LIFEWARMER™

Quantum™

Blood & Fluid Warming System

USER MANUAL

Manufactured by
NORTH AMERICAN RESCUE®
www.NARescue.com • 888.689.6277
35 Tedwall Ct. • Greer SC 29650 • USA

LIFEWARMER™

Quantum™

Blood & Fluid Warming System

CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician.

It is important that users read and understand all information contained in this manual concerning the intended use and proper operation of the Quantum™ Blood & Fluid Warming System. This manual is not intended as a substitute for formal training in the use of intravenous administration systems, which may be required by local, regional, or state protocol. Consult your local medical director or governing agency for further information and requirements. For questions concerning this manual or the device, contact North American Rescue, LLC.

Contact Us:

If you have questions regarding the use of the Quantum™ Blood and Fluid Warming System or any component, please contact North American Rescue at 888-689-6277.

USA

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ZZ-1098 • REV032124

GLOSSARY OF SYMBOLS

The following symbols may appear on components or in information related to the Quantum device.

Symbol	Reference	Title/Meaning
LOT	ISO 7000-2492	Batch Code/ Manufacturer's Lot
	ISO 7000-1051	Do Not Reuse
g	ISO 7000-3832	Gravity type
	EN 50419	WEEE wheeled bin Recyle electronic equipment; Do Not Throw in Trash
	ISO 7000-0434A	Caution
LATEX	ISO 15223 –5.4.5	Not made with natural rubber latex
	ISO 7000-1641	Operating Instructions; eIFU
	ISO 7010-M002	Follow Instructions for Use
	ISO 7000-2724	Non-pyrogenic
	ISO 7000-3079	Single Sterile barrier system with protective packaging outside
	ISO 7000-3724	Distributor
	ISO 7000-0632	Temperature limits; Limits for safe device exposure
	ISO 7000-2621	Atmospheric pressure limitation; Range which device can be safely exposed
	IEC 60086-4	DO NOT disassemble (battery)
	IEC 60086-4	Do NOT incinerate (battery)
	ISO 60417-6045	Rated power input, a.c.
	ISO 7000-2606	Do not use if package is damaged
Li-ion	ISO 7000-1135	Li-ion Battery Recycling

Symbol	Reference	Title/Meaning
REF	ISO 7000-2493	Catalogue Number
	ISO 7000-2607	Use-by date; Date after which the device is not to be used
Rx Only	21 CFR Part 801.109	Caution: Federal (USA) law restricts this device to sale by/or on the order of a physician
MR	ASTM F-2503	MR Unsafe; Device known to pose hazards in all MR environments
	IEC 60417-5333	Type BF Applied Part
PHT DEHP	BS EN 15986-4.2	Non-DEHP Does not contain the phthalate plasticizer DEHP
A →	ISO 7000-3728	Translation; Information has undergone translation
	ISO 7000-3082	Device Manufacturer
	ISO 7000-2497	Date of manufacture
USA	IEC 60417-6049	Country of manufacture
20 ml	ISO 7000-2726	Number of drops per milliliter
%	ISO 7000-2620	Humidity limitation; Range which medical device can be safely exposed
	IEC 60086-4	Do NOT crush (battery)
STERILE EO	ISO 7000-3084	Sterile Fluid Path – Sterilized using ethylene oxide
	ISO 60417-6048	Rated power output, d.c.
Pb	N/A	Lead free
SN	ISO-7000-2498	Serial Number
	ISO-7000-3727	Repackaging; Modification to original medical device packaging configuration

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PRESCRIBING INFORMATION

LIFEWARMER™

INDICATIONS FOR USE:

The Quantum™ Blood & Fluid Warming System is indicated for warming blood, blood products and intravenous solutions prior to administration in adult and pediatric patients greater than 28 days old of normal birth weight. It is intended for use by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothermia. The Quantum is not for use with neonates (birth to 28 days old) or infants of low birth weight.

WARNINGS:

- The Quantum is not for use with neonates (birth to 28 days old) or infants of low birth weight.
- For the safe operation of the Quantum System, all instructions, warnings and precautions in this document must be followed. Failure to follow instructions for proper use may result in device malfunction or injury.
- Only the fluid path and areas under protective end caps are STERILE. If end protectors are not in place, DO NOT USE.
- The TIS/TTS-B is for **SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE.**
- The Quantum Thermal Infusion Set (TIS) IS NOT for standalone use with blood or blood products.
- A RED LED strobe and sustained audible alert on the battery indicates a fluid over-temperature condition which can result in hemolysis of blood and elevation of touch temperature of the thermal tubing.
- The over-temperature Audible Alert System may be manually disabled. Ensure that the Audible Alert System is always enabled unless a tactical hazard is posed.
- Replace Quantum Transfusion (TTS-B) and Infusion Sets (TIS) in accordance with CURRENT AABB/CDC guidelines and/or institutional protocols.
- All IV fluid bags must be vented of air per IV fluid manufacturers' directions prior to connecting to tubing set. Care must be taken to ensure there is not sufficient air in the fluid bag and lines to cause an air embolism.
- DO NOT affix, place or bind the thermal (heated) portion of the thermal tubing directly to a patient.
- It is recommended that the Controller, Battery, and Charger be surfaced cleaned and disinfected after each patient use following the instructions in this manual or according to standard institutional protocol.
- DO NOT touch the Battery contacts and the patient at the same time.
- The Quantum System (including Thermal Tubing TIS and TTS-B) is **MR UNSAFE** .
- DO NOT use a multiple socket outlet or extension cord with any Quantum component.
- Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The Quantum is intended for gravity administration. However, performance testing has been conducted in accordance with ISO 1135-5 for single use transfusion sets with pressure infusion and found to be mechanically stable. Thus, the clinician may apply reasonable pressure to the infusate bag if it is determined that increased fluid flow is clinically indicated.
- DO NOT attempt to use the Quantum System components, including tubing sets (TIS, TTS-B), Controller, Battery, or Charger with fluid warming devices/components from other manufacturers. They are not compatible.
- DO NOT attempt to use charging devices, power cables or components from other manufacturers with the Quantum System components. They are not compatible and pose a safety hazard.
- DO NOT attempt to sterilize, autoclave or submerge the Controller, Battery, or Charger. **Surface clean/disinfect only.**
- There are no user-serviceable parts including the Battery. For all matters concerning functionality and service, contact Life Warmer, Inc.
- DO NOT attempt to open or access the Controller, Battery, or Charger. Doing so may damage the components and/or result in device malfunction, failure or injury.
- DO NOT attempt to modify any component of the Quantum System. There may be NO changes or modifications to the mechanics, electronics, and/or software of the system.
- DO NOT operate or store Quantum components outside of the specified environmental limits. A safety hazard may occur.
- Degradation of sensors can result in inaccurate temperature readings and subsequent outflow temperatures. If this occurs, the Controller will indicate a System Error.

WARNINGS: *(continued)*

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Quantum Fluid Warming System, including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment could result.

