DIGNICAP® DELTA

The DigniCap® Scalp Cooling System

User Manual

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General Information

This Instructions for Use (Professional User Manual) applies to the Delta model of The DigniCap Scalp Cooling System and contains general safety, operating and maintenance information. It is intended for healthcare professionals who treat patients receiving chemotherapy treatments.

Symbols Key

IMPORTANT: Read Instructions

Before operating the device, please read the entire instruction guide. Keep the guide available for future reference.

CAUTION. Consult user manual to determine potential hazards prior to operating the device.

Manufacturer's Part Number

Device Serial Number

Do not smoke around device

Product compliance with North American safety standards

Do NOT Dispose with General Household Waste

Please consult local government / city laws on acceptable method of disposal of electro-mechanical systems in compliance with the Waste Electric and Electronic Equipment Directive (WEEE) 2001/96/EC.

Keep Dry

Type B Applied Part

Medical Device

European Authorized Representative

Device Manufacturing location

Device Manufacture Date Code

RoHS Compliant

RFID

Non-Sterile

Do not use around open flame

Ingress Protection of the Device. Solid Particles > 12.5 mm will be protected from access to hazardous parts. The device does not have any ingress protection against liquids.

Caution: Federal law restricts this device to sale by or on the order of a physician.

CE Mark

Unique device identifier

Importer

ATTENTION: Attentions are added to give more information.

System Parts

DigniCap Delta consists of the following:

- DigniCap Delta device: Cooling and control unit
- Power Cord: Standard A/C power cord
- Cooling Wrap: Adjustable inner cooling wrap
- Thermal Cap: Adjustable neoprene cap
- DeltaCool: Coolant
- Therapy Hose: Hose system that connects cooling wrap to device
- Installation Hose: Hose that connects to the supply and return connector sites on the Therapy Hose and is used to prime (fill) the system with coolant.
- Drain Hose: Hose that connects to the drain port and is used to drain the system for shipment or long-term storage
- Printed Material for professional use

Indications for Use

The DigniCap Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

Contraindications

The use of DigniCap is contraindicated in pediatric patients.

The use of DigniCap is contraindicated in adult patients with:

- Cold sensitivity
- Cold agglutinin disease
- Cryoglobulinemia
- Cryofibrinogenemia
- Cold urticaria
- CNS malignancies (either primary or metastatic)
- Squamous cell carcinoma of the lung
- Small cell carcinoma of the lung
- Cancers of the head and neck
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma
- Hematological malignancies treated with curative intent by chemotherapy
- Solid tumor malignancies with a high likelihood of metastases in transit
- Patients who are scheduled for bone marrow ablation chemotherapy
- Patients who are scheduled to undergo skull irradiation
- Patients who have previously received skull irradiation

Warnings

- **There is a potential for cold injury, even when providing cooling within the prescribed treatment settings.** Special care should be taken when applying the cooling inner cap to ensure that there is **NO direct contact between a patient's exposed skin and the cap's cooling surface**. Individuals who experience any unusual swelling, skin discoloration or discomfort should immediately discontinue the use of the DigniCap System and consult their healthcare professional. Particular attention should be paid to the top of the ear, the forehead and back of the neck. Patients should use a headband to prevent direct skin contact with the inner cooling cap.
- The risk of scalp cooling may outweigh the benefits in patients receiving chemotherapeutic agents with low incidence of inducing alopecia.
- Scalp and/or skin metastases have been reported in patients with non-small cell lung cancer, colon cancer, renal cell carcinoma, ovarian cancer, and bladder cancer. Patients with advanced forms of these cancers may be more likely to experience scalp metastases with the scalp cooling system.
- Use of scalp cooling in the palliative setting in patients with metastatic cancer may also increase the risk for scalp metastases.
- Use of scalp cooling with taxanes plus anthracyclines when used in combination on the same day has not been shown to be successful in preventing chemotherapeutic drug induced alopecia. The DigniCap Scalp Cooling System should not be used in these patients.
- Scalp radiation can cause stenosis of small cutaneous vessels decreasing device effectiveness.
- The effectiveness of this device in patients who have received previous chemotherapy has not been evaluated.
- Long-term effects of scalp cooling and risk of scalp metastasis have not been fully studied.
- Clinical studies have demonstrated variable success rates in patient reduction of chemotherapy induced alopecia with scalp cooling since the outcome is dependent on multiple factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities.
- Data have shown that women who experience hair loss despite using scalp cooling might have worse quality of life than women who did not have scalp cooling.

Background

Hair loss can be one of the most devastating side effects for cancer patients undergoing chemotherapy. Scalp cooling, or scalp hypothermia, is an effective method to greatly reduce chemotherapy-induced alopecia. Scalp cooling has been used since the 1970's and The DigniCap Scalp Cooling System has been available since 1999.

Available clinical studies suggest the following mechanisms for scalp cooling:

- Cooling of the scalp creates vasoconstriction and a lower concentration of chemotherapy is thus delivered to the scalp.
- Scalp cooling reduces cellular uptake of the chemotherapeutic agent and decreases the metabolism in the follicular cells.
- It is unknown which working mechanism is of most importance and additional mechanisms cannot be excluded.

Scalp cooling with DigniCap Delta occurs in 3 phases, starting with the Pre-Cool phase, which cools the scalp prior to the start of chemotherapy infusion. The Active Cooling Phase occurs during chemotherapy administration and then a Post Infusion Cooling Phase is administered after the infusion is complete. The length of treatment is dependent on the type of chemotherapy regimen used. Scalp cooling can be used when chemotherapy is administered as a single drug or in combinations. Scalp cooling has been evaluated primarily for regimens including anthracyclines (doxorubicin, epirubicin), taxanes (paclitaxel, docetaxel), and alkylating agents (cytoxan, carboplatin).

ATTENTION: **The outcome of scalp cooling is dependent on several factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities.**

Scalp cooling therapy sessions exceeding 13 hours are not recommended.

Clinical Data

The efficacy of scalp cooling with DigniCap has been reported in 18 clinical evaluations outside of the U.S. These studies investigated the effects of scalp cooling on the incidence of alopecia in patients with various malignancies using a variety of chemotherapy regimens in both the adjuvant and palliative settings. Efficacy has best been demonstrated in chemotherapy regimens containing docetaxel, paclitaxel, cyclophosphamide, and/or carboplatin. These studies did not have long term follow up and were single armed non-randomized prospective studies. Long-term effects of scalp cooling and scalp metastasis have not been fully studied in the adjuvant setting outside of stage I and II breast cancer. It is not clear whether there is increased risk of recurrence, particularly scalp or skull metastases, based on the data available. Some of the studies did not list the names of the solid tumor malignancies or their frequencies.

A literature review was conducted to address the safety and effectiveness of the DigniCap device. A search in PubMed, EMBASE, Clinical Trial register and Manufacturer and User Facility Device Experience Database - (MAUDE) was performed using the following search terms: DigniCap, Digni and scalp, Digni and alopecia, Digni and hypothermia, and Dignitana. Peer reviewed articles or abstracts (Table 1) of clinical trials covering the majority of the relevance and methodology questions in the appraisal plan of the pivotal clinical trial clinical evaluation report were selected. Due to the literature review method and the design of these studies, safety and effectiveness results presented in these studies may not be accurate.

Based on the published data listed in the back of this manual, there is insufficient evidence to assess long term effect. Use of The DigniCap Scalp Cooling System in these patients may increase the risk of scalp metastasis, metastasis elsewhere in the body or impact the natural course of the disease.

Product information

Overview

DigniCap Delta consists of a thermoelectric cooling unit with a computerized control system to which an adjustable Cooling Wrap is connected. DeltaCool coolant is circulated from the device through the Therapy Hose to small channels within the Cooling Wrap. Circulating coolant temperature is monitored by two separate sensors in DigniCap Delta, one that measures the coolant supply to the Cooling Wrap and one measuring the return flow. An additional sensor monitors supply coolant temperatures as a backup to assure patient safety. The Cooling Wrap can be easily disconnected from the DigniCap Delta device when necessary (for example, to facilitate restroom visits). To insulate and keep the Cooling Wrap in place, a neoprene Thermal Cap is used over the Cooling Wrap.

DigniCap is intended to be used in hospitals and healthcare facilities that treat cancer patients receiving chemotherapy treatment. The System is designed for indoor use, within the temperature, pressure and humidity specifications stated in the technical specification of this manual. DigniCap Delta maintains a constant and controlled temperature during the entire treatment period. Any deviations from the default temperature are automatically adjusted by the system. The default treatment settings for temperature and time can be changed through the touch-screen monitor. A notification is activated if any errors are detected. Information collected during each treatment is available on the touch-screen display for visual monitoring during or after the treatment and available for download.

An applied part refers to the part of the medical device which comes into physical contact with the patient for the device to carry out its intended function. For DigniCap Delta, the Cooling Wrap is the applied part.

DigniCap Delta

DigniCap Delta (Figure 1) is a thermoelectric cooling unit with an integrated control system operated via a touch screen monitor. Components of DigniCap Delta are outlined below.

DigniCap Delta consists of a thermoelectric cooling unit with a computerized control unit that maintains a constant and controlled scalp temperature during the entire treatment period. Any deviations from the default temperature are automatically adjusted by the system.

1. ***Liquid Crystal Display*** – The treatment can be initiated and settings for Cooling Intensity and Post Infusion Cooling time can be changed through the touch-screen monitor. The touch screen will also display notifications if any errors are detected.
2. ***Reservoir Fill Site*** – The device is filled with DeltaCool coolant through the reservoir.
3. ***Overflow Vessel*** – This prevents DeltaCool spills on the device.
4. ***Therapy Hose Connectors*** – On the back of the DigniCap Delta device, there are connectors to which a Coolant Transport Hose is connected.
5. ***ON/OFF breaker switch*** – This switch will disrupt A/C power to the device when plugged into a wall outlet. This switch is used to turn the device ON/OFF.
6. ***Power Cord Connection*** – The A/C power cord (supplied) plugs into the back of the device.
7. ***Push Handle*** – Used when transporting the device.
8. ***Fully Rotating Castors*** – DigniCap Delta has 4 fully rotating and individually locking castors for ease of mobility.
9. ***Release Buttons for Filter Changes*** – These buttons are used to remove the front plates from the device to allow access to the air filters.
10. ***Drain Port*** – This is used to drain the DeltaCool coolant from the device for transport and storage; it is visible on the right side of the device behind the top front panel.
11. ***Air Filters*** – Four (4) filters, are located behind the two front panels to filter particulates from the air flow to the device.
12. ***DeltaCard Reader*** – The DeltaCard (see Accessories section) activates the DigniCap Delta device and is placed here during therapy.
13. ***USB port*** – Under the back surface of the device, this port is used to download therapy data from the device and update software.

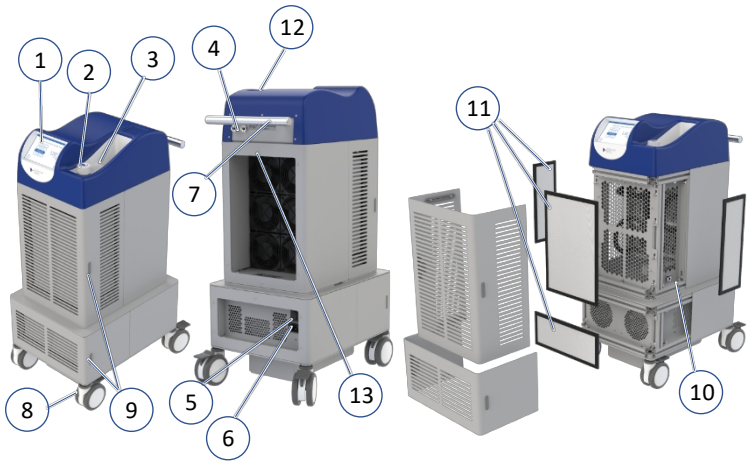


Figure 1. DigniCap Delta

The DigniCap Delta device is supplied (possibly via 2 shipments) with the following components:

1. ***Professional User Manual*** – This instruction manual (included in the Device shipment) is intended for Professional use only and covers all aspects of the device, including description of device and accessories, instructions on correct use, and troubleshooting guide.
2. ***Connection Kit (Figure 2)***
    1. ***A/C Power Cord*** – The A/C power cord (region specific) plugs into the back of the device (Figure 1,6) to supply power to the device. Only use the A/C power cord supplied with DigniCap Delta.
    2. ***Therapy Hose*** – This hose connects to the back of the DigniCap Delta (Figure 1,4) and to the Cooling Wrap (described below).
    3. ***Installation Hose*** – This connects to the end of the Coolant Transport Hose to enable the user to fill the system with DeltaCool.
    4. ***Drain Hose*** – This hose connects to the Drain Port (Figure 1,10) and is used to drain the coolant from the device in preparation for transport or storage (see Shipping and Storage section).

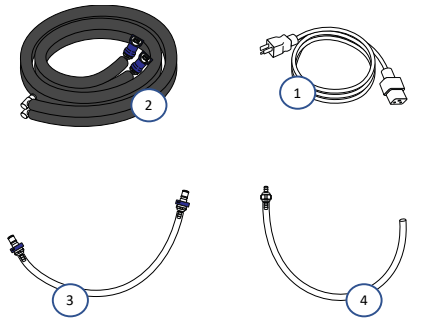


Figure 2. Delta Connection Kit

DigniCap Delta Accessories

DigniCap Delta operates by circulating temperature controlled DeltaCool from the device through the Therapy Hose to the Cooling Wrap. The wrap contains coolant channels (see Cooling Wrap section below) that disperse the coolant to all surfaces of the Wrap.

When a patient elects to receive scalp cooling using DigniCap Delta®, they will receive everything needed for scalp cooling treatment.

- Cooling Wrap
- Thermal Cap with chin strap
- Patient Literature

Cooling Wrap

The Cooling Wrap (patent pending, Figure 3) is designed to be wrapped around the patient's head to create a custom fit for each patient.

- The Cooling Wrap is manufactured to circulate temperature-controlled coolant throughout channels in the wrap (Figure 3).
- The Cooling Wrap is completely adjustable to fit comfortably and uniformly on each patient (see Fitting the Cooling Wrap and Thermal Cap to Patient section below).

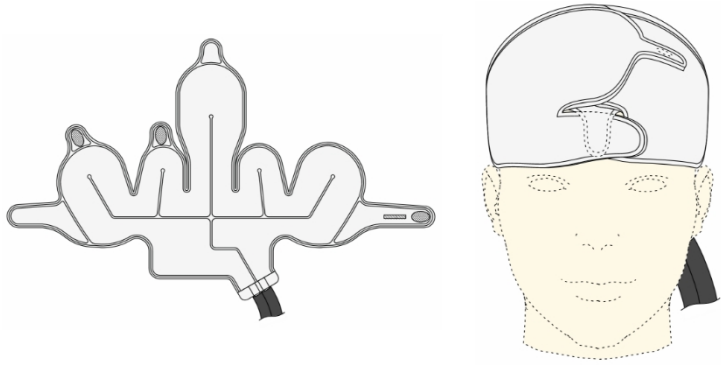


Figure 3. Cooling Wrap

- The Cooling Wrap is designed as Single Patient Use. The patient will keep the Cooling Wrap for their series of cooling sessions.

