529): protected against ingress of solid objects over 12.5mm and protected against vertically falling drops of water or condensation.
	Maximum weight on the IV pole: 5Kg
	Maximum weight on the scale: 10Kg
	Weight of equipment + maximum load of accessories and liquids in operation
	Do not dispose of this product in the unsorted municipal waste stream
	USB Port
	ON
	OFF
	Warning, equipment overturning (see 1.5 - Transportation)
	No pushing

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1. Introduction

1.1 System presentation

The PERFORMER 3 is a prescription electromechanical device for the extracorporeal circulation of fluids in hyperthermic perfusion therapies, and in particular in Hyperthermic Intra-Peritoneal/Intra-Pleural Perfusion with the aim of providing localized hyperthermia by circulating warmed fluids, which may contain chemotherapeutic drugs, in the peritoneal or pleural cavity.

The intended Patient population is typically adult/elderly women or men, ranging from 18 to 80 years old, and adolescents. The PERFORMER 3 must not be used on neonates and children.

Hyperthermic Intra-Peritoneal/Intra-Pleural Perfusion cannot be conducted on pregnant women because of the presence of the fetus.

Hyperthermic Intra-Peritoneal/Intra-Pleural Perfusion could be conducted on nursing women. Chemotherapy side effects are possible also in hyperthermic perfusions, but in much lower measure than those given by the traditional chemotherapy. It is the responsibility of the physician to assess the risk/benefit ratio for the patient.

The clinical benefits of the hyperthermic perfusion therapies deduced from the literature are:

1. Removing all the invisible tumor cells after cytoreductive surgery.
2. Reducing the risk of recurrence.
3. Reducing the risk of peritoneal/pleural and other metastasis.
4. Extending the overall survival rate, when combined with CRS, compared to CRS alone or CRS + systemic chemotherapy.

Use of hyperthermia in the above therapies and its clinical effects are documented in the clinical literature, available upon request at RanD's premises.

1.2 Intended Use

The PERFORMER 3 is indicated for use in the extracorporeal circulation of fluids during hyperthermic perfusion procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

1.3 Contraindications

The PERFORMER 3 is contraindicated for procedures outside of the intended use.

1.4 Side Effects

There is no evidence of side effects related to the use of the system.

1.5 Warnings

General

- The PERFORMER 3 is intended exclusively for hospital use. The PERFORMER 3 is not intended for domestic use.
- **The user must read and understand all user information prior to use. This includes the User manual and the corresponding instructions for use packaged with disposable components. Failure to read and follow all instructions, or failure to observe all stated warnings, could cause serious injury or death to the patient.**

- The PERFORMER 3 is strictly to be used by and under the supervision of a medical professional.
- The PERFORMER 3 is intended to be used by perfusionists or by nurses. Users must have first received the operative training by personnel qualified by RanD. It is forbidden to use the system without being trained.
- Only personnel qualified by RanD may provide training.
- The system must be carefully and constantly monitored by qualified personnel trained in use of the device throughout the procedure.
- Use the system, and any attached devices, according to the applicable instructions and good medical practice. No modification of this equipment is allowed.
- A qualified physician must be directly responsible for the following: patient catheter selection and placement techniques; temperature probe location selection and placement techniques; procedures used to connect the patient catheters to the infusion and withdrawal lines and drug administration.
- Use only catheters compatible with PERFORMER 3 disposable components.
- Do not introduce fluid into the male pressure Luer connections on the console.
- Ensure that the fluid isolator supplied as an integral part the disposable fluid line circuit is always in place. It must be in the pressure monitoring line to prevent contact of sterile fluid path with the instrument and damage to the instrument and pressure system.
- Do not bypass the fluid isolator/filter in the pressure lines (PR1 through PR6) because fluid could enter the transducer and damage internal components.
- Follow standard operating practices for electronic devices. Closely monitor the system when exposure to intense electrical noise or fluctuating line voltage occurs. Strong electromagnetic fields emitted from other equipment in the operating room may compromise performance or damage the PERFORMER 3. These fields could include the following: alternating current (AC) power line voltage fluctuations, internal and external defibrillators, electrocautery devices, etc.
- Portable and mobile radio frequency (RF) communication devices may affect the PERFORMER 3 operation (see “Electromagnetic Emissions and Immunity Declarations”).
- The system has been designed and tested in conformity with the Electro-Magnetic Compatibility standard EN60601-1-2. It is advisable, however, to avoid operating the system in the presence of electromagnetic fields, or other equipment causing interference (e.g. mobile phones). Special information regarding installation, use, and precautions are described in “Electromagnetic Emissions and Immunity Declarations” section.
- If electromagnetic interference occurs, the various external temperature probe measurements may experience transitory variations. This may be seen in the readings on the main display. However, this is not a dangerous condition for the patient because the external temperature measurement signals are not used to control the heater plate temperature. If measurement variations are observed, the user must carefully evaluate the reliability of the temperature values in any subsequent measurements. The user must evaluate the temperature readings in relationship to the real conditions before taking any corrective action or making any control system modification.
- Do not touch the Patient and the equipment simultaneously.
- Do not switch on the equipment if any physical anomalies are noticed that could jeopardize the correct functioning of the equipment. Contact an authorized service technician.
- Do not use adapters or extension cords with the main power cable. If necessary, proceed to replace the equipment plug with one that is consistent with the available power supply system, to be done by an authorized technician.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. The hospital/clinic's electrical environmental department should be contacted for any clarification or questions.
- Switch on the equipment only when it has reached ambient temperature.
- Do not connect other devices than an USB key to the USB port.
- Do not place the device in a position in which it is difficult to reach the power cord in the event that it becomes necessary to unplug it to electrically isolate the PERFORMER 3 from the supply mains.
- If patient volumes higher than 6 liters are required, please make sure to use the dedicated kit Hang&Go 3 HV.

Alarms

- Do not disable or otherwise bypass an alarm without ensuring that the applicable parameter(s) can be effectively monitored by some other means. The user must ensure that all applicable parameters are monitored. Failure to monitor any parameter whose alarm has been disabled or otherwise bypassed can result in less than optimal system performance and/or possible serious injury or death to the patient.

Uninterruptible power Supply (UPS)

- The UPS is a safety feature that provides a low voltage power supply in case of temporary AC power failure, thus allowing continuation treatment . When the Uninterruptible Power Supply (UPS) converts the system to battery power all functions, safety systems, alerts, alarms, monitors and controls are active, except for the heater, which is deactivated.

ON/OFF switch

- Ensure that the ON/OFF switch is off before storage, inspection, cleaning, and preparation for use to disable both the battery power and wall AC power.

Temperature Probes

- The system is not protected against defibrillator discharges. In the case of use of a defibrillator, disconnect the external temperature probes. The operator must rapidly remove all the connected probes before the discharging.
- Use only the thermistor probes specified in “Disposable and accessories”. Failure to do so may jeopardize the performance of the device and, therefore, the measurement reliability.
- Do not connect the external temperature probes in conjunction with electrocautery usage; this may compromise the temperature measurement.
- For correct handling, use and maintenance of these devices, please refer to the manufacturer's instructions for use, included in the device package.

Tubing and Disposable Components

- Use only RanD-approved disposables that are designed to be used with the system. Failure to do so may result in impaired system performance and patient injury.
- Carefully follow the manufacturer’s instructions for a correct disposable circuit set up. Failure to do so may jeopardize the functionality of the instrument, possibly compromising patient and user safety.
- The equipment employs disposable circuits to minimize patient exposure to contamination or infection. In particular, the pressure sensor connectors are provided with internal hydrophobic protective filters that protect the transducer from contaminants if the external protective filter breaks. If this happens, authorized technical service personnel must replace the protection filter in order to avoid errors in pressure detection.
- The RAND disposable devices are intended for single use only. Reuse of the devices brings with it the risk of cross-infection regardless of the cleaning or sterilization method used. Do not resterilize, do not undergo further processing. Resterilization may be ineffective and might compromise the integrity of the device, causing serious harm to the patient.

Peristaltic Pumps

- The pumps rotate in a clockwise direction. Always ensure proper direction of rotation before installing tubing into the peristaltic pump. The direction of forward flow for the tubing must be consistent with the rotational direction of the peristaltic pump. Always ensure that the direction of flow is not in a retrograde direction, which would result in pumping air into the patient.
- Verify that the peristaltic pumps are stopped prior to loading tubing.

Drug Administration

- The system does not administer or control the dosage of chemotherapeutic agents.
- Chemotherapeutic drug administration is only to be performed under the direction and liability of the responsible physician. The chemotherapeutic drug administration must be based on the benefits and risks evaluation for a specific patient and procedure.
- During treatments involving perfusion with chemotherapeutic drugs, health care personnel must take appropriate personal and environmental protection measures in compliance with current laws and internal safety procedures in order to minimize the risks associated with exposure (by contact or inhalation) to these drugs.

Transportation

- In order to avoid overturning of the equipment on a plane inclined at an angle > 5°, move the equipment only in transport configuration, as described in sect 4.2.2. Equipment overturning may cause crush injury and equipment damage.

1.6 Cautions

- Do not use sharp instruments on the display, Main Pump Control Panel, switches or scroll arrows as these may damage the device. Touch the screen and switches with fingers only.
- Do not adjust the occlusion setting on the roller pump insert; doing so will void the warranty.
- Ensure the castor brakes are engaged before use. Unintended equipment motion could cause tubing disconnection and fluid leakage to the environment.

1.7 Cleaning

- After each use, clean the device as per the instructions below.
- If it is suspected that fluid penetrated into the equipment, the unit should be unplugged and immediately examined by a trained, service technician.
- Unplug the equipment before cleaning to avoid electrical shock and verify that the main switch is switched off.
- Do not use chemical solvents such as methyl ethyl ketone, alcohol, ether, acetone, FORANE®1, or a solvent-based solution in or on any part of the equipment, as such solvents may be destructive to the device and its internal components. Do not use abrasive cleaners or cleaning solvents other than those recommended in this manual.
- The surface of the whole system (including pump heads, tube occlusion roller, and tube guide rolls) must be thoroughly cleaned after each use, in order to avoid the accumulation of contaminated or corrosive fluids.
- All the external surfaces can be easily cleaned and disinfected for blood, saline, or other spilled contaminants using normal medical equipment cleaners and disinfectants such as bleach (5.25%) and hydrogen peroxide (3%).
- As fluids should not be allowed to enter any openings, do not apply cleaning solution with a spray.
- Clean the equipment with a sponge or soft cloth moistened with water or a mild detergent.
- After the equipment has been cleaned, wipe the unit with a cloth moistened with water to remove any cleaning solution residue and then wipe the unit with a dry cloth.

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1.8 Maintenance

- Preventive maintenance should be carried out every 12 months to ensure accurate performance and reliability, and to guarantee safe use of the equipment.
- Failure to perform periodic maintenance at appropriate intervals may compromise the equipment functionality and cause serious injury or death to the patient.
- All maintenance is to be performed only by authorized and qualified service personnel.
- Installation, updates, modifications, and repairs must be performed by trained personnel authorized by the manufacturer, using manufacturer-authorized parts. Such operations are comprehensively described in the Service Manual.
- No part of the equipment shall be serviced or maintained while the equipment is in use on a patient.
- The life of rechargeable battery packs is guaranteed for 4 years. After this period, battery replacement and disposal are provided by authorized, trained personnel.

Warning: replacement of the battery by unauthorized and untrained personnel could result in an unacceptable hazard for the operator and the patient.

1.9 Reporting of incident

Any serious incident that has occurred in relation to the device should be reported directly to RanD or to its distributor and the competent authority of the Member State in which the User is established.

2. Safety

2.1 Safety Standards

The PERFORMER 3 equipment complies with the General Safety and Performance Requirements of the Regulation (EU) 2017/745 on medical devices and with Directive 2011/65/EU, commonly known as the ROHS 2 directive.
The PERFORMER 3 equipment also complies with the following international standards:

- IEC 60601-1 3.1 ed.: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-8: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 62304: Medical device software - Software life cycle processes
- IEC 62366-1: Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 60529: Degrees of protection provided by enclosures (IP Code)
- ISO 14971: Medical devices - Application of risk management to medical devices
- ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: general requirements

2.2 Manufacturer's Liability

The manufacturer is liable for equipment safety, reliability, and performance only provided that:

- the installation operations, updating, modifications, and repairs are carried out by personnel authorized by the manufacturer
- the main supply of the equipment destination room complies with local normative requirements
- the internal parts of the equipment are accessed only by personnel authorized by the manufacturer after a training course
- the personnel has been trained according to the present User Manual
- the unit is operated according to the instructions given in the present User Manual

2.3 Disposables and Accessories

Accessories and detachable parts approved by RanD for use with the PERFORMER 3 are:

- RanD Hang&Go 3 (disposable lines set for Hyperthermic Intra-Peritoneal/Intra-Pleural Perfusion).
- RanD Flow Reverser (optional accessory to be used in conjunction with the Hang&Go 3, it is necessary in case the user wants to activate the "flow reverser" function).
- RanD Ch24 round silicone catheters (disposable catheters for the connection of the Hang&Go 3 tubing to the patient's body cavity).
- Mains supply cord (R7102025 EU-type plug, R7102027 UK-type plug, R7102028 India-type plug).
- Multi-purpose temperature probes. RanD recommends the following types:
    - Type: Thermistor probe for medical use, YSI 400 Series, with 3.5mm (1/8") mono jack moulded connector
    - Model: RanD has validated for use with the PERFORMER 3 the Metko oesophageal temperature probes. Use only temperature probes approved by RanD. Please contact RanD / your local distributor for a list of the approved models.

Warning: the use of different probes may jeopardize the performance of the device and, therefore, the measurement reliability. Use only disposables, parts, and accessories approved by RanD. The use of other manufacturers' disposables and accessories has not been validated by RanD

and will void the warranty on the instrument and may jeopardize the functionality of the instrument, possibly compromising patient safety.

2.4 Main Power Supply Failure

The PERFORMER 3 includes an Uninterruptible Power Supply (UPS) system. In case of main power supply failure, the backup battery will allow a limited autonomy (without use of the heater).

Warning: when the Uninterruptible Power Supply (UPS) converts the system to battery, all functions, safety systems, alerts, alarms, monitors and controls are active, except the heater, which is deactivated.

2.5 Electromagnetic Interference

The PERFORMER 3 has been designed and tested to comply with requirements and tests of the electro-magnetic compatibility standard IEC 60601-1-2. It is advisable, however, to avoid its use in the presence of strong electromagnetic fields radiated from other equipment in the operating room (i.e., defibrillators and electrocautery devices) that may cause interference.

Special information regarding installation, use, and precautions are described in “Electromagnetic Emissions and Immunity Declarations”.

The use of any accessories, probes, or cables other than those specified in this document, including replacement parts, may result in either increased emissions or decreased immunity of the PERFORMER 3.

Warning: use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

2.6 End of Life Disposal

The PERFORMER 3 equipment has an expected life of 10 years from the installation date, on condition that maintenance schedule suggested by the manufacturer is complied with and performed by the manufacturer itself or by authorized personnel.

This product complies with EU DIRECTIVE 2012/19/UE.

The crossed-out bin symbol on the appliance and on batteries indicates that the product, at the end of its life, must be disposed of separately from domestic waste to allow adequate recycling.

At the end of its useful life, the separate collection of this equipment is arranged and managed by RanD or by its distributor, when present in the Country of commercialization.

The customer who purchases a new equipment can ask RanD or its distributor to collect the old equipment free-of-charge at the end of its useful life within 15 days from the delivery date of the new equipment.

All batteries inside the equipment cannot be removed by the user and must be left in place.

If the disused appliance is collected correctly as separate waste, it can be recycled, treated and disposed of ecologically, thus avoiding a negative impact on both the environment and health and contributing towards recycling of the product’s materials.

