QinFLOW

NO MORE COLD BLOOD & FLUIDS

Warrior lite

Blood and Fluid Warmer

Model QiF-03

Instruction for Use (IFU)

QIF-IFU00003-1 Rev. A6
December 2022

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Do not use the Warrior lite system before reviewing the training materials and carefully reading the following instructions for use (IFU)!

Training materials (IFU / Quick User Guide) are provided with the Warrior lite device and are also available on QinFlow's designated online resource drive for its distribution partners and end users (for inquiries: info@qinflow.com or sales@qinflow.com).

Training should follow the company's written guidelines, which may be updated from time to time. It shall include careful review of the IFU. Demonstrations for training purposes shall be performed by a certified trainer. The company may release demonstration videos for training purposes.

Operating the Warrior lite device shall be done in accordance with the prevailing protocols in your organization.

Preamble: The Warrior Line of Blood & Fluid Warmers

QinFlow **Warrior lite** device is part of the Warrior line of **Blood and Fluid Warmers**. The Warrior lite is designed for space and weight constrained rescue gears at the point of injury or during short-haul critical care transports. Complementary Warrior configurations include:

- **Warrior***: battery-operable warmer for mid and long-haul critical care transports.
- **Warrior AC***: An AC-operable configuration for surgery and intensive care units.

The **Warrior Hybrid** SKU bundle merges the options above. This SKU includes both battery and AC power supply module thus allowing users to connect it to electrical power or use it during transports. This operational flexibility is particularly relevant for emergency departments, trauma units, and integrated healthcare systems (i.e. prehospital and hospital settings).

All Warrior configurations above use the same Compact Disposable Unit, thus allowing for immediate patients' handoff between setting at a reduced cost of ownership.

* Note: the **Warrior EXTREME** and the **Warrior EXTREME AC** configurations are the military versions of the Warrior and Warrior AC devices, respectively.

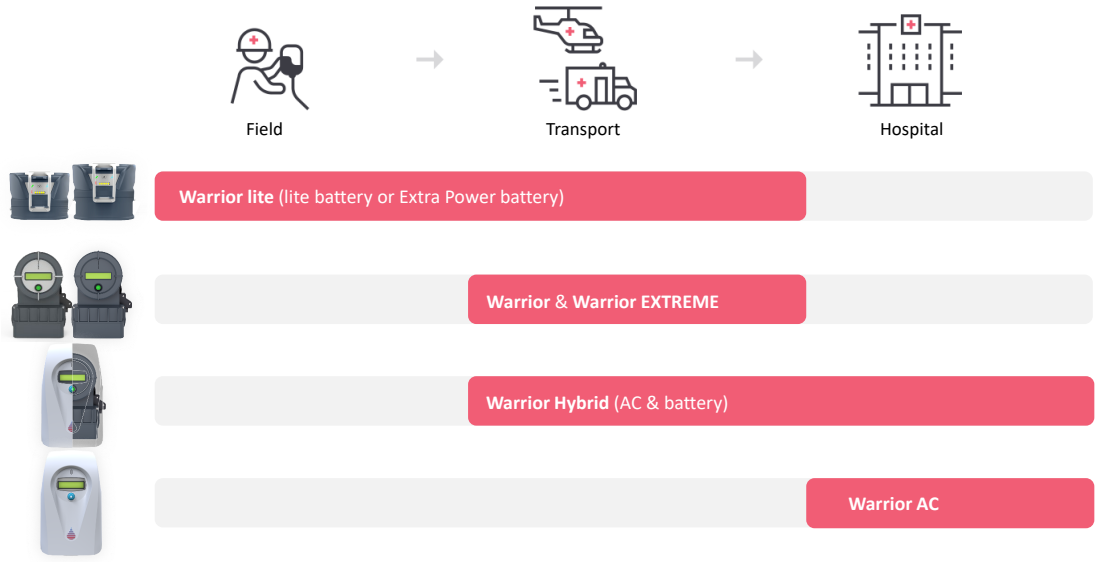


Figure 1. The Warrior Line of Blood & Fluid Warmers

1. Indications for Use

The **Warrior lite Blood and Fluid Warmer** device is intended for warming blood, blood products, and intravenous fluids prior to administration. It is intended to be used by healthcare professionals in hospital, clinics and field environments, to help prevent hypothermia.

2. Intended Use

Whenever parenteral introduction of normothermic fluid is required or indicated.

3. Intended Users

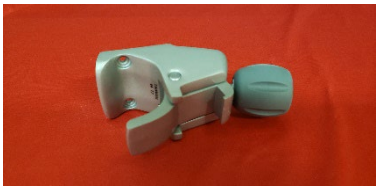
The Warrior lite should only be used by qualified healthcare professionals that have read the training materials and this IFU, and fully understand how to operate this system.

4. Package Content

The **Warrior lite** offering includes the following components:

Table 1. System Components

Core Components	
Base Unit (BU) Hosts the controller, ON/OFF switch, and user indications (LED). A Mount Adapter is secured to the back of the Base Unit. The BU Connects with the battery (bottom) and with the Compact Disposable Unit (top).	
lite Battery Rechargeable, Li-ion, 18.0V, 3.0Ah, 54.0Wh	
– OR –	
Extra Power Battery Rechargeable, Li-ion, 18.0V, 5.5Ah, 99.0Wh	
Charging Components	
Battery Charger lite battery: 100–240 VAC | 50–60 Hz | Max 1.0 A Extra Power battery: 100–240 VAC | 50–60 Hz | Max 2.0 A	

Charging Adapter Connects the battery with the charger (note: different Charging Adapter part number for the lite battery and the Extra Power battery)	
Optional Accessories	
Mounting Unit Connectivity to standard pole, rail or stretcher in critical care transport platforms and hospitals	
Extension Cable 140 cm extension between the Base Unit and the Compact Disposable Unit	
Carrying Bag	
Soft Carrying Bag The Warrior lite core and charging components are provided in a carrying bag. The bag may contain optional accessories: • One Mount Accessory • One extension cable • One spare battery (lite or Extra Power battery) The bag has a detachable compartment that can be used for carrying three Compact Disposable Units (CDUs). (Note: different Soft Carrying Bag part number for the lite and Extra Power configurations)	

5. System Description

The **Warrior lite Blood and Fluid Warmer** is an inline, battery-powered, lightweight and completely portable system, for warming blood, blood product and IV fluids. The Warrior lite can be used to help prevent hypothermia

The system is positioned out of the patient's body, between the IV / blood tubing and the patient, with a temperature set point of 38 °C ± 2 °C (100.4 °F ± 3.6 °F). The Warrior lite provides visual LEDs panel indications.

