

**NO MORE COLD BLOOD & FLUIDS**

# **Warrior Extreme Blood and Fluid Warmer Model QIF-01-12**



## **Instruction for Use (IFU)**

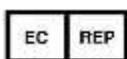
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Do not use the Warrior Extreme system before viewing training materials and carefully reading the following instruction for use!

## 1. Indications for Use

QinFlow (QiF) **Blood and Fluid Warmer** device (the “Warrior Extreme”) 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. Package Contents

The Warrior Extreme package includes the following items:



**Figure 1. Package contents**

- a. One Base Unit (BU) (item a).
- b. One Rechargeable Battery (item b).
- c. One Battery Charger – model Fuyuang FY2552000 (item c).
- d. One Charger adapter (item d).
- e. Quick user guide

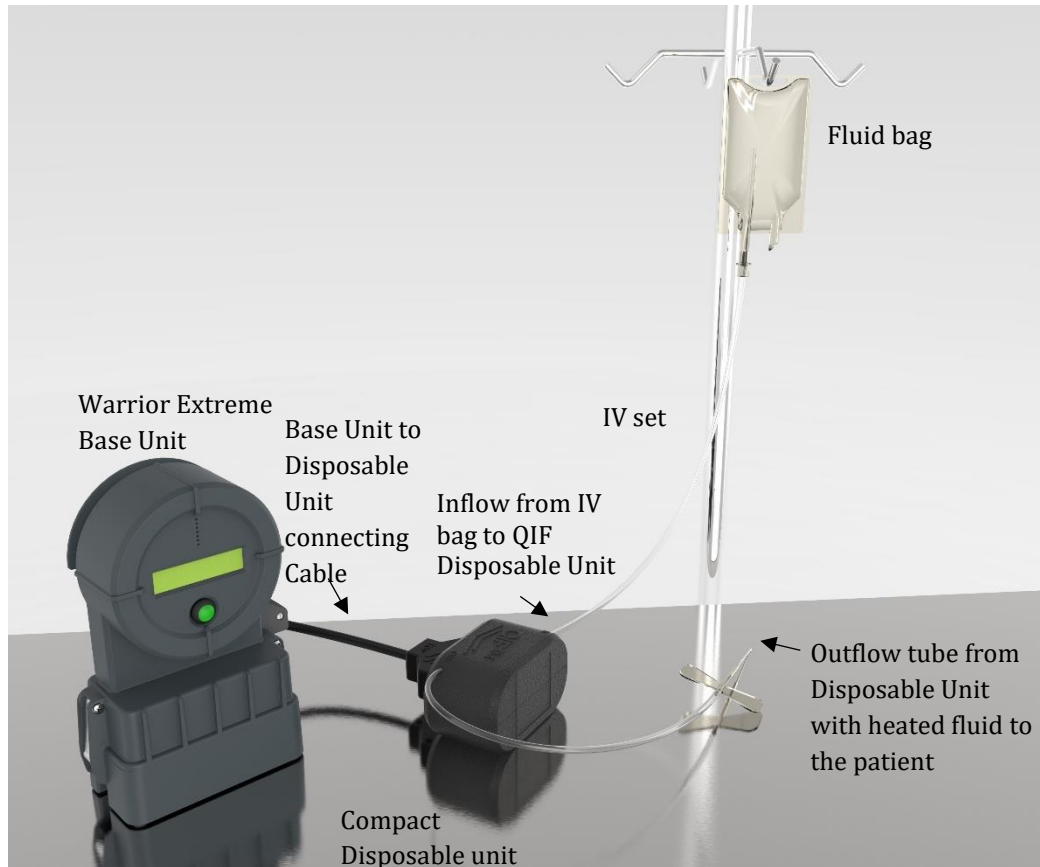
\* The **Warrior Extreme** is provided in a hand carry bag. The bag can contain one additional battery, and its top compartment can be used for carrying two Disposable Units (DU) or up to 4 Compact Disposable Unit.