Illegal disposal of the product by the owner will result in the application of the administrative sanctions set down by the current laws in force.

2.7 Technical Documentation

The Service Manual, with electrical schematics, calibration procedures, and component list, will be provided upon request for exclusive use by authorized, trained personnel.

2.8 Replacing Fuses

No resettable fuses (circuit breakers) are present on the PERFORMER 3 equipment.

The replacement of all fuses must be performed only by authorized, trained personnel.

2.9 Equipotential Connection

A connection for potential equalization (ref. to the requirements of the standard IEC 60601-1 for ME Systems) is available on the back of the PERFORMER 3 in case local regulations require “potential compensation” by means of connection to the potential compensation network.

A potential equalization connection is also recommended if other types of equipment are used in the same room.

2.10 Battery Pack Useful life and Disposal

The life of rechargeable battery packs is guaranteed for 4 years from installation date. After this period, battery replacement and disposal must be provided by authorized, trained personnel.

2.11 Defibrillator Discharge

The equipment is not protected against defibrillator discharges. It is advisable to disconnect the external temperature probes prior to defibrillator discharge to avoid damage to the equipment.

3. Technical specifications

3.1 Statement of Conformity and Classification

The equipment is a Class IIb medical device in conformity with article 51 of EU MDR 2017/745. The equipment is CE marked according to Regulation (EU) 2017/745 on medical devices. The device is also in compliance with the standards listed in chapter 2.

The following sections include technical information of the PERFORMER 3. Additional information can be found in the service manual.

3.2 General Data

Catalogue code	R5100075
Electrical data	
Classification (as for EN60601-1)	Class I, type BF Applied parts: external temperature probes, warmed fluid, disposable lines Internally powered equipment (UPS system, in case of main power supply failure)
Voltage	110-240 VAC
Frequency	50/60 Hz
Power absorption	1400 VA
Earth leakage current	< 500 µA
Patient leakage current	< 100 µA
Potential equalization	Available
IP grade (as for IEC 60529)	IP 21
Environmental Operating Conditions	
Temperature	+18°C to +25°C
Relative humidity	30% to 60% (non-condensing)
Atmospheric pressure	795 to 1060 mbar
Transport and Storage Conditions	
Transport temperature	-20°C to +60°C
Storage temperature	+5°C to +35°C
Relative humidity	10% to 90% (non-condensing)
Atmospheric pressure	700 to 1060 mbar
Dimensions and Weight	
WxDxH	540 x 574 x 1120 mm (transport conditions) 540 x 574 x 1550 mm (operating conditions)
Weight	max. 95 Kg
Essential performances	
In both NORMAL CONDITION and SINGLE FAULT CONDITION the system must not overheat so much as to reach a temperature in the body cavity of higher than 44.5°C. In the event that the above criterion is not met, the system must activate the SAFE STATUS.	
Means for isolation from the supply mains	
Flexible cord with a main plug (power cord)	

3.3 Technical Features

Peristaltic pumps	
Flow rate range	0.4 - 3.0 L/min
Maximum tolerance	≤ 10% in the following conditions: - Inlet pressure: ≥ -180 mmHg - Outlet pressure: ≤ 500 mmHg
Pressure Transducers	
Operating range	-550 to +600 mmHg
Resolution	1 mmHg
Maximum tolerance	± 5 mmHg
Heater	
Type	Plate heater
Operating range	+37°C to +45°C
Maximum tolerance	± 0.3°C
Weighing System	
Operating range	0 to 10 kg
Resolution	1 g
Maximum tolerance	±10 gr
Air Sensor	
Type	Ultrasound
Sensitivity	1 ml at 500 ml/min 2 ml at 1000 ml/min 4 ml at 2000 ml/min 6 ml at 3000 ml/min
Battery Pack	
Type	Lead Acid (12V - 9A/h)
Autonomy (after at least 4 hours of recharge)	- At least 90 min @ 1 Lpm - At least 60 min @ 2 Lpm - At least 30 min @ 3 Lpm
Fully recharging time	12 hours
Replacement	4 years
Temperature probes	
Operating range	+25°C to +46°C
Maximum tolerance	± 0.3°C

3.4 Electromagnetic Emissions and Immunity Declarations

Emissions Declaration

The PERFORMER 3 equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the PERFORMER 3 equipment should ensure that it is used in such an environment.

Table 3-1. Electromagnetic Emissions for all Equipment and Systems
(Reference IEC 60601-1-2 4.1)

<table>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td rowspan="2">The emissions characteristics of the PERFORMER 3 equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
The PERFORMER 3 equipment generates RF energy only as a by-product of its internal function.
Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class A</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>N/A</td><td rowspan="2">N/A</td></tr>
<tr><td>Voltage fluctuation / flicker emissions
IEC 61000-3-3</td><td>N/A</td></tr>
</table>

Immunity Declaration

The PERFORMER 3 equipment is intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the PERFORMER 3 equipment should ensure that it is used in such an environment.

Table 3-2. Electromagnetic Immunity for all Equipment and Systems
(Reference IEC 60601-1-2 4.1)

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV in air	Complies to the Test level	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst (EFT) IEC 61000-4-4	±2 kV for power supply lines 100 KHz repetition rate	Complies to the Test level	Mains power quality must be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies to the Test level	Mains power quality must be that of a typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11	100% reduction for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 100% reduction for 1 cycle and 30% reduction for 25/30 cycles at single phase at 0 degrees 100% reduction for 250/300 cycles (5 sec.) and all devices remain safe	Complies to the Test level	Mains power quality must be that of a typical commercial or hospital environment. Note: in consideration of the possibility of continuous functional operation during mains power interruption, the PERFORMER 3 equipment is provided with an Uninterruptible Power Supply (UPS) with battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Complies to the Test level	Power frequency (50/60 Hz) magnetic field must be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3-3: Electromagnetic Immunity for Equipment and Systems that are not Life-Supporting (Reference IEC 60601-1-2 4.1)

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment-guidance**
			Follow the recommended separation distance calculated from the equation applicable to the frequency of the transmitter when using portable and mobile RF communication equipment in close proximity to any part of the PERFORMER 3 equipment, including cables. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM Bands(2)	3 V (1)	d= 1.2 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	d= 1.2 √P 80 MHz to 800 MHz d= 2.3 √P 800 MHz to 2.7 GHz
			Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be lower than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

1. At 80 MHz and 800 MHz, the higher frequency range applies.

2. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PERFORMER 3 equipment is used exceeds the applicable RF compliance level above, the PERFORMER 3 equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PERFORMER 3 equipment.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Tabella 3-4: test specifications for enclosure port immunity to RF wireless communications equipment

(Reference IEC 60601-1-2 4.1)

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Tabella 3-5: test specifications for enclosure port immunity to proximity magnetic fields (Reference IEC 60601-1-2 4.1)

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7,5 [c]

[a] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] r.m.s., before modulation is applied.

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and PERFORMER 3 Equipment

The PERFORMER 3 equipment is intended for use in an electromagnetic environment in which radiated RF disturbance is controlled. The customer or user of the PERFORMER 3 equipment can help prevent electromagnetic interference by distancing the portable and mobile RF communication equipment (transmitters) as far away as possible from the PERFORMER 3 as recommended in Table 3-4, according to the maximum output power of the communication equipment.

Table 3-6: Recommended separation distance between portable and mobile RF communication equipment and the Equipment that are not Life-Supporting.
(Reference IEC 60601-1-2 4.1)

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.7 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance **d** in metres **(m)** can be determined by using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watt **(W)** according to the transmitter manufacturer.

Note 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by adsorption and reflection from structures, objects, and people.

Warning: portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PERFORMER 3, including cables specified by RanD. Otherwise, degradation of the performance of this equipment could result.

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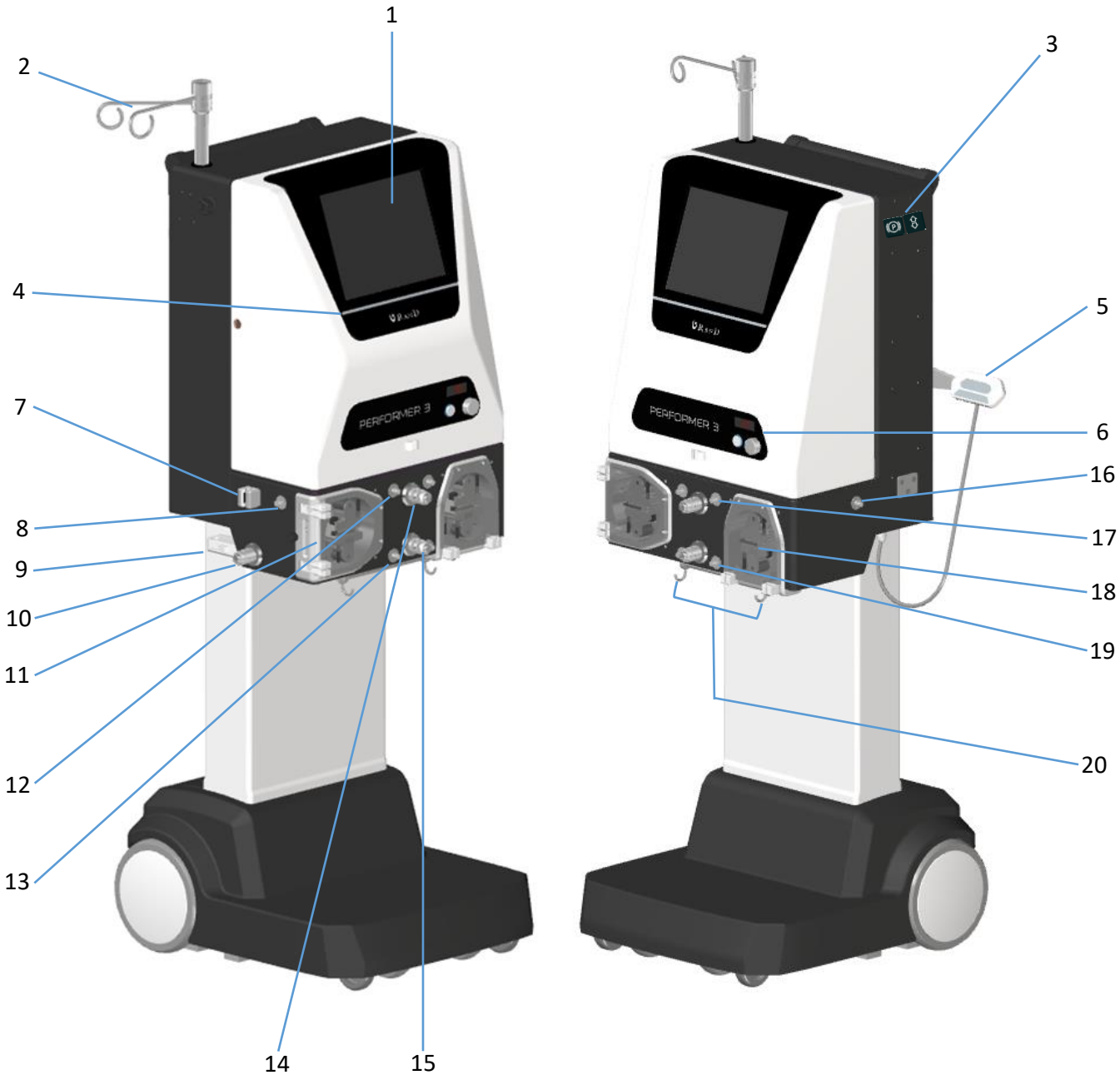
4. System description

4.1. Console description

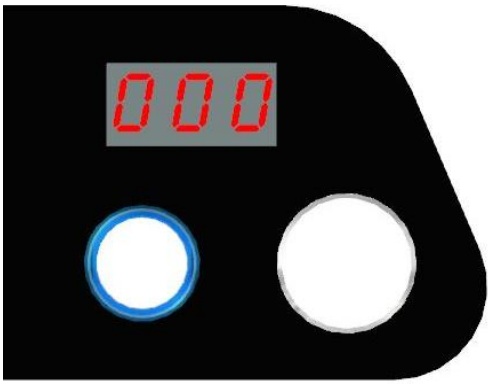


1. **Main Monitor/Touch screen:** a colour graphic display with a touch-screen technology.
2. **IV pole:** to hold the solution bag(s).
3. **Brake switch:** to lock and unlock the wheel brakes.
   Up/down switch: to raise and lower the upper console.
4. **System status LED:** provides a visual indication when a change in an alarm or system status occurs. See chapter 6.1 for a complete description of the meaning of the LED colours.

5. **Hub for temperature probes:** enables connection of the following external temperatures probes:

IN1 / IN2: connections for patient inlet probes (incorporated in the disposable tubing set)
1 to 6: connections for the temperature probes in the body cavity
OUT: connection for patient outlet probes (incorporated in the disposable tubing set)

6. Main Pump Control Panel (MPCP) consists of:



3-digit display: displays the flow rate in L/min (in a range 0.4-3.0 L/min);
ON/OFF switch switches on and off PM1 only, PM2 only or both, depending on the treatment phase;
Speed control knob: enables the user to control the flow rate by turning it clockwise (to increase) or counter-clockwise (to decrease).

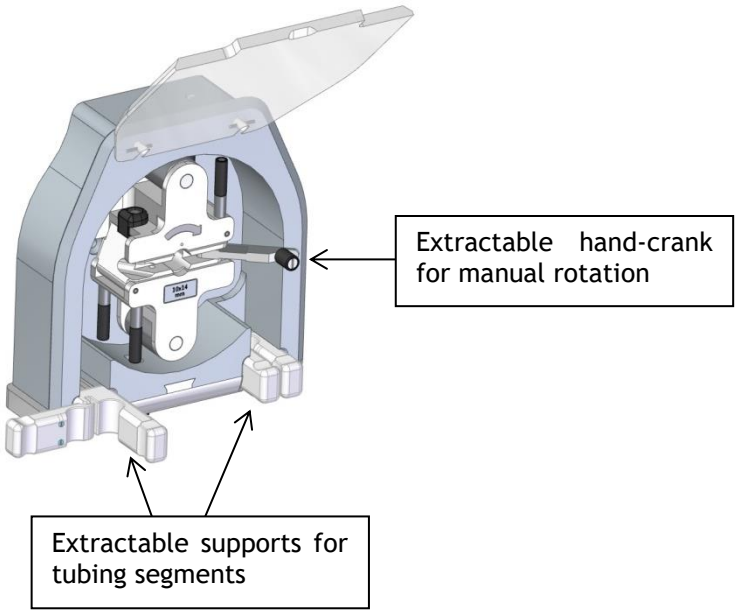
7. **Air sensor:** detects air in tubing as it exits the PM1 pump.

8. **Pressure transducer port (PR1):** for connection of the PR1 pressure monitoring line.