6. System Components

The Warrior lite **core components** include Base Unit (with Mount Adapter secured to its back panel) and a rechargeable battery. **Charging components** include a Charger and Charging Adapter. **Optional accessories** include Mount Accessory, Extension Cable, and spare battery/ies. The Warrior lite components are arranged in a Soft Carrying Bag.

For the purpose of optimizing the Warrior lite to different clinical and operational requirements, the Warrior lite is offered with **two types of rechargeable batteries**: the **lite battery** or the **Extra Power battery**. The batteries differ in terms of their warming volume and delivery rate. NOTE:

unless specific battery type is indicated, the term “battery” in this document shall mean both types of battery.

The Warrior lite system is used with a single-patient use disposable cartridges, the Compact Disposable Unit (CDU).

6.1. Core Components (Base Unit & Battery)

The Base Unit is comprised of a LED indications panel, a silicon strap, and mount adapter.

The LED indications panel is located on the front of the Base Unit. It indicates the fluid outflow temperature, the battery charging level and additional information signals which are further described in section 8 below. It also includes an On/Off switch.

A silicon strap covers the connector when the system is not in use, and secures the Compact Disposable Unit once it is connected to the Base Unit, as further detailed below.

A detachable rechargeable lite or Extra Power battery is inserted at the bottom of the Base Unit, and secured with the latches.

Figure 2. Base Unit and lite battery, front view

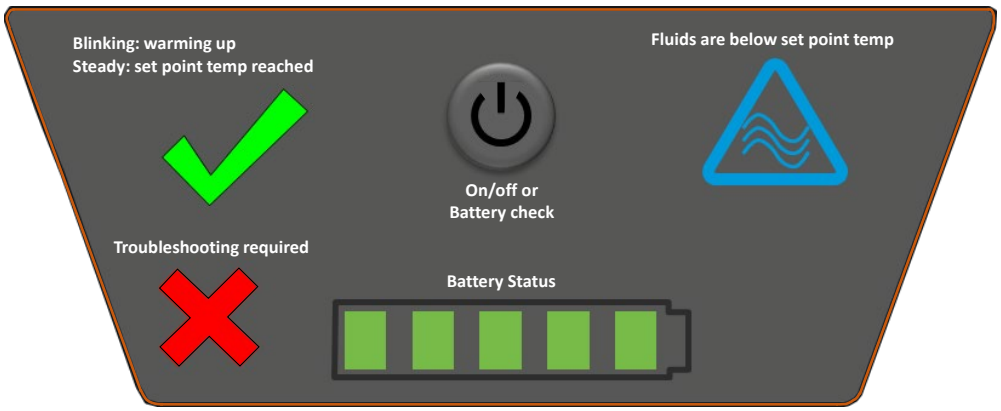


Figure 3. Indication Panel

The Mount Adapter is secured to the back of the Base Unit. It allows to mount the Warrior lite to a pole or rail using standard mounts, hang it with a carabiner, or attach it to an object

using a strap (note: the carabiner and the strap are not part of the offering). For installation instructions of the Warrior lite Mounting Adapter, see document QIF-INS00001-1.

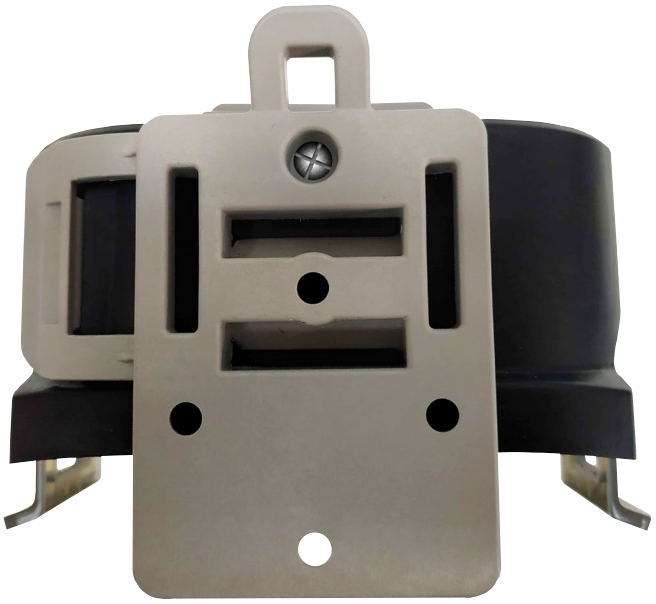


Figure 4. Mount Adapter Secured to the Back of the Base Unit

6.2. Charging Components

The charging components of the lite and Extra Power battery are as follows:

Table 2. Charging Components

	lite Battery	Extra Power Battery
Charger	FUYUANG CH21V1A-01 or MASCOT 2240Li	FUYUANG CH21V2A-01
Charger Adapter	QIF03-CHA1001	QIF03-CHA1002

6.3. Optional Accessories

Optional accessories include Mount Accessory, Extension Cable, and spare battery/ies:

- The Mount Accessory allows to mount the Warrior lite to a pole or rail. Users may use their own mounting solutions as long as these solutions meet the regulatory requirements
- The Extension Cable allows users greater operational flexibility by means of extending the distance between the Base Unit and the Compact Disposable Unit by 140 cm / ~4.6 ft. For Technical sheet of the Extension Cable, see document QIF-TDS00001-1.
- Spare battery provides enhanced operational range. If needed, the batteries can be easily swapped during operation, as further explained below

6.4. Compact Disposable Unit Options

The Warrior line of products comes the Compact Disposable Unit (CDU). The CDU is a sterile, single patient use disposable cartridge which includes a heat exchanger with standard inlet and outlet Luer connectors. The Fluid Bag is connected with a standard IV / blood administration set to the CDU Inlet Luer. The Outlet Luer of the CDU is connected to a standard catheter.