PRECAUTIONS:

- Loss of adequate heating may lead to hypothermia, particularly in infants who may have difficulty with thermoregulation. Conversely, overheating may lead to dehydration and cardio-pulmonary compromise.
- Compromised or breached fluid pathways may lead to increased risk of contamination and possible infection in pediatric patients, particularly in younger infants whose immune systems may not be fully developed.
- Examine all system components for damage, wear, and functionality prior to use. If any component appears faulty, damaged or defective, DO NOT USE. This is especially important for pediatric patients, particularly younger infants. The lack of a fully developed immune system predisposes them to an increased risk of infection from contamination of fluids or compromised fluid pathways.
- Inspect all casings, components and enclosures for damage, cracks, breaks, or loss of integrity. If any of these are observed, do not use and replace component. This is especially important for pediatric patients, particularly younger infants. The lack of a fully developed immune system predisposes them to an increased risk of infection from contamination of fluids or compromised fluid pathways.
- Exceeding recommended flow rates and/or low ambient temperature may result in lower output temperature. Pediatric patients, particularly infants, are more prone to hypothermia due to susceptibility to temperature instability and reduced ability to thermoregulate.
- Any over temperature condition in pediatrics patients may lead to overheating and issues with thermoregulation causing unexpected effects such as cardio-pulmonary compromise and dehydration.
- Some drugs or drug preparations may be sensitive to warming. As with any fluid or blood warming system, carefully review the drug manufacturers' literature for information about thermal sensitivity.
- Do not position the device in a manner that makes it difficult to view or disconnect the Controller and/or change the Battery.
- When the useful life of the lithium Battery has been reached, it should be disposed of separately in accordance with national and local codes. Contact your local environment control or disposal agency for further details.
- Used, single-use components (TIS, TTS-B) should be disposed of in accordance with local, national and/or international biohazard protocols by the appropriate personnel.
- The Controller and Battery are not intended for patient contact.
- Although the Quantum has been tested to insure it will survive a drop of 1 meter (3.28 ft), care should be taken that the system is not dropped to reduce the potential of damage.
- It is recommended proper Battery and Controller performance be verified by observing startup LEDs before each use of the Quantum.
- Fully charge new batteries upon receipt and prior to use or storage to extend battery life.
- Check Battery charge status prior to each use to ensure adequate charge for device operation.
- It is recommended that the Battery be fully charged before initiating warming.
- It is recommended that the Battery be charged after each use, and every 4 months..
- The Battery Charger must be connected to an earthed mains socket outlet.
- The Controller Jacket should be replaced after every 10 uses (approximate) or six months (whichever occurs first) or at anytime the Controller Jacket appears damaged, loose-fitting, or compromised.

INTENDED USERS & USE ENVIRONMENTS

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Intended Users:

Operators of the Quantum should be knowledgeable in the use of IV administration sets for infusion of fluids and transfusion of blood/blood products. The Quantum thermal tubing sets (TIS and TTS-B) deliver IV solutions and blood/blood products in a similar manner as conventional IV infusion and transfusion sets.The Quantum is designed for quick set up and deployment using minimal steps. Intended users include military medics, EMS Paramedics, registered nurses, physicians and mid-level practitioners. Patient-users of the Quantum include any adult or pediatric patient greater than 28 days old of normal birth weight presenting with the need for IV solutions, blood or blood products who may benefit from warmed fluids. Note: Quantum is not for use with neonates (birth to 28 days old) or infants of low birth weight.

Intended Use Environments:

The Quantum Blood & Fluid Warming System is transportable. The intended use environments include hospitals (e.g., in-patient/full services facilities), clinical environments (e.g., satellite emergency centers, outpatient centers, etc.), and field environments (e.g., point of injury including civilian and battlefield locations) and transport environments such as emergency vehicles en route (i.e., fixed and rotary wing aircraft and ground and air ambulance). The Quantum Controller, Battery, TIS/TTS-B are intended for use in the Patient Environment. Note: The Battery Charger should only be used in hospital and protected fixed structure environments.

QUANTUM SYSTEM DESCRIPTION:

Device Description:

The Quantum Blood & Fluid Warming System is a lightweight, battery powered, highly portable, fluid warming system in which the warming element is integrated with specially designed intravascular administration tubing. Fluid warming is achieved in the tubing through the use of proprietary thermoplastic polyurethane and a software control algorithm.

The Quantum IV administration tubing is double-extruded to yield a configuration that has both an inner tubing layer and an outer tubing layer. A conductive heating element is between the two layers but does not come in contact with the fluid path [Figure 1]. The outer tubing layer acts as an insulator while the inner tubing layer transfers the heat from the heating element to the fluid path.

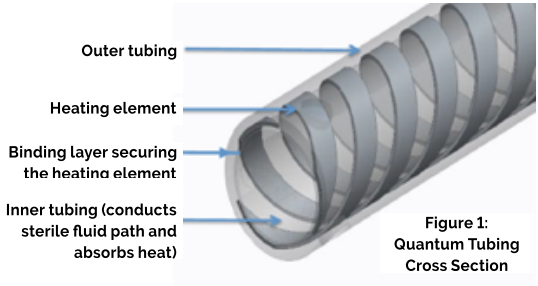


Figure 1: Quantum Tubing Cross Section

The Quantum System, fully charged, is able to warm and maintain up to 1000 mL ± 100 mL of cold (4°C) blood products to a pre-set temperature of 38°C ± 2°C (100.4°F ± 3.6°F) at a flow rate of 100 mL/min (depending on the ambient temperature). Or, approximately 1700 mL of 20°C IV solution to a set point of 38°C ± 2°C at a flow rate of 200 mL/min. Effective warming flow rates, which range from 2 to 200 mL/min, and total volume warmed depend on input fluid temperature and ambient conditions.

Thermistors located in the tubing continually measure temperature and provide that input to the Controller. The Controller assesses the temperature input and regulates the amount of energy applied to the heating element needed to reach and maintain a constant fluid temperature. The monitoring and independent application of energy (heat) along the fluid path allows the Quantum to respond to varying temperature inputs from the fluid source to near the point of patient entry to ensure fluid temperature is ≥ 36°C to < 44°C at delivery.

The Quantum is powered by a rechargeable lithium-polymer battery. The complete Quantum Blood & Fluid Warming System, including the Battery, weighs less than 1.5 lbs. and can travel with the patient across multiple clinical use environments while maintaining optimum fluid temperature.

QUANTUM SYSTEM COMPONENTS:

The Quantum Blood & Fluid Warming System consists of sterile thermal IV tubing (TTS-B or TIS), a Controller (including Jacket), Battery, and Battery Charger.