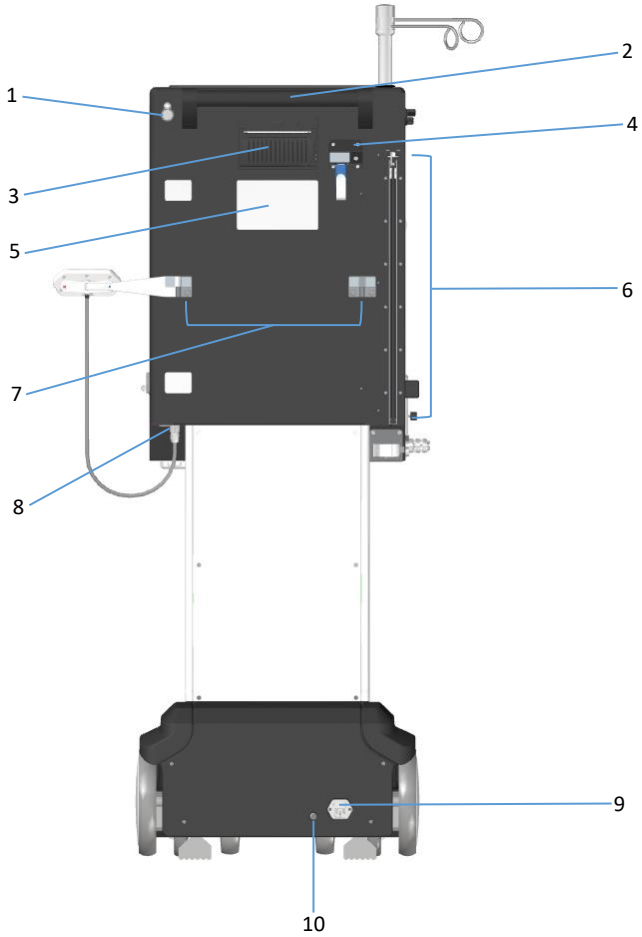
9. **Heater inlet line holder/temperature (T_{IN}):** holds the inlet tube of the heater in position and detects the heater inlet temperature.

10. **2-way tubing clamp (CL1):** automatically opens and closes, as required by the treatment phase, to route fluids through the circuit.

11. **Peristaltic pump (PM1):** moves the fluid in the extracorporeal circuit tubing with a flow speed of up to 3.0 L/min.



12. **Pressure transducer port (PR5):** for connection of PR5 pressure monitoring line.
13. **Pressure transducer port (PR2):** for connection of PR2 pressure monitoring line.
14. **2-way tubing clamp (CL2):** automatically opens and closes, as required by the treatment phase, to route fluids through the circuit.
15. **2-way tubing clamp (CL3):** automatically opens and closes when the diverter is activated.
16. **Pressure transducer port (PR4):** for connection of PR4 pressure monitoring line.
17. **Pressure transducer port (PR6):** for connection of PR6 pressure monitoring line.
18. **Peristaltic pump (PM2):** moves the fluid in the extracorporeal circuit tubing with a flow speed of up to 3.0 L/min.
19. **Pressure transducer port (PR3):** for connection of PR3 pressure monitoring line.
20. **Weight system:** scale for measuring the weight of the fluid in the reservoir.



1. **ON/OFF switch:** for switching the equipment on and off.
2. **Handle:** for moving the PERFORMER.
3. **Printer:** for printing the treatment data report.
4. **USB port:** for connecting a USB key to store treatment data at the end of the procedure. **Port for heater outlet temperature probe:** port for connecting the jack of the heater outlet temperature probe.
5. **Identification data label:** displays device information such as model, serial number, and electrical data.
6. **Heater:** transfers thermal energy to the fluid passing through a plastic heat-exchanger bag (part of the disposable extracorporeal circuit).
7. **Hub support**: for hanging the hub for temperature probes on the side that best fits the patient's position.
8. **Hub cable connection:** plug for connection of the hub.
9. **Power supply cable:** plug for the mains power cable.
   Fuses: external fuses.
10. **Equalization connection:** connects a cable from the potential compensation network to this grounding equalization connection. It is designed for use when local regulations require "potential compensation".

4.2. System preparation

4.2.1. Operation

Expected position of the user is close to the PERFORMER 3 equipment, at a comfortable distance for use of the touch screen and the other devices. The Patient is well away from the PERFORMER 3, being in the sterile field of the operating room.

To operate the PERFORMER 3:

1. Plug the console into an appropriate power socket.
2. Switch the ON/OFF switch to ON.
3. Lift the upper module.
4. Activate the equipment brakes.
5. The Main Monitor will display “SYSTEM INITIALIZATION” for several seconds, followed by the Power ON Self-Test (POST) screen.
6. Tubing set-up, as described in 5.4.
7. Run PREPARATION phase as in 5.6.
8. Place the temperature hub bracket on right or left side of the equipment depending on the most comfortable position for the patient and rotate to open.
9. Run PATIENT FILLING phase as in 5.7

4.2.2. System shutdown, transport and storage inside the hospital

1. Remove the disposable kit (first remove the tube from PM1 pump, then remove all other parts – reservoir, heater bag, clamp tubes etc. – in any order).
2. Close the temperature hub bracket.
3. Clean all the equipment with proper products (CLEANING 1.7).
4. Remove the brake.
5. Lower the PERFORMER 3.
6. Unplug the PERFORMER 3 from AC power (do not switch off the ON/OFF switch).
7. Move the equipment on its wheels by pushing the handle on the back.
8. Store it in a safe place close to a power socket.
9. Activate the equipment brakes.
10. Switch off the ON/OFF switch.

To take the machine to the place of use:

1. Connect the power cord to the power socket.
2. Switch on the machine.
3. Deactivate the brake.
4. Disconnect the cable (the machine remains ON in battery mode)
5. Move the machine to the place of use.
6. Proceed as in 4.2.1.

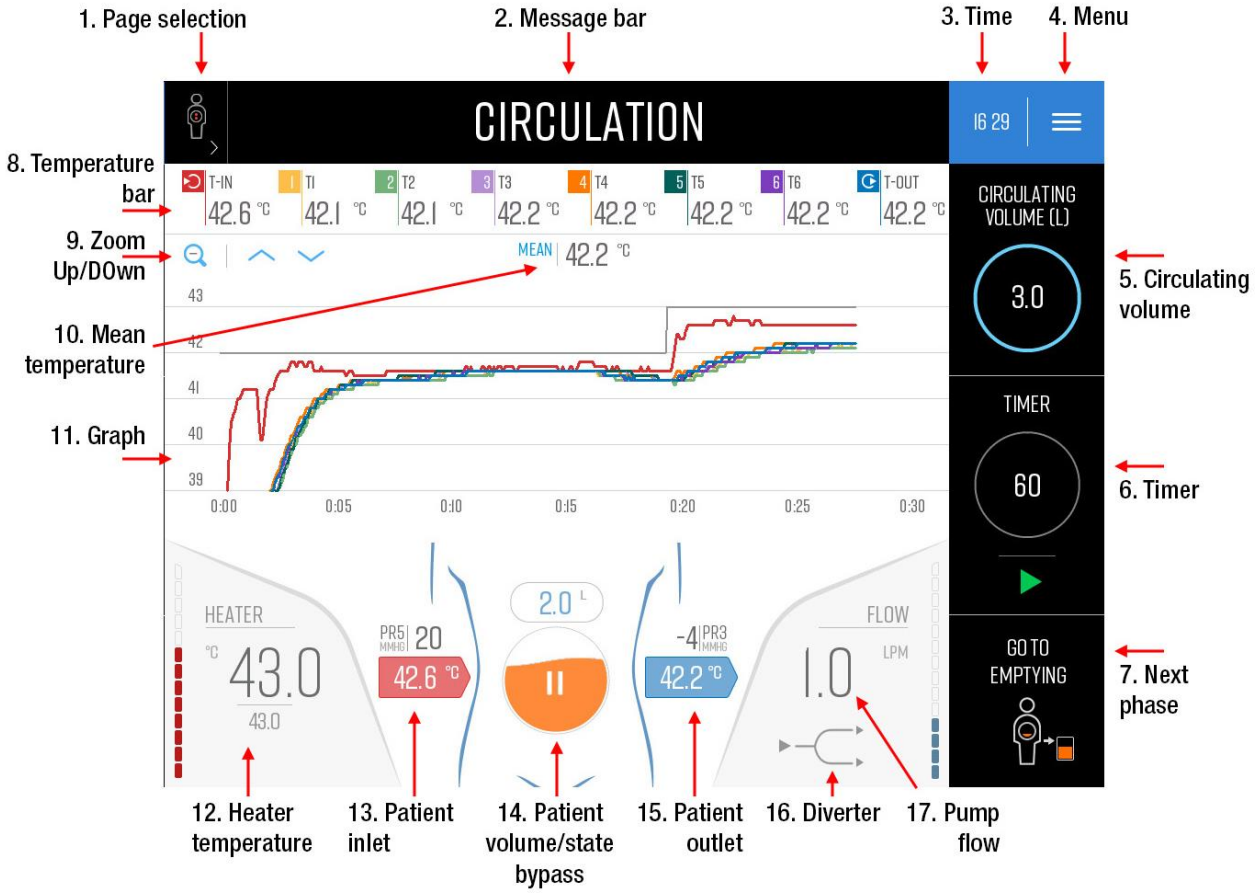
Warning: only authorized personnel are allowed to transport the machine from one building to another building.

4.3. User interface

The user interface provides all treatment parameters and info in two types of screens:

- Graphs screen
- Patient screen

4.3.1. Graphs screen



1. **PAGE SELECTION**: allows switching from graphs screen to patient screen.

2. **MESSAGE BAR:** displays the current phase, alarm messages, and other information. See chapter 6.1 for a complete description of the meaning of the message bar colours.

3. **TIME:** displays the current time. Touch to change hours, minutes and date.

Note: in the event of alarm messages, the time icon (3) is converted to the following icons:

 to silence the alarm.

 to reset the alarm.

Note: some alarms are self-resetting, so once the cause of the alarm is removed, the alarm is automatically reset. The alarms that are not self-resetting should be reset by the user with the reset icon, after removing the cause of the alarm.

4. **MENU:** opens the following menu:

opens the treatment data pages, where the following data can be entered:

- Patient: patient ID (digits only), sex, age, weight, height, pathology, drugs. The BSA (body surface area) is automatically calculated.
- Other: surgeon, operator, disposable lines lot#, notes

prints the treatment file report.

quits the current treatment and goes back to the home page.

Selects the second page of the menu.

Second page of menu before starting PREPARATION phase:

selects the first page of menu.

deactivates or reactivates some alarms.

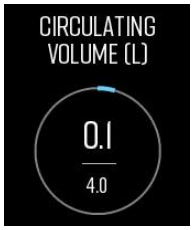
skips directly to the CIRCULATION phase (activatable only before starting the PREPARATION Phase).

Opens the service page where the technician can monitor the technical data.

Second page of menu in CIRCULATION phase

→ activates/deactivates REVERSER.

5. **CIRCULATING VOLUME**: indicates the total circulating volume. Touch to change it. The circle fills with blue as the volume increases to the set value, displayed under the line.
   In EMPTYING and RINSING, the circulating volume changes to RINSING VOLUME, showing the amount of volume of fresh solution given to the patient. If the RINSING phase is repeated more than once, the RINSING VOLUME is the total of all the repetitions.



6. **TIMER**: touch to set a desired timer and press the "green play" icon to start the countdown. The circle fills with green as the time elapses. When it reaches 00:00, the message "CIRCULATION TIME ELAPSED" appears. If desired, the timer can be re-started after at least one minute from the end of the previous one.

Note: the timers are paused each time the treatment is stopped or during patient by-pass, Circulating Volume Increase, Patient Volume Increase, Patient Volume Decrease.

7. **NEXT PHASE**: this icon appears when it is possible to activate the next phase.

8. **TEMPERATURE BAR**: it displays the temperature values of all the probes connected to the hub. IN (red) and OUT (blue) are always displayed. The other probes (T1 – T6), when connected, are displayed in different colours.

Note: the IN temperature displayed is the highest detected value between probes $T_{IN}1$ and $T_{IN}2$, pre-assembled in the circuit tubing.

By touching any of the displayed probes (except T_{IN} and T_{OUT}) the following options are available:

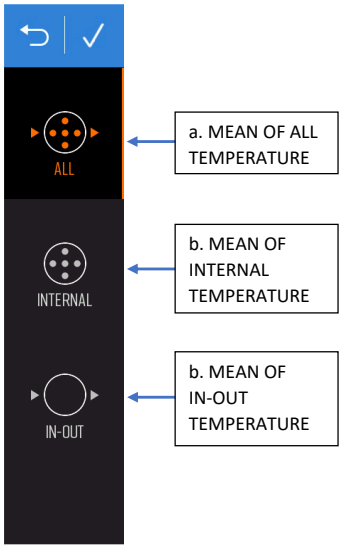
a. Show/Hide: to show or hide the related trend in the graphs

b. Rename: to rename the probe

The colour next to the name of the probe is the same as the corresponding trend.

9. **ZOOM/ARROWS**: the zoom allows the user to zoom in and out from the Y axis and the arrows to move the graphs up and down.

10. **MEAN TEMPERATURE**: displays the mean of:



a. All connected probes (T_{IN}, T_{OUT}, T_1 … T_6)

b. All probes from T_1 to T_6

c. T_{IN} and T_{OUT} only.

11. **TEMPERATURE GRAPH**: area in which temperature trends are displayed, each with a different corresponding colour:
    - Trend of heater outlet temperature (in PREPARATION only)
    - Trend of heater temperature set-point
    - Trends of external temperature probes (in FILLING and subsequent phases)

12. **HEATER TEMPERATURE**: the largest number indicates the actual temperature detected by the probe at the heater outlet, the smallest number indicates the set-point. Touch it to change the set-point. At each Perfusion mode activation, this set-point is reset to its default value (42.0 °C).

13. **PATIENT INLET**: temperature at patient inlet and PR5 pressure are displayed.

14. **RESERVOIR/PATIENT VOLUME/STATUS**:
    a. In PREPARATION: visualizes with graphic animation the status of the priming and solution heating.
    b. From FILLING on: displays the volume inside the patient, enables changing the patient volume, activating the patient by-pass and visualizes the status of the patient filling with graphic animation.

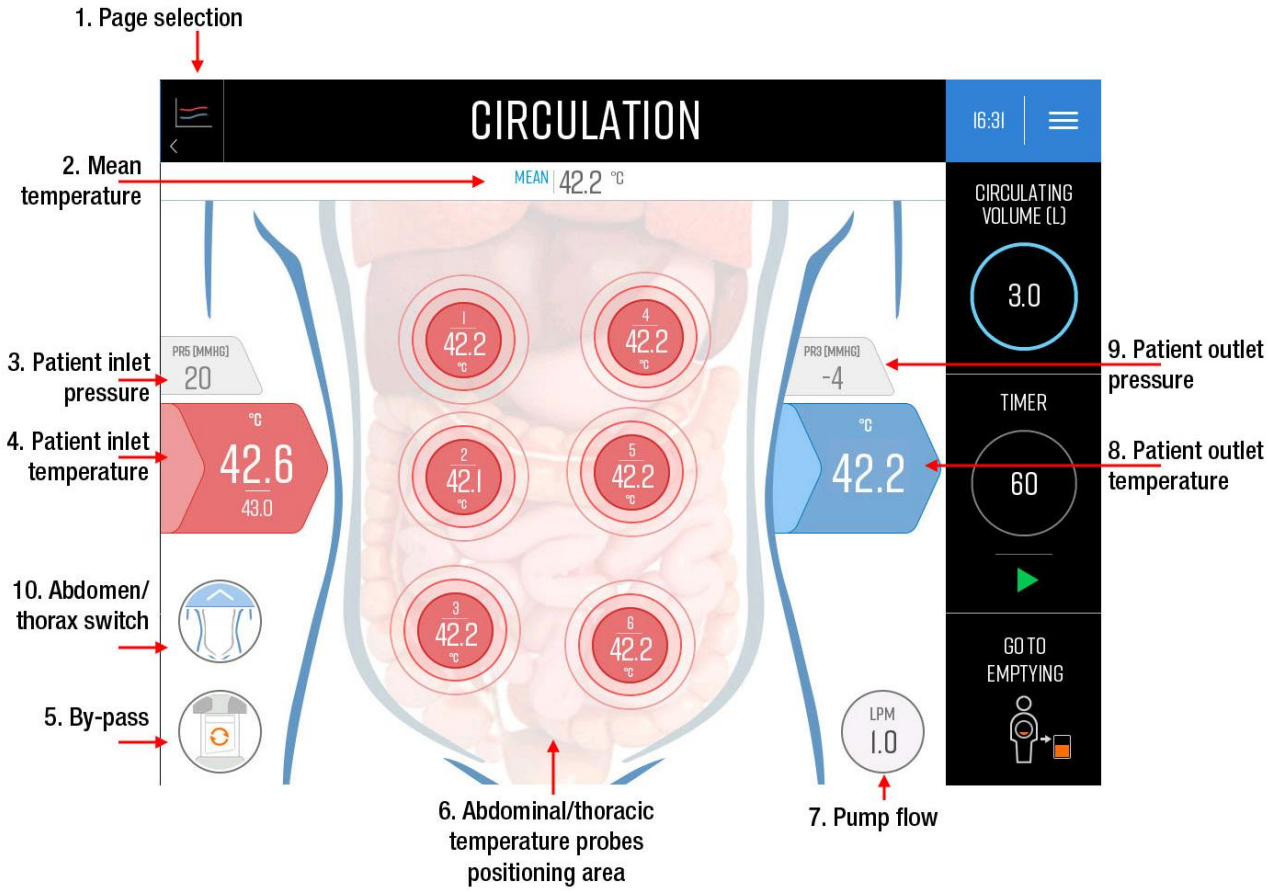
15. **PATIENT OUTLET**: temperature at patient outlet and PR3 pressure are displayed.