Thermal Cap

The Thermal Cap (Figure 4) is a Neoprene-type cap that insulates the Cooling Wrap and prevents condensation. It has a chin strap to secure the cap as well as adjustable tabs across the crown of the cap for complete adjustability to assure a perfect fit.

The Thermal Cap also serves to keep the Cooling Wrap in place during treatment by virtue of its elasticity, thus ensuring optimum contact between the Cooling Wrap and the scalp.

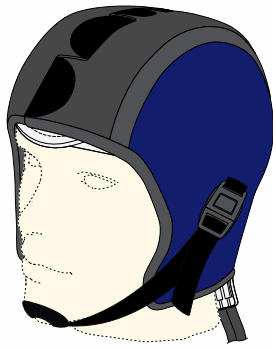


Figure 4. Thermal Cap

DeltaCard

The DeltaCard (Figure 5) is used to activate DigniCap Delta and should be treated like a gift card. The patient will purchase a DeltaCard from Dignitana or receive a card from their infusion center. When administering therapy, the DeltaCard is placed on the reader on the top of the device and is to remain there during the entire treatment. Removal of this card during any stage of therapy may result in therapy termination or DeltaCard malfunction. DeltaCards may be contain a single treatment (as in Figure 5) or contain multiple uses on each card (similar style with a gray face).

Figure 5. DeltaCard

DeltaCool

The DeltaCool coolant is a proprietary blue cooling liquid consisting of diluted isopropyl alcohol. The specific dilution is made to optimally support DigniCap Delta and is provided in single use 500mL bottles.

ATTENTION: Only use DeltaCool coolant in the DigniCap Delta device. The use of any other coolant will result in device malfunction.

System Preparation and Installation

ATTENTION: **Before using the system, this manual should be carefully studied to ensure safe and efficient operations.**

When the device is in use, be sure that the placement does not block ventilations holes.

Do not use the system if the product or any of its components, parts, or accessories show any signs of cracking or other structural damage.

The system should only be operated by personnel who have been trained by Dignitana or authorized distributors in the use of the system.

This device contains a rechargeable battery. This is NOT a user-serviceable item. Contact Dignitana for any service issues.

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth ground. No modification of this equipment is allowed.

Do not use on patients on supplemental oxygen.

Unpacking DigniCap Delta System

The weight of the DigniCap Delta device is 65 kg (143 lbs.) and the package including the system weighs 68 kg (150 lbs.). Additionally, you will receive a Delta Connection Kit, specific to your region. This kit will come in a separate box, often with the device, but may be sent separately. Inspect both shipments for the following items.

DigniCap Delta Shipment:

1. Packing Slip. Attention to ensure that all components have been included.
2. DigniCap Delta device
3. Reservoir Cap
4. Air Filters (4, installed)
5. User Manual (inside the front top cover)

Delta Connection Kit:

1. Packing Slip. Attention to ensure that all components have been included.
2. Therapy hose
3. Installation hose
4. Power cord (Region Specific)
5. Drain hose

If any damage has occurred during transport, or if the delivery does not coincide with the packing slip, contact a Dignitana representative.

Site Requirements

The system measures approximately 37.5”H x 20”D x 15”W (95.25 x 50.8 x 38.1 cm), castors included. To facilitate operation of the system, allow at least 1ft (30.5 cm) free space in the front and behind and at least 0.33ft (10 cm) free space above the system for ventilation.

The site shall provide protectively earthed facility power.

Due to the heat dissipation from the DigniCap Delta device, do not install the system:

- In a very small room, less than 65 ft^2 (6 m^2), or in a room with insufficient ventilation.
- In a place where the room temperature and/or the relative humidity is high (e.g. beside a radiator or humidifier or in direct sunlight).

For more information see Technical Information section.

WARNING: **Depending on environmental conditions (e.g., high humidity and/or high ambient temperature) users may experience condensation that could potentially accumulate on certain components of the DigniCap Delta such as the connectors and Therapy Hose.**

This condensation may transfer to the area around the device potentially creating a “Wet floor” condition which could lead to injury from slipping and/or falling. Wipe down the DigniCap Delta and any wet components as needed at any point in time to avoid hazardous situations

Input Voltage and Current

The site shall provide facility power with a dedicated circuit and shall:

- Match the voltage and frequency stated on the product label.
- Be able to deliver the current stated on the product label.
    - 220 – 240 VAC 50/60Hz 10A
    - 115 – 120 VAC 50/60Hz 15A
    - 100 – 114 VAC 50/60Hz 20A
- Have a protective earth (ground) connection.

Only connect the system direct to a permanently grounded electrical outlet.

Only use the main power cable delivered with the system.

Place the system so the plug to the main outlet is easily accessible and can be quickly disconnected in case of emergency.

Installing the DigniCap Delta device with Coolant

Before installing the system, the installation site should be prepared according to the site requirements above. If device has recently been outside in high or low temperatures, let device sit in a temperature-controlled environment for 30 min before initiating installation.

1. When the DigniCap Delta device is placed in its desired location, lock the brakes on the wheels.
2. Check that the air filters are clean and in place. See Maintenance and Cleaning section.
3. Be sure the User Manual has been removed from inside the front top cover.
4. Connect the main power cable to the A/C port on the back of the device and to a main outlet (Figure 6).
5. Turn the breaker power switch to the ON position.
6. Connect the Therapy Hose to the DigniCap Delta device.

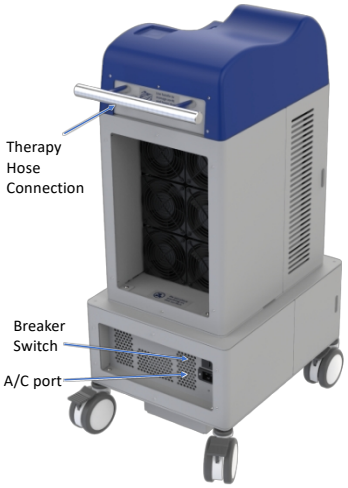


Figure 6. DigniCap Delta - Back

DigniCap Delta has two operating modes, Clinician Mode and Patient Mode. To prevent patients from starting or modifying therapy sessions, the device starts up and performs its primary operation in Patient Mode. When the device powers up it displays the Welcome Screen. To operate the device from the Welcome Screen, enter Clinician Mode by tapping with 1 finger the upper left, right, then center of the screen as shown in Figure 7.

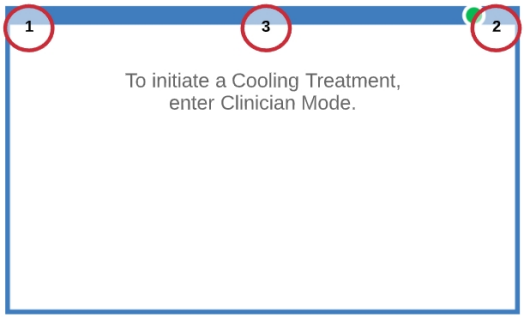


Figure 7. Clinician Mode Sequence

This will bring up the Start Screen (Figure 8), which allows initiation of a new therapy session by pressing the PLAY button or to view Therapy and Device Information by pressing the INFORMATION button (see Therapy and Device Information section below).

Prior to using the Delta to deliver therapy, it must be installed and filled with coolant. If the device is empty of coolant, the device will prompt you to perform installation procedures automatically. This procedure does not need to be repeated unless the system is drained.

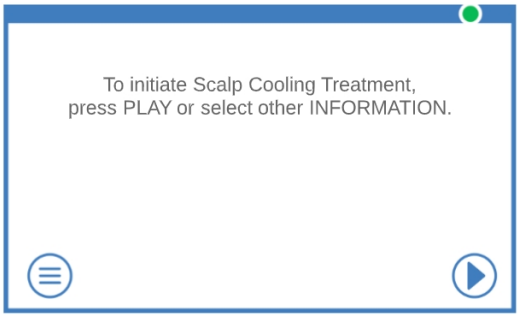


Figure 8. Start Screen

1. Press the PLAY button and an empty device will prompt the user to install the system. If the DigniCap Delta device has been previously installed, the device will initiate therapy setup (see Initiate a New Therapy Session section below).
2. Connect the Installation Hose to the Therapy Hose to create a loop-back for coolant flow (Figure 9).
3. Obtain 1 bottle of DeltaCool coolant, remove the cap from the reservoir (Figure 1,2) and fill with coolant to the top. Keep the cap OFF the reservoir.
4. Press the PRIME button in the lower right-hand corner of the screen to start the priming of the device.
5. As coolant begins to flow, continue to fill the reservoir until the system volume becomes stable and reservoir is full to the neck.

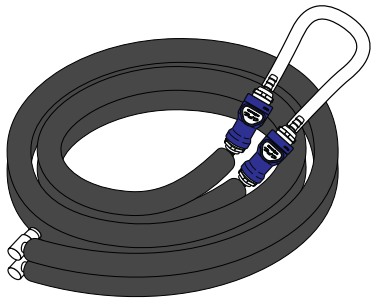


Figure 9. Therapy Hose with Installation Hose installed

ATTENTION: **Do not overfill the reservoir.**

Do not spill DeltaCool or any other liquid on the device. If a liquid is spilled on the device (outside of the overflow vessel), stop therapy, unplug the device from wall power and disconnect patient from the device.

The coolant (DeltaCool) is always supplied in the correct concentration. Do not dilute or use any other coolant than DeltaCool from Dignitana.

6. Once the system volume is stable, replace the cap on the reservoir, and PROCEED .
7. If the coolant levels are appropriate, the device will present the Start Screen.
8. Remove loop back but keep the Therapy Hose installed on the device. System is now ready for patient use.

Charging the Delta Transport Battery

The DigniCap Delta device has the capability to transport the patient during the Post-Infusion Cooling Phase from the infusion chair to another waiting area, without interrupting treatment. Additionally, the battery protects during brief periods of power loss during all phases of treatment. To charge the battery in the Delta device, be sure the device is plugged into A/C power and the breaker switch is in the ON position. After ~5 min, the screen will go to sleep, but you will continue to hear fans run in the device while it charges.

ATTENTION: **In order to charge the transport battery, the device must be left plugged in and the breaker switch in the ON position.**

The device should be charged 4hr to overnight before the first patient is treated to assure the battery charges completely.

It is recommended that the device remains plugged in overnight when it is being used daily.

Do not attempt to insert any object into the DigniCap Delta device via the ventilation holes, since this can cause a risk of fire or electric shock.

Use fingertips when operating the touch screen. Sharp items such as nails or pens can damage the screen.

Switch off the main power and disconnect the system from the wall socket if you:

- **See or smell smoke**
- **Hear unusual sounds**
- **Notice damaged or broken main power cable**

Contact a Dignitana representative or authorized distributor.

Initiating New Therapy Session

Prior to Initiating Treatment

To initiate therapy on DigniCap Delta, the following items will be required:

- Therapy hose connected to the Device, which has been installed as outlined above
- Cooling Wrap and Thermal Cap
- Valid DeltaCard
- Spray water bottle and towel
- DeltaCool coolant

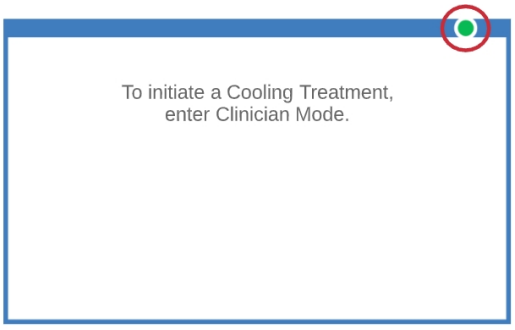


Figure 10. Transport Indicator

On the Welcome Screen, observe the transport indicator in the upper right-hand corner of the screen (Figure 10). If the indicator is green, the patient can be moved during post-infusion phase of treatment without discontinuing treatment. If it is yellow, there is not enough capacity to move the patient and the device should not be unplugged. See the section above, Charging the Delta Transport Battery. The transport process is further described in the Post Infusion Cooling Section.

ATTENTION: Inspect the DigniCap Delta device for any signs of moisture and wipe down before use or any point thereafter.

Using the DeltaCard

To initiate a new therapy session, make sure the device is on and in Clinician Mode, displaying the Start Screen (Figure 8) and press the PLAY button.

ATTENTION: If low coolant levels are detected, DigniCap Delta will prompt the user to perform Installation procedures. (See Installation of the DigniCap Delta device section)

1. As prompted by the device, place the DeltaCard on the card reader. It is located at the top with an NFC symbol (Figure 11). Pressing the BACK button will transition back to the Start Screen.
2. When DigniCap Delta recognizes a valid card, the device will prompt the user to PROCEED to activate treatment session. Once the treatment has been activated, the DeltaCard must remain on the device for the entire treatment session.

ATTENTION: **If the card is not detected or the device indicates the card is invalid, remove it from the card reader for ~3 seconds, replace, and press SCAN ⟲. If the device continues to not detect/initiate the card, see the Troubleshooting section.**

An activated DeltaCard (Single Use, white) can be used to initiate scalp cooling therapy on any DigniCap Delta device. Multiuse DeltaCards (contain multiple sessions, gray) may only be used in certain locations. Once the session has been used to deliver therapy for a continuous 60 min, or a cumulative 180 min, or to activate therapy 10 times the session can no longer be used to initiate therapy. See Troubleshooting Section for more information.

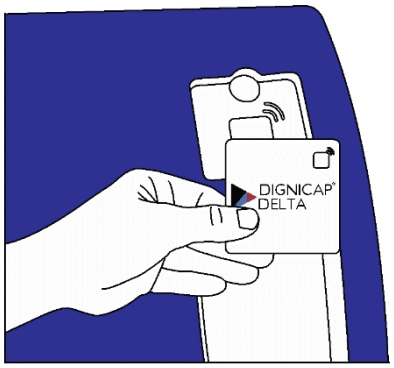


Figure 11. DeltaCard and Reader

3. The device will prompt the user to connect the Cooling Wrap to the Therapy Hose. The Cooling Wrap connects to the Therapy Hose by connecting the 2 connectors as shown in Figure 12. Press PROCEED ⟩.

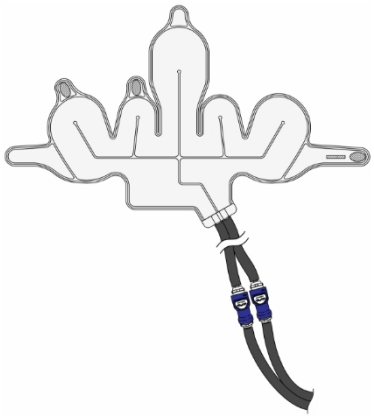


Figure 12. Cooling Wrap connected to Therapy Hose

Priming the Wrap

Priming Setup Screen provides instructions for using a new (empty) or previously used (full of DeltaCool) Cooling Wrap. For this step, have a bottle of DeltaCool ready. Connect the Cooling Wrap to the Therapy Hose and follow the instructions below based on the status of the wrap.

If the wrap is empty, open the reservoir cap and follow the instructions below:

a. Fill reservoir to top if not already full.

b. Press PRIME ⏚ to initiate the priming step.

c. Coolant will begin to flow from the reservoir (the coolant levels will decrease as coolant is pumped into the Cooling Wrap).

d. Continue to top off the reservoir with DeltaCool until the volume is stable and full (to the neck). If reservoir runs empty, the device may present a Low Coolant Level alarm. Fill the reservoir and the priming process can be restarted.

