

ThermoChem™ HT-2500



The HT-2500 device can be separated into three components for easier transport

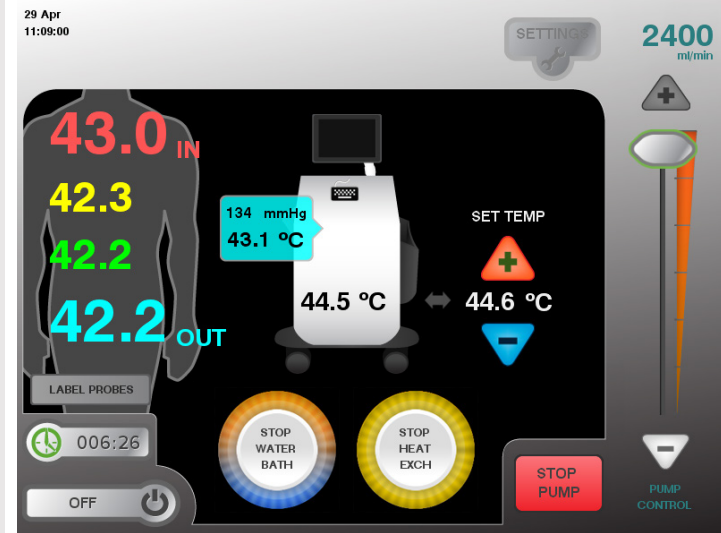
ThermoChem™ HT Series

A fully integrated System for Hyperthermic Intraperitoneal Chemotherapy (HIPEC)

The ThermoChem™ System from ThermoSolutions, is the first fully integrated system specifically designed and manufactured for HIPEC treatment. Used in conjunction with cytoreduction, and by exploiting heat and harnessing its power; this advanced medical technology offers an established choice in adjunctive surgical therapies. Used intraoperatively, the ThermoChem™ HT Series System raises the temperature in the peritoneal cavity by continuously lavaging the peritoneal cavity with heated solution.


The ThermoChem™ HT Series continually circulates heated perfusate throughout the cavity, accurately raising tissue temperature to a pre-determined target selected by the physician.

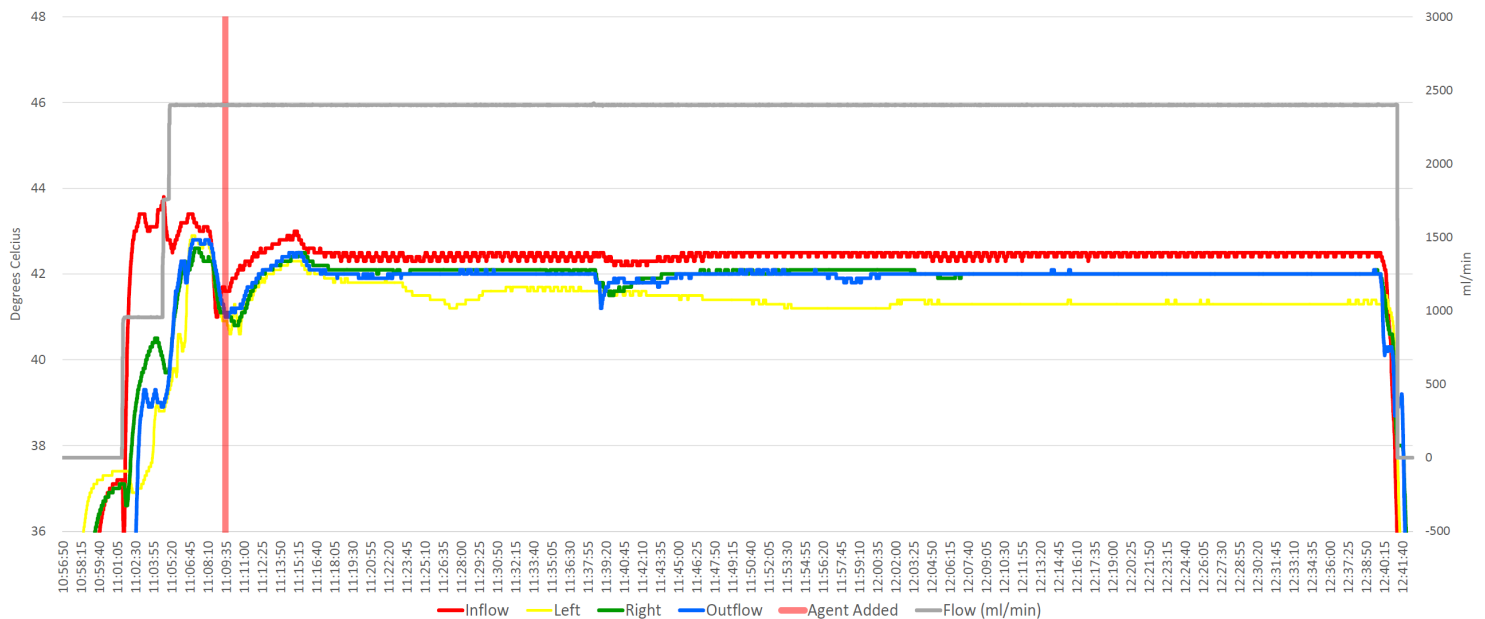
Due to the importance of maintenance of perfusate temperatures at approximately 42°C throughout the abdominal cavity, the ability to track flow rate and inflow/outflow temperatures is vital for an effective treatment.