16. **DIVERTER:** activates or deactivates diverter function.

17. **PUMP FLOW**: shows the actual flow of PM1 pump (or PM2 pump in "Emptying" and "Patient volume – " phases). Touch to change the flow. The message "DISABLE THE FLOW CONTROL KNOB?" appears. Select YES then change the flow on the control bar.

Note: the knob is the default control for the flow. The display control should be used in a case of knob malfunction.

4.3.2. Patient screen



1. **PAGE SELECTION**: enables switching from the patient screen to the graphs screen.

2. **MEAN TEMPERATURE**: displays the mean of the temperatures detected by the selected probes. Touch it to set the mean, as explained in the graphs page.

3. **PATIENT INLET PRESSURE**: displays PR5 pressure.

4. **PATIENT INLET TEMPERATURE**: the largest number indicates the actual temperature at the patient inlet (T_{IN}), the smallest number indicates the heater set-point. Touch to change the set-point.

5. **BYPASS**:

enables manually switching to BYPASS mode.

enables switching back to CIRCULATION mode.

6. **ABDOMINAL/THORACIC TEMPERATURE PROBES POSITION**: graphic representation of the probes' positions in the abdomen/thorax. Once a probe is connected to T1 … T6, the message "PLACE PROBE n" appears on screen. Touch on the abdomen/thorax drawing to place the circle. Touch the circle to change the position. The circles are blue when the temperature detected by the probe is 4°C (or more) lower than the set-point, otherwise they turn red.

7. **PUMP FLOW**: shows the actual flow of the PM1 pump (or PM2 pump in "Emptying" and "Patient volume -" phases). Touch it to change the flow. The message "DO YOU REALLY WANT TO DISABLE THE KNOB CONTROL?" appears. Select YES and then change the flow on the control bar.

8. **PATIENT OUTLET TEMPERATURE**: temperature at patient outlet (T_{OUT}) is displayed.

9. **PATIENT OUTLET PRESSURE**: PR3 pressure is displayed.

10. **ABDOMEN/THORAX SWITCH**: allows to select the image of the abdomen or of the thorax.

4.3.3. Parameter setting bars

The parameter setting bar is automatically activated every time the user touches the icon of a treatment parameter that can be edited.

The bar includes:

- The *Confirmation button* and the *Cancel button.*
- The set value and the unit of measure with arrows to increase or decrease the value.
- The graduated coloured bar, which also can be used to increase or decrease the value.
- Any secondary buttons.

To set a new parameter touch the relative bar or use the arrows. To confirm touch the *Confirmation button* otherwise the *Cancel button* to keep the previous set value.

Note: at each Perfusion mode activation, the temperature set-point is reset to 42.0 °C and the circulating volume set-point is reset to 4 L.

4.3.4. Alarms disabling

This screen allows the user to selectively disable the alarms related to:

- PUMPS COVER
- HEATER INLET LINE
- PINCH VALVES
- AIR SENSOR

These alarms are related to device/functions that can be independently controlled or monitored by the user. On disabling an alarm, the corresponding event is recorded in the event log.

Warning: to continue the therapy when the clamp alarms are disabled, remove the tubing from the clamp and manage the fluid path by means of Klemmer clamps, according to the therapy phase.

To disable an alarm:

1. Touch the corresponding icon in the “alarms disabling” menu and confirm.
2. The message ”<*name of the device*> DISABLED!” is constantly displayed on the message bar.

Warning: do not disable any alarm without ensuring that the applicable parameter(s)/device can be effectively monitored by the user. Failure to monitor any parameter whose alarm has been disabled can result in less than optimal system performance.

4.4. USB key and treatment report

The PERFORMER 3 can save all the treatment data on a USB key after each use.
From this file, by following the instructions below, it is possible to automatically create a report in PDF format with data and graps of the treatment:

1. After the treatment is completed, return to the home screen by pressing the EXIT TREATMENT button in the sidebar.
2. Wait for the file to be saved (the hourglass icon disappears) and switch off the equipment.
3. Remove the USB key and connect it to a PC.
4. Copy the file of the case into an email and send it to the following address: P3.report@rand-biotech.com.
5. After a few minutes you will receive an e-mail with the report in PDF format (with data and graphs) and an Excel file (with data only).

Warning: DO NOT remove the USB while in Perfusion mode.

Warning: do not connect other devices than an USB key to the USB port.

The name of the file has the format YYMMDDHM.SN, where:

- YY = last 2 digits of the year
- MM = month
- DD = day
- H = hour
- M = minute
- SN = serial number of the equipment

If the USB key is not inserted during the treatment, the file is only saved on the SD card inside the machine. In this case it is possible to make a copy of the file from SD to USB at any time by pressing the MENU button at the top right in the Home page and then the appropriate icon.

4.5. Printer

The integrated printer generates a hard copy of the data of the running treatment.

The data printed in the report are grouped into 3 sections:

- **Users:** surgeon and procedure operator.
- **Patient data:** Patient ID, gender, age, weight, height, BSA.
- **Treatment data**:
  - **Header:** Includes relevant treatment dates and times, circulating volume, drugs and notes.
  - **Table:** includes time and temperatures of the 8 external probes, sampled at a 5 minute intervals (the system starts to print the treatment data from Circulation phase and stops when the Rinsing or Emptying phase is activated).

Note: the PERFORMER 3 retains the data from the last treatment performed only until a new procedure starts. A printout of the last treatment data can be carried out at any time before starting the Preparation phase of the new procedure.

4.6. Battery Supply System (UPS)

The PERFORMER 3 is equipped with a battery-powered uninterruptible power supply (UPS) system in case the main power supply fails, allowing the treatment to continue.

Note: during UPS mode, all equipment functions and controls are active, except the heater which is off.

Note: in Battery mode, the estimated remaining time is automatically displayed.

In battery mode:

- the information signal BATTERY LOW is displayed when the estimated remaining time is less than 20 minutes
- the low priority alarm BATTERY LOW is displayed when the estimated remaining time is less than 10 minutes

Warning: if the system does not convert to battery power when disconnected from mains supply, contact a RAND service technician.

It takes approximately 4 hours to completely recharge a fully depleted battery pack. Recharge is possible only if the equipment is switched on.

Warning: if the unit is left unused for a long period, it is recommended to switch it on at least 4 hours before clinical use to allow recharging of the battery.

5. HIPEC

5.1 System Start-up

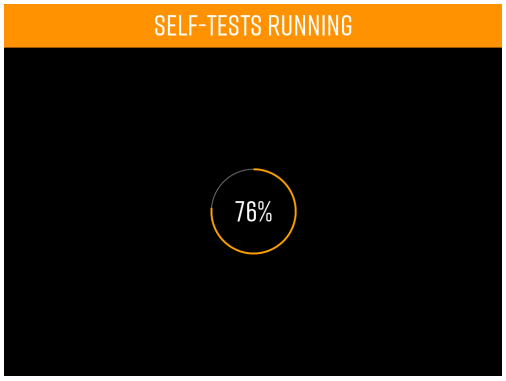
To operate the PERFORMER 3:

- plug the console into an appropriate AC power outlet.
- turn on the ON/OFF switch.
- lift the upper module.
- activate the equipment brakes.
- the main monitor will display “SYSTEM INITIALIZATION” for several seconds, followed by the Power On Self-Test (POST) screen.

Note: before turning on the device, make sure that:

- the disposable kit is not assembled;
- the roller pump covers are closed;
- the weighing system is unloaded.

5.2 Power On Self-Tests (P.O.S.T.)



During POST, the system will cycle through a series of tests to check the correct functioning of the system.

When testing the buzzer and the LEDs, the buzzer sounds, the LEDs flash and the message “CONFIRM LED BAR IS ON AND AUDIO IS WORKING – YES/NO” appears on-screen.

Press YES to confirm, NO if LED or buzzer does not work.

Self-Test Failure

At the end of the POST, if one or more tests FAILED the following will appear:

- RED message bar: SELF-TEST FAILED
- Name of the failed test
- Blue RESTART button

Make sure that no disposable is connected to the PERFORMER 3, then restart the self-test.

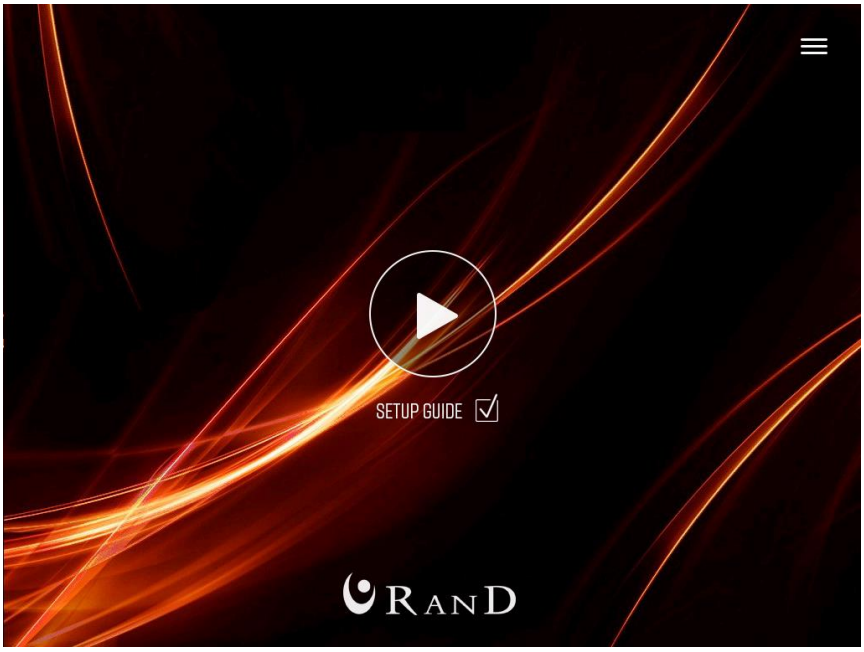
Warning: if the POST repeatedly produces a FAILED indication, contact a RanD service representative.

5.3 Home Screen

After successfully passing the POST, the system will automatically show the Home Screen.

The Home screen allows the user to:

- Start HIPEC (with or without setup guide)
- Open the additional menu (top right icon)



Press the Play button and enter User password.

Check the box next to set-up guide for the step-by-step instructions for the tubing set-up.

5.4 Tubing Set-Up

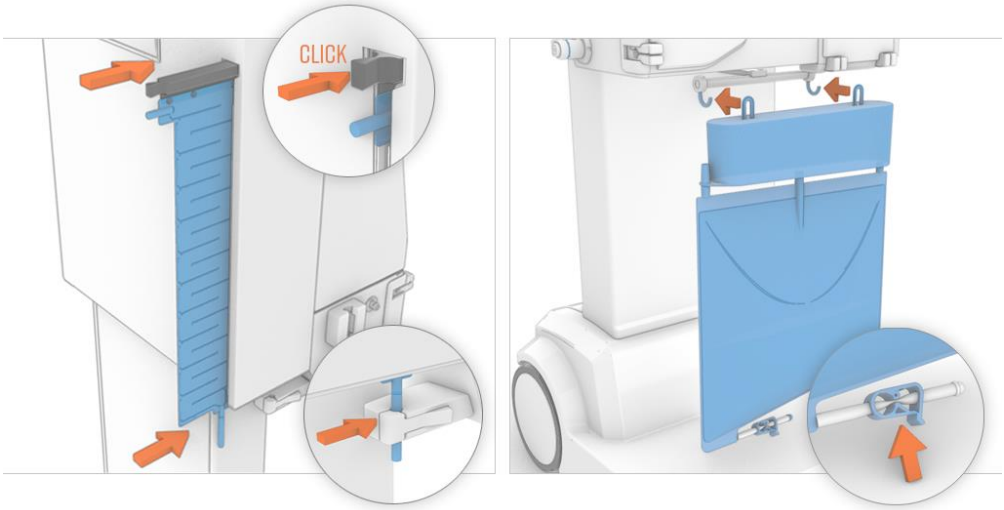
This section describes how to set up the disposable extracorporeal circuit on the PERFORMER 3.

Before initiating therapy, ensure that the required components are available:

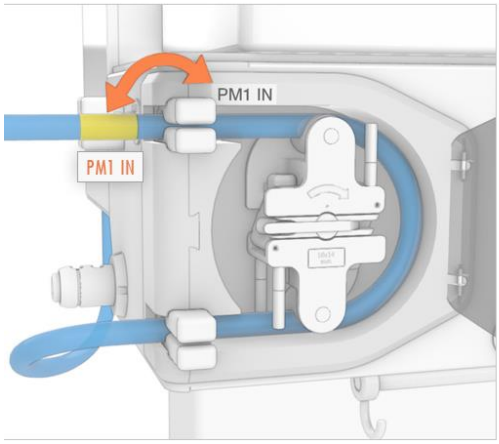
- material supplied by RanD: disposable sterile circuit named Hang&Go 3;
- material not supplied by RanD: sterile normal saline solution (0.9% Sodium Chloride for Injection, USP) or another solution as prescribed by physician.

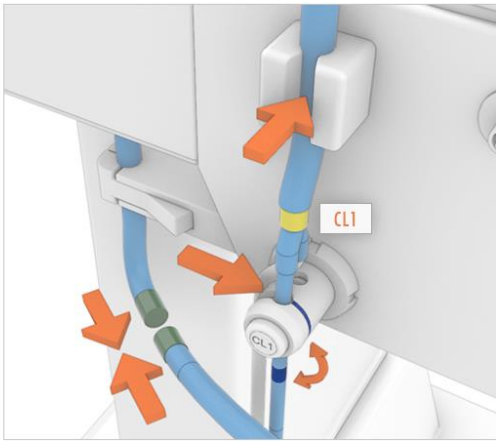
Warning: do not set up the Hang&Go 3 set before the self-tests are successfully completed.

Warning: perform the procedure using an aseptic technique.