The CDU connections to the Base Unit and IV / blood administration set are identical. The CDU can be connected to the Warrior lite Base Unit either directly (by placing it on top of the Base Unit) or through an Extension Cable. The DU can only be connected to the Warrior lite Base Unit through an Extension Cable.

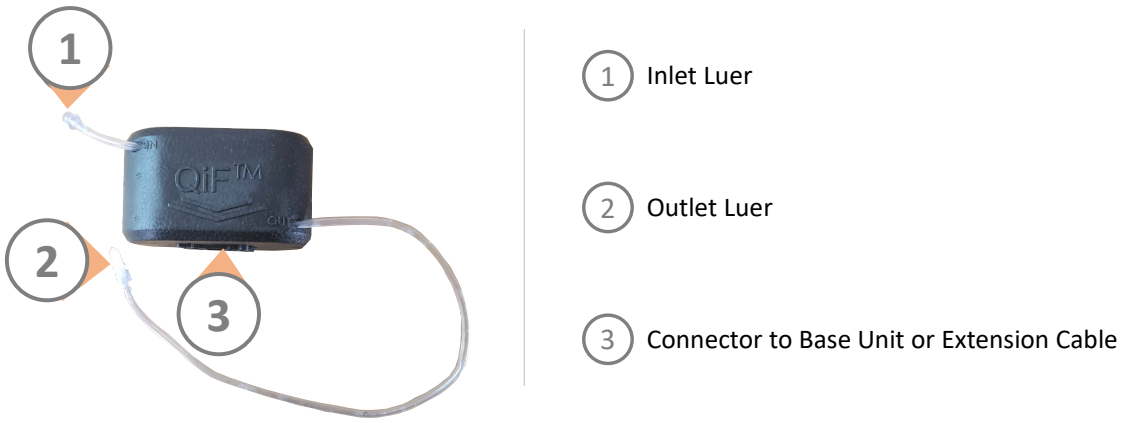


Figure 5. Compact Disposable Unit (CDU)

Figure 6. Warrior lite Base Unit connected to CDU

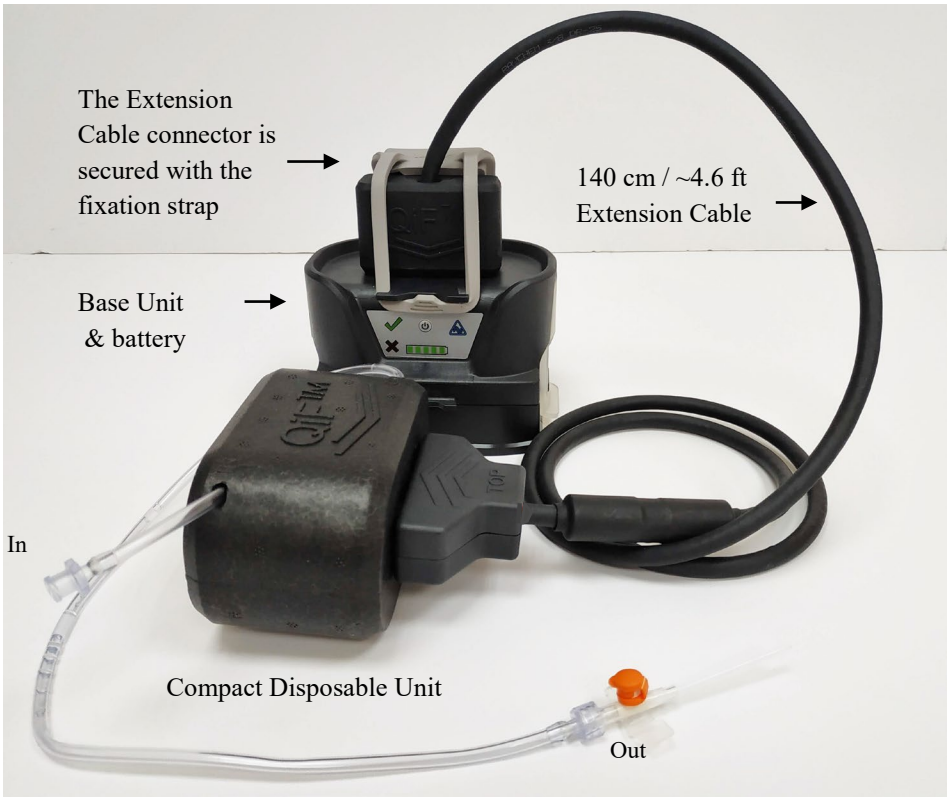


Figure 7. Warrior lite Base Unit connected to CDU through an Extension Cable

6.5. Fluid Warming Capacity

The amount of fluid the Warrior lite can warm depends on the battery configuration (lite or Extra Power battery), the charge level of the battery, inlet fluid temperature, and flow rate. A set of internal sensors constantly measure the fluid temperature and adjusts the power supplied to the heat exchanger accordingly.

lite Battery Capacity

A fully-charged Warrior lite battery can warm up to 1.3 liter of parenterally administrated blood / fluids with an inlet temperature of 4 ° C (39.2 ° F) and up to 2.5 liter of parenterally administrated blood / fluids with an inlet temperature of 20° C (39.2 ° F).

The maximum delivery rate at inlet temperature of 4 ° C (39.2 ° F) is 170 ml/min. (Based on fully charged battery and depending upon starting ambient temperature).

Extra Power Battery Capacity

A fully-charged Extra power battery can warm up to 3 liters of parenterally administrated blood / fluids with an inlet temperature of 4 ° C (39.2 ° F) and up to 5.9 liters of parenterally administrated blood / fluids with an inlet temperature of 20 ° C (39.2 ° F).

The maximum delivery rate at inlet temperature of 4 ° C (39.2 ° F) is 180 ml/min. (Based on fully charged battery and depending upon starting ambient temperature).

