

LIFEWARMER™ Quantum™ Blood & Fluid Warming System

INDICATIONS FOR USE: The Quantum™ Blood and IV Fluid Infusion Warmer 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. Quantum is not for use with neonates (birth to 28 days old) or infants of low birth weight. The Quantum Controller, Battery, TIS/TTS-B are intended for use in the patient environment. The Battery Charger should only be used in hospital and protected fixed structure environments.

IMPORTANT FUNCTIONAL CHECK: Confirm Quantum function before each use. Upon connection of Controller and Battery, all three LEDs (on Battery) will blink red simultaneously with an audible tone while Controller initiates its start-up sequence. As the start-up continues, the LEDs will flash in sequence from blue, yellow, green to clear.

Note: if Audible Alert System is disabled, the three LEDs will blink red and no audible tone will be heard.

Check Battery status before each use. Three Green LEDs = Fully Charged. Two Green LEDs = 50% Charged. One Green LED = Low/Insufficient Charge. Allow the Battery to charge for 90 minutes (if fully discharged).

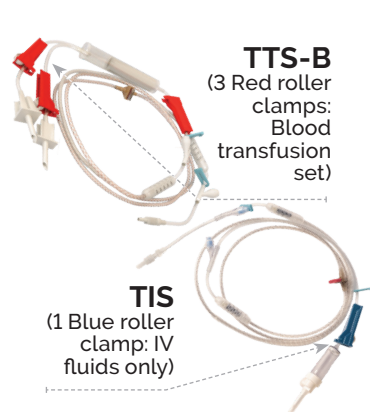
Quantum Charger

Quantum Battery

Quantum Controller

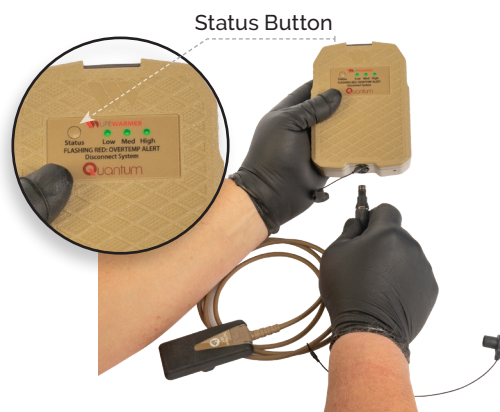
TTS-B Thermal Transfusion Set - Blood

TIS Thermal Infusion Set

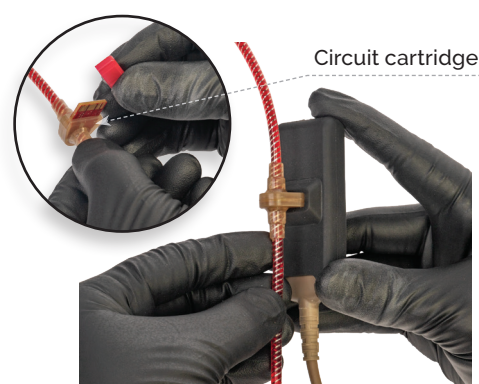


Step 1. Select TTS-B for transfusion or TIS for infusion. Tear pouch open where marked. Prime and purge all air from line.

INVERT the TTS-B drip chamber to facilitate priming. See instructions in tubing pouch. TIS primes like any standard IV set.



Step 2. Briefly press "Status" button once on Battery to check charge status. If charged, connect Controller to the Battery.



Step 3. Remove protective red cap from circuit cartridge and connect the Controller to the tubing by pressing the circuit cartridge into the connector slot. Works in either orientation.




Step 4. Adjust to desired flow rate with roller clamp on tubing. Controller turns on automatically. LEDs on Controller indicate system status during operation. **See LED Legend on opposite side.**

Alert Conditions and further operating information on back.