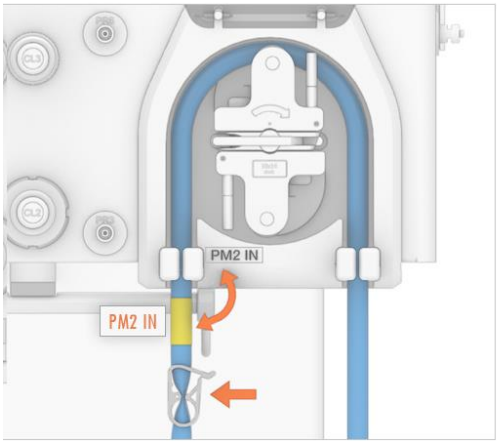


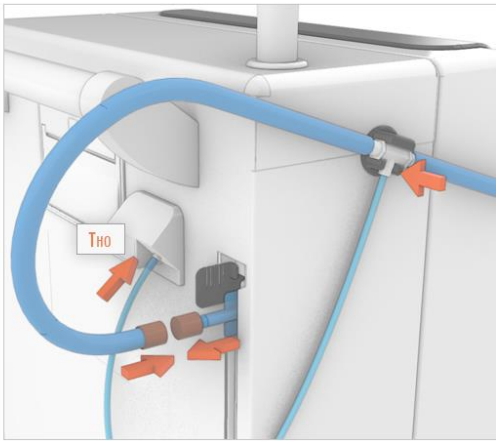
1. Take out the Heater Bag from “Hang&Go 3” line set, remove the sterile wrapping and insert the bag inside the heater. Push the support until a “click” is heard.
2. Insert the tube with the green label at the bottom of the heater bag inside the white holder.
3. Take out the “Hang&Go 3” reservoir from the “Hang&Go 3” line set and hook it onto the scale by means of the two rings.
4. Close the manual clamp at the bottom of the soft bag.





5. Remove the line from the right holder of the reservoir.
6. Open the cover and unlatch the hand crank.
7. Rotate the pump clockwise to optimize space in the pump raceway to accommodate the tubing.
8. Pull out the upper support, close to the PM1 label, and insert the end of the tubing with the PM1 yellow label. Push the support back in position.
9. Rotate the pump clockwise and simultaneously keep the tubing well adherent to the wall of the pump raceway.
10. When the pump is halfway along the raceway, pull out the lower support and insert the other end of the tubing. Push the support back into position.
11. Complete the run with the pump, latch the hand crank into its channel, close the safety cover.
12. Insert the blue-marked soft tubing segment into the outer way of CL1 clamp. The blue label must be positioned below the clamp.
13. Insert the line in the air sensor.
14. Connect the green male quick-connector at the heater bag inlet with the green female connector at the PM1 outlet.





15. Remove the line from the central holder of the reservoir.

16. Carefully place the pump segment tubing into PM2 pump, paying attention to the fitting direction. (Follow the instructions of the PM1)

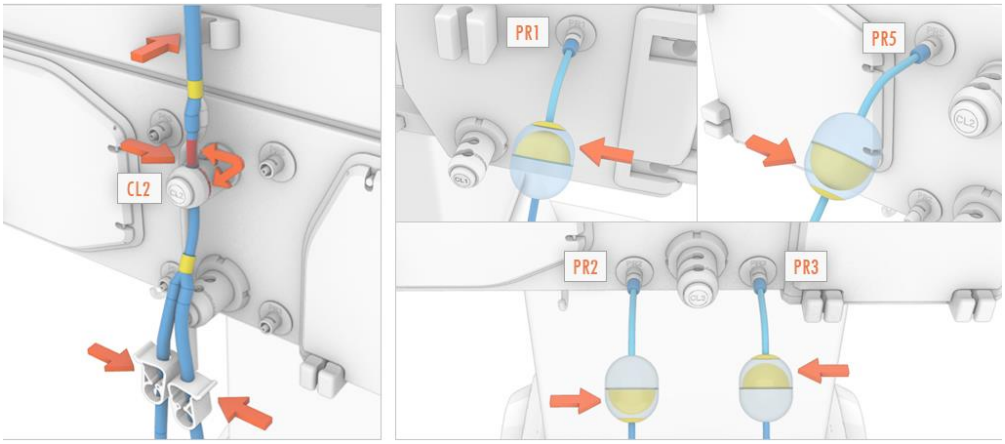
17. CLOSE the white clamp below PM2.

18. Insert the connector with the temperature probe inside the black support.

19. Connect the brown male quick-connector at the heater bag outlet with the brown female quick-connector of the line.

20. Connect the jack of the heater outlet temperature probe (labelled THO) to its port on the back of PERFORMER 3.

Warning: the pumps rotate in a clockwise direction. Also ensure that the direction of forward flow for the tubing is consistent with the rotational direction of the peristaltic pump. Always ensure that the direction of flow is not in a retrograde direction, which could result in pumping air into the patient. Failure to ensure proper tubing installation and subsequent fluid flow can result in less than optimal system performance and/or possible serious injury to the patient.



21. Insert the red-marked soft tubing segment into the outer way of CL2 clamp. Insert the tube on top of CL2 inside the related support.

22. CLOSE the white clamps after CL3.

23. Connect pressure line to PR1 sensor (check the membrane position).

24. Connect pressure line to PR2 sensor (check the membrane position).

25. Connect pressure line to PR3 sensor (check the membrane position).

26. Connect pressure line to PR5 sensor (check the membrane position).

Note - **the membranes must be oriented towards the yellow label.**

If necessary, fit a syringe to the luer-lock connector and then gently inject or remove air until the membrane is correctly oriented.

5.5 Treatment phase

A complete HIPEC treatment consists of the following phases:

- PREPARATION: the disposable kit is filled with the solution and the solution is pre-heated.
- FILLING: the patient's body cavity is filled with the warm solution up to a desired volume.
- CIRCULATION: solution is being circulated through the body cavity at the desired temperature. Chemotherapeutic drugs can be added during this phase.
- EMPTYING: the patient's body cavity is emptied.
- RINSING: the patient's body cavity is rinsed with fresh solution.

Units, Defaults, Minimum and Maximum values
In the following table, the Units, Defaults, Minimum and Maximum values of all settable parameters in the treatment phases are listed:

Parameter	Unit	Default	Min	Max
Circulation time	Min	60	30	120
Temperature	°C	42.0	37.5	45.0
Circulating volume	L	4.0	1.5	7.0 (during PREPARATION phase) 13.0 (during CIRCULATION phase)
Patient volume	L	3.0	0.5	Circulating Volume – 1.0
PR1 pressure alarm limit	mmHg	-180	-	-
PR2 pressure alarm limit	mmHg	+500	-	-
PR3 pressure alarm limit	mmHg	-300	-	-
PR4 pressure alarm limit	mmHg	-	-	-
PR5 pressure alarm limit	mmHg	+300	-	-
PR6 pressure alarm limit	mmHg	-	-	-
Circulation flow	L/min	-	0.4	3.0

Note: *Circulating Volume* is the total volume in which the chemotherapeutic drugs will be diluted during Circulation phase.
The *Patient Volume* is the volume of fluid that will fill the body cavity.

5.6 Preparation phase

The preparation phase fills the extracorporeal circuit with the solution and preheats the circulating fluid.

After the kit set-up a confirmation page will appear: Image A if guided instruction pages have been used otherwise Image B (no guided instruction pages). Follow the illustrated steps and then tick the respective action.

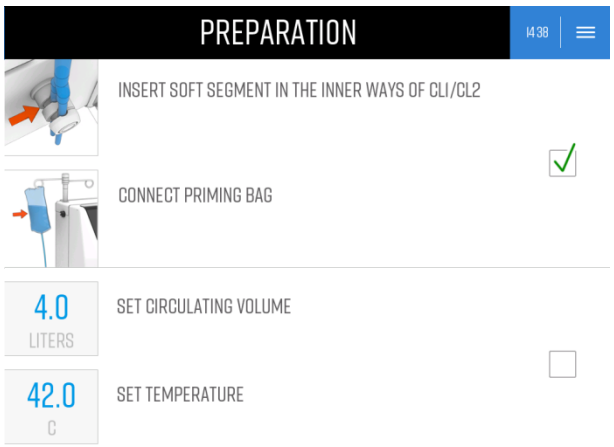


Image A

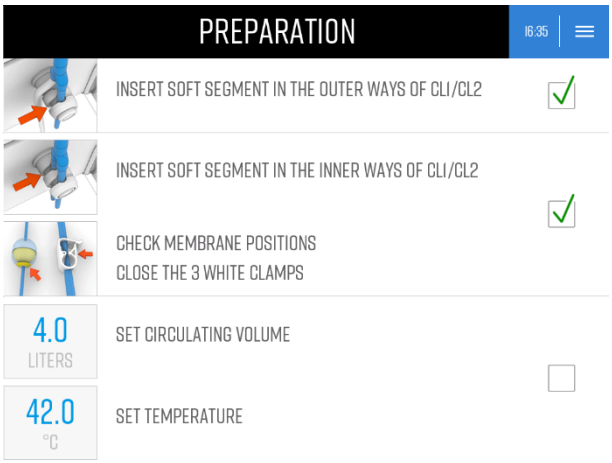


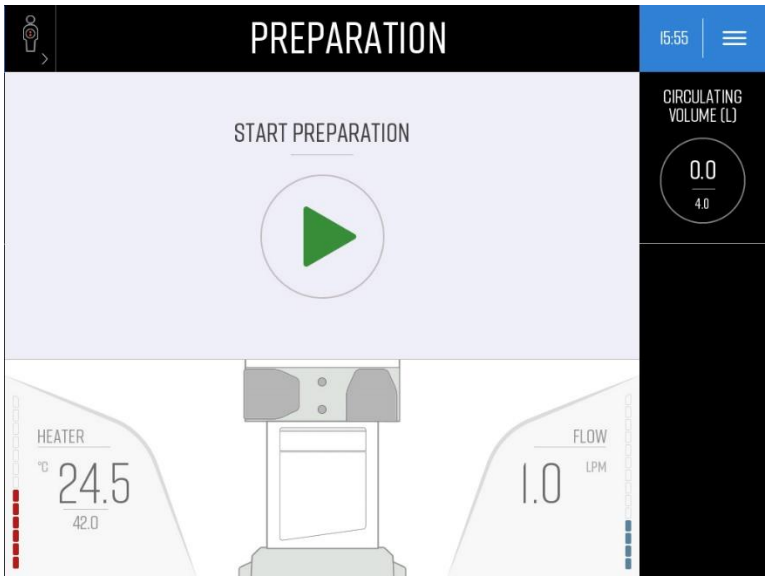
Image B

Note: as soon as the operator ticks the first action in case of Image B, the machine changes the position of CL1 and CL2. Make sure that both tube segments have been properly positioned.

Note: check the Circulating Volume and Temperature parameters and make changes if necessary.

Warning: the target temperature (i.e. the desired temperature in the patient's cavity) should be reached gradually, therefore the set-point on the screen should be close to the target value. This ensures a correct treatment execution. Setting the highest possible temperature does not make any faster reaching the target temperature.

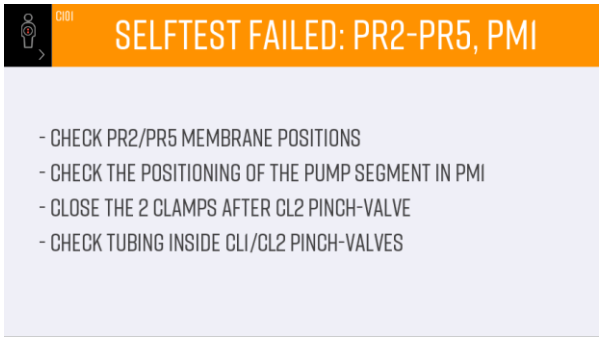
Press the green PLAY button on the screen to start PREPARATION.

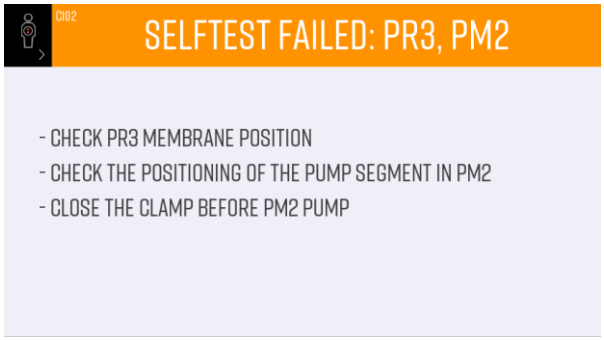


The PERFORMER 3 first checks, with empty tubes, that the PM1/PM2 tubing and PR2/PR3/PR5 membranes are correctly positioned.

Note: make sure that the white clamps under CL2 and PM2 are closed.

If the check is positive, the procedure starts automatically, otherwise an alarm and a message box with some hints to solve the problem appears, as shown below:





Note: if the PR3 membrane fails the check, in order to change its position, the operator must first open the white clamp under PM2. Remember to close it again afterwards.

Note: the system automatically recognizes the use of bottles (that normally contain 500 ml of saline solution) in place of bags, by checking PR1 pressure. If, after 3 seconds from the start of the pump, this pressure falls to lower than -150 mmHg, the PM1 flow is automatically reduced to 500 ml/min to facilitate the user in replacing the empty bottles with new ones (at 1000 ml/min the bottle would empty in only 30 seconds).

Note: during all the PREPARATION phase pump flow is automatically managed by the software, the user is NOT allowed to change it.

Note: by pressing the Circulating Volume icon, the user can change the set value before it reaches the set-point; but:

Increasing Circulating Volume

It is possible to increase the Circulating Volume at any time during the PREPARATION following this procedure:

1. Touch the Circulating Volume icon and enter a new value in the parameter setting bar. The new set-point of the circulating volume must be higher than the present value.
2. A message screen is displayed reminding the user to check the availability of solution and to open the clamps of the bags.
3. Saline solution is taken from the bag to reach the new set value. When the new Circulating Volume set-point is reached, the current phase is automatically re-activated.

When the temperature of the circulating solution reaches the set point, the message “TEMPERATURE SET-POINT REACHED” appears, with an acoustic signal and the blue LEDs. Press the check button to confirm.

5.7 Patient Filling Phase

The following sets out the instructions to connect the table pack tubing and temperature probes before starting the patient FILLING phase.

Patient connection

1. The personnel operating in the sterile zone must connect:
   a) the "Patient Inlet" line to the inlet catheters
   b) the "Patient Outlet" line to the outlet catheters.
2. Connect the "Patient Inlet" line to the male quick-connectors of CL2 external line and open the clamps.
3. Connect the "Patient Outlet" line to the female quick-connector at PM2 inlet and open the clamp.
4. Connect the temperature probes assembled in the “Patient Inlet" line (red marked) to the T_{IN1} and T_{IN2} channels of the hub.
5. Connect the temperature probe assembled in the “Patient Outlet" line (blue marked) to the T_{OUT} channel of the hub.
6. Connect the additional (abdominal/thoracic) temperature probes to the T1 … T6 channels of the hub.
7. Make sure that the 3 white manual clamps under CL2 and PM2 are open.

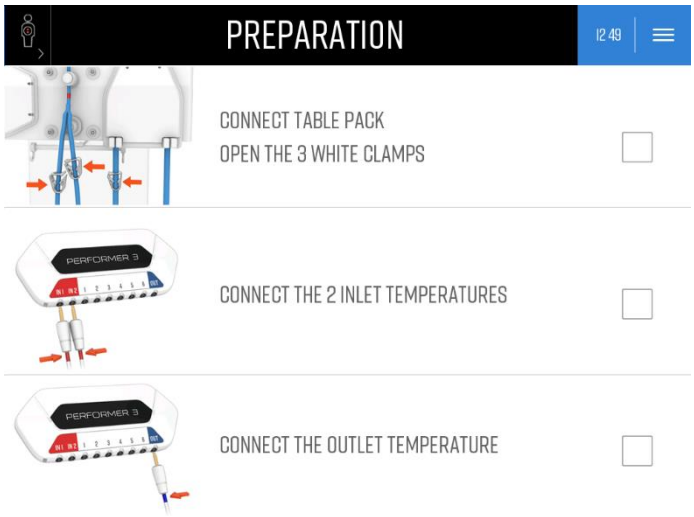
Warning: catheter selection and placement techniques, temperature probe location selection and placement techniques are to be performed at the discretion and under the direct responsibility of the physician.

Warning: only catheters compatible with the table line connectors should be used.