## 4. System Description

### *What is the Warrior Extreme Blood and Fluid Warmer?*

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

The system is positioned out of the patient's body, between the IV tubing and the patient, with a temperature set point of  $38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$  ( $100.4\text{ }^{\circ}\text{F} \pm 3.6\text{ }^{\circ}\text{F}$ ). The Warrior Extreme provides both audio and visual notifications.



**Figure 2. Warrior Extreme Blood and Fluid Warmer (illustrated set-up)**

## 5. System Components

The **Warrior Extreme** includes a reusable Base Unit and a sterile, single patient use disposable cartridge, called the Disposable Unit (DU) or Compact Disposable Unit (CDU).

### 5.1 Base Unit

The **Base Unit** comprises an LCD, On/Off switch, green pushbutton, and a detachable rechargeable battery. It also includes a connecting cable that when not in use, is wrapped around its back side.

The battery is inserted from the bottom of the Base Unit.

The LCD, located on the front of the Base Unit, displays the fluid outflow and inflow temperature, the battery charging level and additional notifications described later on.

The On/Off button is on the Base Unit rear side and the green Mute/"Self-Test" button is on the Base Unit front side.

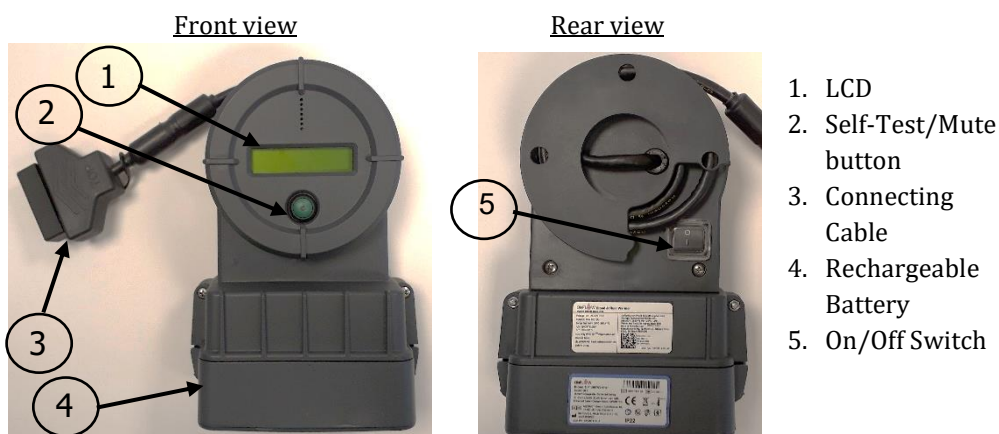


Figure 3. Base Unit front and rear views

### 5.2 Disposable Unit / Compact Disposable Unit

The **Disposable Unit / Compact Disposable Unit** is a sterile, single patient use disposable cartridge which includes a heat exchanger. At the bottom of the Disposable Unit are inlet and outlet fluid flow Luer connectors.

The Fluid Bag is connected with a standard IV / blood administration set to the Disposable Unit **Inlet Luer**. The **Outlet Luer** of the **Disposable Unit / Compact Disposable Unit** is connected to a standard Venflon.

The Compact DU connections to the Base Unit cable and IV / blood administration set are identical to the connections of the Disposable Unit.

A connecting cable connects between the **Base Unit** and the **Disposable Unit / Compact Disposable Unit**.

