HEATED

INTRA-PERITONEAL CHEMOTHERAPY (HIPEC)



HIPEC (PERFORMER HT)

1. HIPEC PROTOCOL: EQUIPMENT LIST AND DISPOSABLES

Performer HT HIPEC Machine Stockert 3T heater-cooler unit Head blanket

Nursing disposable items

- HYPER Protect
- 3 x Mon-a-therm temperature probes
- 6 x 24Fr silicone catheters (6 drains for inflow and outflow)
- 1 withdrawal table pack (1 foil line with 3 outflow connections)
- 1 infusion table pack (1 foil line with 3 inflow connections)

1 Hang&Go disposable pack (including separate heater bag in the same pack)

2 x 2-way luer lock spike connectors 1 extra waste bag Flow reverse cross bridge (optional) Nasopharyngeal and urinary temperature monitoring 6 x temperature monitoring leads on HIPEC machine 1 bag of 6Litre Dianeal solution 1 1Litre of sodium chloride on HIPEC machine (as spare) Chemotherapy drug Large cytotoxic waste bag with a cable tie Cleaning wipes Disposable gown (non-absorbent) Powder free gloves Face mask with shield 8 x tubing clamps Hazardous drugs spill kit

2. PERFORMER HT DISPOSABLES SETUP

"Hang&Go" disposables are stored in the perfusion room. In the Hang&Go kit there are 5 components for perfusion. All disposables are for assembly on the Performer machine.

- 1. Hang&Go HT set
- 2. 2 x 2-way luer lock spike connectors
- 3. Heater bag
- 4. Additional waste bag
- 5. Additional Flow Reverse kit (Optional)

All Hang&Go disposables are labelled (numbered and colour coded), this coding corresponds with where the disposables are placed on the machine.

Identify the heater bag from the Hang&Go Kit, place the heater bag in the side compartment on the left hand side, secure the eyelets at all four corners and close the heater cover.

Take the Hang&Go reservoir and hang it onto the scale. Close the cricket clamp at the bottom of the soft bag. Remove the blue marked tubing from its slot on the reservoirs right side. Carefully place the pump segment tubing into the PM1 pump, paying attention to the fitting direction. The YELLOW adhesive collar indicates the side to be inserted to the pump inlet.

Insert the tubing in the air sensor (SA1) on LHS, paying attention to the correct closure of the sensor cover. Insert the BLUE marked soft tubing segment into the outer channel only of CL1, the blue label must be positioned below the clamp. Do not insert the inner channel tubing yet.

Connect the two GREEN quick-connectors at the heater bag inlet (bottom). Insert PM2 outlet pump tubing, paying attention to the fitting direction. YELLOW adhesive collar to be inserted first prior to the pump inlet. Insert the RED marked soft tubing segment into the outer channel only of CL2. The RED label must be positioned below the clamp. Connect the two brown quick-connectors at the heater bag outlet (Top).

Connect the male quick-connector of the CL2 external line with the female quick-connector at the PM2 outlet pump inlet. Connect the pressure lines PR2 to the PR2 on the machine. <u>Check the position of the internal membrane</u>, it must be oriented towards the yellow label on the tubing. **If necessary**, <u>connect a syringe to the connector and gently inject or remove air until the membrane is correctly orientated</u>. You are now ready for priming.

Note: there is an additional optional component to the setup called "Flow Reverse". This bridge can be inserted during the disposable setup if a flow reverse is predicted.

3. NURSE DISPOSABLES AND SETUP

There are separate disposables packs for the nurses to setup:

- "HYPER Protect" (to exhaust gases)
- 1 or 2 Mon-a-therm temperature probes
- 6 x 24Fr silicone catheters (Usually use 2 drains for inflow and 3 for outflow)
- 1 withdrawal table pack (1 foil line with 3 outflow connections)
- 1 infusion table pack (1 foil line with 3 inflow connections)

The circulating nurse will pass the above components to the scrub nurse and account for the items on the count sheet.

The scrub nurse will assemble components as per the template model provided, they MUST clamp one of the inflow clip-clamps to ensure only two inflow catheters are functioning.

Upon treatment completion, the surgeon, scrub nurse and perfusionist will **ensure all components are accounted for** prior to placement in purple cytotoxic rubbish disposal bag.