Warning: use only thermistor probes (disposable) recommended by RanD. Refer to section 2.3 “Disposable and accessories”. Use of different probes may jeopardize the performance of the device and, therefore, the measurement reliability.

Activating GO TO FILLING

1. Press “GO TO FILLING” icon to start patient FILLING phase. The message “ACTIVATE PATIENT FILLING?” is displayed on the screen. Press YES.
2. A second confirmation screen is displayed: tick the first check-box as soon as table pack lines are connected and the 3 white clamps are opened.
3. Verify the connections of the temperature probes (TIN1, TIN2 and TOUT) to the hub: as soon as they are connected, tick the check-boxes.



4. A third confirmation screen is displayed to verify/pre-set the flow by turning the knob.
5. Press the OK green button to confirm: the filling of the patient's body cavity will start at the pre-set flow.

Note: starting from this phase, the flow of the main pump (PM1) can be manually adjusted by turning the knob located in the Main Pump Control Panel.

Running Patient Filling phase

Patient Filling phase runs until the maximum volume available (= Circulating Volume - 1.0 L) is completely transferred to the patient's body cavity.

Note: hereinafter, the volume of fluid transferred into the body cavity will be called Patient Volume.

Note: by pressing the Patient Volume Stop icon the user can interrupt the transfer of the fluid before it reaches the maximum value: in this case:

- the set-point of the Patient Volume is automatically set to the current value
- the CIRCULATION phase is automatically activated

This function is active only if the current Patient Volume is greater than 500 ml.

The temperature of the fluid that enters the body cavity is measured by the probes ($T_{IN}1$ and $T_{IN}2$) located in the inlet lines of the table pack. The value is displayed in the T_{IN} box of the temperature bar.

The temperature of the fluid that exits the body cavity is measured by the probe located in the outlet line of the table pack. The value is displayed in the T_{OUT} box of the temperature bar.

The temperature of the fluid in the body cavity is measured by one or more probes (up to six) positioned by the surgeon. The values are displayed in the corresponding boxes (whose default labels are "PROBE x", with x = 1 to 6) of the temperature bar.

Warning: the user must monitor all the parameters (temperatures, pressures, volumes and flows) displayed on the screen during all phases, paying particular attention to temperature values:

- verify that the Heater Outlet temperature is consistent with the set-point
- during the PATIENT FILLING and CIRCULATION PHASE, verify that the external probe temperatures are consistent with the Heater Outlet temperature.

If the displayed values are not within the user-set parameters, interrupt therapy and contact the local service representative. Failure to do so may result in patient injury or suboptimal therapy.

5.8 Circulation phase

Activating CIRCULATION phase

When the Patient Volume set-point is reached, the system automatically ends the PATIENT FILLING phase and activates the CIRCULATION phase.

Note: if the CIRCULATION phase is activated via the *Skip to circulation* procedure (described in chapter 6.3 “How to”), the system uses the Circulating Volume parameter and the current weight on the load cell to calculate the Patient Volume.

The solution is circulated through the patient’s body cavity until the mean temperature reaches the desired target. The PM1 draws the solution from the reservoir, conveys it through the heater and sends it to the body cavity, PM2 draws the solution from the body cavity and sends it back to the reservoir.

Once the target temperature in the body cavity has been reached, the chemotherapeutic drug(s) can be injected into the circulating warmed solution through the two blue clave connectors on the Hang&Go lines, using aseptic technique, and the timer can be started (ref. to TIMER in chapter 4.3.1 “Graphs screen” on how to set timers).

The therapy starts from this moment, during which the drugs, diluted in the hyperthermic solution, circulate in the patient's body cavity.

Warning: chemotherapeutic drug administration is to be performed only under the direction and liability of the responsible physician. The chemotherapeutic drug administration must be based on the benefits and risks evaluation for a specific patient and procedure.

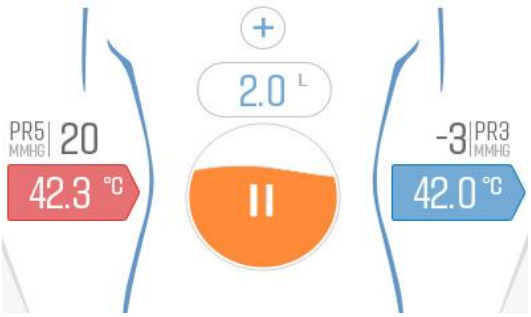
Increasing Circulating Volume

It is possible to increase the circulating volume at any time during CIRCULATION following this procedure:

1. Make sure that sufficient volume is contained in the bags.
2. Touch the Circulating Volume icon and enter a new value in the parameter setting bar.
3. Saline solution is taken from the bag to reach the new set value. When the new Circulating Volume set-point is reached, the CIRCULATION phase is automatically re-activated.

Note: during the Circulating Volume Increase phase, the same mechanism of flow reduction, described in chapter 5.6 “Preparation phase”, is activated if bottles instead of bags are used.

Increasing Patient volume



Patient Volume can be increased in two ways:

1. Touch the Patient Volume value (2.0 L in the example above): the parameter bar is activated
2. Enter the new value and confirm.

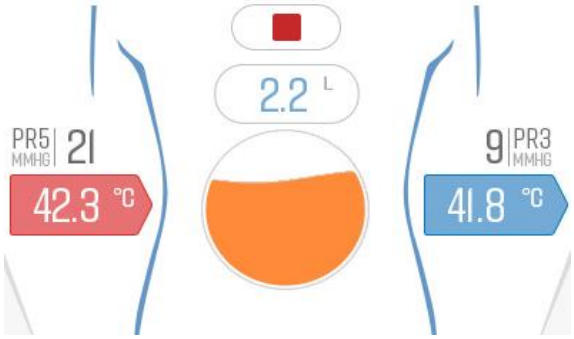
OR

Press "+" icon over the value. Fluid is transferred to the patient's body cavity until the maximum volume available is reached (= Circulating Volume - 1.0 L).

Note: if the two methods above are not available, this means that the maximum volume has been already transferred to the Patient. **THEREFORE, FIRST INCREASE THE CIRCULATING VOLUME.**

When the new Patient Volume set-point is reached, the Circulation phase is automatically re-activated.

Note: the patient Volume Increase can be manually stopped (and Circulation phase re-activated) before the new set-point is reached by pressing the Patient Volume Stop icon. In this case, the Patient Volume set-point is automatically updated to the current value.



Decreasing Patient Volume

To decrease the Patient Volume:

1. Press the Patient Volume value: the parameter bar is activated.
2. Enter the new value for Patient Volume parameter and confirm.

The solution from the patient's body cavity to the reservoir is transferred to reach the new Patient Volume set-point, then the Circulation phase is automatically re-activated.

Note: the Patient Volume Decrease can be manually stopped (and the Circulation phase re-activated) before the new set-point is reached by pressing the Patient Volume Stop icon. In this case, the Patient Volume set-point is automatically updated to the current value.

Note: during the Patient Volume Decrease, the PM1 pump continues to run to circulate the solution in the heater to maintain the solution at the set temperature.

Patient by-pass

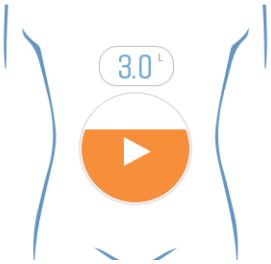
The by-pass phase icon is used to manually activate the by-pass each time the fluid circulation within the body cavity is to be interrupted.

The by-pass can be activated both in the graphs screen and in the patient screen using the icons below respectively:

During the By-pass phase:

- The PM2 pump stops and CL2 switches its status to interrupt the circulation in the body cavity.
- Fluid is circulated through the reservoir and the heater by means of the PM1 pump, so that the temperature of the solution is maintained. The flow of the PM1 pump can be controlled with the knob.
- The By-pass icon changes as depicted above to return to circulation.
- The BY-PASS message is displayed on the message bar.

To re-activate the Circulation phase, press the icons showed below:



- PM2 pump restarts and CL2 switches its status.
- The message CIRCULATION appears again on the message bar.

Note: by-pass phase can be activated only during the CIRCULATION, Patient Volume Increase and Patient Volume Decrease phases. Whenever the user terminates the by-pass phase, the system automatically switches to the Circulation Phase.

Note: the by-pass is automatically activated by the system in case of an alarm whose response is “By-pass”. Please refer to chapter 6.2 “List of the alarms” for a complete list of all the alarms that can occur during the treatment and their corresponding system responses.

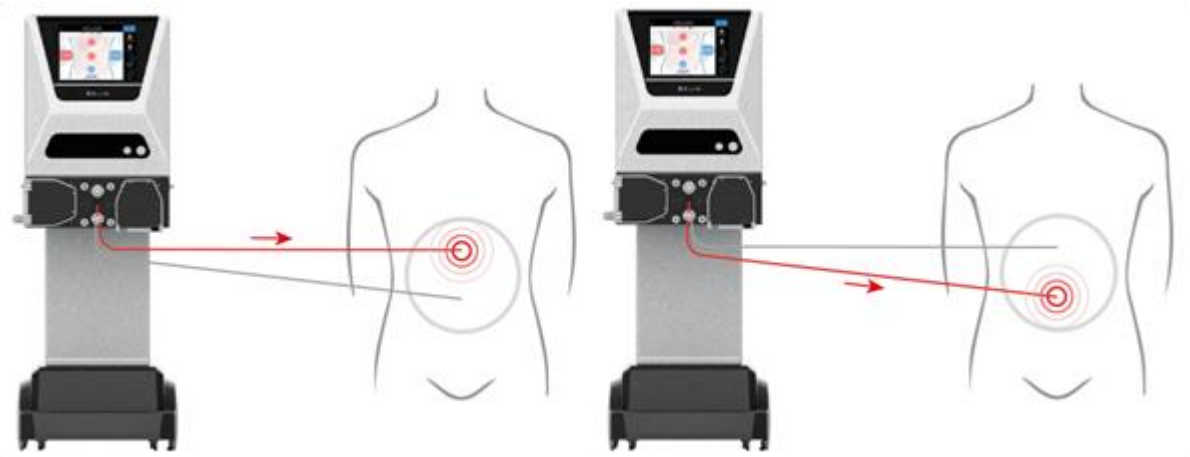
Note: if the by-pass has been automatically activated by the system because of an alarm, it cannot be exited until the cause of the alarm has been removed. Once the cause of the alarm has been removed and the alarm has been cleared, the CIRCULATION phase will be re-activated.

Ending the Circulation phase

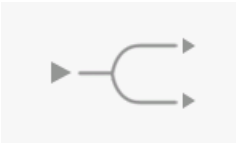
When the Circulation Time has elapsed, the message “CIRCULATION TIME ELAPSED” appears on the message bar. The phase is not stopped but continues to run until the user manually activates the EMPTYING phase.

5.9 Flow Diverter

During the CIRCULATION phase the Flow Diverter function can be activated, a feature that allows the system to send the warm fluid to the patient selectively in one inlet line only at a time switching every 5-30 seconds automatically, in order to improve distribution of the temperature inside the patient's abdomen/thorax.



To activate the diverter:



1. Push on the icon below the flow. A confirmation message will appear.
2. Follow the guided instructions:
   a. Insert the tube in the CL3 external side.
   b. Insert the tube in the CL3 internal side.

The switching interval of the pinch-valves can be set by pressing the blue value (7 in the figure) and then on the desired value in the setting bar (range: 5 – 30 secs).

To deactivate the diverter:

1. Push on the icon below the flow. A confirmation message will appear.

2. Follow the guided instructions to:
   a. Remove the tube from the CL3 internal side.
   b. Remove the tube from the CL3 external side.

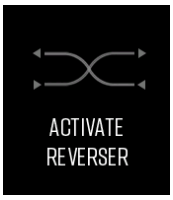
Note: during the guided procedure to activate or deactivate the diverter, the system automatically enters patient by-pass and returns to CIRCULATION as soon as the procedure is completed.

5.10 Flow Reverser

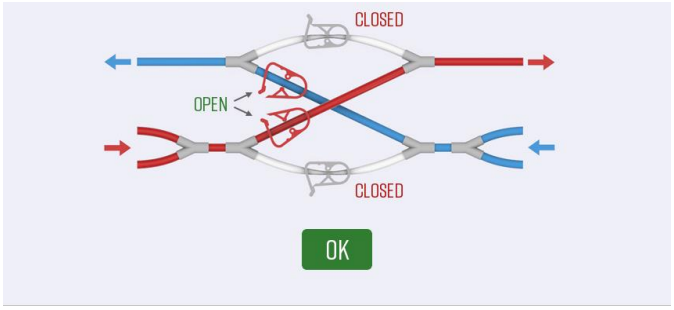
During the CIRCULATION phase, if the return line is obstructed and, consequently, the PR3 becomes too negative and there is no way to remove the obstruction, it is possible to invert the inlet flow and the return flow by using the Flow Reverser device (disposable accessory) and activating the reverser feature. The software will automatically change Inlet and Outlet temperature lines in the graph page.

Note: to install the Flow Reverser during the procedure it is necessary to use some extra clamps to close all the tubes.

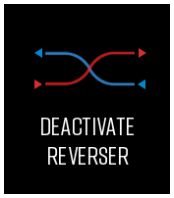
To activate the reverser:



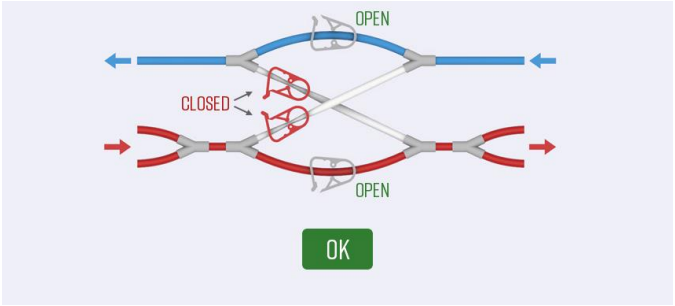
1. Enter the menu and select the icon. A confirmation message will appear.
2. Follow the guided instructions to open the red clamps and close the white clamps on the Flow Reverser device.



To deactivate the reverser:



1. Enter the menu and select the icon. A confirmation message will appear.
2. Follow the guided instructions to open the white clamps and close the red clamps on the Flow Reverser device.



Note: during the guided procedure to activate or deactivate the reverser, the system automatically enters patient by-pass and returns to CIRCULATION as soon as the procedure is completed.

5.11 Emptying Phase

Activating Emptying phase

1. Press GO TO EMPTYING icon.
2. The message “ACTIVATE EMPTYING PHASE?” is displayed. Press YES.
3. A second screen is displayed to set or change the flow, if necessary.
4. Press the OK green button to confirm.

Running Emptying phase

The PM2 pump empties the body cavity, at a flow rate set with the knob of the Main Pump Control panel.
The Patient Volume decreases as the emptying progresses and the graphic animation is displayed.

Ending Emptying phase

The Emptying phase is automatically stopped when the scale does not detect any weight change after 10 seconds.
In case of a too-negative PR3 the alarm PATIENT OUTFLOW PRESS [PR3] TOO NEGATIVE appears, pump PM2 automatically stops and a message screen is displayed with some hints.
The Emptying phase can be also stopped by the user with the Start/Stop button in the Main Control Panel.

5.12 Rinsing Phase

Note: the RINSING phase is not a mandatory phase, it is up to the operator working in accordance with the surgeon to carry out this phase or not.

Activating Rinsing phase

1. Press the GO TO RINSING icon.
2. The message “Activate RINSING phase?” is displayed. Press YES.
3. A screen is displayed to check the availability of the rinsing solution.

Note: in this phase it is possible to connect an additional 5 L waste bag (included in the Hang&Go 3 kit), if the volume to recover from the patient’s body cavity is greater than 7 litres:

1. Connect the 5 litres drainage bag to the female luer connector at the bottom of the reservoir.
2. Open the clamp at the bottom of the reservoir.