7. Operating Steps of the Warrior lite

STEP 1: PREPARE

7.1. Charging the Battery

The Warrior lite is powered by a researchable lite or Extra power battery. The battery should be fully charged prior to operation.

The lite battery shall be charged using the supplied Battery Charger model FUYUANG CH21V1A-01 or MASCOT 2240Li and charger adapter model QIF03-CHA1001. Charging requires 120/240 [V], 50/60 Hz.

The Extra Power battery shall be charged using the supplied Battery Charger model FUYUANG CH21V2A-01 and charger adapter model QIF03-CHA1002. Charging requires 120/240 [V], 50/60 Hz.

⚠ **WARNING:** Always connect battery to charger and AC electrical outlet source with dry hands!

Charging the lite battery:

7.1.1. Plug the lite battery charger into the lite battery using its designated Charger Adapter (point A).

➥ **Note**: there is one way to connect the adapter to the battery: the protrusion on the adapter should face towards the battery; the label should face outside. Rotate the adapter 180 degrees and reinsert it into the battery if it does not plug in.

➥ **Note**: as a safety mechanism, the lite battery Charger Adapter cannot plug into the Extra Power battery.

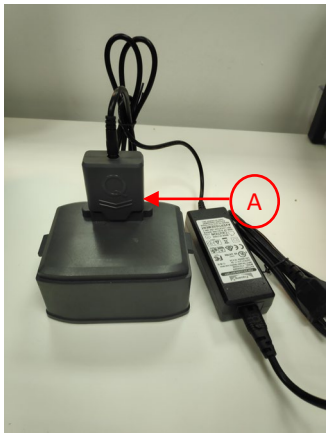
7.1.2. Plug the lite battery charger into an AC electrical outlet.

➥ **Note:** the lite battery shall **only** be charged by its designated Charger Adapter (QIF03-CHA1001).

➥ **Note:** in the event that the lite battery temperature is high, and as a safety mechanism, charging will only commence once it cools down.

Charging the Extra Power battery:

7.1.3. Plug the Extra Power battery charger into the Extra Power battery using its designated Charger Adapter (point A).



➥ **Note**: there is one way to connect the adapter to the battery the protrusion on the adapter should face towards the battery; the label should face outside. Rotate the adapter 180 degrees and reinsert it into the battery if it does not plug in

➥ **Note**: the lite battery Charger Adapter can plug into the Extra Power battery however charging time will double.

7.1.4. Plug the Extra Power battery charger into an AC electrical outlet.

➥ **Note:** the Extra Power battery shall **only** be charged by its designated Charger Adapter (QIF03-CHA1002).

➥ **Note:** in the event that the Extra Power battery temperature is high, and as a safety mechanism, charging will only commence once it cools down.

Allow the battery to charge until it reaches full capacity: a green LED on the lite charger will indicate that the battery reached full capacity. For a fully depleted battery, and assuming that charging starts immediately (i.e. the battery does not need to cool-down, as explained above), the charging process is expected to last approximately 3 hours.

Once the battery reaches full capacity, disconnect it from the charger and place the battery inside the Base Unit or store it for later use. There is no degradation in the battery capacity should you select to keep the battery connected to the charger for longer time.

The battery does not have a memory effect and may be recharged even though it has not been fully discharged. If the battery has reached its end of life, please contact your QinFlow representative for purchasing a new battery.

➥ **Important!** Recharge the battery after each use and ensure that it is fully charged as part of your preparation-for-use protocols. To check battery status, simply connect it to the Base Unit and press the On/Off switch.

Store only fully charged batteries.

When placed in long storage, charge the battery every 4-6 months.

⚠ **WARNING:** Never throw the battery into the trash. The battery should be disposed of at a designated battery disposable collection point.

7.2. Connecting the Battery to the Base Unit

Insert the battery into the Base Unit and properly lock the side latches which are located on both sides of the Base Unit. The latches fit both types of batteries (i.e. the lite and the Extra Power battery). NOTE: to protect the Base Unit's battery pins, place the battery directly below the Base Unit when inserting the battery.

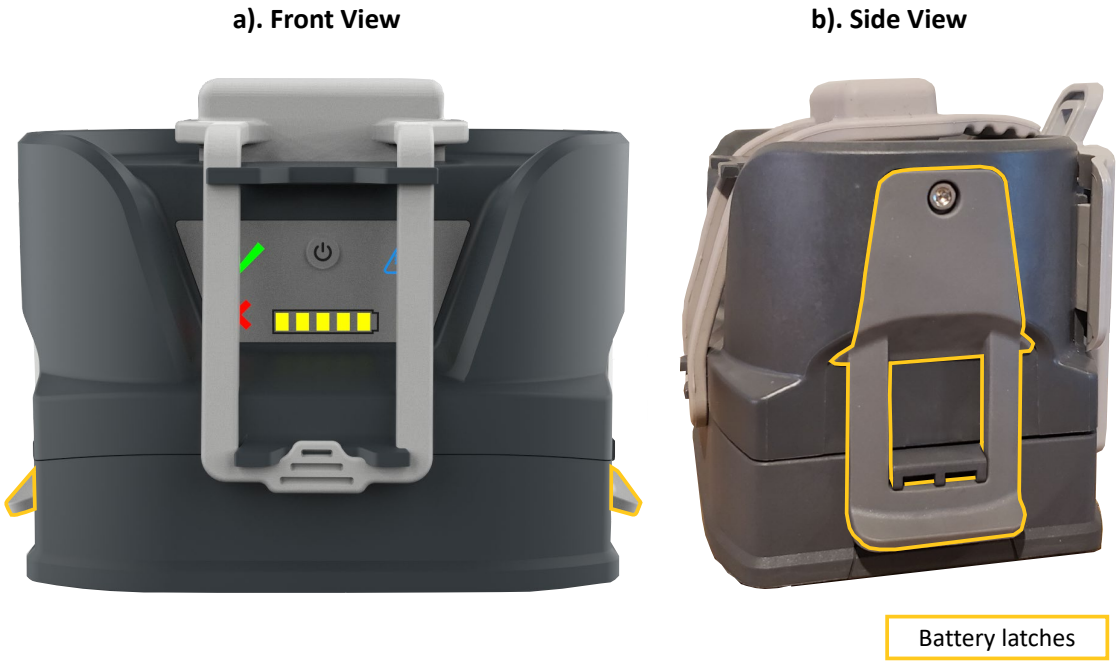


Figure 8. Battery latches (a) Front View & (b) Side View

Pay attention to the correct battery insertion orientation. If you insert the battery in the wrong orientation, the battery will not dock with the **Base Unit**. If this happens, turn the battery 180 degrees and reinsert it into the **Base Unit**.