WARNINGS: For full prescribing information and detailed instructions for use, see the Quantum User Manual (www.lifewarmer.com). For safe operation, all warnings, precautions and instructions in the User Manual must be followed. Failure to do so, could result in device malfunction or injury. **ONLY FLUID PATH** and area under protective caps are **STERILE**. **DO NOT** place tubing or protective caps in sterile field. Quantum is **MRI UNSAFE**. TIS/TTS-B for single patient use only. **TIS TUBING IS NOT** for standalone use with blood products. **DO NOT** open any Quantum component. **DO NOT** attempt to modify any Quantum component. **NO** user serviceable parts. **DO NOT** operate or store Quantum components outside of specified environmental limits. **DO NOT** use components from other manufacturers with the Quantum. **DO NOT** use a multiple socket power strip or extension cord. **DO NOT** touch Battery pins and the patient at the same time. **RX ONLY**. Gravity administration.

QUANTUM ALERT CONDITIONS

 **Yellow Flashing (Controller)** = Dry line, poor connection/disconnection, or tubing mechanical failure. **Action:** Disconnect Controller from tubing set, ensure the tubing is completely primed and no air in line. If properly primed, reattach Controller to the tubing set and the Yellow flashing should stop.

If Yellow flashing persists: Tubing set may have a mechanical failure. Disconnect Controller and tubing from patient. Obtain a new tubing set, prime (Step 1) and attach to patient.


Yellow flashing also occurs when Controller is disconnected from tubing set during use as a reminder to reattach to tubing set if further warming is desired. Disconnect Controller from Battery to conserve charge power if no further warming is desired.


 **NO LEDs on Controller** = Poor connection to Battery, Battery dead, or Controller failure. Action(s): Check Battery connection. Check Battery charge status. If connection is good and Battery charged, replace Controller.

Audible Alert and/or Red Strobe (On Battery) = **Infusion over temperature.** Action: Stop fluid flow. Disconnect Controller from Battery and tubing. (Note: Power is cut automatically as well.) Check fluid source and line. If fluid source bag does not feel warm to the touch, reconnect.

Note: If Audible Alert System is disabled, only Red Strobe will be initiated.

CONTROLLER NORMAL OPERATION INDICATORS

 **Green flash every 4 seconds (not connected)** = Self-check OK; ready for use. **Action:** Connect to primed tubing set.

 **Green flash every second (connected to tubing)** = Stand-By Mode, No Flow, or Flow Rate too slow to warm. **Action:** Increase flow rate if warming is desired. If no further warming desired, disconnect Controller.

 **Blue Flashing** = Fluid warming, but temperature is < 36° C.

 **Green solid** = Fluid is warmed to ≥36°C (in steady state)

 **Yellow Solid** = Low Battery Condition. **Action:** Change or replace Battery

QUANTUM COMPONENTS

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
35-0009	Quantum Cleaning Kit



AUDIBLE/VISUAL INFUSION OVER TEMPERATURE ALERT

The fluid over temperature audible alert tone and the red LED alert (on Battery) activate briefly each time the Controller is connected to the Battery in the normal condition with a charged battery as a test. If either fail to occur, it indicates the Audible Alert System may be deactivated, or the alert has a malfunction. To check if the audible alert is deactivated, press and hold the "Status" button for 15 seconds. The audible alert should beep one time, and the three red LEDs should blink one time reactivating the alert.

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 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 quick beep occurs and the Red LEDs flash one time.

DISCONTINUING QUANTUM USE

1. Disconnect Controller from tubing and from the Battery.
2. Tubing can stay in use for 24 hours or per current guidelines/protocols.
3. Dispose of tubing per facility infection control policy. Tubing sets are for single patient use only.
4. Surface clean Controller/Jacket, Battery and Charger after each use. (70-90% Ethyl or Isopropyl Alcohol, or Sodium Hypochlorite (5.25-6.15% household bleach diluted 1:500), or commercial medical grade wipe (e.g. Kim-Wipe). Dry all surfaces.
5. Recharge Battery by attaching to the Charger. Charge status is continuously displayed by green LEDs on the Battery until full charge is attained, then LEDs turn off.
6. Blue Flashing LED (Charger) indicates battery charging failure. **Action:** Disconnect battery from charger, wait 15 seconds and reconnect to charger. If condition persists, obtain a new battery.
7. After recharging, store system for next use.



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