4. Tick the checkbox after completing the instructions.
5. Another screen is displayed to set the flow, if necessary.
6. Press the OK green button to confirm.

Running Rinsing phase

As soon as the Rinsing phase is activated, the machine fills the body cavity with fresh solution taken from the bags, at the set flow rate and at the default temperature of 37°C.

Use the speed control knob on the Main Pump Control Panel to adjust the flow rate.

The rinsing volume delivered is displayed in the Rinsing Volume box.

Ending Rinsing phase

The RINSING phase terminates when the volume of rinsing solution reaches the latest value of Patient Volume used in CIRCULATION phase.

1. A screen gives the instruction to close the clamp of the 5 L waste bag.

   If the reservoir does not have enough space to collect the rinsing volume from the body cavity, this screen is preceded by the message “WAITING FOR RESERVOIR EMPTYING”, which automatically disappears when enough volume has been transferred from the reservoir into the 5 L waste bag.

2. Tick the checkbox to start the EMPTYING phase

Alternatively, the RINSING phase can be manually stopped by the operator at any time by pressing the “GO TO EMPTYING” icon.

1. The message “ACTIVATE EMPTYING PHASE” is displayed. Press YES.
2. A screen is displayed to set or change the flow.
3. Press OK to confirm.
4. A screen gives the instruction to close the clamp of the 5 L waste bag.
5. Tick the checkbox to start the EMPTYING phase

5.13 End of the procedure

When the EMPTYING/RINSING phase has completed, to end the procedure:

1. Press PRINT REPORT icon in the menu bar.
2. The message “PRINT TREATMENT REPORT?” is displayed. Press YES.
3. Press the END OF TREATMENT icon in the menu bar.
4. The message “END THE TREATMENT AND RETURN TO HOME SCREEN?” is displayed. Press YES.
5. Remove the disposable kit (first remove the tube from the PM1 pump, then remove all other parts – reservoir, heater bag, clamp tubes etc. – in any order).

Warning: the personnel operating in the sterile zone can disconnect the circuit from the patient using an applicable sterile technique. Remove the disposable kit from the machine WITHOUT OPENING ANY CONNECTION, in order to avoid leakage of the contaminated fluids.

Warning: discard all fluids and disposable components in accordance with local environmental requirements and institutional protocols.

6. Clean all the equipment with proper products (CLEANING 1.7).
7. Lower the PERFORMER 3.
8. Remove the brake.
9. Switch off the PERFORMER 3.
10. Unplug the PERFORMER 3 from the AC power.

6. Troubleshooting

6.1 Alarm system overview

The PERFORMER 3 equipment implements an *Intelligent alarm system* able to detect *Alarm conditions* and, as appropriate, generate *Alarm signals* to indicate unsatisfactory physiological Patient statuses, unsatisfactory functional statuses of the equipment or to warn the Operator of *Hazards* to the Patient or Operator.

OPERATOR'S POSITION
In the present Manual, the Operator's position is intended to be in front of the equipment.

TERMS AND DEFINITIONS (IEC 60601-1-8)

Alarm system
Part of the equipment that detects *Alarm conditions* and, as appropriate, generates *Alarm signals*.

Intelligent alarm system
An *Alarm system* that makes logical decisions based on monitored information without Operator intervention.

Alarm condition
Status of the *Alarm system* when it has determined that a potential or actual *Hazard* exists.

Alarm signal
Type of signal generated by the *Alarm system* to indicate the presence (or occurrence) of an *Alarm condition*.

Reminder signal
Periodic signal that reminds the Operator that the Alarm system is in an *Alarm signal* deactivation status.

Information signal
Any signal that is not an *Alarm signal* or a *Reminder signal*.

Alarm limit
Threshold used by an *Alarm system* to determine an *Alarm condition*.

Alarm off
Status of indefinite duration in which an *Alarm system* does not generate *Alarm signals*.

Audio paused
Status of limited duration in which an *Alarm system* does not generate an auditory *Alarm signal*.

Alarm reset
Operator action that causes the cessation of an *Alarm signal* for which no *Alarm condition* currently exists.

Alarm preset
Set of store configuration parameters, including selection of algorithm and initial values for use by algorithms, which affect or modify the performance of the *Alarm system*.

Default alarm preset
Alarm preset that can be activated by the *Alarm system* without Operator action.

Alarm settings
Alarm system configuration, including but not limited to:
- *Alarm limits*
- the characteristics of any *Alarm signal* deactivation statuses
- the values of variables or parameters that determine the function of the *Alarm system*

High priority alarm
Alarm indicating that immediate Operator response is required.

Medium priority alarm
Alarm indicating that prompt Operator response is required.

Low priority alarm
Alarm indicating that Operator awareness is required.

Operator's position
Intended position of the Operator with respect to the *Alarm signal* generating part of the *Alarm system*.

Hazard
Potential source of *harm*.

Harm
Physical injury or damage to the health of people or animals, or damage to property or the environment

ALARM CONDITION PRIORITY

When the *Alarm system* detects an *Alarm condition*, the Alarm status is activated:
1. Visual and Auditory signals are activated based on the Alarm priority
2. Pumps and Heater statuses are maintained or changed based on the *Alarm condition*

Each Alarm condition is assigned to one of the following priorities:
- High priority
- Medium priority
- Low priority

The criteria for the assignment to one of the above categories are defined in the following table:

Potential result of failure to respond to the cause of Alarm condition	**Onset of potential Harm (a)**		
	Immediate (b)	**Prompt (c)**	**Delayed (d)**
Death or irreversible injury	High priority	High priority	Medium priority
Reversible injury	High priority	Medium priority	Low priority
Minor injury or discomfort	Medium priority	Low priority	Low priority

a) Onset of potential harm refers to when an injury occurs and not to when it is manifested

b) Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action

c) Having the potential for the event to develop within a period of time usually sufficient for manual corrective action

d) Having the potential for the event to develop within an unspecified time greater than that given under "prompt".

High, medium and low priority alarms are identified by different auditory and visual signals, described in the following tables:

Auditory signals

Alarm category	**Pulses**	**Single pulse duration**	**Fundamental frequency**	**Number of harmonic components**
High priority	10 pulses every 2.5 seconds	170 msec	975 ± 24 Hz	4 Harmonic Peaks within ±15 dB (1 to 4 kH)
Medium priority	3 pulses every 7.5 seconds			
Low priority	2 pulses every 20 seconds			

Sound pressure level
The auditory signals of the High, Medium and Low priority alarms are generated by the same buzzer with the same sound pressure level.

Short duration alarms
- in the case of a High priority alarm condition of short duration, the auditory signal completes at least 5 pulses (one half of one full burst).
- in the case of a Medium priority alarm condition of short duration, the auditory signal completes at least one full burst (3 pulses).

Visual signals

Alarm category	Visual signal (leds)	Message bar background colour
High priority	Flashing red (Frequency = 2 Hz, Duty cycle = 50%)	Red
Medium priority	Flashing yellow (Frequency = 0.5 Hz, Duty cycle = 50%)	Yellow
Low priority	Steady Yellow	Yellow

SIMULTANEOUS ACTIVATION OF ALARMS

In case of two or more Alarm conditions of **different** priority, the Alarm system activates Alarm conditions as follows:

<table>
<tr><th>Alarm category</th><th>System response</th><th>Message bar</th><th>Visual signal (leds)</th><th>Auditory signal</th></tr>
<tr><td>High & Medium priority</td><td rowspan="4">The equipment changes the status of pumps and heater to reach the safest condition for the Patient: e.g., if a high priority alarm response is “Pumps stop” and a Medium priority alarm response is “Heater off”, the equipment will deactivate both pumps and heater.</td><td rowspan="4">The description of the highest priority alarm condition is displayed in the Message Bar</td><td rowspan="3">Flashing red</td><td rowspan="3">High priority</td></tr>
<tr><td>High & Low priority</td></tr>
<tr><td>High, Medium & Low priority</td></tr>
<tr><td>Medium & Low priority</td><td>Flashing yellow</td><td>Medium priority</td></tr>
</table>

In case of two or more Alarm conditions of **equal** priority, the Alarm system activates Alarm conditions as follows:

Alarm category	System response	Message bar	Visual signal (leds)	Auditory signal
High Priority	The equipment changes the status of pumps and heater to reach the safest condition for the Patient: e.g. if the response of the first alarm is "*Pumps stop*" and the response of a second alarm, with the same priority, is "*Heater off*", the equipment will deactivate both pumps and heater.	The message bar displays a single alarm message and in particular displays the message that has the lowest ID (alarm identification code). If a second alarm condition still exists after the first has been cleared, then that alarm description is displayed.	Flashing red	High priority
Medium priority			Flashing yellow	Medium priority
Low priority			Steady yellow	Low priority

ALARM RESET

When the Alarm status is activated, the Alarm silence icon is displayed in the message bar:

To activate the *Audio paused* status press the *Alarm silence* icon:

- the auditory signal is paused for 60 seconds then reactivated if the alarm cause has not been cleared
- the *Alarm silence* icon is replaced by the *Alarm paused* icon:

To reset the alarm:

- identify and remove the cause of the alarm
- reset the alarm by pressing the *Alarm paused* icon

By pressing the *Alarm paused* icon while in *Audio paused* status, the *Audio paused* status is immediately terminated and the auditory signal re-activated.

ALARM DEACTIVATION

Some alarms can be deactivated (*Alarm off* status): see chapter 4.3.4 for detailed information regarding deactivation procedure.

SELF-RESETTING ALARMS

Some alarms are self-resettable (Non-latching), that means that when the cause of the alarm is cleared, the alarm is automatically reset, without the need for the user to press the mute and reset icons.

ALARM EVENTS LOG

The system displays a log of events that occur during treatment, including alarms, in the MONITORING screen. A copy of the event log is saved on USB at the end of the treatment, if the treatment is exited following the correct procedure. A copy of the event log is saved on SD during the treatment. The time of powering down is not captured in the log.

If the maximum memory capacity of USB or SD card is reached, the event log cannot be saved.

INFORMATION SIGNALS

In addition to *Alarm signals*, the system can activate *Information signals*, with auditory and visual signals distinguishable from those of *Alarm signals*, to warn the User of particular events not related to the safety of the User or the Patient.

Information signals that need confirmation by the user:

- blue LED bar
- blue text message on black background
- beeps every 30 seconds

The following information signals belong to this group:

- Temperature set-point reached
- Circulation time elapsed
- Emptying completed

Information signals that do not need confirmation by the user:

- yellow LED bar
- yellow text message on black background
- 3 beeps every 30 seconds

The following information signals belong to this group:

- Stand-by
- By-pass
- Missing return flow
- Missing infusion flow
- Restoring patient volume
- Battery mode
- Battery low
- On-screen flow control
- Alarm disabled: air sensor
- Alarms disabled: pinch-valves
- Alarms disabled: pump doors
- Alarm disabled: heater inlet line
- UPS fuses failure
- Self-test running

If more than one information signal is present at the same time, the message bar will cyclically display the messages at 2 second intervals.

6.2 List of alarms

ID	Alarm identification code.
Message	Alarm message displayed on the alarm bar
Cause	Probable cause for the alarm.
Resolution	Recommended user intervention to clear the alarm condition. If the problem persists, interrupt the treatment and contact the local service representative.
Priority	High, Medium or Low

ID	Message	Cause	Resolution	Priority
C44, P9	HIGH HEATER OUTLET TEMPERATURE	Heater outlet temperature: THO > Tset + 1 for 60 secs OR THO > 50 °C	Silence the alarm and wait for temperature to fall to below the alarm threshold.	Low
C42	HEATER OUTLET TEMPERATURE DISCONNECTED	Heater outlet temperature probe (THO) not connected	Connect THO jack	Low
P7	HIGH RESISTORS TEMPERATURE	Heater resistors temperature > 160 °C	Silence the alarm and wait for resistors temperature to fall to below the heater reactivation threshold.	Low
P8	HIGH PLATE TEMPERATURE	Heater plate temperature > 110 °C	Silence the alarm and wait for the plate temperature to fall to below the heater reactivation threshold.	Low
P11	HIGH PATIENT INLET TEMPERATURE	1) 45.5 < TINx ≤ 46 for more than 15 secs 2) TINx > 46	Verify consistency of the temperature value detected by the TINx probe with the heater outlet temperature value and with the values detected by the other probes. If the values are consistent, reduce the temperature set-point to bring the temperature detected by the probe back to the safety limit.	Low
C52, P12	HIGH MEAN TEMPERATURE	Mean temperature (Patient inlet/outlet) > 44.5	Verify consistency of the temperature value detected by MEAN with the heater outlet temperature value and with the values detected by all the other probes. If the values are consistent, reduce the temperature set-point to bring the temperature detected by the MEAN back to the safety limit.	Low
P10	PATIENT INLET TEMPERATURE DISCONNECTED	TIN1 or TIN2 not connected	Check the connection of both TIN1 - TIN2	Low
C45, C46, C47, C48, C49, C50	HIGH TEMPERATURE OF Tx PROBE (Tx = T1…T6)	Tx > 44.5 °C	Check that the jack is connected to the correct channel of the HUB module. Verify the consistency of the temperature value with the temperature of the other probes: if the values are consistent, reduce the temperature set-point to bring the temperature back to the safety limit. In a case of inconsistency, try to disconnect the temperature probe. If the alarm is cleared (defective probe) complete the treatment by monitoring the body cavity temperature through the remaining probes, then contact the local service representative.	Low
C51, P13	HIGH PATIENT OUTLET TEMPERATURE	Patient outlet temperature (TOUT) > 44 °C	Verify consistency of the temperature value detected by the TOUT probe with the inlet temperature value and with the values detected by the other probes. If the values are consistent, reduce the temperature set-point to bring the temperature detected by the probe back to the safety limit.	Low
C43	PATIENT OUTLET TEMPERATURE DISCONNECTED	Patient outlet temperature (TOUT) not connected	Check the connection of the TOUT probe.	Low

ID	Message	Cause	Resolution	Priority
P25	HEATER INLET TEMPERATURE SENSOR (THI) FAILURE	The heater inlet temperature sensor (THI) does not communicate.	Reset the alarm. If the problem persists, contact the local service representative.	Low
C56	EXCESSIVE FLUID WEIGHT	Weight on the loadcell ≥ 8.5 Kg	Reduce the amount of weight hanging on the scale.	Low
C57	MISSING INFUSION FLOW	Error < -400	See “Manage a Patient Balance Error” section in the “HOW TO” section	Low
C58	MISSING RETURN FLOW	Error > 400	See “Manage a Patient Balance Error” section in the “HOW TO” section	Low
C61, P14	PM1 INFLOW PRESSURE [PR1] TOO NEGATIVE	PR1 < -180	Check membrane position of PR1. Check that the clamps on the lines from bags hanging on the IV pole are open. If bottles are used in place of bags, check that the spike vent is open. Verify the absence of any line kinking in the pump inlet line.	Low
C62, P15	PM1 INFLOW PRESSURE [PR1] TOO HIGH	PR1 > 150	Check the membrane position of PR1. Check that the pressure lines are connected to the right luer connectors. Check that the pump segment is correctly inserted in the pump (not reversed).	Low
C63, P16	HEATER INLET PRESSURE [PR2] TOO NEGATIVE	PR2 < -50	Check the membrane position of PR2. Check that the pressure lines are connected to the right luer connectors. Check that the pump segment is correctly inserted in the pump (not reversed).	Low
C64, P17	HEATER INLET PRESSURE [PR2] TOO HIGH	PR2 > 500	Check the membrane position of PR2. Check for any anomaly in the line exiting from PM1 pump including clamp closed, kinked line or catheter position impeding flow. Check for the correct positioning of the heat exchanger bag. Try to reduce the flow rate.	Low
C65, P18	PATIENT OUTFLOW PRESS [PR3] TOO NEGATIVE	Circulation phase: PR3 < -300 Emptying phase: PR3 < -200	Check the membrane position of PR3. Check for any anomaly in the Patient’s withdrawal line (PM2 pump inlet including clamp closed, kinked line or catheter position impeding flow. Try to reduce the flow rate. Try to use the flow reverser. See “Manage Patient Outflow Press [PR3] Too Negative” paragraph in the “HOW TO” section.	Low
C66, P19	PATIENT OUTFLOW PRESSURE [PR3] TOO HIGH	PR3 > 100	Check the membrane position of PR3. Check that the pressure lines are connected to the right luer connectors. Check that the pump segment is correctly inserted in the pump (not reversed).	Low
C69, P22	PATIENT INFLOW PRESS [PR5] TOO NEGATIVE	PR5 < -50	Check the membrane position of PR5. Check that the pressure lines are connected to the right luer connectors.	Low