If the wrap is full, DO NOT remove reservoir cap as the reservoir may overflow due to pressure in the wrap. If this occurs, the overflow vessel will catch it and it can be easily cleaned.

a. With the reservoir cap still on, press PRIME ⏚ to initiate the priming step.

b. Remove reservoir cap to check coolant levels. Top off if coolant is below reservoir neck.

c. Once the system is full and with the coolant flowing, remove any significant bubbles from the Cooling Wrap by holding the wrap by the tubes (upside down) and gently shaking the Wrap. This may require to you top off the reservoir again.

d. Once the Cooling Wrap is primed, replace the reservoir cap and fit the patient with the Cooling Wrap and Thermal Cap. The coolant will continue to flow during the fitting process (below), but the coolant will not start cooling.

Fitting the Cooling Wrap and Thermal Cap

ATTENTION: **Inform the patient that scalp cooling does not guarantee hair preservation and that scalp cooling treatment can be interrupted or discontinued at any time if desired.**

Contraindications are cold sensitivity, cold agglutinin disease, cryoglobulinemia and cryofibrinogenemia. Scalp cooling is contraindicated if chemotherapy is given with a curative intent in patients with hematological malignancies.

While a primed Cooling Wrap is connected, do not remove reservoir cap unless device is running. Doing so may cause the reservoir to overflow into the overfill vessel. If this does occur, remove excess coolant from the vessel and top off reservoir once therapy is started/resumed.

Step 1 – Prepare materials and patient's hair

1. Ask the patient to wet their hair, focusing on the scalp.
2. The patient should remove any hair accessories as well as earrings, and hearing aids.
3. Ask the patient to take off his/her glasses while the cap is being fitted. They can wear their glasses outside the Cooling Wrap during the scalp cooling session.
4. Place a towel around the patient's shoulders to prevent their clothes from becoming wet. If the patient has long hair, ensure that it is over the towel.
5. Fill the spray bottle with room temperature water and wet the scalp thoroughly. The patient may wish to do this in the restroom with a mirror or with the help of a friend or caregiver. Saturate hair by sections, lifting the hair and spraying the roots. It is important that the hair and roots are completely wet but not dripping. Only the hair covering the scalp needs to be wet. If the patient's hair is longer than shoulder length, this part of the hair does not have to be wet.

   ATTENTION: **It is important that the hair is well saturated to achieve an optimal temperature at the scalp.**

6. Brush hair, parting the hair in the center. Brush straight down and as flat as possible. The patient should use his/her hands to gently smooth hair down against their head. Do not tuck hair behind ears.

Step 2 – Fit the Cooling Wrap and Thermal Cap to the patient's head

The Cooling Wrap is fitted to the patient's head in 4 steps (Figure 13) and secured with the Thermal Cap.

1. Place the headband over the patient's forehead, lower lobes of ears, and nape of neck (around the hairline). Adjustment may be required.
2. Fit the wrap around the back of the patient's head, (Figure 13,1-2). Patient will pull forehead tabs forward and slightly up near temple, to lock wrap against occipital lobe. Staff will bring center flap from back of head forward and place it so it's lying flat on head and tuck the tab behind the forehead tabs.
3. Secure the forehead tabs over the forehead, while the patient holds the wrap in place to prevent movement while you finish fitting the wrap. The wrap should be snug but not uncomfortably tight. The wrap should fit comfortably behind the ears. The wrap is designed to not cool the forehead. Make sure this area is positioned correctly. Do not place the wrap over the ears and be sure to protect any skin without a hair barrier.
4. Fit the top tabs across the top of the patient's head (Figure 13,4) ensuring that they lay as flat as possible. It may help to unattach/reattach the tabs to fix any buckling that occurs with successive attachment.

5. Flip the tab on the center flap up between the 2 forehead tabs, to lock the center flap in place.
6. Fit the Thermal Cap over the Cooling Wrap and attach the chin strap (Figure 13).
7. Adjust the fit of the Thermal Cap by adjusting the tabs across the crown of the head, after the patient has started the PreCool phase (shown by arrow).
8. Once the Wrap and Cap are secured to the patient's head, press PROCEED ⓒ to complete therapy setup.

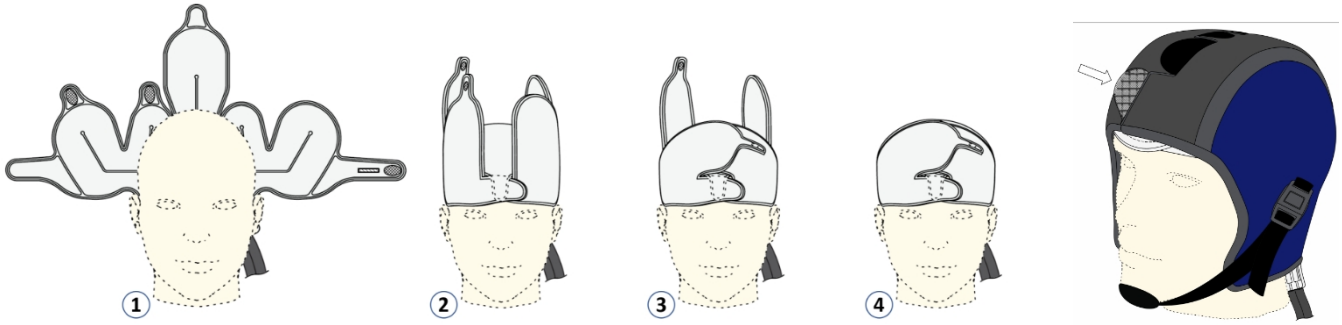


Figure 13. Fitting the Cooling Wrap and Thermal Cap

It is important that the wrap be fitted straight on the head as the front of the wrap that fits over the forehead does not cool. If this section of the Wrap is over regions with hair, that area of scalp will not cool.

The cooling wrap must NOT be in contact with the ears or any bare skin surfaces. To protect those surfaces, place gauze or fabric between the wrap and the skin. Failure to do apply the wrap properly can result in cold injury.

The patient will want to avoid any movement of the wrap or cap during the scalp cooling procedure. It is important that the Cooling Wrap is in close contact with the scalp on the whole area of hair growth throughout the treatment.

- Instruct the patient not to move the wrap or cap during their treatment and to inform you if they have been moved accidentally. If this happens, immediately readjust the wrap and cap to the correct position.
- When leaning back in the chair the wrap may shift, resulting in a loss of contact between the wrap and the scalp. Advise patient to be aware of this.

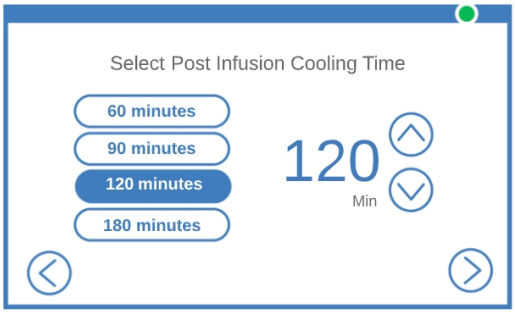


Figure 14. Post Infusion Time

- If the patient falls asleep during the scalp cooling treatment, check to see if the wrap and cap have moved. If the either has moved, wake the patient and re-adjust.

Post Infusion and Settings Verification

1. Select the desired Post Infusion Cooling Time (Figure 14) by selecting one of the pre-programmed buttons or using the up ⌃ and down ⌄ arrows to set a custom time (60-300 min) and press proceed ›.
2. Confirm Therapy settings and press OK ✓ to start cooling treatment.

ATTENTION: **Pre-Cool time is automatically set to 30 min and cannot be changed by the user. If the device does not reach set cooling temperature within that time, the device will alert the user and extend Pre-Cool time.**

Cooling therapy automatically initiates at a Cooling Intensity of 08. After therapy is initiated, Cooling Intensity and Post Infusion Cooling time can be changed at any time in Clinician Mode (see below in Clinician Mode section).

DigniCap Delta operates cooling therapy in Patient Mode by default, meaning that any therapy adjustments are hidden and unavailable unless a clinical staff member unlocks Clinician Mode (see below in Clinician Mode section).

Scalp Cooling Therapy using DigniCap Delta

Therapy Run Screens

Scalp cooling using DigniCap Delta occurs in 3 phases, Pre-Cool Phase, Active Cooling Phase, and Post Infusion Cooling Phase. When therapy is initiated, DigniCap Delta will start in Pre-Cool Phase (Figure 15).

Figure 15. Pre-Cool Run Screen

The Therapy Run screens for all 3 phases have a similar format and display the following information:

1. ***Phase Indicator:*** The title at the top displays the current Phase/State of therapy.
2. ***Therapy Status Bar:*** The status bar at the top and border around the screen provides the user with the device status.
    a. If therapy is running as prescribed, the bar will appear solid and green.
    b. If the device is running as prescribed but needs attention, the bar will remain green but also blink.
    c. If the device is not running as prescribed or requires attention, the bar will present blinking yellow and indicate a notification or alarm state (see Alarm Summary Section)
3. ***Phase Timer:*** The timer indicates the time remaining (or time elapsed as in Active Cooling Phase) in the current Phase.
4. ***Pause (or Play):*** This button allows the patient to pause therapy for up to 6 min. This feature is disabled for patient use in the Pre-Cool Phase and requires Clinical Staff input (see below in the Clinician Mode section).
5. ***User Notifications:*** Important information is displayed here during different phases of therapy.
6. ***Transport Indicator:*** This indicator dot displays the capacity to transport the patient from the infusion chair during Post Infusion Cooling Phase (see Post Infusion Cooling Phase).

Adjust Cooling Settings

The therapy settings can be adjusted by entering Clinician Mode and is available in any Phase of Cooling Therapy (Figure 16). Here the clinical staff can change cooling parameters or transition to other phases of therapy. Clinical staff can access this screen entering the Clinician Mode sequence described in Figure 7.

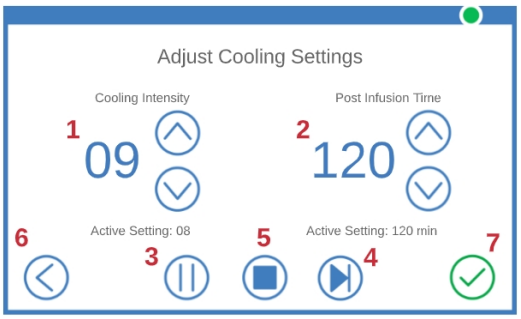


Figure 16. Adjust Cooling Settings

1. Cooling Intensity can be set from Level 01 (warmest) to Level 10 (coldest) by pressing UP ⌃ and DOWN ⌄ buttons. Therapy will initiate at Level 08 by default but can be changed at any phase of cooling therapy. The current Active Setting is displayed below the new setting.
    a. For patients with very thin hair (by looking at the hair, one can see through to the scalp) due to having thin hair or due to shedding, the Cooling Intensity should be changed to *Level 4*
    b. For patients with almost no hair at all, the Cooling Intensity should be changed to *Level 2*
    c. The Cooling Intensity Level is adjusted in the Clinician Mode once a patient is in the Pre-Cool phase of treatment.
2. Post Infusion Cooling Time can be set from 60 to 300 minutes by pressing UP ⌃ and DOWN ⌄. The Active Setting is displayed below the new setting. During the Post Infusion Cooling Phase, the Time Remaining in the

phase is displayed and the user will be given the option to change the remaining time to up to 13 hours.

3. Therapy can be paused by pressing PAUSE ⏸ (see Pausing Therapy section). Pausing in Pre-Cool Phase is only available in Clinician Mode.

   ATTENTION: It is not recommended that therapy be paused during the Pre-Cool Phase, however if therapy must be paused, the clinical staff can do so in Clinician Mode. If therapy is paused during Pre-Cool Phase, the session timer will start over once therapy is resumed (see Pre-Cool section).

4. TRANSITION ⏭ is used to transition through the phases of scalp cooling – from Pre-Cool Phase to Active Cooling Phase and from Active Cooling Phase to Post Infusion Cooling Phase.

   ATTENTION: TRANSITION ⏭ will not be available during the Pre-Cool Phase until the Phase has completed or during Post Infusion Phase as there are no further phases to complete.

5. STOP ⏹ is used to Terminate the Cooling session and to return to the Welcome Screen. This function will be used to terminate therapy at the end of a patient's cooling session or if a session needs to be terminated prematurely.

   ATTENTION: If the Cooling session is terminated prematurely and more than 60 min of therapy has elapsed, the therapy session will not be able to restart the using the same DeltaCard (see Troubleshooting section).

6. BACK ⏴ allows the user to return to the therapy run screen and exit out of Clinician Mode without saving any changes made.
7. The OK Button ✓ does not appear when first entering into Clinician Mode and will only appear if setting changes are made. Pressing OK ✓ allows the user to accept any changes made to the Active Cooling Settings. The user must press the OK ✓ button after changes are made or the changes will not be saved.

Pre-Cool Phase

During the Pre-Cool Phase, DigniCap Delta slowly reduces the circulating coolant temperatures to bring scalp temperatures down to therapeutic levels. It is critical for efficacy that the scalp be at set temperature for 10 min prior to starting the chemotherapy infusion. Therefore, the duration of the Pre-Cool Phase is automatically set to 30 min. Once the device reaches and maintains set temperature for 10 min, the device will allow the user to advance to the next phase of therapy. If after 20 min the device has not reached set temperature, the Pre-Cool time will be extended by 20 min (see Alarm Summary) and a message noting such will be presented at the bottom of the Pre-Cool screen.

- The Pre-Cool Run Screen (Figure 15) shows the time remaining in this phase of therapy.
- The capability to pause this phase of therapy is disabled in Patient Mode (as indicated by the grayed-out button). If the clinical staff choose to pause during the Pre-Cool Phase (in Clinician Mode, see above), the Pre-Cool phase timer will restart.
- When Pre-Cool Phase is complete, and the timer reaches 0:00, the indicator bar and timer will blink and the device will emit an audible chirp to get the user's attention.

- The DigniCap Delta screen will display a message that Pre-Cool Phase is complete but continues to deliver the prescribed cooling therapy, even though the timer has reached 0:00.
- If Pre-Cool phase completes before the 30 min elapses (the device reaches and maintains set temperature for 10 min), TRANSITION will appear on the screen, the timer will present 0:00, and the screen will indicate that Pre-Cool is complete (Figure 17).

Figure 17. Pre-Cool Complete

As DigniCap Delta begins to cool the coolant circulating through the Cooling Wrap, the patient might experience some discomfort.

- This is most common during the first 15 minutes as the temperature initially drops. The discomfort usually wears off as the patient gets accustomed to the cold.
- Shivering is not a common symptom of scalp cooling treatment, but it may occur as a result of a reaction to one of the cytostatic drugs, e.g. Taxol (anaphylactic reaction).
- If the system is touching any part of the patient outside of the areas of hair growth and the cold temperatures are uncomfortable, place a towel/gauze between the cold areas and the patient's skin during scalp cooling.

Active Cooling Phase

Once Pre-Cool is complete, Active Cooling Phase can be initiated by pressing TRANSITION.

- Active Cooling Phase will initiate at the therapy settings defined at the time of phase transition.
- During the Active Cooling Phase, DigniCap Delta delivers the prescribed cooling therapy for the duration of the chemotherapy infusion.
- The duration of the Active Cooling Phase is dependent on the infusion time and can run for up to a total therapy time of 13 hours (including the time in Pre-Cool).