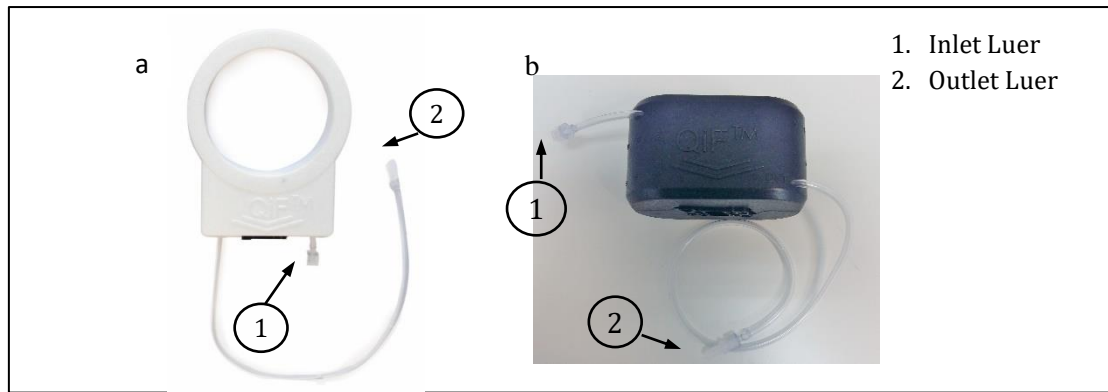


Figure 4. a) Disposable Unit b) Compact Disposable Unit

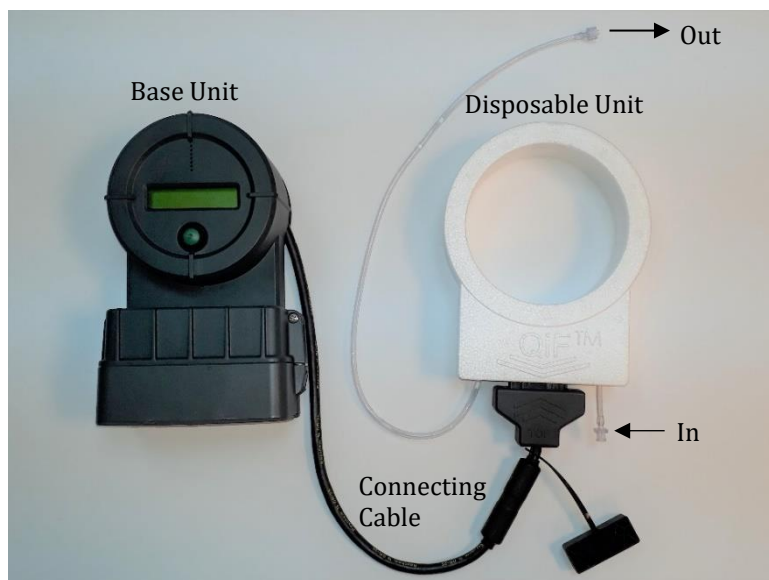


Figure 5a. Base Unit connected to the Disposable Unit

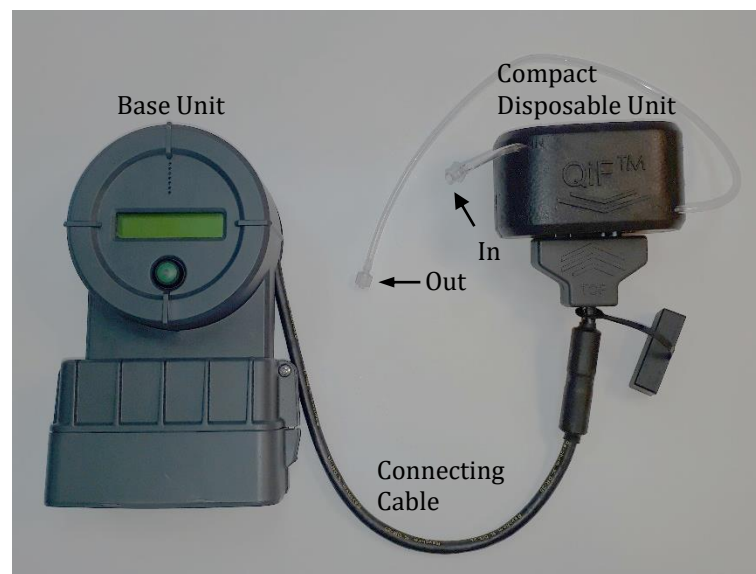


Figure 5b. Base Unit connected to the Compact Disposable Unit

### 5.3 Intended Users

#### *Who should use the Warrior Extreme Blood and Fluid Warmer?*

The Warrior Extreme 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.