Touchscreen Monitor Display (Treatment Screen)

- Adjustable temperature from 36 to 47°C
- Flow-rate adjustment up to 2400 ml/min
- Interactive touchscreen monitor:
 - system temperatures (adjustable)
 - system pressure measurement
 - patient fluid temperature (adjustable)
 - treatment timer

 ThermoSolutions Summary for Case performed on 14 May 2019



Case data is readily available

- A simple USB upload produces useful time-stamped information including:
- Inflow and outflow temperatures (up to four sites)
 - Flow rate
 - Treatment initiation

Disposable Procedure Kits

Single Use HIPEC Perfusion Kit

- Optimized for open, closed (semi-closed) and laparoscopic procedures
 - Packaged as an all-inclusive, pre-connected complete set
 - 3L fluid reservoir
 - High efficiency heat exchange
 - Patient temperature probes and pressure sensor
 - Fluid waste bag for secure closed-system disposal
 - FDA approved or CE Mark Procedure Kits available



IPH Procedure Kit (FDA)

111-2000:

-2 inflow + 2 outflow

-Waste Bag available (part# 101-3500)



QR Code for
IPH Procedure Kit
Training

TSP Procedure Kit (CE)

- Multiple options for inflow and outflow cannulas
- Multi-perforated silicon drains with outflow protectors

TSP 1016:

1 inflow + 3 outflow

TSP 2011:

2 inflow + 3 outflow



QR Code for
TSP Procedure Kit
Training



Who we are: ThermaSolutions manufactures and sells hyperthermic devices and disposable procedure kits for regional cancer treatment including HIPEC (hyperthermic Intraperitoneal Chemotherapy).

Used in conjunction with cytoreductive surgery, HIPEC is a proven adjunctive treatment for cancers including:

- Pseudomyxoma Peritonei - A build-up of mucus in the peritoneal cavity
- Ovarian Carcinoma – Cancer that forms in the tissue of the ovary
- Mucinous Adenocarcinoma of Appendix - A type of cancer that begins in cells that line the appendix and produces mucin
- Gastric Carcinoma – Cancer that forms in tissues lining the stomach
- Colorectal Carcinoma – Cancer that forms in the colon
- Mesothelioma - A benign (noncancerous) or malignant (cancerous) tumor affecting the lining of the chest or abdomen
- Low-Grade Sarcoma - Sarcoma is a cancer of the bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue



HT-2000 - benchmark HIPEC device also available

We train physicians and medical staff how to use the HT Series and sterile disposables with unparalleled customer service and support.

ThermaSolutions has been intricately and consistently involved in cancer treatment with HIPEC since 1995, partnering with physicians world-wide in 5 continents and over 45 countries.

ThermaSolutions

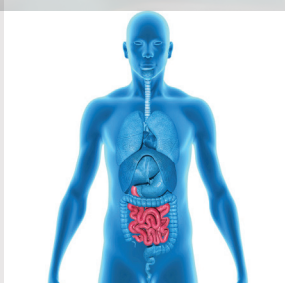
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Indications for Use: The intended use is to raise the core temperature of the peritoneum to a desired target temperature by continuously lavaging the peritoneum with circulating and warmed Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution.