The Active Cooling Phase Run Screen shows the time elapsed in this phase of therapy (Figure 18).

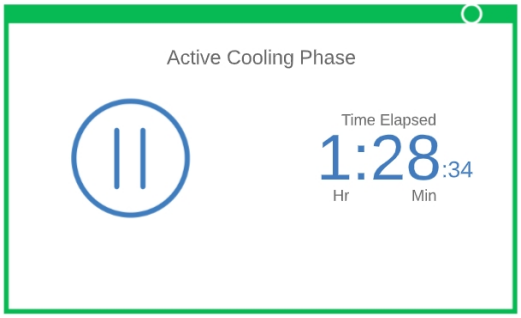


Figure 18. Active Cooling Phase Run Screen

- The patient has the capability to pause their cooling therapy by pressing PAUSE during the Active Cooling Phase as needed for bathroom breaks, etc. Pausing therapy is only recommended for periods less than 6 minutes (see the Pausing Therapy section below).
- When the chemotherapy infusion is complete, the clinical staff can enter into Clinician Mode and transition to the Post Infusion Cooling Phase using the Transition Button (Figure 16,4).

Pausing Therapy

DigniCap Delta can be paused by the patient or clinical staff as breaks are needed.

- Pauses during treatment should be as few and as short as possible. The temperature of the scalp increases when the patient is disconnected from DigniCap Delta and this may affect the outcome of the scalp cooling treatment. Patients should therefore be asked to visit the restroom before starting treatment.
- As a result of the reduced scalp temperature during cooling, some patients may feel dizzy when standing up or walking so care should be taken when patient stands up from chair.
- To pause the Cooling Session, press PAUSE ⏸ on the Therapy Run Screen (Figure 19) or in Clinician Mode (Figure 16,3).

Figure 19. Cooling Therapy Paused

- When the device is paused, the timer will pause and blink, the indicator bar will turn yellow and blink, and the device will emit an audible chirp. A message at the bottom will indicate that the device is paused (Figure 19).
- Disconnect the Cooling Wrap from the Therapy Hose by pressing the connector buttons to allow the patient to move away from the DigniCap Delta system.
- Once the patient returns, reconnect the Cooling Wrap to the Therapy Hose (verify by listening for the audible click), assuring that the wrap and cap did not shift during break.
- To resume therapy, press PLAY ⏵. The indicator bar will stop blinking and turn green, the audible chirp will subside, and therapy delivery will continue as indicated by the timer continuing.

ATTENTION: **The Cooling Wrap or Thermal Cap should NOT be removed from the patient's head during any Pause sessions.**

Pausing for more than 8 minutes is NOT RECOMMENDED and may affect the cooling treatment outcomes. If the device is paused for more than 8 min, the device will present a Low Priority Alarm (see Alarm Summary section below).

Cooling therapy can be paused in any phase of therapy, however pausing in Pre-Cool Phase is NOT RECOMMENDED and may reduce Cooling Therapy efficacy. If the system must be paused during Pre-Cool, the pause function is only available in Clinician Mode and will reset the Pre-Cool Phase timer.

Post Infusion Cooling Phase

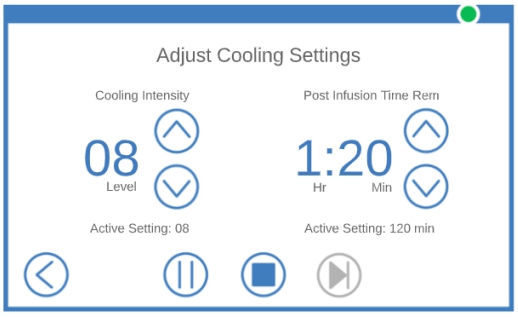


Figure 20. Adjust Cooling Settings - Post Infusion

The Post Infusion Cooling Phase occurs after the chemotherapy infusion is complete and during this phase the timer displays the Time Remaining for the phase to complete. The duration of Post Infusion Cooling Phase is set by the clinical staff during therapy setup. In this phase, the patient is able to pause therapy by pressing the Pause Button ⏸ if breaks are needed. As in the Active Cooling Phase, it is recommended that any breaks are kept to less than 6 minutes or efficacy may be affected. While in the Post Infusion Cooling Phase, the remaining Post Infusion Cooling time may be adjusted by entering into Clinician Mode (see Clinician Mode section above). Instead of displaying the total Post Infusion Cooling Time, it presents the Time Remaining in the current set time (the Active Setting will display the time remaining when the user entered into Clinician Mode) and the user can adjust the remaining time by pressing UP ⏶ and DOWN ⏷ (Figure 20) to a total of 13 hr, minus time already expired in previous phases. The system will provide an alarm when treatment is 15 min prior to expiration.

Transporting the Patient During the Post Infusion Phase

DigniCap Delta offers a unique transport that allows patient to be moved from the infusion chair to an alternative location during Post Infusion Cooling Phase without disrupting therapy delivery. This allows the infusion chair to be available for the next patient. The Transport Indicator (Figure 15,6) in the upper right-hand corner alerts the user to the battery status, thus indicating the availability to transport.

To move the patient, follow the instructions below.

1. Check that the Transport Indicator is green indicating that it is safe/capable to move the patient.
2. Unlock the castors so that the device can freely roll
3. Switch the breaker switch to the OFF position. When the breaker switch is off, the indicator bar will turn yellow and blink and the device will emit an audible chirp. It will also display a message on the screen indicating that the device is operating without A/C power (Figure 21).
4. Unplug DigniCap Delta from the wall (keep the A/C cord plugged into the back of the device). Transport should be completed within 15 min. During Transport Mode the device continues to cool.
5. Using the handle on the back of the device, transition the device and the patient to an alternative location.
6. Reconnect the device to A/C power and switch the breaker switch to the ON position. The Transport Mode screen will automatically change back to the normal Run Screen when A/C power is restored.

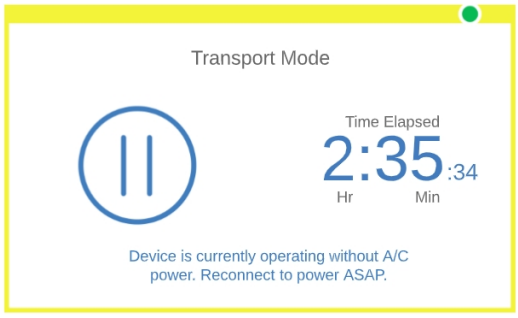


Figure 21. Transport Mode

ATTENTION: **If DigniCap Delta remains off A/C power for > 15 min, the device will Alarm, indicating minimal operating time available (see Alarm Summary section).**

If A/C power is lost during other phases of the device and the battery is used, this will shorten the time available for transport.

Therapy Completion/Termination

At the end of the Post Infusion Cooling Phase, the cooling therapy will stop. The timer will read 0:00 and the yellow indicator bar and timer will blink. DigniCap Delta will emit an audible chirp and the message at the bottom of the screen will indicate that the therapy is complete (Figure 22). The patient can disconnect the Cooling Wrap from the Therapy Hose at any time after Post Infusion Phase is complete. To terminate the session, enter Clinician Mode (see Clinician Mode section above) and Terminate Therapy session by pressing STOP ⏹, however the device will reset to the Welcome Screen after 5 min.

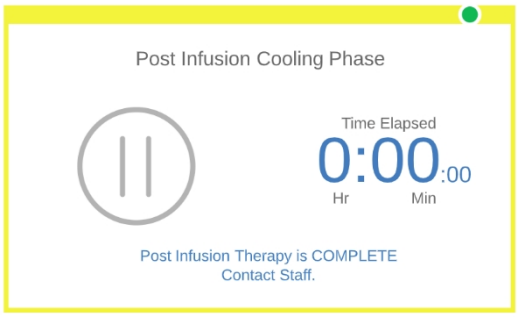


Figure 22. Therapy Complete

After moving the device for storage overnight, be sure to plug in the device and switch the breaker switch to the ON position in order to charge the transport battery. You may hear fans running while the device is in sleep mode and/or when the battery is charging.

ATTENTION: **Terminating the therapy session early may affect efficacy and treatment may not be able to be restarted using the same DeltaCard.**

The device WILL NOT CHARGE the battery unless the breaker switch in the back is in the ON position and the device is plugged into A/C power.

Do not unplug the A/C power cord from the device or from the wall unless the main power switch is in the OFF position.

After Scalp Cooling

- When the post infusion cooling time is finished, stop the treatment and loosen the Thermal Cap chin strap but keep both the wrap and cap on for another 5-10 minutes to let the temperature and the circulation increase gradually and to diminish discomfort.
- Remove the Cooling Wrap and Thermal Cap carefully. Let the hair dry naturally and do not use a hairdryer after the scalp cooling treatment.

ATTENTION: **Patients typically see a heavy shedding period anywhere from 14-21 days after their first treatment, depending on chemo regimen. This heavy shedding period does tend to taper off for most patients. It is recommended the patient to undergo at least two or three treatments before evaluating the result.**

Therapy and Device Information

DigniCap Delta continuously stores treatment data, device usage, and alarms history. To access the Therapy and Device Information from the Welcome Screen, enter Clinician Mode (Figure 7) to bring up the Start Screen. Press the Other Information ☰ button.

If Cooling Treatment is in process, enter Clinician Mode and then repeat the Clinician Mode touch sequence to access Information screens. This process will not disrupt therapy.

The Information Screens allow the user to toggle between several information types. Each icon on the left will display information selective to that icon. Icon lists can be toggled by pressing the Menu Toggle ☰ button. Use the up/down buttons to scroll through information. Pressing the back button will return to the previous screen.

Session Info displays a summary of individual therapy sessions ordered by session number. The first session to display is the most recent (or currently running) session on the device. This record displays the following information. Additional details on each data point are available in other information screens.

- ***Session Number and Date/Time and End time***: A session is assigned any time the device begins the priming setup (the date and time are the time of session assignment). If the session is aborted at that time, the session data with respect to therapy will be blank. If session ends due to power loss, the end time will read 0's.
- ***Device and Card ID***: Device ID is the s/n of the device and the Card ID is the s/n of the card used to activate the therapy session
- ***Duration***: Total minutes of the session
- ***Session Status***: Current (if still running) or last recorded status of the session.
- **Low Set Lvl**: Lowest set cooling intensity level during the session
- ***Temp Min, Max, and Avg***: The min, max and avg temperature during the session. The values start calculating when cooling temperatures reach acceptable therapy range (+1.5C) and include time in Pause
- ***Pause Num and Time***: The number and total time in Pause state.
- ***Batt Time***: Total time on backup battery power
- ***P Inf Time***: Total time in Post Infusion Phase.

Therapy Records are a chronological order listing of all therapy events. There will be several therapy records for each therapy session. Each time one of the following events occurs, a new therapy record will be created: Prime start, Pre-Cool start, Pre-Cool temp reached, Active Cooling start, Post Infusion start, Post Infusion end/complete, Terminate by user, Terminate by system, Pause, Resume, Transport Mode start, Transport Mode end, Cooling settings change, Post Infusion Time change,

Therapy records are identified by Session ID-Therapy record number, date and time of record, Phase of record, Record number, and state that induced a new record creation. Each record contains the following:

- ***Set Lvl***: Cooling Intensity level setting at record creation,
- ***PI Time***: Post Infusion Time at record creation.
- ***Dur***: Time duration of that record.
- ***Temp Avg, Min and Max***: Supply coolant temperature Average, Minimum, and Maximum temperatures in that phase. Values are cumulative to the end of that record.
- ***Ret, Flow and Amb Avg***: Average Return coolant temperature, Flow rate, and Ambient temperature in that phase. Value is cumulative to the end of that record.

Viewing Therapy Records will automatically display the most recent treatment record. Scrolling using the up and down arrows will skip by 2 records. Scrolling using the page up and down buttons will scroll between sessions.

Treatment Records are a listing of each time a DeltaCard is scanned by the device. Records include DeltaCard ID (card serial number), time stamp, and scan result. Scan results may be any of the following:

- ***Module Fail***: Reader module did not power on or never tried to read a card
- ***Not Detected***: Reader module powered up but no card was detected.
- ***Access Fail***: Failed to access card after original card access was successful.
- ***Empty***: No treatments available.
- ***Invalid***: Invalid card data detected.
- ***Activated***: Card activated and ready for treatment.
- ***Aborted***: User cancelled treatment after card activation but before transitioning to Prime.
- ***Unknown***: Anything else including corrupted records.

Alarm History is a log of the alarms that have occurred during therapy. Records include a time stamp, session ID-sequence number of alarm event, and the ID of the alarm event. The alarm history is stored in non-volatile memory and retained if the system is powered down for up to 5 years. The device does not log the time when device shut down due to the loss of AC power. Once the storage capacity is reached, any new alarms will overwrite the oldest entry.

Device Usage presents device usage categorized by session status (Figure 30). For example, number of sessions that started therapy, Pre-Cool, Active Cooling, Post Infusion Cooling, and completed therapy session. Numbers display for the lifetime of the device, current calendar year, current calendar month, 1 month previous, and 2 months previous.

System Info displays serial number, software versions, real-time clock, and lifetime use of . Using the down arrow gives access to Battery Drain and Card Reading Functions. These functions are unavailable while therapy is running.

- ***Batt Drain***: This function will be used to deplete the battery charge in order to safely ship the device to another location (air freight). See Transportation and Shipping Section.
- ***Read Card***: This feature allows a user to determine if a card has valid treatments available and to determine how the card was previously used (see DeltaCard Reading section).
- ***Send Info:*** Therapy and device information may be downloaded using this function. Please contact Dignitana for further instruction on this process.

Clock Settings include setting Time Zone (set using +12 to -12 hour adjustment) and Daylight Savings On/OFF. The time zone setting is the offset from GMT, for example Central Time is GMT -6 so the time zone setting would be -6. Daylight savings ON adds an hour to local time, so during daylight savings time the local time displayed on the machine is GMT – 5 hours (-6 time zone +1 DST).

Device Monitor displays device operation information and is used for technical service issues by the manufacturer.

Troubleshooting

DigniCap Delta has many internal software safeguards to help protect the user and the unit from unsafe operation. In this section, you will find a list of all possible system warnings and alarms the DigniCap Delta may present when a potentially unsafe situation or reduced therapy efficacy occurs.

ATTENTION: **Refer to Setup Information and Technical Information for a list of acceptable environmental conditions for safe operation of DigniCap Delta.**

Neither DigniCap Delta nor the Cooling Wraps are intended for field repair. Do not attempt to service the unit in any way other than using the instructions listed in this guide.

If the unit is displaying an alarm, notification, or system error not listed in the

below Troubleshooting Guide, contact Customer Support. See the Clinical Support contact information below.

Notifications (Figure 23) are used to indicate to the user that the device requires attention or is operating outside of normal but within safe conditions. Notifications are NOT alarms, do not halt or discontinue therapy, and are used simply to communicate with the user important information during therapy delivery. Notifications are provided by messaging at the bottom of the run/pause/transport screens and may be accompanied by an audible alert of a single frequency tone that repeats every 10 to 30 seconds.