TUBING SETS:

Thermal Transfusion Set -Blood (TTS-B) | Thermal Infusion Set (TIS)

Intravascular administration sets for infusion (TIS) of IV fluids and transfusion (TTS-B) of blood/blood products and IV fluids. The sets are assembled and consist of Life Warmer's proprietary thermoplastic tubing with integrated copper-nickel heating elements, temperature sensing thermistors, and standard IV administration components (see Figures 2 and 3). The TIS and TTS-B connect to the Controller via the circuit cartridge connector. The TIS and TTS-B are provided sterile, for single-patient use only.

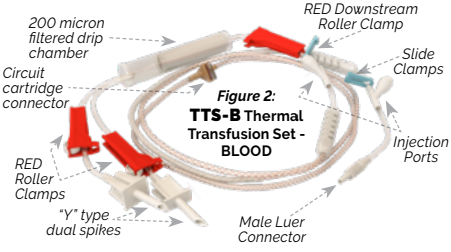


Figure 2: **TTS-B Thermal Transfusion Set - BLOOD**

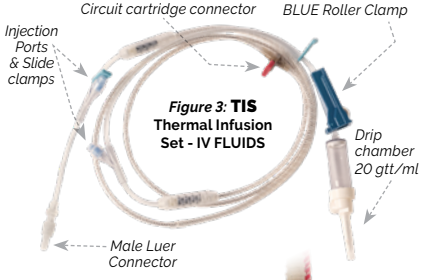


Figure 3: **TIS Thermal Infusion Set - IV FLUIDS**

Controller:

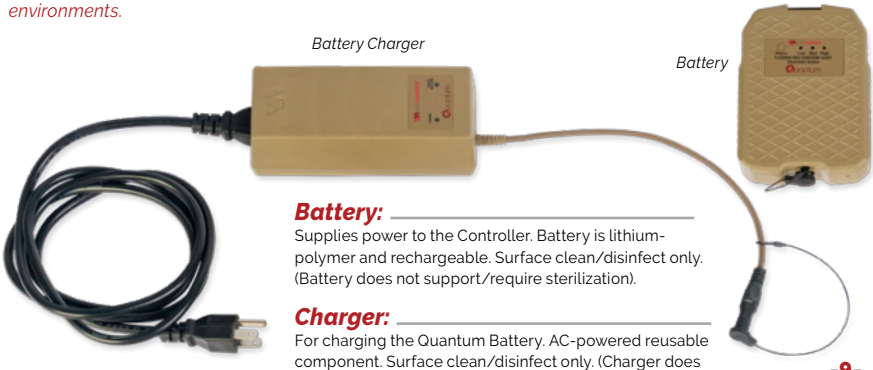
The Controller is the command center of the Quantum System. It contains the microprocessor and control algorithm that continually assesses temperature input from tubing thermistors and regulates the energy provided to the tubing heating elements in the proximal and/or distal segments to reach and maintain temperature between 38°C ± 2°C (100.4°F ± 3.6°F) at patient delivery. The Controller receives power when connected to the Battery. The Controller is reusable. Surface clean/disinfect only. (Controller does not support/require sterilization).

Controller in jacket

Controller Jacket:

The Controller comes fitted with a Jacket that permits the mating (connection) of the TIS or TTS-B tubing circuit connector to the connector slot on the Controller. The Jacket must remain in place for device operation. The Jacket also protects the Controller and should be replaced after approximately 10 uses or 6 months.

Note: *The Charger should only be used in hospital and protected fixed structure environments.*



Battery:

Supplies power to the Controller. Battery is lithium-polymer and rechargeable. Surface clean/disinfect only. (Battery does not support/require sterilization).

Charger:

For charging the Quantum Battery. AC-powered reusable component. Surface clean/disinfect only. (Charger does not support/require sterilization).

QUANTUM OPERATION:

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To begin using the Quantum Blood & Fluid Warming System, select the appropriate tubing set for infusion of IV solutions (TIS) or transfusion of blood/blood products or IV solutions (TTS-B). Follow the directions on page 9 for either the TIS or TTS-B tubing selected.

THERMAL INFUSION SET (TIS) – *For Infusion of IV Solutions*

WARNING:
TIS IS NOT for standalone use with blood products.

- Standard spike with vent
- 15 micron particle filter
- Luer activated injection sites (2)
- Male Luer lock adapter
- Tubing length: 85" (216 cm) long
- Priming volume: 16 mL

TIS USE: *(Use Aseptic Technique):*

1. Open pouch where indicated. Remove tubing set and close roller clamp.
2. Remove Spike protector end cap. Insert spike into the fluid container. Note: keep vent cap closed unless infusing from a rigid solution container.
3. Fill the drip chamber by squeezing the drip chamber until approximately half full.
4. Remove protector end cap from male Luer adapter.
5. Slowly open roller clamp to prime tubing and purge air. Once primed, close roller clamp until flow stops.
6. Attach adapter to vascular access device.
7. Slowly open roller clamp and adjust for desired flow rate.

Luer Activated Injection Site:

Use only standard Luer connection devices. DO NOT USE needles or blunt cannulas to access the swabable valves. Using a sterile alcohol pad, swab the Luer activated surface and let it air dry. Carefully connect the syringe or Luer connector STRAIGHT into the valve in a clockwise twisting motion. To disconnect, twist counter clockwise. Flush the Luer activated site after each use per facility protocol.

To Initiate Fluid Warming:

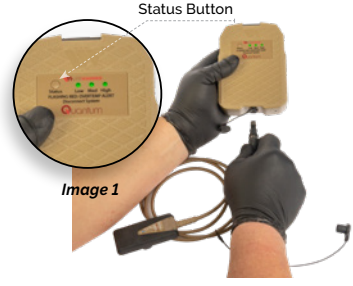

Image 1

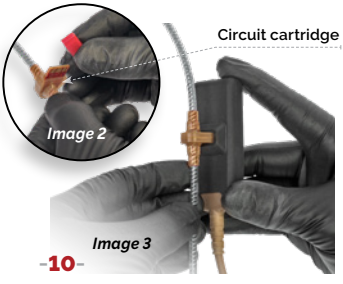

Image 2

Image 3

1. Completely prime the system following the steps above, purging all air from the line, and start infusion at desired flow rate. (Note: 7 mL/minute minimum flow rate is needed to initiate warming. Once warming begins (Flashing Blue LED), User may titrate to lower flow rates if desired.
2. Briefly press the 'Status' button on the Battery to check battery charge. Three green LEDs indicate a full charge. One LED or no LEDs indicate insufficient charge to operate the device. If the Battery has sufficient charge, remove the protective cover and connect the Controller to the Battery. A green blinking Controller LED indicates system is ready for use. *(Image 1)*
3. Connect the Controller to the circuit cartridge of the TIS by removing its red protective cap exposing the circuit cartridge. *(Image 2)*
4. Connect the Controller to the tubing by firmly pressing the tubing's circuit cartridge into the connector slot on the Controller *(Image 3)*. A Blue flashing LED indicates the fluid is warming but is <36°C. A solid green LED indicates fluid is ≥36°C and < 44°C. At steady state, the System strives to maintain infusion at a set point of 38°C +/- 2°C. *(Image 4)* Note: the System will attain set point only during flowing infusion.
5. Depending on fluid temperature and flow rate, the User may need to adjust the infusion rate to stay in the set point range (as indicated by solid green LED).
6. When infusion is complete, disconnect the Controller from the TIS and battery to conserve power.

