TECHNICAL DATA

Power supply	110/230V - 50/60Hz
Power adsorption	Max 700VA
Electrical classification	Class I - Type BF
Protection IP	IP 21
Flow rates	2 peristaltic pumps ranging from 100 to 2000 ml/min
Pressures	6 pressure sensors ranging from -450 to + 450 mmHg
Volumes	Load cell ranging from 0.5 to 20 liters
Temperature	Plate warming system (28 to 46°C) Monitoring through 8 external temperature probes
Dimensions (WxDxH)	500x550x960 mm (stand-by/transport mode) 500x550x1600 mm (operative conditions)
Weight	80 kg
Safety standards	CEI/EN 60601-1 General requirements for basic safety and essential performance CEI/EN 60601-1-2 General requirements for safety: Electromagnetic compatibility EN 62304 Medical device software - Software lifecycle processes EN 62366 Application of usability engineering to medical devices

The Performer ® HT equipment has been developed in accordance to the most updated safety standards in order to guarantee the patient and the operator protection.

CE 0123

The Performer ® HT equipment and the dedicated disposable are CE marked in accordance to the medical device directive 93/42/EEC and following modifications.

CLASSIFIED C UL US

The Performer ® HT equipment owns the C-UL-US mark which guarantees the product conformity to the Canadian and US safety requirements.

RANDD

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TÜV SÜD ISO 13485:2003

R2100462 - Rev. 2

Performer® HT

An advanced system for hyperthermic perfusion

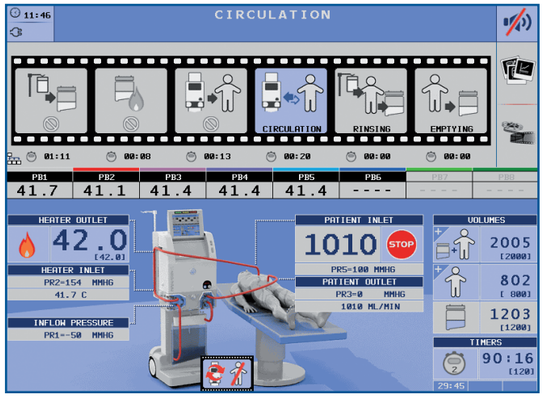
RANDD

MAIN FEATURES

Innovative design, high performances in the specific control and monitoring of hyperthermia, extreme simplification of the operative management and high level of safety are the main characteristics of the HT system, result of the long-term experience achieved on the Performer ® platform.

The pre-assembled disposable circuit simplifies and minimizes the setup time of Performer ® HT, and can be thus identified as a ready-to-use system.

The new graphic interface assists and guides the operator throughout each treatment phase by means of a clear and complete visualization of all the main functional and patient parameters.

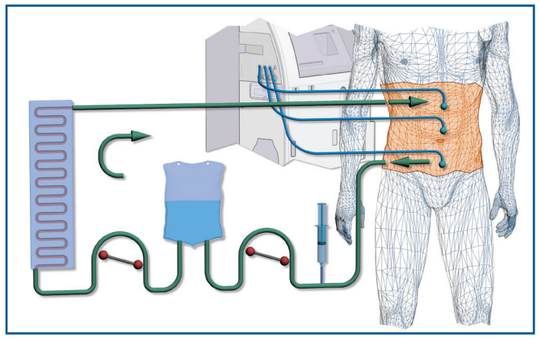


- Perfusion flow rate up to 2 L/min
- High-efficiency integrated heating system
- Monitoring of 8 temperature probes
- Patient by-pass function
- Circuit filling automatic procedure
- Real-time visualization of temperature diagrams
- Online trouble-shooting function
- Patient and treatment data saving, with possibility of file transfer to PC by means of USB port
- Integrated thermal printer
- Uninterrupted power supply system (UPS)
- Electrical regulation of the equipment height, for easier transport and utilization

THERAPEUTIC SCHEMES

- Intraperitoneal/Intrapleural Hyperthermic Perfusion
- Isolated Limb/Organ Hyperthermic Perfusion

INTRAPERITONEAL/INTRAPLEURAL HYPERTHERMIC PERFUSION

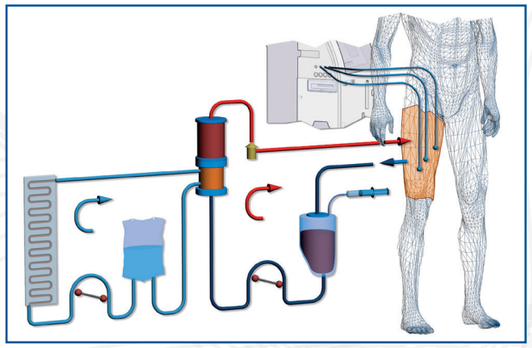


Perfusion of the peritoneal or pleural cavity with a hyperthermic solution containing chemotherapeutic drugs, for a period of 30-60-90 minutes depending on the relevant protocols.

Main indications

The hyperthermic perfusion may be indicated as a complementary treatment to surgery in case of peritoneal and pleural cavity malignancies.

ISOLATED LIMB/ORGAN HYPERTHERMIC PERFUSION



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

Main indications

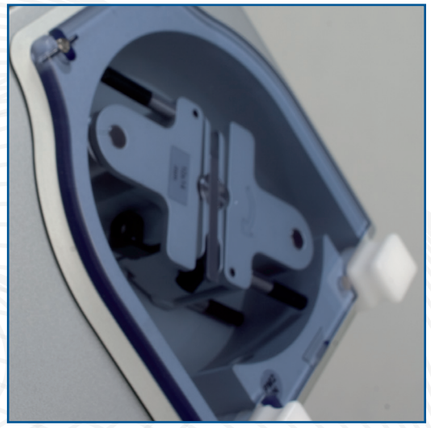
Melanoma of the limbs (stages III accordig to the MD Anderson Cancer Center staging system), primary sarcoma of the soft tissues of the limbs which cannot be radically resected, recurrent sarcoma of the soft tissues of the limbs.

HEATING SYSTEM

The high-efficiency plate warmer is able to raise the temperature of the fluids circulating inside the dedicated disposable bag, up to the preset hyperthermia value (max 46°C). The temperature control and precision (+/- 0.2°C) are guaranteed by 4 built-in independent sensors.

PATIENT BY-PASS

It is an exclusive function of Performer ® HT, which is managed through 2-way electroclamps allowing the operator to interrupt the circulation in the patient, and keeping at the same time the preset value of the solution temperature. The same function is utilized to automatically manage alarm conditions in complete safety and without the operator's intervention.



PERFUSION FLOW

2 high-flow peristaltic pumps allow the adjustment and control of the perfusion circulation rate to/from the patient up to 2 L/min.

TEMPERATURE MONITORING

A specific temperature monitoring module integrated in the equipment allows a real-time detection of up to 8 values by means of medical grade probes which can be located into the perfusion circuit and in the Patient.