For more instructions on how to replace the battery during administration, see section 7.7.

For checking the battery level and the indications panel LED lights, switch on the Base Unit, by pressing the On/Off switch on the indications panel. The indication panel LED lights will light up and the battery level will show on the battery bar lights.

If possible, maintain a spare battery to ensure continuous operation in the event that your battery runs out of power during administration.

7.3. Preparing the CDU

Ensure that the CDU package integrity has not been compromised and that the date has not expired.

Do not use the CDU if the sterile package is damaged or is not fully sealed.

YY/MM; Do not use if the date has passed the end of the indicated expiration month (i.e. 20/03, valid until 31st of March 2020).

Make sure that you have an Extension Cable in the event that DU is used (and not CDU).

STEP 2: CONNECT

7.4. Connecting the Compact Disposable Unit To the Fluid Bag and Flushing the Air out of the Line

⚠**WARNING:** Follow all the instructions provided by the manufacturer of the blood/intravenous fluid administration set when administrating blood or fluids through the Warrior lite.

Do not use the CDU if the sterile package is damaged or is not fully sealed.

Do not reuse the CDU. The Compact Disposable Unit is for a single use only.

YY/MM; Do not use if the date has passed the end of the indicated expiration month (i.e. 20/03, valid until 31st of March 2020).

Do not re-sterilize the Compact Disposable Unit.

The Warrior lite is compatible with any standard IV / blood administration set that utilizes standard Luer connections.

Open the CDU sterile package.

Remove the Inlet Luer cap from the inlet tube of the CDU (marked as "IN" on the CDU casing).

Connect the IV / blood tubing outlet Luer to the Inlet Luer of the CDU, and tighten until resistance is met.

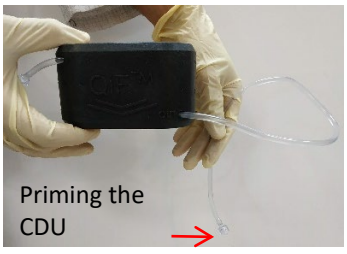
➥ **Note:** When connecting the IV / blood tubing to the Inlet Luer do not over tighten! (apply similar force as applied when connecting the IV / blood tubing to the catheter).

Remove the Outlet Luer cap from the outlet end of the outlet tube (marked as "OUT" on the CDU casing).

The outlet tube connects to the catheter.

Connect the IV / blood line to the fluid bag and flush the line with the intravenous fluid / blood.

The priming volume is approximately 19 ml.



⚠ **WARNING**: Always flush the line with intravenous fluid / blood / blood product before administrating to patient.

⚠ **WARNING**: Warming medications through the Warrior lite was not validated.

➥ **Note**: The CDU is a single use item, supplied sterile and ready for use. If cleaning during use is necessary, wipe the external surfaces of the Compact Disposable Unit with a damp cloth with water or alcohol (Iso-Propanol/Ethanol).

STEP 3: OPERATE

7.5. Connecting the CDU to the Base Unit

➥ **Note:** When connecting the CDU to the Base Unit, verify that the protruding arrows on the CDU face the front of the Base Unit (i.e. the indications panel).

➥ **Note:** The DU can only be connected to the Base Unit by using an Extension Cable. The CDU can be connected directly to the top of the Base Unit or through an Extension Cable.

➥ **Note:** When connecting the CDU to the Base Unit, heating will commence automatically.

⚠ Pushing IV fluids / blood at flow rates higher than 170 ml/min (with lite battery) or 180 ml/min (with Extra Power battery) by using for example a pressure infusion bag or a pump may result in output temperature lower than 38 ± 2 °C.

⚠ **WARNING:** Do not use the Warrior lite in MRI, X-ray and CT environments.

⚠ Warming medications through the Warrior lite was not validated

⚠ No modification of this equipment is allowed!

Use of the Warrior lite inconsistent with these Instructions for Use may result in failure of the system or injury to patient or to the caregiver.

Remove the connector cap at the top of the Base Unit and connect the CDU to the connector. Optionally, you may use an Extension Cable.

Once the CDU is connected to the Base Unit, the Base Unit will turn on automatically and start heating. Make sure that all indication lights turn on and then secure the CDU to the Base Unit using the strap.

➥ **Note:** In case that the Base Unit does not turn on automatically when connecting the CDU, use the On/Off button to turn on the system.

7.6. Warming Blood / Blood Products or Intravenous Fluids

⚠ **WARNING:** Always flush the line with intravenous fluid / blood / blood product before administration to the patient

Once the CDU is primed and connected to the Base Unit, you can start delivering warm IV fluid / blood / blood products to your patient. The system will reach the set-point temperature in a few seconds.

Verify that the system operates normally by checking the indications panel from time to time. System indications and troubleshooting are detailed in section 8.

➥ **Note:** Follow the fluid or blood administration instructions provided by the manufacturer of the IV fluids / blood administration set and the protocols of your organization.

➥ **Note**: You can administer several fluid bags using the same CDU. The Warrior lite does not need to be shut off while replacing the IV fluid / blood bag.

➥ **Note**: During infusate administration, the Base Unit can be positioned beside the patient in an upright position or on its back, ensuring the indication panel is visible to the caregiver. The Warrior lite can also be mounted on an IV pole, rail, gurney, or rack using the Mount Adapter. Strap and carabiner can also be used to fix the Warrior lite.

➥ **Note**: The CDU can be located beside the patient or hung on a pole / gurney in a secured position to avoid a sudden pull.