Image 4

THERMAL TRANFUSION SET - BLOOD (TTS-B) – *for Blood/Blood Products and IV Solutions*

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- Dual spike/one vent
- 200 micron filter
- Luer activated injection sites (2)
- Male Luer lock adapter
- Tubing length: 85" (216 cm) long
- Priming volume: 23 mL

WARNING: Only fluid path and area under protective end caps are STERILE.

TTS-B USE: *(Use Aseptic Technique)*

1. Open pouch where indicated. Remove the tubing set and close all three roller clamps.
2. Remove Spike protector end cap. Insert one spike into the fluid container, open roller clamp under fluid container. Note: keep vent cap closed unless infusing from a rigid container.
3. Partially open roller clamp downstream of filter chamber. Allow approximately ¾ of chamber to fill with fluid. Close downstream (regulating) roller clamp.
4. Tap to displace air trapped in filter. Slowly open downstream roller clamp to prime, purge air and fill tubing. Invert and tap injection ports while fluid is flowing. Ensure air is expelled, repeat prime if necessary.
5. Attach adapter to vascular access device
6. Slowly open roller clamp and adjust for desired flow rate.
7. To administer additional units, attach to previously used lead or attach to second (unused) lead and prime before administering.

Luer Activated Injection Site:

Use only standard Luer connection devices. DO NOT USE needles or blunt cannulas to access the swabable valves. Using a sterile alcohol pad, swab the Luer activated surface and let it air dry. Carefully connect the syringe or Luer connector STRAIGHT into the valve in a clockwise twisting motion. To disconnect, twist counter clockwise. Flush the Luer activated site after each use per facility protocol.

To Initiate Fluid Warming:

Image 1

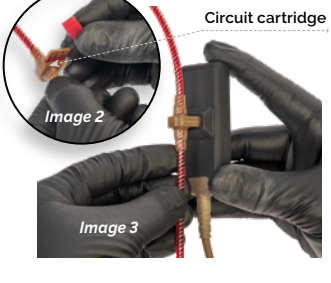


Image 2

Image 3

1. Completely prime the system following the steps above, purging all air from the line, and start infusion at desired flow rate. (Note: 7 mL/minute minimum flow rate is needed to initiate warming. Once warming begins (Flashing Blue LED), user may titrate to lower flow rates if desired.
2. Briefly press the 'Status' button on the Battery to check battery charge. Three green LEDs indicate a full charge. One LED or no LEDs indicate insufficient charge to operate the device. If the Battery has sufficient charge, remove the protective cover and connect the Controller to the Battery. A green blinking controller LED indicates system is ready for use. *(Image 1).*
3. Connect the Controller to the circuit cartridge of the TTS-B by removing its red protective cap exposing the circuit cartridge. *(Image 2).*
4. Connect the Controller to the tubing by firmly pressing the tubing's circuit cartridge into the connector slot on the Controller *(Image 3).* A Blue flashing LED indicates the fluid is warming but is < 36°C. A solid green LED indicates fluid is between ≥36°C and < 44°C. At steady state, system strives to maintain infusion at a set point of 38°C +/- 2°C. *(Image 4)* Note: the System will attain set point only during flowing infusion.
5. Depending on fluid temperature and flow rate, the User may need to adjust infusion rate to stay in the temperature set point range (as indicated by solid green LED).
6. When infusion is complete, disconnect from TTS-B and battery.

Image 4

CHARGING/CONNECTING THE BATTERY

STEP 1: *Charging the Battery*

- Plug the Charger into an AC wall outlet using the AC power cord provided. The Charger is powered from 100 to 264 Vac, 50/60 Hz
- Connect the Battery to the Charger as shown.
- A solid green LED on the Charger indicates ready for use. A flashing blue LED on the Charger indicates a battery charging failure and the battery should be disconnected for 20 seconds and then reconnected. If condition persists, replace battery.
- Charge status progression is displayed by green LEDs on the battery. This may be delayed when battery is warm and will initiate automatically once the battery temperature is safe to charge. When fully charged, the battery enters sleep mode and the LEDs turn off.
- Allow the Battery to charge for 90 minutes (if fully discharged).

STEP 2: *Checking Battery Charge Status*

Verify the charge status of the Battery by briefly pressing the Status button and observing the LED indicators:

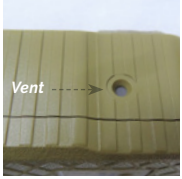
- Low - 1 LED illuminated: Battery charge is below 50% charge. Charge the Battery.
- Med - 2 LEDs illuminated: Battery is between 50% to 90% charged.
- High - All 3 LEDs illuminated: Battery is fully charged, 90% charge or higher.

Note: Battery charge status should be checked prior to each use.

STEP 3: *Connecting the Battery to the Controller* *(if preparing to warm fluids)*

- Remove the protective cover from the Battery.
- Connect the Controller to the Battery by inserting the barrel connector end.
- Upon connection, all three (3) Battery RED LEDs will blink simultaneously with or without an audible tone (depending on whether the Audible Alert System is enabled) while the Controller initiates its start-up sequence (i.e., LED flash sequence: blue, yellow, green, clear).
- A green, blinking LED indicates the Controller is ready for use.
- The Controller (with connected Battery) is now ready for connection to the TIS or TTS-B.

Important Battery Use Information:



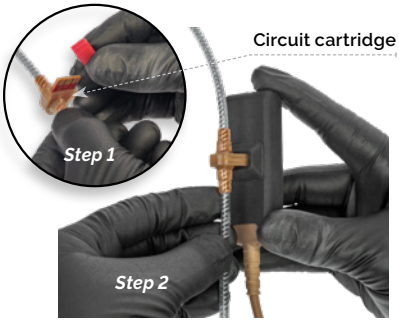
- Fully charge Batteries upon receipt from issuing (manufacturer, NAR or logistics) facility.
- Fully charge Batteries prior to storage.
- When in storage, Batteries should be recharged every 4-6 months. (Note: For Batteries stored in high ambient temperature extremes, 55˚C-60˚C, recharge every 4 months.)
- Fully charge batteries within 7 days of use.
- Replace the Battery if no LEDs are illuminated on status check.
- Connect to charger to troubleshoot.
- The waterproof vent on the bottom of the Battery is important to maintaining protection from moisture and particles. Before use, ensure the vent is intact. If the vent is worn, frayed, or not securely attached, obtain a new Battery).
- Like most Batteries, Battery capacity is reduced in cold environments. This can decrease warmed volume output.