### 5.4 Fluid Warming Capacity

#### *How much fluid can the Warrior Extreme warm using a fully charged battery?*

The amount of fluid the Warrior Extreme can warm depends on the battery charge level, inlet fluid temperature and flow rate.



When using a fully charged battery, at flow rate of 160–180 ml/min, the Warrior Extreme can warm up to three liters of parenterally administered fluid with an inlet temperature of 4 °C (39.2 °F).

When there are extreme changes in the flow rate or the inlet fluid temperature, the Warrior Extreme will require an adjustment period of up to 20 seconds. A set of internal sensors constantly measure the fluid temperature and adjust the power supplied to the heat exchanger accordingly.

## 6. Preparing and Operating the System

### 6.1 Charging the Battery

The Warrior Extreme is powered by a rechargeable battery, which should be fully charged before use. The battery shall be charged using the supplied Battery Charger model FUYUANG FY2552000. Charging requires 120/240 [V], 50/60 Hz.

<p>a.</p>	<p>Plug the Battery into the Battery Charger using the charger adapter, and plug the Battery Charger into an AC electrical outlet.</p> <p>➔ <b>Note:</b> the battery shall be charged using <b>only</b> its designated charging adapter.</p> <p>➔ <b>Note:</b> the battery charger adapter shall be attached to the battery in the correct orientation: the charger adapter label is on the <b>opposite</b> side of the battery label, as shown in the picture on the right</p>	
<p>b.</p>	<p>Allow the battery to charge until the battery is fully charged. When the battery is fully charged, the battery charger green LED lights.</p> <p>(This is expected to be approximately 4—5 hours if the battery is empty).</p> <p>When the battery is fully charged, disconnect the battery from the battery charger adapter and place the battery inside the Base Unit or store it for later use.</p>	
	<p>➔ <b>Note:</b> The battery has a correct insertion orientation. Before inserting, make sure the battery label is alongside the Base Unit label. If the battery is inserted in the wrong orientation, the battery will not dock into the Base Unit.</p>	

➔ **Important!** Recharge the Battery after each use and ensure it is full before each use

Store only fully charged batteries.

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










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

## 6.2 Preparing the System for Warming





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

**Note:** The following instruction show the Disposable Unit yet they also apply to the Compact Disposable Unit; the connection of the Compact Disposable Unit to the Base Unit and IV set are identical to the Disposable Unit connections. See section 5.2 for more details.

<p>a.</p>	<p>The Disposable Unit / Compact Disposable Unit cartridge is provided sterile in a sterile bag. Visually inspect the Disposable Unit / Compact Disposable Unit package before opening to ensure that there is no damage to the packaging or to the product.</p> <p> Do not use the Disposable Unit / Compact Disposable Unit if the sterile package is damaged or is not fully sealed.</p> <p> Do not reuse the Disposable Unit / Compact Disposable Unit. The Disposable Unit is for a single use only.</p> <p> YY/MM; Do not use if the date has passed the end of the indicated expiration month (i.e. 20/03, valid until 31<sup>st</sup> of March 2020).</p> <p> Do not re-sterilize the Disposable Unit / Compact Disposable Unit</p>	
<p>b.</p>	<p>Insert the battery into the Base Unit and close the side latches.</p> <p>Pay attention to the correct battery insertion orientation: the battery label should be alongside the <b>Base Unit</b> label. If you insert the battery in the wrong orientation, the battery will not dock with the <b>Base Unit</b>. If this happens, remove the battery, turn it 180 degrees and reinsert into the <b>Base Unit</b>.</p> <p>For more instructions on how to replace the battery during administration, see section 6.9.</p>	

c.	Open the Disposable Unit / Compact Disposable Unit sterile package.	
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### 6.3 Connecting the Base Unit to the Disposable Unit / Compact Disposable Unit