Warnings: Read Operator's Manual in its entirety before operating the ThermoChem system, as failure to do so could result in harmful effects to the user, patient, and/or system. Hyperthermic perfusion at high temperatures (43°C) for extended periods of time (> 60 minutes) may result in acute or chronic thermal injury locally and/or systemically. Do not use electrocautery or other electrosurgical devices when the disposable tubing has been placed in the patient and the device is operating. The Disposable kit is for single use only and should not be re-sterilized. Disposable components not used during the procedure, must be discarded and disposed of properly. If the Disposable kit package is damaged, do not use. Only Disposable kits supplied by ThermaSolutions are to be used with the ThermoChem unit. Use aseptic technique when connecting patient catheters to the Disposable inflow tube and return tube. The system is designed to work with disposable patient temperature probes supplied by ThermaSolutions. If a ThermoChem system malfunction occurs or the patient needs immediate attention, turn off the roller pump by pressing 'Stop Pump' on the touchscreen monitor. After treatment has been initiated, the non-disposable heat exchanger water lines and connectors will be hot and may present a scald hazard. Do not disconnect water lines while the unit is at operating temperature or is powered on and the water bath is circulating. To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth ground. No modification of this equipment is allowed without authorization of the manufacturer. This device is not defibrillator proof and should not be connected to a patient when using a defibrillator. The ThermoChem unit is not intended to be used in an oxygen rich environment or around flammable agents. The system should be used only by medical professionals who are trained in the use of the device and who have an understanding of the English language. Do not fog or humidify the system or the operating room while the ThermoChem HT-Series is inside the room.

Precautions: If using a physiological, compatible, sterile solution other than Lactated Ringer's solution, follow the alternate solution's manufacturer labeling regarding handling and disposal. To prevent power surges to the unit, prior to plugging the ThermoChem unit in, the power switch must be in the off position and the power cord properly connected to the back of the unit. After mounting the Disposable kit on the unit, start circulation of the water bath, start the heat exchanger, and, before starting the patient pump, inspect the heat exchanger and Disposable tubing for fluid. If fluid is visible anywhere in the Disposable, the heat exchanger is faulty, and the Disposable must be replaced. Notify Customer Service at the number listed on the back of the operator's manual. Connection of the Disposable kit to the unit, Disposable priming, and temperature probe setup must be completed prior to initiating patient treatment. Failure to thoroughly follow the setup instructions will prevent the system from operating properly. When moving the ThermoChem unit, make sure to use handles provided on the device to avoid tipping. Make sure when operating the unit that it is placed in a location and position that will allow easy access to the power cord and switch. When power cycling the unit wait 10 seconds before turning back on.

Bibliography: Loggie BW, Flemming RA, McQuellon RP, Russel GB, Geisinger KR. "Cytoreductive surgery with intraperitoneal hyperthermic chemotherapy for disseminated peritoneal cancer of gastrointestinal origin." American Surgeon. 2000;66:561-568. Mi DH, Li Z, Yang KH, Cao N, Lethaby A, Tian JH, Santesso N, Ma B, Chen YL, Liu YL. "Surgery combined with intraoperative hyperthermic intraperitoneal chemotherapy (HIC) for gastric cancer: a systematic review and meta-analysis of randomised controlled trials." Int J Hyperthermia. 2013;29(2):156-67.

FDA Disclaimer: ThermoChem™ HT-2000 has not been cleared for use to treat any specific disease state or condition. Chemotherapy drugs used during the Hyperthermic Intraperitoneal Chemotherapy (HIPEC) procedure are currently approved for the treatment of certain cancers. A number of clinical studies and literature exist regarding the use of HIPEC in the peritoneum using intraperitoneal heating devices, such as the ThermoChem™ HT-2000. Physicians should decide which drugs to use with ThermoChem™ HT-2000 based upon their good judgment and understanding of the strengths and limitations of the data, and should consider the literature to guide their use of HIPEC with ThermoChem™ HT-2000