Important Battery Maintenance Information:

- **Fully charge Batteries upon receipt from issuing (manufacturer, NAR or logistics) facility.**
- **Fully charge Batteries prior to storage.**
- **When in storage, Batteries should be recharged every 4-6 months. (Note: For Batteries stored in high ambient temperature extremes, 55˚C-60˚C, recharge every 4 months.)**
- **Fully charge batteries within 7 days of use.**

CONNECTING THE CONTROLLER

Connecting the Controller to the TIS or TTS-B tubing



STEP 1: Remove the red protective cap from the middle connector of the tubing set to expose the circuit cartridge. Discard the red protective cap.

STEP 2: Firmly press the circuit cartridge on the tubing into the connector slot on the black Controller Jacket as shown in the photo.

STEP 3:
Refer to Controller LED illumination for System status.

- A flashing Blue LED that increases in intensity and speed indicates the fluid is warming but is <36°C.
- A solid green LED indicates the fluid is between ≥36°C and < 44°C.
- One green LED flash every second (while connected to tubing) indicates stand by mode, no flow or fluid flow is too slow to warm.
- A solid yellow LED indicates a low Battery condition.
- A yellow strobe LED indicates a dry line, poor connection, disconnection or tubing mechanical failure.

Disconnecting Components /Discontinuing Use

- When infusion is complete, disconnect the Controller from the tubing.
- Disconnect the Controller from the Battery.
- Dispose of contaminated biohazard materials according to CDC and institutional Guidelines.
- Surface clean/disinfect Controller, Battery, and Charger.
- Connect Battery to Charger and allow to charge for 90 minutes for a fully depleted battery.

ENABLING/DISABLING AUDIBLE ALERT SYSTEM

The Quantum Blood & Fluid Warming System is equipped with a visual and Audible Alert system in the event of an over-temperature condition. An over-temperature condition can result in hemolysis to blood and/or elevated touch temperature of the intravascular tubing. Quantum Systems are provided with this feature fully enabled.

However, the Audible Alert System may pose a hazard to certain military and/or tactical medical users depending on the use environment. For these users and use cases only, if the presence of the audible alert presents a potential hazard, it may be disabled by following the instructions below.

Disabling Audible Alert System

1. Press and hold the Status button on the Battery continuously for 15 seconds. The LED light sequence for the state of charge will appear before the 15 seconds has been reached; however, this can be ignored. The Audible Alert System is disabled when the Battery beeps 3 times and the Red LEDs flash 3 times.
2. The Audible Alert System is now deactivated. The audible alert self check tone on component connection and in the event of a fluid over-temperature condition is now silenced until user re-enables. (Note: the visual over-temperature alert (Red LED strobe) remains active.

Re-enabling/Self Check of the Audible Alert System

1. Press and hold the Status button continuously for 15 seconds until hearing the audible alert beep 1 time and the 3 LEDs blink once.
2. The Audible Alert System is now reactivated.
3. The audible self-check tone will now be active when the controller is connected to the battery.

It is strongly recommended that the (over-temperature) Audible Alert System remain enabled unless a tactical hazard is posed. Re-enable the Audible Alert System following the steps above as soon as possible after the tactical hazard is no longer present.

STERILITY STATUS

Sterile Components

Only the fluid path and area under the protective end caps of the TIS and TTS-B tubing sets are STERILE. Sterilization is achieved by exposure to Ethylene Oxide (EO). Note: the protective end caps on the tubing sets should ONLY be removed immediately prior to tubing use.

Product must be stored in the original unopened packaging where temperatures are between -20°C to 60°C. Verify the 'Use By' date on the packaging. If it is past the 'Use By' date, DO NOT USE.

Single [Patient] Use Components

The Quantum TIS (Thermal Infusion Set) and TTS-B (Thermal Transfusion Set – Blood) are disposable, for Single Patient Use Only. Do not reprocess or resterilize.

Non-Sterile/Reusable Components

The Controller with Jacket, Battery and Charger are reusable and are provided non-sterile. These components do not support sterilization, but instead should be surface cleaned/disinfected after each patient use according to the instructions contained in this manual.

CLEANING AND DISINFECTING

Cleaning and Disinfecting Instructions

The Quantum Controller with Jacket, Battery, and Charger are supplied non-sterile and should be surface cleaned/disinfected after each patient use.

Before cleaning, disconnect the Controller from the Battery. Remove the Battery from the Charger and/or unplug the Charger from AC power. (Failure to do so before initiating cleaning may expose personnel to unsafe conditions and result in damage to the device). Note: the following procedures are not guaranteed to control the spread of pathogens. Consult the local hospital infection control administrator regarding cleaning procedure policies at your institution.

Cleaning

After each use, clean all exterior surfaces of the Controller (with Jacket in place), Battery, and Charger, with a soft cloth moistened with a mild detergent solution. Remove any residual cleaner from the component surfaces. Dry all component surfaces.

Disinfecting

After each use, disinfect all exterior surfaces of the reusable components, i.e., Controller with Jacket, Battery, and Charger, with a low-level disinfectant (sufficient for normal use conditions) with one of the following: 70-90% Ethyl or Isopropyl Alcohol, Sodium Hypochlorite (5.25-6.15% household bleach diluted 1:500). or commercial medical-grade wipe (e.g., Kim-Wipe). Dry all component surfaces.

Controller Cleaning/Jacket Replacement

After the Controller is used approximately 10 times (or six months), remove the Jacket and clean the entire Controller, including the inside of the Circuit Cartridge, with 70-90% Ethyl or Isopropyl Alcohol. Let dry 2 minutes. Install a new Jacket. Note: Once a Jacket has been removed, it should be discarded and replaced with a new Jacket.

When using in conditions of excessive moisture (e.g., field use/rain, etc.), replace the Jacket after each use. (Note: do not reuse Jackets. If the Jacket is removed, it must be replaced with a new Jacket to ensure proper fit).

Note: Do not use caustic or abrasive cleaners or strong solvents.

VISUAL/AUDIO INDICATORS

LIFEWARMER™

The Life Warmer Quantum Blood & Fluid Warming System is designed for simple, reliable operation. Refer to the Visual/Audio Indicators Legend presented below.