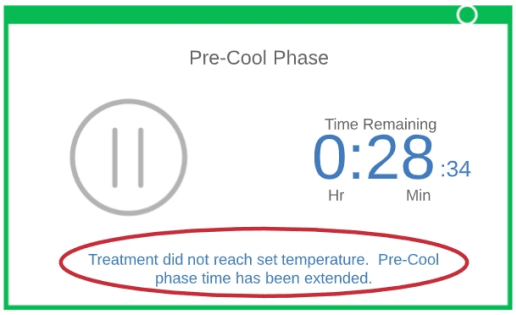


Figure 23. Notifications

Alarms can present as LOW priority (allows therapy to continue) or MEDIUM priority (halts therapy). Anytime the device presents an Alarm condition, the LCD screen will provide information to the user for possible ways to mitigate the issue. It will also provide an auditory and visual signal to the operator (Figure 25).

The operator needs to view the LCD screen for the nature of the alarm and possible mitigations. Please read entire screen for exact alarm issue, fault and corrective action. The audible alert may be silenced by the user by pressing SILENCE. If the alarm is not acknowledged, the audible alert will unsilence after 3 minutes.

The time duration for a fault to trigger an alarm varies based on the fault type and risk to the patient/operator or device. Once the trigger point is reached, the alarm system presents the message on the LCD and informs the user within 5 seconds.

The alarm trigger levels, notification display, and alarm sound volume are all factory set and cannot be changed by the user. If power is interrupted and the device shuts down the alarm detection is inactive until power to the device is restored. Once power is restored, the alarm detection is fully functional after the system initializes and presents the welcome screen.

Low Priority Alarms (Figure 25) indicate a potential condition that may allow continued operation without redundant checks or operate at a reduced capacity, while providing cooling temperatures within the prescribed treatment range. The low priority alarm state does not halt or discontinue therapy delivery. Alarm notification combines the use of "ALARM ACTIVE – LOW PRIORITY" text on the upper line and an alarm description on the lower line of the display. Pressing OK on a low priority alarm will continue with treatment, if desired. Once acknowledged by the user, most low priority alarms will not be presented for the remaining treatment time. Some low priority alarms will repeat, however, if there is a higher risk of a patient's therapy being interrupted. If the issue that triggered the low priority alarm is not resolved, the fault state could escalate to a medium priority alarm event, at which point therapy is halted and the medium priority message is presented to the user.

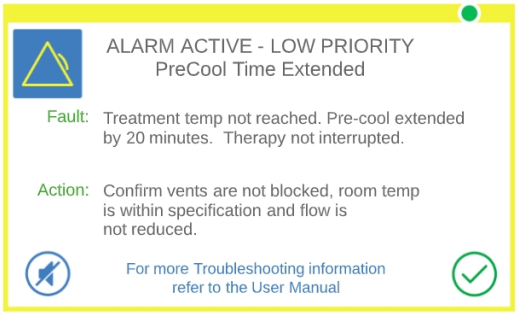


Figure 24. Low Priority Alarm

Medium Priority Alarms (Figure 26) indicate that a potentially unsafe condition is currently present or that a low priority alarm has persisted too long and halts all current therapies to protect the patient. The medium priority alarm state must be corrected before any therapy can be restarted (therapy will restart from the beginning of the Pre-Cool phase). Alarm notification combines the use of "ALARM ACTIVE – MED PRIORITY" text on the upper line and an alarm description on the lower line of the display. A medium priority alarm also has an audible notification of a three-tone burst that repeats every 5 seconds. The medium priority alarm has an audible level of 70 dBA. Pressing OK will clear the alarm screen, however if the alarm state is still present, the alarm message will reappear and prevent the start of therapy. If the alarm is clear, pressing OK will return to the Welcome Screen.

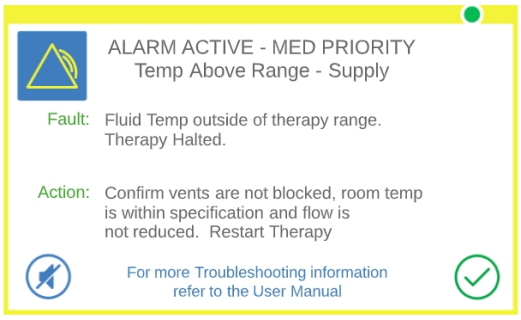


Figure 25. Medium Priority Alarm

Detail on all alarms, their causes and suggested actions are outlined in the tables below. Common device alarms and notifications are highlighted below.

- **Low flow** occurs when flow rates drop below acceptable levels to deliver therapy. This most often occurs when connectors are not placed properly, if the wrap gets kinked or there are large air bubbles in the system.
- **Low coolant level** signals that the reservoir is empty and the system needs more coolant.
- **Temperature outside of set point** lets the user know that the coolant temperature is outside of the level set by the clinician. This may result in an extension of the Pre-Cool time or a message at the bottom of the run screen.
- **High or Low fluid temperatures** lets the user know that the coolant temperatures are outside of acceptable therapy range.
- **Device not cooling** indicates that the device cannot reach coolant temperatures to within therapy range. Therapy will stop.
- **A/C disconnect** alarm occurs if a user disconnects the device from A/C power during the Pre-Cool or Active Cooling Phases.
- **Time limit – Pause** alarm occurs if a user pauses the device for more than 8 minutes at a time. If the device is paused for more than 30 min, the therapy will stop.
- **Time Limit – Treatment** indicates that the device is reaching the limit for allowable therapy duration. Additionally, the device will alert the user when 15 min are remaining in Post Infusion Cooling phase.
- **Time Limit - Transport** alarm lets the user know that transport capacity is minimal and moving a patient during Post Infusion Cooling Phase may not be possible.
- **Card not valid on this device** notifies the user that the DeltaCard used to activate the device is not valid.

Alarms Messages – Medium Priority

Problem	Cause	Suggested Actions
Medium Priority ALARM **ADC** **Reset Failure** **Calib Failure** **Conv Failure**	Internal temperature measurement module hardware fault. This check is performed during system check after power up. ADC Conv Failure is performed continuously when the system is powered and operational. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **2.5V Ref** **High Limit** **Low Limit**	Internal temperature measurement module hardware fault. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **5.0VDC** **High Limit** **Low Limit**	Internal temperature measurement module hardware fault. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **3.3VDC** **High Limit** **Low Limit**	Internal process measurement module hardware fault. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Backup** **Sensor Open** **Sensor Short** **Sensor Locked**	Backup temperature measurement sensor hardware fault. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Supply** **Sensor Open** **Sensor Short** **Sensor Locked**	Primary temperature measurement sensor hardware fault. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions

Medium Priority ALARM **Return** **Sensor Open** **Sensor Short** **Sensor Locked**	Wrap return fluid temperature measurement sensor hardware fault. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **HW Temp Lockout Failure**	Hardware safety temperature detection activated due to backup temperature sensor readings outside range. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **HW Temp Lockout Indication**	Temperature detected outside of hardware safety cut off on Backup Sensor without hardware safety detection activated. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Heatsink(#) Sensor** **HSink1 Sensor Open** **HSink1 Sensor Short** **HSink2 Sensor Open** **HSink2 Sensor Short** **HSink3 Sensor Open** **HSink3 Sensor Short**	Cooling engine heat sink temperature measurement sensor hardware fault. This check is performed continuously when the system is powered and operational. Treatment session is halted or cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Ambient** **Sensor Open** **Sensor Short**	Ambient sensor measuring the environment temperature hardware fault. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Low Temp** **Supply** **Backup** **Return**	Temperature measurement sensor detects coolant temperature <-7.1C for 30 sec. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 30 minutes Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **AC Disconnect – Card Activation**	Treatment activation attempted with A/C disconnected. This check is performed when initiating treatment. Treatment halted when this alarm is active.	Make sure the device is connected to A/C source and the power which is turned on before initiating treatment. Try an alternate outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Low Temp - Manifold**	Cooling engine fluid manifold temperature measurement sensor detects surface temperature <-12C. This check is performed during system check after power up and during operation. Treatment session cannot start or continue when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. If issue occurs during startup, let unit rest for 30 minutes. Reconnect unit to AC outlet, power up system and initiate therapy. If issue occurs during therapy, check for kinks in the wrap and hoses and restart therapy. Make sure proper DeltaCool fluid is installed. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Low Temp** **HSink1** **HSink2** **HSink3**	Cooling engine heat sink temperature sensor(s) detects temperature <6.0C for 5 seconds. This check is performed continuously when the system is powered and operational. Treatment session cannot start or continue when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 30 minutes to acclimate to the environment. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Temp Above Range** **Supply** **Backup** **Return**	40 minutes after start of treatment, or Resume from a Pause event, or change in cooling intensity level, the Supply OR Backup temperature sensor detects coolant temperature >1.6C for 30 sec or the Return temperature sensor detects coolant temperature >3.6C for 30 sec. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Make sure the intake and exhaust opening are not blocked. Make sure the air filters are clean. Make sure coolant hose is not directly exposed to the warm exhaust air. Let unit rest for 30 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **High Temp** **Supply** **Backup** **Return**	Temperature sensor detects coolant temperature >35C for 5 seconds. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 30 minutes to acclimate to the environment. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **High Temp - Manifold**	Cooling engine fluid manifold temperature measurement sensor detects surface temperature >35C for 5 seconds. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 30 minutes Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **High Temp** **HSink1** **HSink2** **HSink3**	Cooling engine heat sink temperature measurement sensor detects temperature >59.1C for 5 seconds. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Make sure the intake and exhaust opening are not blocked. Make sure the air filer is clean. Let unit rest for 30 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Low Coolant Level**	Coolant level is low on DeltaCool fluid. This check is performed continuously when the system is powered and operational. During treatment, session set to PAUSE state.	Open the reservoir cap. Check the fluid level and if necessary, add fluid to the bottom of the neck. Close the cap. Press Resume to restart treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Low Flow Alarm**	The system has detected a fluid flow rate <0.5 LPM. This check is performed continuously when the system is powered and operational. During treatment, session set to PAUSE state.	Make sure the cooling wrap is connected to the hose and the hose is connected to the device. Make sure the hose or cooling wrap is not kinked. Make sure the thermal cap is not impeding on the flow. Loosen some of the tabs to see if this is the cause. Make sure the cooling wrap is fully primed and all visible air bubbles have been removed If priming a filled wrap: press PRIME, remove reservoir cap, top off coolant. Make sure the reservoir is full of fluid. Press PLAY to resume treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Time Limit - Pause**	The system has been in the pause state for >30 min. This check is performed continuously during pause. Treatment halted when this alarm is active.	Restart treatment activation. Continuous pause events should be kept to <8 min. If the device has been paused for >30 min, the treatment will terminate. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **AC Disconnect**	AC power loss detected outside of Post Infusion Phase for >2 mins. This check is performed continuously during setup, Pre-Cool and Active Cooling phase of therapy. Treatment halted when this alarm is active.	Reconnect to AC source and do not disconnect A/C power outside of Post Infusion Phase. Restart treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **High Current** **PS1A** **PS1B** **PS2A** **PS2B** **PS3A** **PS3B**	The Cooling engine power module current draw is >4.05A DC for 60 seconds. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **I2C Bus Read Alarm**	There was a read or write error to the external memory and/or the clock via I2C communication. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **EE Memory Read Error** **EE Memory Write Error**	There was a read or write error to the external non-volatile memory. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **IPC Failure** **IPC Mode Mismatch**	There were >5 nonconsecutive communication errors between the SYS and GUI processor within the device. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **SYS IC Reset (WDT)**	There were 3 consecutive SYS processor watchdog restart events. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **UI IC Reset (WDT)**	UI processor watchdog restart event occurred. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Time Limit – Transport Mode**	Total time on battery power has exceeded 30 min. A total time of 30 min is allowed per session to operate without A/C power. This check is performed continuously when the system in transport mode. Treatment halted when this alarm is active.	Plug back into AC power immediately. Be sure to only disconnect A/C power during Post Infusion Cooling phase and reconnect A/C power and to turn the breaker switch on within the specified 30 min time. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Card Reader Module Failure**	The device failed to detect the card reader module hardware. This check is performed during system check after power up. Treatment session cannot start when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Time Limit – Session Cooling**	Cooling time has reached allowable time limit (13 hr). This check is performed continuously during therapy delivery. Treatment halted when this alarm is active	Complete therapy within the allowable time period. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Medium Priority ALARM **Battery Level Depleted**	The device has detected the battery level to be depleted. Battery use is not available during any therapy phase. Disconnecting AC will cause the system halt treatment and power off. This check is performed continuously when the system is powered and operational.	Patient must be on facility AC power until the battery indicator on the top right turns green (from yellow). Between treatments be sure to leave the device plugged in and the breaker switch on. Contact customer service if problem persists

Problem	Cause	Suggested Actions
Medium Priority ALARM **BMC System Failure**	Battery management card reports an internal hardware fault. Power source defaults to AC power and battery power is not available. This check is performed continuously when the system is powered and operational Transport mode unavailable when this alarm is active.	Turn the unit off by disconnecting the unit from the AC outlet. Let unit rest for 10 minutes. Reconnect unit to AC outlet power up system and initiate therapy. Contact customer service if problem persists.