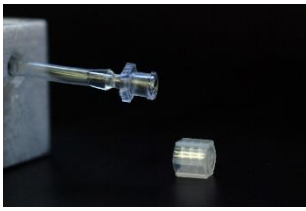
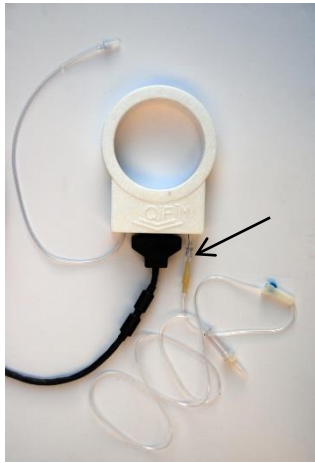
	<p>➡ <b>Note:</b> When connecting the cable to the Disposable / Compact Disposable Unit, verify the top side of the cable connector is next to the protrusions on top of the Disposable Unit / Compact Disposable Unit</p>	 
d.	Connect the Base Unit cable to the Disposable Unit / Compact Disposable Unit	 

## 6.4 Connecting the Warrior Extreme to the Fluid Bag and Patient

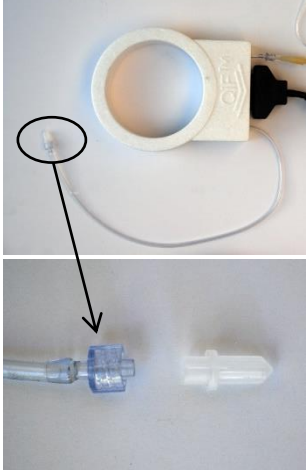
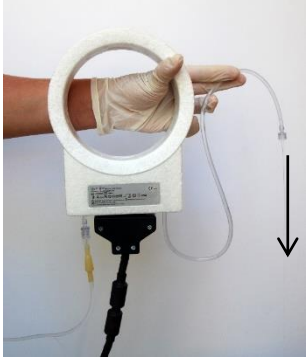
The Warrior Extreme is compatible with any standard IV administration set that utilizes standard Luer connections.

**⚠ WARNINGS:**

- Warming IV fluids/blood at flow rates higher than 200 ml/min (for example by using a pressure infusion bag or fluid pump) may result in temperature outputs of lower than  $38 \pm 2$  °C.
- Do not use Warrior Extreme in MRI, X-ray and CT environments!
- Warming medications through the Warrior Extreme was not validated!
- No modification of this equipment is allowed!
- Use of the Warrior Extreme inconsistent with its instructions may result in failure of the system or injury to patient.



a.	<p>Remove the Inlet Luer cap from the inlet tube of the Disposable Unit / Compact Disposable Unit (marked as "IN" on the DU casing). The inlet tube connects to the IV set outlet.</p>	
	<p>➡ <b>Note:</b> When connecting the IV tubing to the Inlet Luer do not over tighten! (apply similar force as applied when connecting the IV tubing to the venflon).</p>	
b.	<p>Connect IV tubing to the Inlet Luer, and tighten until resistance is met.</p>	

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<p>c.</p>	<p>Remove the Outlet Luer cap from the outlet end of the IV extension tube (marked as "OUT" on the DU casing). The outlet tube connects to the venflon.</p>	
	<p><b>⚠ WARNING:</b> Always flush the line with intravenous fluid / blood / blood product before administrating to patient.</p> <p><b>⚠ WARNING:</b> Warming medications through the Warrior Extreme was not validated.</p> <p><b>➡ Note:</b> The Disposable Unit / Compact Disposable Unit is a single use item, supplied sterile and ready for use. If cleaning during use is necessary, wipe the external surfaces of the Disposable Unit / Compact Disposable Unit with a damp cloth with water or alcohol (Iso-Propanol/Ethanol).</p>	
<p>d.</p>	<p>Connect the IV line to the fluid bag and flush the line with the intravenous fluid/blood.</p>	 <p>Flowing Fluid/Blood through the Disposable Unit</p>