⚠ **WARNING:** Do not cover the Indication Panel.

⚠ **WARNING:** Do not use the Warrior lite if there is a malfunction in the indication panel.

7.7. Battery Level and Battery Replacement

The battery status is reported by 5 green LED bars on the indications panel.

The number of active LED bars indicate the charge level.

When the battery is near exhaustion, all battery LED bars blink. The system will continue to warm fluids until it is fully depleted. At this point, the system will shut off without notice.

During battery replacement there is no need to stop the fluid flow; however, unheated fluid will flow through the system during this time.

To replace the lite battery/Extra power battery and resume heating, follow the instructions below without delay.

A. Shut off the Warrior lite Base Unit by pressing the On/Off switch on the indications panel. Note: to avoid accidental power off, the system will turn off after long press of ~3 seconds.

⚠ **WARNING:** While the Base Unit is in the “Off” position, the fluid/blood continues flowing through the system without being warmed until the system is turned on, completes initialization and resumes warming.

B. Remove the empty battery from the Warrior lite by releasing the two side latches and pulling out the battery.

C. Replace the empty battery with a fully charged battery and lock the side latches.

NOTE: to protect the Base Unit's battery pins, place the battery directly below the Base Unit when inserting the battery.

Pay attention to the correct battery insertion orientation. If you insert the battery in the wrong orientation, the battery will not dock with the **Base Unit**. If this happens, turn the battery 180 degrees and reinsert it into the **Base Unit**.

D. The system shall turn on automatically after inserting the battery (if not, press the On/Off switch on the indications panel). The indication panel LED lights will light up and the system will start warming the fluids inside the CDU.

E. Start (or continue) flowing IV fluid / blood through the CDU. The system will reach the set-point temperature in a few seconds.

7.8. Stopping Fluid / Blood Warming

You do not have to replace the CDU when replacing the fluid or blood bag. You can administer several fluid / blood / blood products bags using the same CDU.

You do not have to shut off the Warrior lite system when replacing the fluid / blood / blood product bag.

Always replace the CDU when replacing the blood administration set (repeat the stages detailed in 7.3-7.4 above).

⚠ **WARNING:** Always flush the line with intravenous fluid / blood / blood product before administration to the patient's body.

Notes Regarding Stopping the Warm IV Fluids / Blood Administration Process:

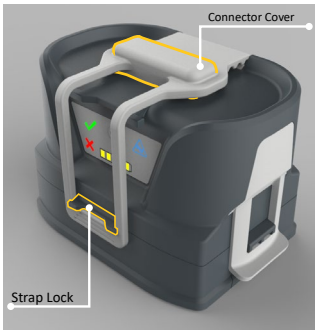
A. When you decide to stop the blood / intravenous fluid administration, stop the flow, and disconnect the CDU outlet from intravenous catheter and Base Unit.

B. When the CDU is disconnected from the Base Unit, the Base Unit will shut off automatically and stop warming.

C. If you wish to stop the warming without disconnecting the CDU, press the on/off button for ~ 3 sec until the indication panel shuts off.

D. If you wish to disconnect the CDU from your device and reconnect it to another Warrior device (e.g. transfer patient from Warrior lite device at the point of injury to a Warrior device positioned on a critical care transport platform), simply unplug the CDU and replug it to the other Warrior device, without disconnecting the patient.

E. Clean reusable components in accordance with the cleaning guidelines in section 10. Cover the Base Unit connector.



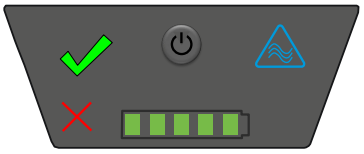
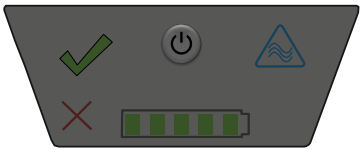
F. Fully charge the battery. In the event that the lite battery/Extra power battery temperature is high, and as a safety mechanism, the charging will only commence once it cools down.

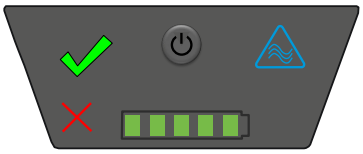
G. Dispose of the CDU taking biohazard precautions.

8. System Notifications and Troubleshooting

The following table provides descriptions of the system visual indications and messages and suggested user actions to resume operation (where applicable).

Table 3. System Notifications and Troubleshooting

State	Indications on Panel	User Action (if required)
Activation and Start Heating: flushed CDU is connected to the Base Unit. The system is powered on and commences initialization.	All indication panel lights turn on for few seconds.  Thereafter, the blue and red indications disappear while the battery lights remain on and the green ✓ light starts blinking	A. Monitor the indications panel and make sure that all indications appear during activation. B. Do not operate the unit if part of the indications are not presented during the initialization stage
Reaching Set Temperature: flushed CDU is connected; the system starts heating until reaching set temperature (38 ± 2 °C / 100.4 ± 3.6 ºF).	The battery lights are on and the green ✓ light blinks. When blinking stops and steady ✓ light appears, it indicates that set temperature has been reached 	Keep monitoring the indications panel. After connecting the CDU, there is no need to wait for the green ✓ light to stop blinking before resuming the flow. Target temperature will be reached in seconds
No Indications on Panel: CDU is connected but the system does not turn on and perform initialization	No indications on panel 	A. Press the on/off switch and check the battery level. B. If there are no indications on the panel, replace the battery with a fully charged battery. C. If the issue repeats – replace the CDU D. If the problem is not resolved, do not use the device and contact the manufacturer or its representative for service.
Fluid/Blood Temperature Is Below Set-Point Temperature (i.e. below 36 °C / 96.8 °F): the flow-rate is higher than the system's delivery capabilities*. * The max delivery rate is dependent on battery type, charging status, ambient conditions, and flow rates	The battery lights and the blue indication are on 	A. Reduce the flow rate until the blue indication light disappears