Alarms Messages – Low Priority

Problem	Cause	Suggested Actions
Low Priority ALARM **Supply** **Sensor Open** **Sensor Short** **Sensor Locked**	Supply temperature measurement sensor hardware fault after treatment start. If the primary sensor fails, the system will automatically switch to the backup sensor and continue treatment. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Acknowledge the alert to continue treatment using the backup temperature sensor. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **BMC Card** **Sensor Open** **Sensor Short**	BMC card temperature sensor fault. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when the alert is active, however transport mode may be unavailable.	Acknowledge the alert to continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Excess BMC Message Errors**	BMC card communications fault. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when the alert is active	Acknowledge the alert to continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Battery Compartment** **Sensor Open** **Sensor Short**	Battery compartment temperature sensor fault. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when the alert is active, however transport mode is unavailable.	Acknowledge the alert to continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Battery Ambient** **Sensor Open** **Sensor Short**	Battery ambient temperature sensor fault. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when the alert is active	Acknowledge the alert to continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **RFID Module Config Invalid**	RFID configuration invalid. This check is performed at power up. Treatment session not available when the alarm is active.	Acknowledge the alert to continue. Power cycle device. If error continues, the device will be unable to read the card and therapy will be unavailable. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **High Voltage** **PS1A** **PS1B** **PS2A** **PS2B** **PS3A** **PS3B**	The Cooling engine power module output voltage is > 55V DC for 60 seconds. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when the alert is active	Acknowledge the alert to continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Return** **Sensor Open** **Sensor Short** **Sensor Locked**	Wrap return fluid temperature measurement sensor hardware fault after treatment start. This sensor checks if the return temperature from the fluid is within therapy range. If this sensor fails, the system will continue treatment with the supply or backup sensor controlling within required treatment parameters. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Acknowledge the alert to continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Manifold** **Sensor Open** **Sensor Short**	Internal fluid manifold temperature sensor hardware fault. This is a backup sensor to detect freeze conditions that could cause coolant flow to stop. The flow sensor is the primary fault detection for loss of coolant flow. Manifold sensor is available as a secondary fault detection.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

	This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	

Problem	Cause	Suggested Actions
Low Priority ALARM **Ambient** **Sensor Open** **Sensor Short**	Ambient temperature sensor hardware fault. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Temp Above Set Level** **Supply** **Backup** **Return**	The device did not reach the set cooling intensity but is still cooling within therapeutic range. The supply or backup coolant temperature is >2.1C above setpoint or the return temperature is >4.1C for 5 minutes after therapy has been running for 40 minutes. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Make sure there is a min 12” open space around entire device. Make sure the room temperature within specifications Make sure the flow rate through the system is > 1.0 LPM. Acknowledge the alert and continue treatment Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Pre-Cool Time Extended**	The device did not reach the set cooling intensity. Pre-Cool time is extended by 20 min. This check is performed continuously after 20 minutes have expired in the PreCool phase. Treatment session not interrupted when this alert is active.	Make sure there is a min 12” open space around device Make sure the room temperature within specifications. Make sure air filters are clean. Make sure the flow rate through the system is >1.0 LPM. Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Temp Below Set Level** **Supply** **Backup** **Return**	The delivered cooling intensity is >2.1C below setpoint for 5 min but is still within therapeutic range. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Make sure the room temperature within specifications. Make sure the flow rate through the system is >1.0 LPM. Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Clock Read Error**	There was a read error with the real time clock. This check is performed during system check after power up. Treatment session not interrupted when this alert is active. Treatment records will not contain valid time stamps.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **High Temp - Ambient**	The device detected the ambient temp greater than 29.5C. The system will continue operate as long as it can maintain the coolant temperature within therapy range. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Make sure there is a min 12” open clear air path in the front, sides and back of the unit. Make sure the room temperature is within specification. Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Low Temp - Ambient**	The device detected the ambient temp is lower than 6C. The system will continue operate as long as it can maintain the coolant temperature within therapy range. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Make sure the room temperature is within specifications. Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Low Temp** **HSink1** **HSink2** **HSink3**	Cooling engine heat sink temperature measurement sensor(s) detects temperature less than 6C for 30 seconds. The system will continue operate as long as it can maintain the coolant temperature within therapy range. This check is performed continuously when the system is powered and operational Treatment session not interrupted when this alert is active.	Make sure there is a min 12” open clear air path in the front, sides and back of the unit. Make sure the room temperature is within specifications. Make sure the flow rate through the system is > 1.0 lpm. Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **BMC System Failure**	Battery management card reports an internal hardware fault. Primary and default power source is AC power with the BMC system failure, battery power may not be available. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active, however Transport mode may not be available.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Time Limit – Post Infusion**	Post infusion time nearing end of set time. Treatment will end soon. This check is performed continuously during the Post Infusion Cooling phase of therapy. Treatment session not interrupted when this alert is active.	Acknowledge the alert and continue treatment. Therapy delivery will terminate in 15 minutes. Post Infusion time can be extended in Clinician Mode.

Problem	Cause	Suggested Actions
Low Priority ALARM **Time Limit – Pause**	A single pause event has exceeded the maximum pause time of 8 minutes. This check is performed continuously during pause events. Treatment session not interrupted when this alert is active.	The patient needs to be reconnected to the device and cooling resumed. Be sure to limit pause time to <8 min. Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Time Limit – Total Pause**	Total patient pause time has exceeds 60 minutes during a single session. This check is performed continuously during pause events. Treatment session not interrupted when this alert is active.	The patient needs to be reconnected to the device and cooling resumed. Extended pause time will negatively affect treatment efficacy. Acknowledge the alert and continue treatment. Contact customer service if problem persists

Problem	Cause	Suggested Actions
Low Priority ALARM **Time Limit – Session Cooling**	Allowable cooling time nearing limit. This check is performed continuously during therapy delivery. Treatment session not interrupted when this alert is active.	Complete therapy within the allowable time period. Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Battery Level Low**	Internal battery charge is low. The device cannot transport the patient during Post Infusion Cooling phase. This check is performed continuously when the system is powered and operational Treatment session not interrupted when this alert is active.	Patient needs to be on facility AC power until the battery indicator on the top right turns green (from yellow). Acknowledge the alert and continue treatment. Between treatments, be sure to leave the device plugged in and the breaker switch on. Contact customer service if problem persists

Problem	Cause	Suggested Actions
Low Priority ALARM **AC Disconnect**	AC power loss when the system is in Pre-Cool or Active Cooling phase. This check is performed continuously from treatment initiation until transition to Post Infusion cooling phase. Treatment session not interrupted when this alert is active.	Connect the device back to AC power within 2 minutes. Acknowledge the alert and continue treatment Contact customer service if problem persists

Problem	Cause	Suggested Actions
Low Priority ALARM **Time Limit – Transport Mode**	Time in transport mode has exceeded 20 min. This check is performed continuously during Post Infusion phase while in transport mode. Treatment session not interrupted when this alert is active	Reconnect to A/C power and to turn the breaker switch on ASAP. Limit transport time to 20 min or less. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Low Current** **PS1A** **PS1B** **PS2A** **PS2B** **PS3A** **PS3B**	The Cooling engine power module current draw is <0.2A DC. If the loss of cooling engine performance cannot provide temperature control within therapeutic range, the temp out of range alarm will inform the user. This check is performed continuously when the system is powered and operational. Treatment session not interrupted when this alert is active.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **I2C Bus Read Alarm**	There was a read or write error to the external memory and/or the clock via I2C communication. If treatment has started, the device will continue the current treatment session with information stored in the processor memory. Treatment session not interrupted when this alert is active.	Acknowledge the alert and continue treatment Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **EE Memory Read Error** **EE Memory Write Error**	There was a read or write error to the external non-volatile memory. If treatment has started, the device will continue the current treatment session with information stored in the processor memory. Treatment session not interrupted when this alert is active.	Acknowledge the alert and continue treatment Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **IPC Mode Mismatch Alert**	There were >2 consecutive communication errors between the SYS and GUI processor within the device. This check is performed continuously when the system is powered and operational. Treatment has been halted when this alarm is active.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Clock Read Error**	There was a read error to the real time clock memory. If treatment has started, the device will continue the current treatment session with information stored in the processor memory. Treatment session not interrupted when this alert is active, however treatment records may not contain valid time stamps.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
Low Priority ALARM **Clock Error Not Available**	Real time clock is unavailable. This check is performed during system check after power up. Treatment sessions are available when this alert is active. Treatment records will not contain valid time stamps.	Acknowledge the alert and continue treatment. Contact customer service if problem persists.

General Questions

Problem	Cause	Suggested Actions
Nothing happens when I turn the unit to the ON position.	No power to the unit.	Make sure the unit is connected to an appropriate AC outlet.
	Internal fault within the therapy unit.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists

Problem	Cause	Suggested Actions
The unit is leaking.	The fluid ports are not connected/seated properly.	Make sure the unit is unplugged from the AC outlet. Check the Therapy Hose connections; disconnect and reconnect the ports to make sure they are seated properly.
	Physical damage to the unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents and is leaking, the unit should not be used. Contact customer service if problem persists
	Condensation on the wrap.	Remove the Cooling Wrap and wipe it down with a clean, dry cloth. Moisture buildup could be condensation rather than a leak. If water returns immediately, discard the wrap and contact customer service if problem persists

Problem	Cause	Suggested Actions
My unit gives me an ALERT **No Treatment Available on Card**	The treatment card presented to the reader does not contain any available treatments. This check is performed prior to treatment initiation.	Treatments are unavailable after 60 min of continuous therapy, 10 successful therapy initiation events, or a cumulative 180 min and cannot be used to reinitiate therapy. Obtain a new card and rescan. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALERT **Invalid Card Detected**	The device detects a functional card, but the card information is invalid This check is performed prior to treatment initiation.	Remove the card from the card reader for ~3sec and replace and rescan. Obtain a new card and rescan. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALERT **No Valid Card Detected**	The device does not detect a card on the reader. This check is performed prior to treatment initiation.	Place a DeltaCard on the reader and initiate treatment. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
The wrap is leaking fluid.	The connectors are not connected/seated properly.	Disconnect and connect the connector on the Therapy Hose/Wrap.
	Physical damage to the Wrap	If the Cooling Wrap is leaking, Pause the therapy delivery and remove the wrap from the patient immediately. Inspect the wrap for physical damage. If the wrap shows any signs of puncture or tear, the wrap should not be used. Discard the wrap and contact customer service. Obtain a new Cooling Wrap to continue therapy.

Problem	Cause	Suggested Actions
The wrap is uncomfortable and/or is too tight.	The wrap is kinked or folded.	Check if Cooling Wrap is kinked or folded and creating a pressure point. Readjust or reapply wrap to alleviate the kink.
	The wrap may be fitted too tightly.	Remove and reapply following the ‘Fitting the Cooling Wrap’ instructions.

Problem	Cause	Suggested Actions
Unit turns on but it is not cooling.	Cooling therapy has not been started.	Check the display to see if therapy has been initiated and that Pre-Cool phase is running. See section on therapy initiation for instructions to start Therapy.
	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents and is leaking, the unit should not be used. Contact customer service.
	Coolant ports not properly connected.	Check the connections on your unit and wraps.
	Internal fault within the therapy unit.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists

Problem	Cause	Suggested Actions
The unit is noisy.	External material lodged in fan blade.	Check for foreign objects or material caught in inner fan blade.
	Internal fault within the therapy unit.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists

Problem	Cause	Suggested Actions
The touchscreen is not functioning.	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents the unit should not be used. Contact customer service if problem persists
	Unit not connected to AC power or the breaker switch is set to OFF.	Make sure the unit is connected to an appropriate AC outlet and that the breaker switch is ON.
	Internal fault within the therapy unit.	Turn the unit off by disconnecting the unit from the AC outlet. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists

Maintenance and Cleaning

Do not use abrasive or solvent-based cleaners on the unit.

There are no user serviceable internal parts. The system warranty is voided if the tamper seals are breached or removed.

Keep water away from vents, power ON/OFF switch and the power cord connection of the unit.

To avoid possible electric shock, do not remove the back or top covers of the unit.

DeltaCard Reading

DeltaCards are sent directly to the patient or facility and are programmed to initiate DigniCap Delta to deliver therapy. If a card is found or is not recognized as valid by the device to activate therapy, the user can determine if the card contains valid therapy uses. If the card type is not valid to use on the machine, the card data will not be presented.

1. From the Welcome Screen, enter Clinician Mode, and select Other Information. Select the SYSTEM INFORMATION and press DOWN to scroll to the next page (Device Management; not available during therapy) and press READ CARD.
2. Place the card to be read on the reader and press SCAN.
3. The top line of the data presented (Curr) shows the last time the card was accessed and whether the card is used (4th column). If there is an available treatment on the card, the “Avail” column will read ‘Yes.’ The Usage will show

the used and total sessions on the DeltaCard separated by a slash.

4. If the card has no available sessions, the Avail column will read No-Cnt (the card has been activated 10 times), No-Min (the card was used to deliver therapy for a cumulative 180 minutes, or No (the card was used to deliver therapy for 60 continuous minutes).
5. The screen also presents the previous 2 times the card was accessed.

DeltaCool Coolant

Keep reservoir full of coolant and only use DeltaCool in the DigniCap Delta, see Troubleshooting.

If the DeltaCool becomes discolored or offensive to smell, contact Dignitana Technical Support.

Do not use any coolant other than the supplied DeltaCool in the DigniCap Delta device.

Do not drink or ingest the coolant mixture.

Cleaning the DigniCap Delta Device

Make sure that the power is switched off and is disconnected from A/C power.

- Clean the surfaces (including the therapy hose) with a damp soft cloth or Sani Wipes.
- Clean the touch screen with screen wipes or a damp cloth (make sure it is not too wet).
- Remove any spilled coolant with a soft cloth.
- Do not use abrasive or solvent based cleaners on the unit.

Cooling Wrap

Immerse a rag or sponge (**Do not** use paper towels) in warm, soapy water (mild detergent) and squeeze out excess liquid. Gently clean surface; Repeat cleaning process as necessary to remove all contaminants from surface. To rinse soap residue from wrap, immerse clean rag or sponge in warm water and wipe surface clean. **Do not** immerse wrap in soapy water.

ATTENTION: **DO NOT use the Cooling Wrap for Cooling Therapy unless it is completely dry.**

DO NOT store the Cooling Wrap in the plastic in which it was shipped.

Thermal Cap

The Thermal Cap may be cleaned using the process defined for the Cooling Wrap or by washing machine. Turn garment inside out and machine wash cold and air dry. Do not use bleach or fabric softener. Thermal cap may also be wiped down with alcohol-based or germicidal wipes (non-bleach) for 2 minutes.

ATTENTION: **DO NOT use the Thermal Cap for Cooling Therapy unless it is completely dry.**

DO NOT store the Thermal Cap in the polybag in which it was shipped

Air Filter

DigniCap Delta has 4 air filters, which should be changed or cleaned once every second month during normal use, see Figure 1. To remove the filters, open the front covers by pressing the release buttons on each side, remove the filter and install the new filter in the same position. To clean, wipe down with a damp to dry paper towel or a gloved hand to remove all dust. Reinstall filters, once completely dry, and replace the device front covers.

ATTENTION: **DigniCap Delta should not be used unless the air filters are in place.**

Do not install filters unless they are completely dry.

Transportation/Storage of DigniCap Delta Device

DigniCap Delta can be moved while a treatment is running, although it is not advisable to move it for a longer distance than the cord allows, unless during Transport Mode during Post Infusion phase . Power/AC extension cords are not to be used. Be careful not to tip over or collide with the system during transportation.

Before using the system, ensure that the brakes on the wheels are locked. Before moving the system, ensure that the brakes on the wheels are unlocked.

Discharging the Battery: Prior to shipping DigniCap Delta, the battery must be discharged. Follow the steps below.

1. Assure that the device is plugged in and the breaker switch is on
2. While the device is not delivering therapy, enter clinician mode and press the OTHER INFORMATION .
3. In System Info , press DOWN to display the Device Management screen.
4. Connect the installation hose to the therapy hose (see Figure 9) and be sure the device is full of fluid.
5. Press BATT DRAIN button and confirm this action.
6. The device will show that the battery drain procedure is running and the estimated battery charge remaining.
7. If alarms present during this procedure, clear and continue procedure. If an alarm halts the battery drain procedure, resolve the alarm and restart.
8. When the battery drain procedure is complete (2-4hrs), the device will present a screen indicating process complete. Press OK and immediately turn the breaker switch off and unplug the device.

ATTENTION: **The device may remain on the 'Battery Drain Complete' screen indefinitely and the battery will not recharge. However, pressing OK will start recharging the battery unless the breaker is turned off/AC is disrupted.**

Draining the Coolant: The coolant needs to be drained if the system is to be transported outside the clinic or not used for more than 1 month. To drain the system of coolant:

1. Turn the unit OFF and unplug from electrical source.
2. Disconnect all the hoses from the unit.

   a. Remove the front panel of the air box (Figure 1)
   b. Connect Drain Hose (Figure 2, 4; stored in bottom side compartment, below drain connection) to Drain Hose Connection (Figure 1, 10) with the open end of the Drain Hose in a bucket that is at least 500mL in volume
3. Remove the reservoir cap from the unit
4. DeltaCool will flow from the device through the drain hose.
5. Continue to empty until all the coolant drains from the reservoir. There is no need to force coolant out of the device.