## 6.5 Warming Blood or Intravenous Fluid Products


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


a.	<p>Switch on the Base Unit, by moving the On/Off switch on the back side of the system to “I” position.</p> <p>The LCD displays the “Initializing...” message and you will hear a steady beep.</p>	
b.	<p>Start flowing IV fluid / blood through the Disposable Unit / Compact Disposable Unit. The system will reach the set-point temperature in a few seconds.</p> <p>During this time the LCD displays:</p> <p>Heating            Tout: outflow temp °C (inflow temperature °C); the temperature is presented in Celsius degrees (°C).            For example: “Tout: 38 °C (8 °C)”.</p>	
c.	<p>Verify the system warms the intravenous fluid, blood or blood product to the set-point temperature; and check the LCD display from time to time to verify normal system operation.</p> <p>Read the notification on the LCD display following each audio notification (short or steady beep).</p>	
d.	<p>From this stage on, follow the fluid or blood administration instructions provided by the manufacturer of the IV/blood administration set and your facility protocols.</p>	
	<p><b>➡ Note:</b> You can administer several fluid bags using the same Disposable Unit / Compact Disposable Unit. The Warrior Extreme does not need to be shut off while replacing the fluid bag.</p>	

## 6.6 General Operation Instructions

During infusate administration, the Base Unit can be positioned beside the patient in an upright position or on its back, ensuring the LCD is visible.

The Disposable Unit / Compact Disposable Unit can be located beside the patient or hung on a pole/gurney, in a secured place to avoid a sudden pull.

 **WARNING:** Do not cover the display or the speaker of the Base Unit.

 **WARNING:** Do not use the Warrior Extreme if there is a display and/or a speaker malfunction.

During administration keep track of the display and sound notifications. For details on system notifications and troubleshooting, see Chapter 7.

## 6.7 Self-Test

To check the Base Unit is properly communicating with the Disposable Unit / Compact Disposable Unit (i.e., in case the system is not heating the fluid/blood), use the “Self-Test” feature by pressing the green pushbutton for 3 seconds.



**Figure 5. Self-Test/Mute Button**

In “Self-Test” mode the blood or fluid flows through the system but is not warmed. See additional details in the troubleshooting chapter (Chapter 7).

## 6.8 Stopping the Warrior Extreme device Fluid / Blood Warming

You do not have to replace the **Disposable Unit / Compact Disposable Unit** when replacing the fluid or blood bag. You can administer several fluid bags using the same Disposable Unit / Compact Disposable Unit.

You do not have to shut off the **Warrior Extreme** system when replacing the fluid bag.

When blood / intravenous fluid administration is stopped, verify that the fluid / blood flow also stopped, and disconnect the **Disposable Unit / Compact Disposable Unit** outlet from intravenous catheter.

Always replace the **Disposable Unit / Compact Disposable Unit** when replacing the blood IV administration set, and repeat stages a—d in section 6.4 above.

Dispose of the **Disposable Unit / Compact Disposable Unit** taking biohazard precautions.

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

## 6.9 Battery Replacement during Administration


The battery status is reported by audio and visual notifications.

**Table 1. Battery Indications**





Battery Indications	Battery Status	Required Action
Note: Battery is getting Low! The LCD blinks, and a steady beep is sound.	25—30% capacity	Pay attention, a "Battery Empty" message will follow.
Battery Empty	5—10% capacity	The device will continue warming the fluid until the battery is fully depleted. The system will then shut down.

During battery replacement there is no need to stop the fluid flow; although unheated fluid will flow during this time.