USER INTERFACE VISUAL/AUDIO LEGEND

Quantum Controller* NORMAL *Conditions			
LED INDICATOR		**MEANING(S)**	**ACTION REQUIRED**
Start-Up Sequence Blue Flash, Yellow Flash, Green Flash, Clear Flash		Controller initializing sequence	No action required.
	Green Flash - every 4 seconds when ***NOT Connected to Tubing***	Self-Check OK Ready for Use	Connect Controller to primed tubing set
	Green Flash - every second when ***Connected to Tubing***	Controller connected to tubing and ready for flow. (Standby Mode). No flow or flow too slow to warm	Increase flow rate if warming is desired. If no further warming desired, disconnect system
	Blue Flashing **RAMP UP** (Flashing LED with increasing intensity/speed)	Fluid is warming and/or temperature (<36°C)	Flow rate may be exceeding heating capacity. Consider reducing flow rate if clinically acceptable. Check tubing for possible contact with cold surface outdoors.
	Green Solid	Fluid is warmed to ≥36°C (in steady state).	No action required Refer to Quantum System Response by Temperature Table in Appendix.
	Yellow Solid	Low battery condition	Charge or replace Battery Pack

Quantum Controller* ALERT *Conditions			
LED INDICATOR		**MEANING(S)**	**ACTION REQUIRED**
	Yellow – Flashing (3 flashes – 1 every half second)	Dry line Poor connection ***Intentional disconnection**** Tube mechanical failure. *Reminder to reattach to tubing set if further warming is desired.	Disconnect Controller from tubing set, ensure tubing set is completely primed and no air in line. If properly primed, reattach the Controller to the tubing set and the yellow strobe should stop. If yellow strobe persists, tubing set may have a mechanical failure. Disconnect Controller and tubing from patient. Obtain a new Quantum Tubing Set, follow Quick Start to prime and attach to patient. Disconnect Controller from Battery to conserve battery power if no further warming is desired.
	NO LEDS	Poor connection to Battery, Battery Dead or Controller failure	Unplug Controller and reconnect to Battery. Check charge status of Battery. If connection is proper and Battery is charged, replace the Controller.

USER INTERFACE VISUAL/AUDIO LEGEND *(continued)*

Quantum Battery Pack* ALERT *Conditions		
LED INDICATOR	**MEANING(S)**	**ACTION REQUIRED**
Red –STROBE and/or AUDIBLE ALERT (Sustained)	**FLUID OVER TEMPERATURE**	Stop fluid flow. Disconnect Controller from Battery and from tubing set. Check infusion solution container and line. If solution container does not feel warm to the touch, reapply (reconnect) the Quantum System. Note: If audible alert is disabled, then only RED LED will strobe.
3 Red LEDs flash simultaneously during Start-Up and Audible Alert	Audible Alert is enabled	The Red Battery LEDs and Audible Alert will activate briefly each time the Controller is connected to the Battery in the normal condition with a charged battery as a functional test. If NO LEDs, the Battery may be out of charge or malfunctioning.

Military and Tactical Medicine users: If the presence of an audible alert presents a hazard, it may be deactivated by the user. Press and hold the status button continuously for 15 seconds until hearing three quick beeps and seeing three flashes of the Red LEDs, the audible alert is now disabled. To reactivate, press and hold the status button again for 15 seconds until one beep occurs and the Red LEDs flash once.

Quantum Battery Pack* NORMAL *Conditions			
LED INDICATOR		**MEANING(S)**	**ACTION REQUIRED**
	Green Solid (Battery Status)	Low - 1 Green LED: Battery below 50% charge	Charge or replace Battery
		Med - 2 Green LEDs: 50% to 90% charged (approximate)	Sufficient to power device, but recommend charging until fully charged
		High - 3 Green LEDs: Fully charged	No action required
	3 Red LEDs flash once	Successful connection to controller or charger	No action required

Quantum Charger Conditions			
LED INDICATOR		**MEANING(S)**	**ACTION REQUIRED**
	Green Solid	Charger is AC Powered	Continue charging until Battery status indicates fully charged (three LEDs illuminated). A fully depleted Battery requires 90 minutes to fully charge in normal use cases.
	Blue - Flashing	Battery charging failure	Disconnect Battery from Charger, wait 20 seconds and reconnect to Charger. If condition persists, obtain a new Battery.

TECHNICAL SPECIFICATIONS

LIFEWARMER™

The Quantum Blood & Fluid Warming System has been tested and found to comply with recognized standards for electrical safety and electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interferences in clinical use environments. The System generates radio frequency energy and should be installed and used in accordance with these instructions.

Essential Performance:

The Essential Performance of the Quantum Blood & Fluid Warming System is to indicate outflow fluid temperature when at or outside the pre-set temperature range (≥ 36 to < 44°C at steady state) to the operator and to detect proper operational status.

Essential performance is confirmed by verifying start-up LED sequences of the Battery and Controller upon connection. This confirmation should be performed before each use of the System. Upon connection, all three (3) Battery RED LEDs will blink simultaneously with or without an audible tone (depending on whether the Audible Alert System is enabled) while the Controller initiates its start-up sequence (i.e., LED flash sequence: blue, yellow, green,clear).

System Information/Safety Classifications:

BF Applied Part – TIS/TTS-B Fluid Path

ME System	Battery, Controller, TIS/TTS-B, Charger
ME Equipment	Battery, Controller, TIS/TTS-B
Type of protection against electrical shock	Class 1 / internally powered
Degree of protection against electric shock	Type BF
Mode of Operation	Continuous

Performance (Warming):

Fluid Temperature Set Point	38°C ± 2°C (100.4°F ± 3.6°F)
Fluid Warming Volume*	Up to 1000 mL of blood products at 4°C fluid input at a flow rate of 100mL/min Up to 1700 mL of IV solutions at 20°C input at a flow rate of 200 mL/min
Effective Set Point Warming Flow Rate*	2 to 100 mL/minute 4°C fluid input 2 to 200 mL/min 20°C fluid input

*Based on fully charged battery and depending upon starting ambient temperature.

TECHNICAL SPECIFICATIONS

LIFEWARMER™

Component Specifications:

Controller

PARAMETER	VALUE
Operating Input Voltage (Vdc)	33.0 (min); 44.4 Typical; 55.0 Max
Input Voltage Absolute Max (Vdc)	56.0
Operating Current (A)	0.001 minimum / 8.0 Max
Power interruption tolerance (ms)	30
Liquid/Solid Ingress	Controller with Jacket: IP 53
Weight	2.5 oz
Service (Use) Life	1000 insertions/removals

TIS/TTS-B

PARAMETER	VALUE
Sterility – Fluid path/ area underneath protective end caps	Ethylene Oxide
Biocompatibility	ISO 10993
Infusion Set Compatibility	ISO 8536-4
Liquid/Solid Ingress With protective cap on card connector	IP 53
Weight:	≤ 60g (TIS) ≤ 75g (TTS-B)
Service (Use) Life (Per)	Single Patient Use

Charger

PARAMETER	VALUE
AC Power	100 to 264 Vac, 50, 60 Hz
Equipment Class	Class I
Type Part	B
Charge Voltage (Max)	50.4Vdc +/- 1%
Liquid/Solid Ingress	IP 22
ESD	Level 3, 4KV direct contact; +/-8KV air discharge
Weight	20 oz
Service (Use) Life	2500 insertions/removals