Packaging and Returning Device

If a device requires service, it needs to be packaged and sent back to the manufacturer. A replacement device will be shipped to the user in a crate and the crate will be used to return the original. Unpack the replacement device (and any Connection Kits/DeltaCool) and repack the unit to be returned. Be sure the device is securely in the crate and that the back wheels are locked. Do not include any hoses, cords, or coolant in the return shipment.

Technical Information

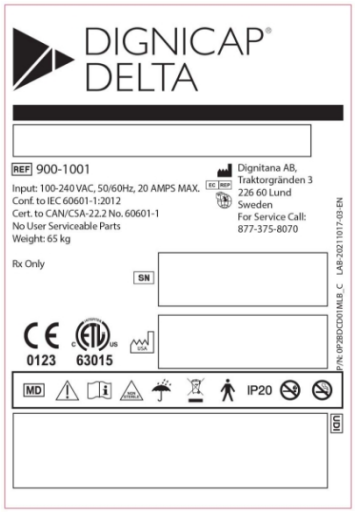
DigniCap Delta consists of a thermoelectric cooling unit with a computerized control unit to which an adjustable Cooling Wrap is connected. DeltaCool coolant is circulated from the device through the Therapy Hose to small channels within the Cooling Wrap. The cooling wrap is attached to the patient to cool the scalp during treatment. To insulate and keep the Cooling Wrap in place, a neoprene Thermal Cap is used over the Cooling Wrap.

Two separate sensors in DigniCap Delta, one that measures the coolant supply to the Cooling Wrap and one measuring the return flow monitor circulating coolant temperature. An additional sensor monitors supply temperatures as a backup to assure patient safety.

DigniCap Delta maintains a constant and controlled temperature during the entire treatment period. Any deviations from the default temperature are automatically adjusted by the system. The default treatment settings for temperature and time can be changed through the touch-screen monitor. A notification is activated if any errors are detected.

The DigniCap Scalp Cooling System is intended to be used in hospitals and healthcare facilities that treat cancer patients. The system is designed for indoor use, within the temperature, pressure and humidity specifications stated below. The intended user of the device are health care professionals.

Safety Signs Marked on the Equipment



IMPORTANT: Read Instructions

Before operating the device, please read the entire instruction guide. Keep the guide available for future reference.

CAUTION. Consult user manual to determine potential hazards prior to operating the device.

REF — Manufacturer's Part Number

SN — Device Serial Number

Do not smoke around device

Product compliance with North American safety standards

Do NOT Dispose with General Household Waste

Please consult local government / city laws on acceptable method of disposal of electro-mechanical systems in compliance with the Waste Electric and Electronic Equipment Directive (WEEE) 2001/96/EC.

Keep Dry

Type B Applied Part

MD — Medical Device

EC REP — European Authorized Representative

Device Manufacturing location

Device Manufacture Date Code

RoHS Compliant

RFID

Non-Sterile

Do not use around open flame

IP20 — Ingress Protection of the Device. Solid Particles > 12.5 mm will be protected from access to hazardous parts. The device does not have any ingress protection against liquids.

Rx ONLY — Caution: Federal law restricts this device to sale by or on the order of a physician.

CE Mark

UDI — Unique device identifier

Importer

ATTENTION: Attentions are added to give more information.

DigniCap Delta Technical Specification

DigniCap Delta Part Number	0P9PTDCD01
Operating Environment	50°F – 77°F [10°C – 25°C]
Relative Humidity	30% to 60%, Non-Condensing
Operating Altitude	< 3000 meters
Device Coolant Temperature Range	23°F – 31.1°F [-5°C to -0.5°C]
Dimensions	37.5”H x 20”D x 15”W [95.25cm H x 50.8cm D x 38.1cm W]
Weight	143 lbs. [65 kg]
Circulatory Pump	12 VDC Centrifugal Pump
Reservoir Coolant Capacity	8.5 fl oz. [250 ml]
Temperature Accuracy	±3.6°F [±2°C]
Input Voltage	100-240 VAC, 50/60 Hz
Input Current (Max)	20 A
Recommended Coolant	DeltaCool, MSDS # S1144
Transport & Storage Environment	32°F – 122°F [0°C – 50°C] 10% - 95%, Non-Condensing
Device Firmware Part No	0P5SDCDUG1 0P5SDCDSY1
Electromagnetic Interference (EMI) Electromagnetic Compatibility (EMC)	The DigniCap System was designed to minimize the effects of external EMI upon the device and to minimize the effect upon the environment from the device. The device conforms to the EMC standards. See Tables below.
Equipment Classification	Type 1, Class B
Safety Conformance	IEC 60601-1, CAN/CSA C22.2 No. 601.1
Electromagnetic Compatibility	IEC 60601-1-2

DigniCap Classification Information

US FDA Medical Device	21 CFR 878.4360
EU Medical Device	Class IIa per Medical Devices Directive 93/42/EEC
Protection Against Electric Shock Hazard	Class I per UL/EN/IEC 60601-1
Protection Against Fluid Ingress	IP20
Applied Part	Type B

DigniCap Conformance Information

Quality Assurance	FDA 21 CFR 820 QSR ISO 13485
Safety	IEC 60601-1
Electromagnetic Compatibility (EMC)	IEC 60601-1-2
Restriction of Hazardous Substances	Directive 2011/65/EU
REACH	Directive (EC) 1907/2006

DigniCap Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment - Guidance
Radiated Emissions EN 55011	Complies to Group 1, Class A	The DigniCap System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference to nearby electronic equipment. The DigniCap System is suitable for use in all hospitals and health service clinics connected to the public low-voltage power adapter network that supplies buildings used for domestic purposes.
Conducted Emissions EN 55011	Complies to Group 1, Class A	
Harmonics Emission EN 61000-3-2	Complies	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

DigniCap Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge EN 61000-4-2	± 8kV contact ± 156kV air	± 8kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered in synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient / Burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 6100-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power adapter lines EN 61000-4-11 (per EN60601-1-2, 4th ed)	<5% U_T, 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T 95% dip in U_T) for 5 sec	<5% U_T, 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field EN 61000-4-8	30 A/m (60 Hz)	30A/m (60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF EN 61000-4-6 Radiated RF EN 6100-4-3	3Vrms 0.15MHz to 80 MHz 3V/m 80 MHz – 2.7 GHz	3Vrms 0.15MHz to 80 MHz 3V/m 80 MHz – 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the DigniCap system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

EMC Notice

This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been designed to provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.

MRI Notice

This equipment contains electronic and ferrous components whose operation can be affected by intense electromagnetic fields. Do not operate the system in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or shortwave therapy equipment. Electromagnetic interference could disrupt the operation of the device.

Internal Battery

DigniCap Delta uses a 48V, 20AH LiFePO4 battery back to provide backup power for treatment during the post-infusion phase of the treatment. This battery is not user replaceable or serviceable. The device uses a 3V, 48 mAH, Lithium coin cell battery for maintaining its real-time clock. This battery is not user replaceable or serviceable.

Calibration

DigniCap Delta is comprised of components that are of high accuracy and low drift. Under normal operation, the therapy unit does not require calibration. The end user has the option to send the unit back to Dignitana for testing and calibration.

Electromagnetic Interference

This device has been tested and found to comply with the limits for Medical Devices according to IEC60601-1-2: 2007. These limits are designed to provide reasonable protection against harmful interference in typical medical installations. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user can try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the physical separation between the equipment and other device(s).
- Connect the equipment into an outlet or circuit different from the one where the other device(s) are connected.

FCC Statement

This device contains an FCC compliant RFID device, FCC ID: SX9RFID2, operating at 132.56 MHz. It is advisable that other electrical and electronic equipment be kept at least 8” from the device’s reader location. It is further advised that no other reader device should be operated or stored near the reader location.

Replacement Parts

All replacement parts and accessories can be ordered from Dignitana using the contact info noted below.

ATTENTION: The use of unapproved parts/accessories with DigniCap Delta will result in nullification of the warranty.

Clinical Support
10925 Estate Lane, Suite W-185
Dallas, TX 75238
877.350.2150
support@dignicap.com
https://mydignicap.com/supplies/

Additional Information

Clinical Study Design

The basis for FDA's finding that The DigniCap Scalp Cooling System is safe and effective for its intended use was a clinical study in women with Stage I or II breast cancer undergoing at least 4 cycles of specific anthracycline or taxane based chemotherapy regimens. This was a prospective, non- randomized, age- and treatment-matched control, open label study designed to assess the ability of scalp hypothermia using the DigniCap to reduce the frequency and severity of chemotherapy induced alopecia. A group of 16 patients (controls) volunteered to participate in the study and underwent all study procedures except scalp cooling.

Patients received scalp cooling as delivered by The DigniCap Scalp Cooling System. Scalp cooling began 30 minutes prior to administration of chemotherapy and continued during the chemotherapy infusion and up to 150 minutes after completion of the chemotherapy infusion. Eligible chemotherapy regimens included docetaxel/cyclophosphamide, docetaxel/carboplatin, weekly paclitaxel, docetaxel and doxorubicin/cyclophosphamide. Docetaxel/carboplatin and docetaxel were given with HER2-targeted therapy. No patients who participated in this study received an anthracycline and patients who were to receive both an anthracycline and taxane, either in combination or in sequence, were excluded from this study.

Efficacy was based on patient self-assessment of hair loss up to one month after the last chemotherapy session using a standardized set of photographs of the head from 5 different angles. The study was conducted at 5 breast cancer centers in the United States.

Success of The DigniCap Scalp Cooling System to reduce hair loss was defined as a maximum Dean score of ≤ 2 using standardized photographs graded by the patient up to 4 weeks after the last chemotherapy treatment.

- Grade 0: no hair loss
- Grade 1: > 0 up to 25% hair loss
- Grade 2: > 25 up to 50% hair loss
- Grade 3: > 50 up to 75% hair loss
- Grade 4: > 75% hair loss

Results

One hundred twenty-two patients were enrolled (106 in The DigniCap Scalp Cooling System treatment group and 16 in the control group) and were included in the tolerability assessment; 117 (101 DigniCap, 16 control) completed their prescribed chemotherapy or dropped out for any reason other than toxicity of the chemotherapy and were included in the efficacy analysis.

The mean age of participants was 53.0 years (range 28 - 77); 77.4% were White, 10.4% were Black and 9.4% Asian. The most common chemotherapy regimen was docetaxel/cyclophosphamide for 4-6 cycles (75%, 76 of 89 for 4 cycles), with additional regimens including docetaxel/carboplatin (12%), weekly paclitaxel (12%), and docetaxel (1%). Docetaxel/carboplatin and docetaxel were given with HER2-targeted therapy.

Efficacy of Scalp Cooling

Of the 101 evaluable patients in the DigniCap treatment group, 67 (66.3%) demonstrated treatment success (Dean Score ≤ 2) compared to none in the control group (95% CI, 56.2, 75.4%; $p < 0.001$).

Success rate was also analyzed by chemotherapy regimen. In the DigniCap treatment group, success was documented in 83.3% ($p=0.022$) of patients receiving docetaxel/carboplatin, 60.5% ($p<0.001$) of those treated with docetaxel/cyclophosphamide, and 83.3% ($p=0.066$) of patients treated with a taxane alone. Success rate did not differ when analyzed by hair thickness, history of previous chemotherapy, median age, median body mass index, use of prior hormone replacement therapy, and menopausal status.

The maximum Dean score reported over the course of the study up to 4 weeks after the last chemotherapy is summarized in Table 1 showing that 35.7% of patients had minimal or no hair loss.

Dean Score	The DigniCap System	Control
N	101	16
0 (No Hair Loss)	5 (5.0%)	0 (0.0%)
1 (Greater than 0 up to 25% Hair Loss	31 (30.7%)	0 (0.0%)
2 (Greater than 25 up to 50% Hair Loss)	31 (30.7%)	0 (0.0%)
3 (Greater than 50 up to 75% Hair Loss)	19 (18.8%)	1 (6.3%)
4 (Greater than 75% Hair Loss)	15 (14.9%)	15 (93.8%)

Table 1. Alopecia Self-Report Maximum Dean Score (Evaluable Population)

At one month after the last chemotherapy treatment, 45.3% of patients never used a wig, cap, scarf or other head cover due to hair loss. Patients reported a median score of 100 out of 100 when asked about their satisfaction with the decision to use a scalp cooling system.

Safety Results

Six (6) patients of the 106 patients in the safety population experienced 7 adverse events that were considered related to the DigniCap Scalp Cooling System treatment, which included headache (4), pruritus (1), pain of skin (1) and head discomfort (1); none of these events were rated severe and one headache was rated moderate.

The DigniCap Scalp Cooling System tolerability was measured by completeness of all planned cycles of chemotherapy using the DigniCap; 83.0% of patients completed all planned cycles of chemotherapy using the DigniCap. Most patients who discontinued did so because of hair loss. Three patients discontinued because of cold discomfort of the cap. The feeling of chilliness during the cooling down period was reported by most patients (n=102) with an average score of 49.0 out of 100 (range 7.5 to 97.5) and with overall cooling treatment (n=104), with an average score 49.5 out of 100 (range 2.5 to 92.5).

A total of 43 patients reported that headaches were triggered or exacerbated by scalp cooling treatment and the average level of pain experienced by these patients was 39.3 on a scale of 0 to 100 with 100 being the worst pain. Among these 43 patients, headaches occurred during only 1.0 cycle on average, but ranged up to 10 cycles, so although headaches occurred, they were not frequent.

Scalp pain associated with cooling was reported by 75 patients with an average level of any scalp pain experienced by these patients of 24.2 out of 100 (range 1.7 to 85.0).

Overall Conclusions from Clinical Data

Clinical results show that The DigniCap Scalp Cooling System demonstrates treatment success in reducing hair loss (≤50% hair loss, Dean score ≤2) in at least 66% of women at one month (3-6 weeks) after all patients completed their last chemotherapy cycle. A statistically significant superiority in treatment success was observed in comparison of The DigniCap® Scalp Cooling System to control where all patients had >50% hair loss (Dean score >2).

The DigniCap Scalp Cooling System appeared to be safe and well tolerated with only mild discomfort associated with the scalp cooling and highly effective in reducing the likelihood of chemotherapy-induced alopecia.

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S.