			Check that the pump segment is correctly inserted in the pump (not reversed).	
C70, P23	PATIENT INFLOW PRESSURE [PR5] TOO HIGH	PR5 > 300	Check the membrane position of PR5. Check for any anomaly in the line exiting from CL2 including clamp closed, kinked line or catheter position impeding flow. Try to reduce the flow rate.	Low
C95, C100	PMx COVER OPEN (x = 1, 2)	PM1 (PM2) pump cover is open	Make sure the PM1 pump cover is closed. If the problem persists, disable the alarm by means of the Alarm Disabling Menu to complete the treatment, then contact the local service representative.	Low
C82, C85, C88	CLx CLAMP NOT CLOSED (x = 1, 2, 3)	Wrong position of the 2-way clamp (CL1/CL2/CL3)	Reset the alarm. If the problem persists, disable Pinch-valve alarms. To continue the therapy when the clamp alarms are disabled, remove the tubing from the clamp and manage the fluid pathway using Klemmer clamps, according to the therapy phase.	Low
C83, C86, C89	CLx CLAMP NOT OPEN (x = 1, 2, 3)	Wrong position of the 2-way clamp (CL1/CL2/CL3)		Low
C41	HEATER INLET LINE NOT INSERTED IN THE SENSOR	Heater inlet line not inserted in the sensor	Check the tube is inserted in the sensor. Reset the alarm. If the problem persists, disable the alarm using the Alarm Disabling Menu to complete the treatment, then contact the local service representative.	Low
C101	SELFTEST FAILED: PR2-PR5, PM1	Wrong PR2/PR5 membrane position. Wrong PM1 pump segment placement. Clamps after CL2 open. Wrong CL1/CL2 segment position	Check the PR2/PR5 membrane position. Check the PM1 pump segment placement. Close the clamps after CL2. Check CL1/CL2 segment position	Low
C102	SELFTEST FAILED: PR3, PM2	Wrong PR3 membrane position. Wrong PM2 pump segment placement. Clamp before PM2 open.	Check PR3 membrane position. Check PM2 pump segment placement. Close the clamp before PM2.	Low
C103	SELFTEST FAILED: LOADCELL	Incorrect increase of weight on the loadcell.	Reset the alarm to repeat the test. If the problem persists, interrupt the treatment and contact the local service representative.	Low
C104	SELFTEST FAILED: HEATER INLET TEMPERATURE	Failure of heater inlet temperature sensor	Reset the alarm to repeat the test. If the problem persists, interrupt the treatment and contact the local service representative.	Low
C105	FATAL ERROR CON	Fatal error	Interrupt the treatment and contact the local service representative.	Low
C106	FATAL ERROR TMP	Fatal error	Interrupt the treatment and contact the local service representative.	Low
C38	BATTERY LOW	Remaining time < 10 mins	Connect the equipment to the Mains	Low
C76	AIR IN AIR SENSOR	Air in the heater inlet line.	Check for presence of air in the heater inlet line.	Low

TECHNICAL ALARMS

ID	Message	Resolution	Priority
C31, P1	USER-INTERFACE NOT RUNNING	Reset the alarm. If the problem persists, interrupt the treatment and contact the local service representative.	Low
C32	PROTECTIVE SYSTEM NOT RUNNING		Low
C33	PROTECTIVE VOLTAGE OUT OF RANGE		Low
C34	PROTECTIVE SYSTEM WRONG STATUS		Low
C35	TEMPERATURE PROCESSOR NOT RUNNING		Low
C36	POWER SUPPLY FAILURE		Low
C37	INCORRECT UPS MODE		Low
P2	CONTROL SYSTEM NOT RUNNING		Low
P3	CONTROLLER VOLTAGE OUT OF RANGE		Low
P4	CONTROLLER SYSTEM WRONG STATUS		Low
P5	POWER SYSTEM NOT RUNNING		Low
P6	FATAL ERROR PRO: x		Low
P30	FATAL ERROR PWR: x		Low
C91, C96	PMx PUMP DRIVER FAILURE (x = 1, 2)		Low
C92, C97	EXCESSIVE CURRENT ON PMx PUMP (x = 1, 2)		Low
C93, P26, C98, P27	PMx PUMP NOT RUNNING (x = 1, 2)		Low
C94, P28, C99, P29	PMx PUMP FAILED TO STOP (x = 1, 2)		Low
C81, C84, C87	CLx CLAMP DRIVER FAILURE (x = 1, 2, 3)	Reset the alarm. If the problem persists, disable the Pinch-valve alarms. To continue the therapy when the clamp alarms are disabled, remove the tubing from the clamp and manage the fluid pathway using Klemmer clamps, according to the therapy phase.	Low

6.3 How to

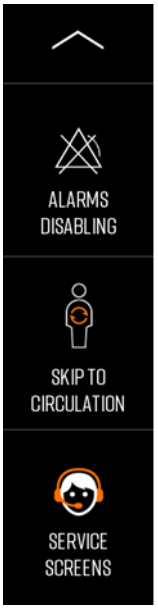
6.3.1 Skip to Circulation

In case of problems forcing the user to exit the treatment while CIRCULATION is running, this function allows the user to quickly re-activate CIRCULATION by skipping PREPARATION and FILLING:

Within 30 seconds of leaving circulation:

1. Enter HIPEC.
2. The message “SKIP PREPARATION AND ACTIVATE CIRCULATION?” will appear. Press YES.
3. The Circulation phase is activated.
   - The Circulating Volume is the latest set value.
   - The Patient Volume is automatically calculated.

After 30 seconds of leaving circulation:



4. Enter HIPEC and tick the check-boxes of the screens in 5.6 “Preparation phase”
5. Open the MENU and move to the second page
6. Touch SKIP TO CIRCULATION
7. The message “SKIP PREPARATION AND ACTIVATE CIRCULATION?” will appear. Press YES.
8. The Circulation phase is activated.
   - The Circulating Volume is the latest set value.
   - The Patient Volume is automatically calculated.

Warning: do not activate CIRCULATION with the procedure described above if the PREPARATION and FILLING phases have not been previously completed.

Warning: any Patient balance error accumulated during Circulation phase will be reset in case Circulation phase is re-activated with the procedure described above.

6.3.2 Manage “PATIENT OUTFLOW PRESS [PR3] TOO NEGATIVE” alarm

During the CIRCULATION and EMPTYING phase, the alarm and message “PATIENT OUTFLOW PRESS [PR3] TOO NEGATIVE” can appear when a problem in the Patient Outlet line causes a too-negative pressure on PR3 (value < -300 mmHg). In this case, the machine automatically activates the patient by-pass.

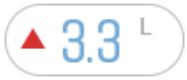
Some hints are given in the message screen to solve the problem. Applying one or more of these tips usually helps in recovery from the alarm status:

- Check for any fault in the patient’s withdrawal line (e.g. clamp closed, line kinking, catheters position).
- Reduce the flow.
- If possible, increase patient volume (in accordance with the surgeon).
- (Suggest to the surgeon to) move and purge the drains.
- Invert inlet/outlet (using the “Flow Reverser”).

By pressing the alarm mute and reset icon, the alarm is removed only if the problem has been solved and pressure is back to normal, otherwise the machine continues to stay in alarm mode.

6.3.3 Manage a Patient balance error

In case of insufficient return flow, the message “MISSING RETURN FLOW” is displayed to warn the user that the patient volume is increasing.

Note: next to the patient volume number, a small red triangle is displayed. 

The User should activate the by-pass in order to avoid any further increase of the patient volume. The User should then try to identify the cause of the error by checking for any faults in the circuit lines (clamp closed, kinked lines, catheters position, …).

If the Patient Volume continues to increase and it reaches the alarm threshold, the alarm “MISSING RETURN FLOW” is activated and a message screen with some hints to solve the problem is displayed:

Slightly reduce the flow, then:

- Check for any anomaly in the patient’s withdrawal line (e.g. clamp closed, line kinking, catheters position).
- Suggest the surgeon to check that outlet drains are completely immersed in the liquid.
- If possible, increase patient volume (in accordance with the surgeon).

If there is not enough volume in the reservoir to transfer to the abdominal/thoracic cavity, the User should first increase the circulating volume. Once the new circulating volume has been reached, the machine will automatically set a new set-point value for Patient volume, corresponding to the increase of circulating volume.

Note: if necessary, the By-pass phase can be activated (PM2 stops while PM1 continues to circulate the solution through the reservoir, maintaining it at the set temperature).

In response to the alarm, the PATIENT VOLUME DECREASE mode is automatically activated (PM1 pump circulates the solution through the reservoir while PM2 continues to draw the solution from the patient).
On pressing the alarm mute and reset icon, the alarm is replaced by the RESTORING PATIENT VOLUME information signal. The RESTORING PATIENT VOLUME information signal is automatically cleared when the patient volume reaches the set-point and the machine automatically goes back to CIRCULATION.

6.3.4 Calibrate the touch screen

Calibration of the touch screen is possible during initial self-tests or in the home screen by keeping the pumps start/stop button pressed for 5 seconds.

Then, tap the centre of the targets following the instructions on the screen.

6.3.5 Recover the HIPEC treatment

The system provides an emergency procedure to be used in case of serious failure that prevents the User from operating the equipment (e.g. block of the User Interface).

In this case, the User can try to recover the treatment by executing the following procedure:

1. Switch off the equipment.
2. Switch on the equipment within 5 minutes. During Self-Test phase, a Confirmation screen will appear asking "RESUME TREATMENT?"
3. Press the YES green button to confirm. The system will try to recover the machine status as it was before switching-off, and in particular:
    - Phase
    - Temperature set-point
    - Circulating volume
    - Patient volume
    - Treatment/patient info
    - Timers (when applicable)

The following parameters will not be recovered:

- Safety system status (all alarms will be enabled)
- Graphs data

Note: the successful recovery of the treatment depends on the type of system failure.

6.3.6 Force the interruption of the procedure

In the case of a system failure that cannot be solved with the Recovering procedure described in the previous paragraph (LCD back-light does not illuminate, Touch screen failure, Hardware or Software communication failure), the treatment should be interrupted.

To interrupt the treatment, proceed as follows:

1. Switch off the equipment.
2. Draw the solution from Patient's body cavity by manually turning the PM2 pump rotor with the integrated hand crank or remove the pump segment from the pump raceway to withdraw the solution by gravity.
3. When the fluid has been completely removed, disconnect the circuit from the patient, using the appropriate sterile technique.
4. Discard all fluids and disposable components in accordance with local environmental requirements and institutional protocols.

6.3.7 Manage the treatment when the pinch valves do not work

If one or both CL1 and CL2 pinch valves do not work, the related alarms can be disabled to complete the treatment. See how to disable the alarms in chapter 4.3.4.

The closure of the lines in CL1 e Cl2 shall be executed manually with a klemmer clamp according to the running phase, as indicated in the table below:

PHASE	CL1	CL2
PREPARATION: PHASE 1 (RESERVOIR FILLING)	Close the line from the reservoir	Close the line to the patient
PREPARATION: PHASE 2 (RECIRCULATION)	Close the line from the priming bags	Close the line to the patient
PREPARATION: PHASE 3 (RESERVOIR FILLING)	Close the line from the reservoir	Close the line to the patient
PREPARATION: PHASE 4 (PRE-HEATING)	Close the line from the priming bags	Close the line to the patient
PATIENT FILLING	Close the line from the priming bags	Close the line to the reservoir
CIRCULATION	Close the line from the priming bags	Close the line to the reservoir
PATIENT VOLUME INCREASE	Close the line from the priming bags	Close the line to the reservoir
PATIENT VOLUME DECREASE	Close the line from the priming bags	Close the line to the patient
CIRCULATION VOLUME INCREASE	Close the line from the reservoir	Close the line to the patient
BY-PASS	Close the line from the priming bags	Close the line to the patient
EMPTYING	Close the line from the priming bags	Close the line to the reservoir
RINSING	Close the line from the reservoir	Close the line to the reservoir

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7. Warranty

IMPORTANT NOTICE - LIMITED WARRANTY

THE FOLLOWING LIMITED WARRANTY APPLIES ONLY TO CUSTOMERS OUTSIDE THE UNITED STATES.

A. This **LIMITED WARRANTY** provides the following assurance to the purchaser of the **RanD PERFORMER 3**, hereafter referred to as the "Equipment" that should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year commencing with the installation of the Equipment to the purchaser, RanD will at its option: (a) repair or replace any defective part or parts of the Equipment; (b) issue a credit equal to the original Equipment purchase price (but not exceeding the value of the replacement Equipment), against the purchase of replacement Equipment, or (c) provide functionally comparable replacement Equipment at no charge.

B. To qualify for this repair, replacement or credit set forth in Section A, the following conditions must be met:

(1) All installation, updates, modifications, and repairs to the Equipment must have been performed only by personnel authorized by RanD.

(2) The Equipment must have been serviced, repaired, altered, or its internal components accessed only by persons or entities authorized by RanD to perform such work on the Equipment.

(3) The Equipment must have been (i) operated only by personnel who have been properly trained in operation of the Equipment, (ii) operated only in accordance with the instructions given in the User Manual for the Equipment, and (iii) subjected to no misuse, abuse or accident.

C. This LIMITED WARRANTY is limited to its express terms. In particular, RanD is not responsible for any incidental or consequential damages based on any use, defect or failure of the Equipment, whether the claim is based on warranty, contract, tort or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

E. No person has any authority to bind RanD to any representation, condition or warranty except this Limited Warranty.

8. Privacy

Compliance with European Regulation (EU) 2016/679 on privacy

To guarantee the confidentiality of the patient undergoing treatment and to provide the user with security measures in line with the requirements of EU Regulation 2016/679 regarding the protection of personal data, the PERFORMER 3 equipment includes:

- Alphanumeric keypad: the user interface features an alphanumeric keypad to enter an ID code that can be linked to the patient. In this way the user can enter an alphanumeric code referable to the patient without indicating the name and will be able to keep the data coming from the treatment separate from the patient's identity (this security measure is called pseudonymisation);

- Authentication system: the option of changing the user password (11111) and the service password (99999), provided by the technical operators when the machine is installed, in order to provide safe and secure access to the equipment only by authorized users;

- Storage of treatment data in 2 removable memories:

    - an SD inside the machine (accessible only by means of a tool), which stores all the data of the treatments performed;

    - a USB key where the treatment data can be saved;

- The treatment data saved on the USB key are encrypted.

- Paper report for each performed treatment.

The paper report and USB key are tools provided by the manufacturer and made available to the hospital. These tools shall therefore be managed according to the hospital policies in order to prevent risks of destruction, loss, modification and unauthorized access to the data therein.

RanD S.p.A.
Via Statale 12, 62
41036 Medolla (MO) Italy
Tel. +39-0535-49283
Fax +39-0535-660636
Internet: www.rand-biotech.com
E-mail: info@rand-biotech.com

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