To replace the battery and resume fluid heating, follow the instructions below without delay.

	<b>⚠ WARNING:</b> 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 starts warming again.	
a.	Shut off the Warrior Extreme Base Unit by pressing the On/Off switch on the back of the system to “0” position.	



<p>b.</p>	<p>Remove the empty battery from the Warrior Extreme by opening the two side latches and pulling out the battery.</p>	
<p>c.</p>	<p>Replace the empty battery with a fully charged battery and close the side latches. Pay attention to the correct battery insertion orientation: the battery label should be alongside the <b>Base Unit</b> label. If you insert the battery in the wrong orientation, the battery will not dock with the <b>Base Unit</b>. If this happens, remove the battery, turn it 180 degrees and reinsert into the <b>Base Unit</b>.</p>	
<p>d.</p>	<p>Switch on the Base Unit. The LCD displays the “Initializing...” message and a steady beep is sound. Start flowing IV fluid / blood through the Disposable Unit / Compact Disposable Unit The system will reach the set-point temperature in a few seconds. During this time the LCD displays: Heating Tout: outflow temp °C (inflow temperature °C); the temperature is presented in Celsius degrees (°C). For example: “Tout: 38 °C (8 °C)”.</p>	
<p>e.</p>	<p>Follow the fluid or blood administration instructions provided by the manufacturer of the IV/blood administration set and your facility protocols.</p>	



## 7. System Notifications and Troubleshooting

The following table provides descriptions of possible issues that may occur while operating the system including the visual and audible notifications, and suggested actions for fixing the problem.

**Table 2. System Notifications and Troubleshooting**

Description	LCD Notification	Audio Notification	User Action (if required)
System Initializing	QiF-01 (VX.X) Is Initializing	Steady beep	Monitor the LCD
System waiting for Disposable Unit / Compact Disposable Unit connection	System is Ready Connect the DU	No	Connect the <b>Base Unit</b> to the <b>Disposable Unit / Compact Disposable Unit</b> with the Connecting Cable.
Normal Operation	Heating Tout: XX °C (YY °C) XX °C is the outflow temperature; YY °C is the inflow temperature	No	Keep monitoring the LCD display
Fluid flow irregularities	Change in Flow	No	<ul style="list-style-type: none"> <li>• Open the IV set roller clamp until the required flow is reached.</li> <li>• Look for IV kink and release it.</li> <li>• Replace the IV tubing if necessary.</li> </ul>
No display on LCD, though the system is turned on	No display	No	Check the On/Off switch is turned on. If it is, replace the battery. If after replacing the battery the display is still not working, do not use this Warrior Extreme until repaired by the manufacturer or by its representative.
Fuel gauge	Battery bar	No	Monitor and pay attention to the battery status
Battery energy status is at 25-30% capacity	Note: Battery is Getting Low! The LCD blinks	Steady beep	Pay attention, a "Battery Empty" message will follow. You can Mute the audio notification with a short press on the Self-Test/Mute button.

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System Notifications and Troubleshooting