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Hernández et al., 2016 American British Cowdray, ABC Medical Center, Mexico City	Retrospective Consecutive series of patients; December 2010 - January 2015	Weekly TX for 12 cycles (n=4). Weekly TX for 12 cycles and AC every 3 weeks for 4-6 cycles (n=66). AC every 3 weeks for 6-8	N/A	204 patients with **Stage I-V breast (n=120**), ovary, lung, uterus, esophagus, prostate, chest, urethra, rectum, larynx, bladder, colon, liver cancer and non- Hodgkin´s lymphoma.	Not stated	Hair loss - Photos Dean scale	72% (98/120)	84% (82/98)	At follow-up: no side effects or scalp metastasis present.	Hair loss.
Fehr et al., 2016 Clinic of Kempten-Oberallgäu, Germany Cantonal Hospital Frauenfeld, Switzerland	Non randomized prospective	PT 175 mg/m2 and carboplatin 6 AUC (area under the curve) for 6 three-week cycles [n = 12 (22%)] D 60 mg/m2 and C 600 mg/m2 for 4 three-week cycles, followed by DT 100 mg/m2 for 4 three-week cycles [n = 11 (20%)] E 90 mg/m2 and C 600 mg/m2 for 4 three-week cycles, followed by PT 80 mg/m2 weekly for 12 weeks [n = 10 (18%)] PT 80 mg/m2 weekly for 16 weeks [n = 8 (15%)] DT 75 mg/m2 and C 500 mg/m2 for 4 three-week cycles [n = 6 (11%)] F 500 mg/m2, E 100 mg/m2, and C 500 mg/m2 for 3 three-week cycles, followed by DT 100 mg/m2 for 3 three-week cycles [n = 64 (7%)] DT 75 mg/m2, D 50 mg/m2, and C 500 mg/m2 for 6 three-week cycles [n = 4 (7%)	N/A	Women with breast, endometrial, or ovarian cancer (n=55) Breast cancer 35adjuvant, 5 palliative, 2 neo-adjuvant Ovarian cancer 12 (22%) Endometrial cancer 1 patient (1.8%)	Not stated	Photographs of the patient's head from 5 different views. WHO scale. Grade 0: no hair loss Grade 1: minimal hair loss (>0% to 25%). Corresponds to Dean score 0 and 1.	78% (43/55)	56% (28/50) (up to 25% hair loss)	1.8% (1/55) could not tolerate scalp cooling.	Hair loss (n=7), death (n=3), change of treatment centre (n=1), and doubts about study participation resulting in withdrawal of consent within 30 minutes of initiation of the 1st cycle (n=1).

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S. (Cont.)

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Drinkut et al., 2016 Medizinische Hochschule Hannover, Klinik für Frauenheilkunde und Geburtshilfe, Hannover, Germany	Non randomized prospective June 2014 - February 2016	4 x E/C 90/600 mg/m2 + 12 x PT 80 mg/m2	N/A	Women with breast cancer (n=34)	Not stated	Quantification of hair loss by patients and nursing staff. Photos.	56% (19/34)	100% (Patient assessm.: all <50% hair loss, Nurses assessm.: all <25% hair loss)	Not stated (>50% of patients did not report any side effects.)	Cold sensation (n=6) Other (n=9)
Schaffrin-Nabe et al., 2016 Gemeinschaftspraxi Bochum, Germany	Non randomized prospective	Neo-adjuvant EC-PT	Neo-adjuvant EC-PT	Breast cancer patients (n=40) Scalp cooled (n=32), controls (n=8)	Not stated	Hair-mass- index (trichometer) No visible hair loss was considered treatment success.	100% (32/32)	63% (20/32) (no visible hair loss) Complete hair loss in controls.	Not stated.	N/A
Traub et al., 2016 Agaplesion Markus Krankenhaus Frankfurt am Main, Germany	Non randomized prospective October 2015 -	4 × EC → 12 × PT (n = 7) 4 × PT → 4 × EC (n = 1) 4 × EC (n = 1) 18 × PT Mono (n = 1) 4 × Nab-PT Mono (n = 1) 18 × PT plus Myocet (n = 1)	N/A	Women with breast cancer (n=12)	Not stated	Objective assessment of photographs.	75% (9/12)	75% (9/12) (<20% hair loss)	Cooling-induced side effects	Hair loss (n=1), or cooling-induced side effects (n=2)
Campennì et al., 2016 European Institute Oncology, Milan	Non randomized prospective	EC EC-TX +/- Trastuzumab TC	N/A	Patients with stage I-III breast cancer receiving adjuvant chemotherapy (n=109).	Not stated	Hair loss Patient self-assessment & assessment by treating physician Dean scale	79% (86/109)	77% (84/109)	Headaches and coldness. No serious adverse events.	Hair loss (n=12), Discomfort during the cooling period (n=4), other reasons (n=7).

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S. (Cont.)

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Schaffrin-Nabe et al., 2015 Gemeinschafts praxis für Hämatologie und Onkologie Bochum, Germany	Non randomized prospective	E 90 mg/m² + C 3w→PT w E 90 mg/m² + C 2w→ PT w E 90 mg/m² + C 3w →DT 100 mg/m² F + E 100 mg/m² + C F + E 90 mg/m² + C DT 75 mg/m² Carboplatin AUC6 F + E 100 mg/m² + C →DT 100 mg/m² E 150 mg/m² + PT 225 mg/m² + C 2000 mg/m² DT 75 mg/m² + A50 C 500 mg/m² PT 100 mg/m² + Carboplatin AUC2 Gemcitabine 1000 mg/m² + Carboplatin AUC2 DT 75 mg/m² + C 600 mg/m²	N/A	In total 226 cancer patients with solid tumors. Breast cancer receiving (neo) adjuvant and palliative chemotherapy (n=136).	Not stated	Hair loss, common toxicity criteria (CTC German version 1.0) scale for alopecia. No or not visible hair loss, CTC 0-1.	3.1% (7/226)	65% (no or not visible hair loss, CTC 0-1.)	Slight and well tolerable sensation of cold and mild cranial pressure. No skin irritations recorded.	Cold intolerance and aversion.
Andrews et al., 2014 Patricia Ritchie Centre, the Mater Hospital Sydney, Australia	Prospective feasibility	AC or combination FEC or FEC-D TC Other	N/A	Early stage breast cancer (n=122)	Not stated	Completion rate Hair loss: Dean score	80.5% (98/122)	50% (61/122)	Not stated	Adverse events not listed specifically for patients using the DigniCap.

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S. (Cont.)

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Friedrich and Carstensen, 2014 Mammazentrum, Jerusalem Hospital, Hamburg, Germany	Non randomized prospective June 2011-December 2012	Multiple combinations (Neo-) adjuvant chemotherapy E 90 mg/m² + C 600 mg/m² (q3w*4)→ DT 100/175 mg/m² (q3w*4) F 500 mg/m² + E 100 mg/m² + C 500 mg/m² (q3w*6) F 500 mg/m² + E 100 mg/m² + C 500 mg/m² (q3w*6)→ DT 100 mg/m² (q3w*3) E 90 mg/m² + C 600 mg/m² (q3w*4) CarboplaPt/DT (q3w*6) Palliative chemotherapy Taxol 135/Herceptin 8mg/kg Halaven 1.23	N/A	Breast cancer (n=83) Adjuvant (n=58) Palliative (n=6) Drop outs (n=19)	Not stated	Hair loss: Photo documentation Numerical VAS (1- 10)	77% (64/83 finished chemotherapy and scalp cooling.)	52.6%	Feeling of cold Headaches Heaviness of head Scalp pain Frequency differed between patients with (neo-) adjuvant and palliative CT	Out of 19 patients; hair loss (n=5), Cancer related emergency cases or disease progression (n=3), Feeling of cold/headaches (n=2), Unspecified intolerance (n=9).

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S. (Cont.)

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Udrea et al., 2014 Medisprof Oncology day hospital, Cluj, Romania	Non randomized prospective March 2012 - November 2013	E 100mg/m² + C 600 mg/m² (n=53) DT 100 mg/m² (n=10) PT 175 mg/m² + carboplatin AUC5-6 (n=21) Irinotecan 80 mg/m² (n=4), Etoposide 100 mg/m² day 1-3 + Carboplatin AUC5 (n=3) TXT 75 mg/m² (n=2) DT 75 mg/m² + Cisplatine 75 mg/m² + Capecitabine 1000 mg/m² (n=2) Other combinations (n=13)	N/A	108 cancer patients (Treatment ongoing for 8 patients).	Not stated	Hair loss: US NCI (CTCAE) v4.0. No alopecia / crown like alopecia	96% (104/108)	57% (62/108) (No alopecia / crown like alopecia)	Not stated	Discomfort (n=4)
Meunier et al., 2013) Service de chimiothérapie, Clinique Charcot, Lyon, France) Centre Alexis Vautrin, Nancy, France) Jerusalem Krankenhaus Mammazentrum Hamburg, Germany	Non randomized prospective multicenter	(Neo-) adjuvant chemotherapy 4 E90 C600 + 4 Taxotere (n=26) 3 FEC100 + 3 Taxotere (n=10) 6 FEC 100 (n=15) 4 T75C600 +/- Trastuzumab (n=7) Taxane +/-anthracyclines (n=11) Palliative chemotherapy Paclitaxel, Eribuline, Carbo + cisplatin, gemcitabine (n=6)	N/A (Comparison 3 versus 8 degrees C)	Cancer patients (total n=133). Breast cancer (n=75) (Neo) adjuvant (n=69) Palliative (n=6).	Not stated	Hair loss: Patient self- assessment VAS 0-100, with 100 being total hair preservation. (success: keeping 60-100% of hair)	44.6%	(neo) adjuvant: 65% Palliative: 83%	Headaches (22%) Cold sensation or pain to the scalp (4%)	Intolerance (9%) Headaches (9%) Unknown (9%) Hair loss (22%) Stopped chemo/disease progression (9%)

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S. (Cont.)

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Ekwall et al., 2013 Örebro University Hospital, Örebro, Sweden	Randomized prospective	PT (175 mg/m2) + carboplatin (AUC 5-6)	N/A	Gynecological cancer (total n=43); Ovarian cancer (n=22) Endometrial cancer (n=17) Cervical cancer (n=2) Tubal cancer (n=1) Peritoneal cancer	Not stated	Hair loss: Photo documentation as assessed by two Investigators VAS (0-10) as assessed by the patients	91% (43/47)	51%	Scalp cooling was generally very well tolerated. Headaches VAS ≤ 1 Coldness VAS ≤ 3.4	Anaphylactic reactions, peripheral neuropathy and regimen modification.
Abramov et al., 2011 N.N Blokhin Russian Center Research, Chemo-therapy and combined treatment Moscow. Russian federation	Non randomized prospective	ANR (n=5) TX (n=8) ANR+TX (n=7)	N/A	Breast cancer (n=20)	Not stated	Hair loss: CTCAE v3.0 Grade 1: (thinning or patchy)	Not stated.	100% ANR: 100% no hair loss TX: 50% no hair loss, 50% grade 1 ANR+TX: 29% no hair loss, 71% Grade 1	Not stated	N/A
Kato et al., 2011 Kato Breast Clinic, Shiga, Japan	Non randomized prospective August 2007-October 2010	PT 60 mg/m2 weekly + C 400 mg/m2 (n=252) PT+ H (n=29) E 40 mg/m2 biweekly+ C 400 mg/m2 (n=54) Other combinations (n=24) (Combination by 5FU, CPT-11, Gemcitabine and CBDCA.)	N/A	Breast cancer (n=359)	Not stated	Modified WHO scale (Grade 1-5) Success defined as <30% hair loss. Photos	Not stated	96%	No abnormal scalp sensation or headaches during or after treatment. No scalp metastasis.	N/A
Byahov et al., 2006 Semashko Central Clinical Hospital, Moscow, Russia	Non randomized prospective	ANR (n=43) Non-ANR (n=34)	N/A	Breast cancer, ovarian cancer, colorectal cancer (total n=77)	Not stated	Hair loss CTCAE v 3.0	Not stated	ANR: 79% Non-ANR: 94%	Well tolerated by all patients.	N/A

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S. (Cont.)

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Ridderheim et al., 2003 Lund University Hospital, Sweden	Non randomized prospective pilot	PT 175 mg/m², Carboplatin AUC 5PT 175 mg/m², E 75 mg/m2, Carboplatin AUC 5DT 100 mg/m² PT 175 mg/m² Gemcitabine 1,000 mg/m² day 1+8, E 75 mg/m² day 1E 60 mg/m², C 600 mg/m², 5-FU 600 mg/m²D 50 mg/m², Cisplatin 50 mg/m²E 50 mg/m², Carboplatin AUC 5 Vinorelbine 30 mg/m² D 25 mg/m² Bleomycin 10,000 E/m² Vinblastin 6 mg/m² Darcabazin 375 mg/m²Bleomycin 30,000 day 1, 5, 16 Etoposide 100 mg/m² day 1–5 Cisplatin 20 mg/m² day 1–5Topotecan 1.0 mg/m² day 1-5 Etoposide 50 mg/day 6–12 Topotecan 1.0 mg/m²		In total 74 cancer patients Ovarian cancer (n=60) Hodgkin´s Lymphoma (n=8) Breast cancer (n=3) Endometrial cancer (n=2) Sarcoma (n=1)	15 months (range 3-44).	Hair loss: Photo documentation Numerical VAS (0-10)	97% (72/74)	Minimal to no hair loss in ANR or TX treated patients. Median hair loss was VAS 6 (range 1.5– 8) in patients treated when combining ANR and TX.	Discomfort was modest (median value 1.5; range 0.5–8). No presence of scalp metastases	Discomfort

Clinical Data with The DigniCap Scalp Cooling System Outside of U.S. (Cont.)

Publication (author, year, institution)	Type of study (RCT, retrospective, single arm prospective nonrandomized studies.)	Treatment group	Control group	Sample size	Length of Follow-up	Follow-up schedule	Completed Cooling %	% Success with <50% hair loss	List of Adverse Events	Reason for discontinuation of cooling
Henriksen et al., 2003 Herlev Hospital, University of Copenhagen Denmark	Non randomized prospective interim	Seven cycles of FEC (Adjuvant). Dose not stated.	N/A	Breast cancer (n=26)	Not stated	Hair loss: Patients self- assessment Clinical photos Numerical VAS, wig use Side effects: Numerical VAS Post-treatment questionnaire	Not stated	88% success rate, 23/26 patients choose not to use a wig.	Side effects and extra time accepted by the patients.	N/A
Lundgren et al., 1999 Umeå University Hospital & Lund University Hospital, Sweden	Non randomized prospective pilot	PT 135-175 mg/m² (n=3) DT 100 mg/ m² (n=3) FEC (n=2) CMF (n=1)	PT	Ovarian cancer (n=3) Breast cancer (n=6) Ovarian cancer control (n=2)	Not stated	Hair loss: Numerical VAS (1-10) assessed by independent observers. Discomfort assessed by the patients.	100%	Scalp cooled patients: 100% Controls: 0% (Minimal to no hair loss (VAS < 2.5) in all scalp cooled patients.)	Discomfort level initially low (mean VAS 3) and decreased after 10 min (mean VAS 1.5). No presence of scalp metastases	N/A

Chemotherapy and Abbreviations

ANR: anthracyclines
H: Herceptin
TCH: docetaxel + carboplatin + trastuzumab
AC: doxorubin + cyclophosphamide
M: methotrexate
TC: docetaxel + cyclophosphamide
C: cyclophosphamide
Mi: mitoxanthrone
D: doxorubicin
PT: paclitaxel
DT: docetaxel
TX: taxanes
E: epirubicin
Vc: vincristine
F: 5-fluoroura

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Warranty Information

Dignitana AB provides a one-year limited system warranty for the system. Dignitana AB (“Manufacturer”) warrants that the system meets the Manufacturer’s specifications and is free from manufacturing defects at the time of delivery. This warranty is contingent upon proper use of the system in the application for which it was intended. The warranty shall not extend or apply to any damage or defect resulting from product misuse, abuse, neglect, modification, alteration, unusual stress or improper storage and handling.

Contact Information

If you have questions about DigniCap Delta, or require service, please contact Dignitana at:

Clinical Support:
10925 Estate Lane, Suite W-185
Dallas, TX 75238
877.350.2150
support@dignicap.com

Manufacturer:
Dignitana AB
Traktorgränden 3
226 60 Lund, Sweden

Operations:
Dignitana, Inc.
10925 Estate Lane,
Suite W-185
Dallas, TX 75238
USA

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