State	Indications on Panel	User Action (if required)
Trouble Shooting Required: (system error X sign results from either internal communication problem between the CDU and the BU or represents warming cutoff to prevent overheating)	The battery lights and a steady red X light are on 	A. Fix flow complications and restart the unit. Ensure that the CDU is primed. B. Shut off the system, replace the CDU with a new one, flush the air out of the fluid line, and connect it to the BU. C. If the problem is not resolved do not use the device; contact QinFlow or its representative for service.
Battery Level is Low	One bar remains on the battery bar indication. (the battery indication can be shown during operation along with green ✓ light) 	Keep track on the battery status; the battery is close to be depleted. Consider to replacing the battery.
Battery Level is Critically Low (soon to be completely depleted)	All battery LED lights blink. In addition, at this state the blue light may turn on as well, subject to flow rate. 	The system will continue to warm fluids until the battery is fully depleted. At a certain point, the system will shut off without notice. Replace the empty battery with a fully charged lite battery (see section 7.7 for instructions).
System Indications and Battery Level Check: the system is powered on through the on/off switch and commences initialization. Note: warming will not start until CDU is connected	The battery indication lights turn on for few seconds to indicate the battery status. Thereafter, all indication panel lights turn on for few seconds. 	A. Monitor the indications panel. B. If the initialization passed successfully, all the indication panel lights turn on and then turn off after approximately 3 seconds. C. Make sure that all indication panel lights appear during activation. D. Do not operate the unit if some or all the indications are not presented during the initialization stage E. If the initialization process failed, the battery light and X light will appear.

9. Specifications and Characteristics

➥**Note:** Operating the Warrior lite out of its design specifications may result in a lower outflow temperature and/or damage to the system.

➥**Note:** Warrior lite is IEC60601-1-12 certified

➥**Note:** Warrior lite complies with MIL-STD 461G RE102 & RS103

9.1. Electrical Specifications

Table 4. Electrical Specifications

Parameter	Value
Nominal Input Voltage	18 VDC from a fully charged battery
Max Current	26 A
lite battery life expectancy	Up to 250 charging cycles
Extra Power battery life expectancy	Up to 350 charging cycles
lite battery Charger – • FUYUANG CH21V1A-01 or • MASCOT 2240Li	 100-240 VAC 50-60 Hz Max 1.0 A
Extra power battery charger – FUYUANG CH21V2A-01	 100-240 VAC 50-60 Hz Max 2.0 A
Defibrillation Proof type CF Applied Part	 The CDU is safe to be used when joined with a defibrillator

9.2. Physical Properties

Table 5. Physical Properties

Parameter	Value
Weight of Base Unit with lite battery	Approximately 800 g (1.76 lb)
Weight of Base Unit with Extra Power battery	Approximately 1088 g (2.39 lb)
Dimensions of Base Unit with lite battery (H × W × L)	Approximately 84×88×115 mm (3.30×3.46×4.52 in)
Dimensions of Base Unit with Extra Power battery (H × W × L)	Approximately 105×88×115 mm (4.13×3.46×4.52 in)
Weight of Compact Disposable Unit in sterile bag	Approximately 117 g (0.26 lb)
Dimensions of Compact Disposable Unit (H × W × L)	Approximately 72.2×68.5×117.5 mm (2.84×2.70×4.63 in)

9.3. Environmental Conditions

Table 6. Environmental Conditions

Parameter	Value
Storage & Transport conditions	-20 °C to 70 °C & 93% RH (-4 °F to 158 °F & 93% RH)
Operation Temperature & Humidity	-5 °C to 50 °C & 90% RH (23 °F to 122 °F & 90% RH)
Transient Operating Conditions	-20 °C to + 50 °C & 90% RH
Atmospheric Pressure/(Altitude)	549 to 1,060 hPa (-400 to 4,572 meters); (-1312 to 15,000 ft)
CDU Shelf Life	3 years
Base Unit Service Life*	5 years
Water and particles Ingress rate**	IP56

* The Base Unit does not require any calibration or maintenance. At the end of the service life period, turn to the manufacturer for Base Unit refurbishing options.

** The system components water and particles Ingress rate (IP rating) is the Base Unit IP rating when connected

9.4. Electromagnetic Compatibility (EMC) Conditions

Table 7. Electromagnetic Compatibility Conditions

Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The QIF-03 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
RF emissions CISPR 11	Class B	The QIF-03 is battery powered equipment.
Harmonic emissions IEC 61000-3-2	Not required	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not required	

Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby

equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Warrior lite device or shielding the location.

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.

Warning: Use of accessories, 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.

Warning: 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 QIF-03, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: QIF-03 needs special precautions regarding EMC and needs to be installed and put into service according to the specific instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life provided in section 7.

Essential performance of the Warrior lite device is that the outflow temperature stabilizes on 38 ± 2 °C (100.4 ± 3.6 ºF).

Warrior lite device shall only be used with the cables provided by the manufacturer. Base Unit cable length is approximately 1.4 Meter (approximately 55 in.).

Portable and mobile RF communications equipment can affect the Warrior lite device.

The system may recognize the disturbance and initialize a self-test.

Table 8. Electromagnetic interference resistance

Immunity test	**IEC 60601 level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 5 %.
Electrical fast transient/burst, IEC 61000-4-4	2 kV for power supply lines 1 kV for SIP/SOP lines	Not required	The QIF-03 is battery powered equipment.
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	Not required	The QIF-03 is battery powered equipment.

Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	Not required	The QIF-03 is battery powered equipment.
Power frequency magnetic field, IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Table 9. Electromagnetic Interference Resistance

Immunity test	**IEC 60601 level**	**Compliance level**
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz)	[V] = 3 Vrms [V] = 6 Vrms
IEC 61000-4-3 Radiated RF	10 V/m 80 MHz to 2.7 GHz	[E] = 10 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	

	1720 MHz	
	1845 MHz	
	1970 MHz	
	2450 MHz	
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	
IEC 61000-4-39 Immunity to magnetic fields in close proximity	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz

Table 10. Recommended Safety Distances between Portable and Mobile RF Telecommunications Devices

Recommended safety distances between portable and mobile RF telecommunications devices and the Warrior lite			
The Warrior lite is intended for use in an electromagnetic environment in which radiated RF disturbance variables are controlled. The customer or user of the Warrior lite can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Warrior lite as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Protection distance according to transmitter frequency m**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.7\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended distance can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

10. Cleaning the System

10.1. Cleaning the CDU

a. STERILE EO The CDU is provided sterile and ready for use.

b. The CDU is a single patient use item; do not reuse it!

c. **WARNING**: Do not submerge, sterilize or autoclave the CDU. Deconex® SOLARSEPT

10.2. Cleaning and disinfecting the Base Unit and Battery

The Warrior lite reusable parts -- Base Unit, battery, Extension Cable and Mount Accessory -- are supplied non-sterile and should be surface cleaned/disinfected after each patient use.