Battery

PARAMETER	VALUE
Configuration	12 S1P / Li-Pol pouch cells (3.68V)
Chemical System	Lithium
Nominal Voltage	44.2V
Capacity	Rated: 1050mAh Minimum: 1020mAh
Configuration	12S1P
Discharge Current (Max)	6A continuous 15A peak, 200 Hz 50% duty cycle
Discharge Cutoff Voltage	33.0V (2.7V per cell)
Charge Voltage (Max)	4.20V +/- 0.03V /cell
Charge Current (Max)	2.0A
Energy Rating	46.4Wh
Liquid/Solid Ingress	IP 67
Weight	16 oz
Service (Use) Life	500 cycles
Shelf-Life	Batteries should be stored fully charged. Batteries in storage should be recharged every 4-6 months. (Note: For batteries stored in high ambient temperature extremes, 55°C-60°C, recharge every 4 months)

OPERATING, STORAGE and DISTRIBUTION CONDITIONS

LIFEWARMER™

TIS / TTS-B Tubing Sets		
PARAMETER	**OPERATING CONDITIONS**	**SHIPPING/STORAGE CONDITIONS**
Temperature	-15°C to +50°C	-20°C to +60°C
Humidity	0% to 95% relative humidity, non-condensing	0% to 95% relative humidity, non-condensing
Atmospheric Pressure	62 kPA to 106 kPA	62 kPA to 106 kPA
Warm-up/ Cool-Down from Storage Extremes	2 minutes	2 minutes
Altitude	12,000 ft	12,000 ft

Controller		
PARAMETER	**OPERATING CONDITIONS**	**SHIPPING/STORAGE CONDITIONS**
Temperature	-15°C to +50°C	-20°C to +60°C
Humidity	0% to 95% relative humidity, non-condensing	0% to 95% relative humidity, non-condensing
Atmospheric Pressure	62 kPA to 106 kPA	62 kPA to 106 kPA
Warm-up/ Cool-Down from Storage Extremes	2 minutes	2 minutes
Altitude	12,000 ft	12,000 ft

Battery		
PARAMETER	**OPERATING CONDITIONS**	**SHIPPING/STORAGE CONDITIONS**
Temperature	0°C to +40°C (charging) -20 to +50°C (discharging) Battery capacity is reduced at lower ambient temperatures - see pg. 12 for more information.	-20°C to +60°C
Humidity	0% to 95% relative humidity, non-condensing	0% to 95% relative humidity, non-condensing
Atmospheric Pressure	62 kPA to 106 kPA	62 kPA to 106 kPA
Warm-up/ Cool-Down from Storage Extremes	2 minutes	2 minutes
Altitude	12,000 ft	12,000 ft

Charger		
PARAMETER	**OPERATING CONDITIONS**	**SHIPPING/STORAGE CONDITIONS**
Temperature	-20°C to +40°C	-20°C to +60°C
Humidity	0% to 95% relative humidity, non-condensing	0% to 95% relative humidity, non-condensing
Atmospheric Pressure	62 kPA to 106 kPA	62 kPA to 106 kPA
Warm-up/ Cool-Down from Storage Extremes	2 minutes	2 minutes
Altitude	12,000 ft	12,000 ft

EMC COMPLIANCE and WARNING STATEMENT

The Quantum Blood & Fluid Warming System equipment has been tested and found to comply with the limits of the standard for medical devices, IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The Quantum Equipment is Class B. Class B equipment is equipment suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. However, there is no guarantee that interference will not occur in a particular installation. If the Quantum System should cause interference to other devices, the following actions may be taken to attempt to correct the interference:

- Ensure the Quantum System is at least 30 cm (12 inches) away from any portable RF communication system.
- Confirm proper functioning of Controller by disconnecting the Battery and restarting the System.
- Consult the manufacturer for assistance.

The Quantum is intended for use in the electromagnetic environment specified below. The customer or the user of the Quantum should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF Emissions, CISPR 11	Group 1, Class B	The Quantum uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
IMMUNITY TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Radiated RF EM Fields, IEC 61000-4-3	80 MHz – 2.7 GHz, 10 V/m Amplitude modulation 80% 1 KHz	
Rated Power Frequency Magnetic Fields, IEC 61000-4-8	30 A/m, 60 Hz	
Electrostatic Discharge, IEC 61000-4-2	± 8 kV contact, ±2, ±4, ±8, ±15 kV air discharge	

FAA Regulations: In accordance with the US Department of Transportation (DOT) and the Federal Aviation Administration (FAA), the operational Quantum components (Battery, Controller, TIS/TTS-B) meets the applicable safety requirements for Medical Portable Electronic Devices (M-PED) by not exceeding the maximum level of radiated radio frequency interference as described in the RTCA/DO 160F, Section 21, Category M.

The Quantum Charger should only be used in hospital and protected fixed structure environments, and has not been tested for use on aircraft.

APPENDIX

- Troubleshooting Guide
- Quantum Response by Temperature Table
- Glossary of Terms
- Components List
- Warranty

TROUBLESHOOTING GUIDE

Quantum Controller **NORMAL** *Conditions*			
LED INDICATOR		**MEANING(S)**	**ACTION REQUIRED**
	Green Flash - every second when ***Connected***	Controller is in Standby Mode (connected to Tubing/ready for flow). No flow detected or flow too slow to warm	Increase flow rate if warming is desired. If no further warming desired, disconnect system
	Blue Flashing **RAMP UP** (Flashing with increasing intensity/speed)	Fluid is warming and/or temperature (<36°C)	Flow rate may be exceeding heating capacity. Consider reducing flow rate if clinically acceptable. Check tubing for possible contact with cold surface outdoors.
	Yellow Solid	Low battery condition	Charge or replace Battery Pack

Quantum Controller **ALERT** *Conditions*			
LED INDICATOR		**MEANING(S)**	**ACTION REQUIRED**
	Yellow – Flashing (3 flashes – 1 every half second)	Dry line Poor connection ***Intentional disconnection**** Tube mechanical failure. *Reattach to tubing set if further warming is desired.	Disconnect Controller from tubing set, ensure tubing set is completely primed and no air in line. If properly primed, reattach the Controller to the tubing set and the yellow strobe should stop. If yellow strobe persists, tubing set may have a mechanical failure. Disconnect Controller and tubing from patient. Obtain a new Quantum Tubing Set, follow Quick Start to prime and attach to patient. Disconnect Controller from Battery to conserve battery power if no further warming is desired.
	NO LEDS	Poor connection to Battery, Battery Dead or Controller failure	Check connection to Battery. Check charge status of Battery. If connection is proper and Battery is charged, replace the Controller.

Quantum Battery Pack **ALERT** *Conditions*		
LED INDICATOR	**MEANING(S)**	**ACTION REQUIRED**
Red –STROBE and/or AUDIBLE ALERT (Sustained)	**FLUID OVER TEMPERATURE**	Stop fluid flow. Disconnect Controller from Battery and from tubing set. Check infusion solution container and line. If solution container does not feel warm to the touch, reapply (reconnect) the Quantum System. Note: If audible alert is disabled, then only RED LED will strobe.
3 Red LEDs blink simultaneously during Start-Up and Audible Alert	Audible Alert is enabled	The Red Battery LEDs and Audible Alert will activate briefly each time the Controller is connected to the Battery in the normal condition with a charged battery as a functional test. If NO LEDs, the Battery may be out of charge or malfunctioning.