4. HEAD BLANKET SETUP AND CONDUCT, THEATRE AND PATIENT

TEMPERATURES

The head blanket should be connected to the HIPEC heater/cooler unit and primed by the Perfusionist. The anaesthetist will place an absorbent sheet over the patient's forehead (to act as a skin barrier). Drape the head blanket over the patient's forehead. The temperature on the heater/cooler should be set to 2°C and de-aired/circulated for approximately 20 minutes before the commencement of the HIPEC. Ice packs may also be placed around the head if the temperature rises quickly. When the treatment is over, disconnect the heater/cooler from the head blanket and discard the head blanket into the cytotoxic waste bag.

The patient should have a nasopharyngeal temperature probe inserted (T1) and a urinary temperature catheter (T2) to monitor the temperatures. Approximately one hour prior to the introduction of HIPEC, the Anaesthetic Team should allow the patient nasopharyngeal temperature to drift to approximately 34.5°C. Temperature drifting is enhanced by turning the operating room temperature down to 15°C and the cooling blanket setting to 4°C.

Note: The half-life of the drug *Mitomycin* is 53 minutes. Decreasing the fluid temperature after this period to manage nasopharyngeal temperature could be considered an option to stabilise or reduce the nasopharyngeal temperature.

At the conclusion of 90 minutes circulation, the peritoneal cavity is drained and flushed with Dianeal fluid. *Remember to have at least 1.5 litres of Dianeal fluid remaining in the bag on the IV pole, for the final Flush and drain* (Note: HIPEC Protocol conduct of procedure). The heater cooler unit is switched off. Allow the patient's temperature to drift downward. Room temperature is adjusted to 22^oC.

5. PERFORMER HT CIRCUIT PRIMING

Plug the HIPEC machine into the AC power outlet and switch power on, raise the touch screen and the machine and turn on the breaks. A self-test will start automatically and the inner channel tubing of the CL1 and CL2 clamps will need to be inserted when prompted on screen.

Enter HIPEC perfusion mode by selecting HIPEC on the screen. An alert will appear to remind the user to insert two unmarked soft tubing segments into the applicable inner channels (as stated above). Next, press the Green check-mark on the screen to confirm the alert once you have completed this. One of the two spike connector from the priming line needs be inserted into the 6L Dianeal bag hanging on the IV pole, and the other needs to be clamped off. Open the clamp on the priming line connected to the solution bag.

Set the total volume (start at approximately 2200 - 2400ml depending on patient size), patient volume and heater temperature on the screen (as required by patient/surgeon). Patient volume = Total volume – 1Litre.

Touch the green icon in order to start the "Priming phase". The circuit will prime and continue to circulate. Once this is complete, the machine will alert and you can then press the 'Heating phase' which takes approximately 10-15 minutes to prime and heat to 42°C. Note: the machine will continue to circulate and keep the prime at this temperature until connection to the patient. The machine will need to be plugged into an AC inlet to provide heating. Note: if the machine is on battery, the heating process will not activate. Once the priming fluid has reached the set temperature the priming phase is complete.

6. HIPEC PROTOCOL: CONDUCT OF PROCEDURE

The cavity of the patient will have 5 drains placed in it, 3 outflow catheters are placed deep in the cavity and 3 inflow catheters are placed above the outflow for even distribution. The catheters are then connected to the withdrawal x 3, and infusion x 2, from the table packs which contain the 2 separate foil lines and outflow/inflow connections. These two foil lines are then handed off to the perfusionist.

Note: one of the three inflow catheters needs to be clamped off as it is not currently used.

A Mon-a-therm temperature probe is placed into the open cavity to monitor abdomen temperature.

The perfusionist will take the withdrawal line from the table (foil line) and use the quick connect to connect it to the outflow of the machine and do the same with the infusion line from the table (foil line). The patient is now connected to the HIPEC machine.

In addition, there are two built-in temperature probes in the foil lines. One analyses the outflow temperature (blue) and the other reads the inflow temperature (red). The 3 temperature probes all need to be connected to the temperature monitoring leads and then plugged into the temperature sockets at the rear of the HIPEC machine. All 3 temperatures will be displayed on the HIPEC screen as T1 for temperature inflow, T2 for temperature outflow and T3 for abdominal cavity temperature.

To start the HIPEC treatment, select "Patient filling phase". The "patient filling phase" automatically begins, ensure to remove any bubbles caught in the tubing lines. When the preset volume inside the abdomen is reached the circulation phase will begin automatically. Note:

- Additional fluid may be added if required by increasing the total volume.
- PR3 (patient outlet pressure) should be around 0mmHg
- Prior to the fluid being introduced to the peritoneal cavity the perfusionist should liaise with the anaesthetist to ensure the patient is adequately paralysed and to verify that the table is level. The introduction of fluid applies pressure to the diaphragm and may cause the patient to "breath-up" causing spillage of fluid.