Before cleaning, disconnect the Battery form the BU.

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.

The following process was validated in accordance with 2015 FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling":

a. Cleaning and disinfection procedure shall perform with damp cloth with 70 % medical grade alcohol solution (i.e Isopropyl, Ethanol), Deconex® SOLARSEPT or a medical grade wipe soaked with 70% alcohol.

b. After each use, clean all exterior surfaces of the reusable parts.

c. Use a soft bristle brush, moistened with 70% medical grade alcohol / Deconex® SOLARSEPT solution, to thoroughly clean all grooves.

d. Repeat wiping the components using a damp cloth.

e. The components shall be placed on a clean surface and allowed to completely dry.

* if the device is determined not to be visually clean at the end of the cleaning step, please repeat the relevant previous cleaning steps or contact the manufacturer for further instructions.

WARNING: Do not submerge, sterilize or autoclave the Warrior lite reusable parts.

11. System Precautions

a. Do not use the Warrior lite if the visual indications are not functioning.

b. For blood / blood product / intravenous fluid infusion instructions, refer to your facility / organization protocol.

c. Always use with a designated standard blood / intravenous fluid administration set.

d. Follow all the instructions provided with the blood / intravenous fluid administration set when infusing blood / blood product / intravenous fluid through the CDU.

e. Always position the CDU under the fluid bag, between the IV / blood bag and patient, and connect it using a standard IV / blood administration set.

f. In case of a problem or error that is not resolved following the troubleshooting instructions, contact the manufacturer or its representative. Do not use this system until it is repaired or replaced by Quality in Flow Ltd., or one of its representatives.

g. Always replace the CDU when replacing a blood administration set.

h. Charge the rechargeable lite battery only with the supplied FUYUANG CH21V1A-01 or MASCOT 2240Li lite battery charger.

i. Charge the rechargeable Extra Power battery only with the supplied FUYUANG CH21V2A-01 Extra Power battery charger.

12. ⚠ Warnings

a. Never throw the battery into the trash. The battery contain toxic materials and need to be disposed of at a designated battery disposable collection point.

b. Pushing IV fluids / blood at flow rates higher than 170 ml/min (with lite battery) or 180 ml/min (with Extra Power battery) by using for example a pressure infusion bag or a pump may result in output temperature lower than 38 ± 2 °C.

c. Do not use the Warrior lite in MRI, X-ray and CT environments.

d. Warming medications through the Warrior lite was not validated.

e. No modification of this equipment is allowed!

f. Use of the Warrior lite not according to its instructions may result in failure of the system or injury to user or patient.

g.  Do not use the CDU if the sterile package is damaged.

h.  The CDU is for single use only and does not require any calibration or maintenance. Do not reuse it! Re-use of the product can cause Infection and contamination.

i. 

Do not re-sterilize the Compact Disposable Unit.

13. Disclaimer

Quality in Flow Ltd. shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of the Warrior lite, other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto.

14. Warranty

The Warrior lite is manufactured by Quality in Flow Ltd. and is warranted to be free from manufacturer defects. The system is covered for one year from date of purchase.

15. Support, Service, and Subsequent Order Information

For support, service, and subsequent order information contact:

info@qinflow.com or support@qinflow.com.

Note: we offer premium support packages with extended warranty options. Contact us for more information.

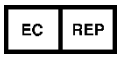
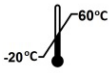
16. Part Number Information

Table 11. Part Numbers

Part Number	Suffix	Description	Comments
QIF03-BUA1000	SUC	Base Unit	The unit's controller
QIF03-BTA1000	SUC	lite Battery	-
QIF03-BTA2000	SUC	Extra Power Battery	-
QIF03-CHR1000	N/A	lite Battery Charger	Model FUYUANG CH21V1A-01 or MASCOT 2240Li Or MASCOT 2240Li
FY2102000	N/A	Extra Power Battery Charger	Model FUYUANG CH21V2A-01
QIF03-CHA1001	N/A	lite battery Charger Adapter	Adapter for charging the lite battery
QIF03-CHA1002	N/A	Extra Power battery Charger Adapter	Adapter for charging the Extra Power battery
QIF03-SBG1000	N/A	Carrying Bag with lite battery	-
QIF03-SBG2000	N/A	Carrying Bag with Extra Power battery	-
QIF03-MUA1000	N/A	Mounting Accessory	Pole or rail mounting option
QIF-CBL00019	N/A	Extension Cable	140 cm / ~4.6 ft. BU-DU extension option
QPORT0500	SUC	Compact DU	-

17. Symbols and Legends

Table 12. Symbols and Legends

Symbol	Description
	Manufacturer
	Authorized representative in the European community
	Catalogue number
	Serial Number
	Warning
	Refer to instruction manual/booklet
	Defibrillation proof CF applied part
	Temperature limitation
	Do NOT reuse
 YY/MM	Use by YY/MM (meaning the end of the indicated month. i.e., 20/03 is valid until March 2020)
	Do NOT re-sterilize
	Sterilized using Ethylene Oxide
	Do NOT use if package is damaged
	Keep away from sunlight
	Do NOT throw to trash
IP56	Water and particles ingress rate: dust protected; Powerful water jets protected
	Non pyrogenic fluid path - the CDU is free of substances that might produce fever
Temp. set point: 38 °C (100.4 °F)	Temperature is set to 38 °C (100.4 °F)