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TROUBLESHOOTING GUIDE *(continued)*

Quantum Charging Conditions			
LED INDICATOR		**MEANING(S)**	**ACTION REQUIRED**
	No LED on Charger	No AC Power or Charger Failure	Check connections to Power Source and Charger. If power source and connections are confirmed and condition persists, then replace Charger.
	Blue Flashing on Charger	Battery charging failure	Disconnect Battery from Charger, wait 20 seconds and reconnect to Charger. If condition persists, obtain a new Battery.
	No LEDs on Battery	Battery too warm to initiate charge - If successful connection was confirmed by RED LEDs flashing once on Battery Possible dead battery (Upon connection to Charger, no RED LEDs illuminate once on Battery)	Wait for Battery to cool down. If Battery does not cool down within 30-60 minutes, blue LED on Charger will illuminate. Disconnect Battery from Charger, wait 20 seconds and reconnect to Charger. Disconnect Battery from Charger, wait 20 seconds and reconnect to Charger. If condition persists, obtain new Battery.

QUANTUM SYSTEM RESPONSE BY TEMPERATURE

FLUID TEMP	HEATING ELEMENT	LED INDICATIONS		
		CONTROLLER	BATTERY	THERMAL CUT-OUT
≤ 30°C	Active	Blue -Flashing		
31°C	Active	Blue -Flashing		
32°C	Active	Blue -Flashing		
33°C	Active	Blue -Flashing		
34°C	Active	Blue -Flashing		
35°C	Active	Blue -Flashing		
36°C	Active	Green- Solid		
37°C	Active	Green- Solid		
38°C	Active	Green- Solid		
39°C	Off	Green- Solid		
40°C	Off	Green- Solid		
41°C	Off	Green- Solid		
42°C	Off	Green- Solid		
43°C	Off	Green- Solid		
≥ 44°C	Off	Green Solid: ≤ 5 min sustained;		After 5 minutes
		No LED: >5 min sustained	Red Flashing & Audible Alert	
> 47°C	Off	Green Solid: ≤ 2 min sustained		After 2 minutes
		No LED >2 min sustained	Red Flashing & Audible Alert	
> 48°C	Off	Green Solid : ≤ 10 sec sustained		After 10 seconds
		No LED: >10 sec sustained	Red Flashing & Audible Alert	
> 49°C	Off	Green Solid: ≤4 sec sustained		After 4 seconds
		No LED: >4 sec sustained	Red Flashing & Audible Alert	
> 50°C	Off	No LED	Red Flashing & Audible Alert	Immediately

NOTE 1: The Thermal Cut-Out cuts power to the Controller and triggers the Visual/Audible Alert System (i.e., RED flashing LEDs with Audible Alert on Battery).

NOTE 2: If the Audible Alert System has been manually disabled, the Battery will display Red flashing LEDs Only. No audible alert.

GLOSSARY OF TERMS

TERM	DESCRIPTION
Controller	Command center of the System. Contains the microprocessor that assesses and regulates temperature.
Controller Jacket	Jacket permits the mating (connection) of the TIS or TTS-B tubing circuit connector to the connector slot on the Controller. Protects the Controller and should be replaced after approximately 10 uses or 6 months. The Jacket must remain in place for device operation.
Set point temperature	The manufacturer pre-set temperature of the System = 38°C +/- 2°C
mL/min	Milliliters per minute
IP	Ingress Protection. Rating system for for electronic equipment and/ or housings to against solids (1st digit) and liquids (2nd digit).
IP 22	Solids: Protected from solids >12.5mm Liquids: Protected from dripping water.
IP 53	Solids: Protected from limited dust ingress. Liquids: Protected from water spray less than 60 degrees from vertical.
IP 64	Solids: Protected from total dust ingress Liquids: Protected from water spray from any direction
IP 67	Solids: Protected from total dust ingress. Liquids: Protected from immersion between 15 centimeters and 1 meter in depth.

Quantum Blood & Fluid Warming System COMPONENTS LIST

PART NUMBER	DESCRIPTION
35-0001	Quantum Battery
35-0002	Quantum Charger
35-0003	Quantum Controller
35-0004	Quantum Thermal Infusion Set (TIS)
35-0005	Quantum Thermal Transfusion Set (TTS-B)
35-0006	Quantum System (Kit): 1 x Controller, 1 x Battery, 1 x Charger, 2 x TTS-B
35-0007	Quantum System (Kit): 1 x Controller, 1 x Battery, 1 x Charger, 2 x TIS
35-0008	Quantum Hard Case
35-0010	Quantum Controller Cover
ZZ-1181	Quantum Cleaning Brush

LIFEWARMER™ Quantum™

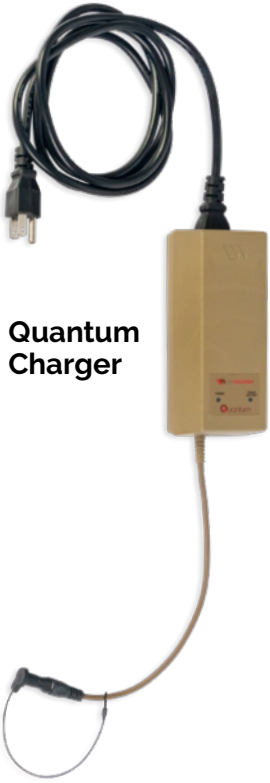
Blood & Fluid Warming System

COMPONENTS

Quantum Battery

LIFEWARMER™

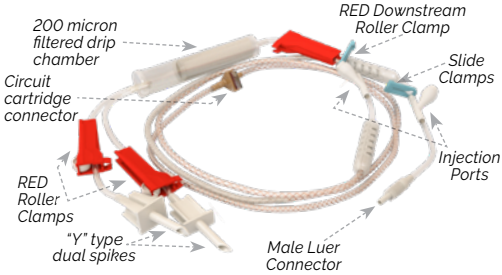
Quantum Controller



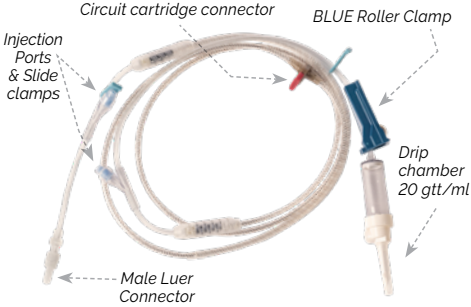
Quantum Charger

TTS-B Thermal Transfusion Set - Blood

(Blood, blood products & IV solutions)



TIS Thermal Infusion Set *(IV solutions ONLY)*



FOR INFORMATION ON WARRANTY FOR THE QUANTUM SYSTEM
AND COMPONENTS, PLEASE REFER TO

HTTPS://WWW.NARESCUE.COM/TERMS-AND-CONDITIONS

Manufactured by
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