The RPM can now be increased to 1000 RPM for effective circulation. Wait for the patient abdomen temperature to reach 41 - 43°C. Now the chemotherapy drug can be added (see chemotherapy drug section below). Start the timer on the machine and communicate this to everyone in the room.

Once the correct drug circulation time (90 minutes for mitomycin or 30 minutes for cisplatin) has elapsed, touch "Rinsing phase" in order to end the circulation phase and begin the "rinsing phase". The treatment drug is then washed out thoroughly with approximately 3 – 4 Litres of Dianeal solution. Enter the "Empty phase" to empty the cavity of fluid back into the Hang&Go waste bag. This is the end of the procedure.

The patient data can be printed via the HIPEC machine. Press print and place this Perfusion Record Sheet in the Patient notes. Obtain a second copy and place it in the Perfusion Department HIPEC folder.

The remaining circuit including all HIPEC disposables from the patient field need to be counted and placed along with the disposables from the HIPEC machine, in a cytotoxic waste bag. The bag is then sealed with a cable tie for formal disposal and put in a purple waste bin for correct cytotoxic disposal.

NOTE:

- FLUID TEMPERATURE MANAGEMENT
 - Fluid temperature is controlled by modifying the temperature on the screen (heater bag in the circuit). Allowing for thermal loss from the circuit, the target temperature in the peritoneal cavity is 41.5 - 43°C, which usually requires the machine to be set at 2°C higher around 44 - 46°C.
- PATIENT TEMPERATURE MANAGEMENT
 - Bladder temperature will predictably rise due to the proximity of heated peritoneal fluid and is considered of little concern.
 - However nasopharyngeal temperature needs to be strictly managed and should not reach 38 degrees Celsius, but this is at the discretion of the anaesthetist.

7. <u>PROTOCOL: HANDLING AND ADMINISTRATION OF CHEMOTHERAPY AGENT</u> FOR HEATED INTRA-PERITONEAL CHEMOTHERAPY. (HIPEC)

INTRODUCTION:

Typically, intra-peritoneal chemotherapy is administered to treat malignant peritoneal mesotheliomas and pseudomyxoma peritonei.

The Chemotherapy Agent of choice is usually Mitomycin C Accord or Cisplatin.

The drug dosage is calculated and prepared by the Hospital Pharmacy, with instruction form the surgeon. It is delivered to the operating theatre on the morning of the procedure and stored in a purple cytotoxic labelled hinged box, which has ice packs within. Drug preparation is supplied in a luer-lock 20ml syringe sealed in two plastic envelopes. The patient details, drug name and dosage are provided on a label attached by the pharmacy, and should be checked by the Perfusionist. The Drug is administered by the attending perfusionist into a closed circuit which heats and circulates fluid through the peritoneal cavity for 90 minutes, if Mitomycin is used or 30 minutes if Cisplatin is used.

EQUIPMENT

- Cytotoxic spill kit.
- Disposable gown, non-absorbent.
- Powder free gloves
- Face mask with shield
- Purple cytotoxic waste bucket
- Purple cytotoxic waste bags

IMPLEMENTATION

Once it is ascertained there are no fluid leaks at the operative field, the desired temperature and flows have been established, chemotherapy treatment can be commenced. All unnecessary staff are advised to leave the operating theatre. Remaining staff are made aware the drug is to be infused, avoid distraction.

The perfusionist must wear appropriate gown, gloves and face protection. A spill kit should be available nearby. The drug is removed from the storage box. Patient details, drug name and dosage are checked with the anaesthetist. The drug envelopes are cut by the perfusionist, exposing the syringe. (Envelopes should be placed in the sealed waste).

The cap from the clave connector near the bubble reader is removed. The syringe cap is removed and is then secured to the clave connector and the drug is slowly infused (care should be maintained to prevent air entrapment). On completion the clave connector is immediately recapped. The syringe is recapped and sealed in the cytotoxic waste bucket.

Throughout the 30 or 90 minutes of circulation a high vigilance is maintained for any leakage/spill from the circuit.

The spill kit is used for spills outside the operative field. The attending surgeon dressed in the appropriate attire will address action required to contain fluid loss in the operative field.