Description	LCD Notification	Audio Notification	User Action (if required)
Battery is critically low	Battery Empty Tout: XX °C (YY °C)	Steady beep	Replace the empty battery with a fully charged, battery (see section 6.9 for instructions). You can Mute the audio notification with a short press on the Self-Test/Mute button.
Fluid is warmer than 41 °C	Fluid is hot! Tout: XX °C (YY °C) The LCD blinks	No	"Fluid is Hot" message might appear due to flow irregularities (e.g. block, back flow, large bubbles) or sudden and significant changes in flow rate (e.g. changing from 180 ml/min to 40 ml/min).
Fluid is warmer than 42 °C	Fluid is hot!!! Tout: XX °C (YY °C) The LCD blinks	Steady beep	If none of the above conditions is apparent, turn off the Base Unit and replace the Disposable Unit / Compact Disposable Unit with a new one. You can mute the audio notification with a short press on the Self-Test/Mute button.
Fluid outflow temperature decreased to 35 °C (95 °F) or colder, even though it reached a temperature above 35 °C (95 °F) before.	T out indication is 35 °C (95 °F) or below	Short beep	Check if fluid input temperature is at least 4 °C (39.2 °F) and check the battery status.  Keep track of the LCD display.
System malfunction (HW/SW)	System Error	Steady beep	Make Sure that the Disposable Unit / Compact Disposable Unit is flushed and filled with fluid and restart the system by shutting it off and then on again.
General malfunction	*MALFUNCTION!!* Tout: XX °C (YY °C)  The LCD blinks	Steady beep	If the problem is not resolved shut off the system, replace the Disposable Unit / Compact Disposable Unit with a new one, flush the air out of the Disposable Unit / Compact Disposable Unit, and turn the system back on.  If the problem is not resolved contact the manufacturer or its representative.

## 8. Specifications and Characteristics

➔ **Note:** Operation out of the design specifications may result in a lower outflow temperature and/or damage to the system.

### 8.1 Electrical Specifications

**Table 3. Electrical Specifications**

Parameter	Value
Nominal Input Voltage	22 VDC from a fully charged battery
Max Current	26 A
Battery life expectancy	Up to 400 charging cycles
FUYUANG Charger FY2552000	 100–220 VAC 50–60 Hz Max 0.9 A
Defibrillation Proof type BF Applied Part	 The Disposable Unit / Compact Disposable Unit is safe to be used when joined with a defibrillator

### 8.2 Physical Properties

**Table 4. Physical Properties**

Parameter	Value
Weight of Base Unit with battery	Approximately 1720 g (3.79 lb)
Weight of Disposable Unit	Approximately 135 g (0.30 lb)
Weight of Compact Disposable Unit in sterile bag	Approximately 117 g (0.26 lb)
Dimensions of Base Unit with battery H × W × L	Approximately 232×156×78 mm (9.13×6.14×3.07 in)
Dimensions of Disposable Unit H × W × L	Approximately 210×159×44 mm (8.27×6.26×1.73 in)
Dimensions of Compact Disposable Unit H × W × L	Approximately 72.2x68.5x117.5 mm (2.84x2.70x4.63 in)

## 8.3 Environmental Conditions

**Table 5. Environmental Conditions**

Parameter	Value
Storage & Transport conditions	-20 °C to 60 °C & 93% RH (-4 °F to 140 °F & 93% RH)
Transient conditions	20 °C to + 50 °C & 15% to 90% RH
Storage conditions**	-30°C to 70°C (-22°F to 158°F)
Operation Temperature & Humidity	5 °C & 15% RH to 40 °C & 93% RH (41 °F & 15% RH to 104 °F & 93% RH)
Operating Temperature**	-5°C to 40°C (23°F to 104°F)
Atmospheric Pressure/(Altitude)***	549 to 1,060 hPa (-400 to 4,572 meters); (-1312 to 15,000 ft)
Disposable Unit/Compact Disposable Unit 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.

\*\* In Compliance with EN1789:2007 +A2:2014

\*\*\* In compliance with IEC60601-1-11:2010 section 4.2.2c

\*\*\*\* Water and particles Ingress rate (IP rating) of the system is the Base Unit IP

## 8.4 Electromagnetic Compatibility (EMC) Conditions

**Table 6. Electromagnetic Compatibility Conditions**

Emission Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	NA
RF emissions CISPR 11	Class B	The Warrior Extreme is 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.
Harmonic Emissions	NA	
Voltage Fluctuations	NA	

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 QiF 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.

Essential performance of the QiF device is that the outflow temperature stabilizes on  $38 \pm 2 \text{ }^\circ\text{C}$  ( $100.4 \pm 3.6 \text{ }^\circ\text{F}$ ).

QiF device shall only be used with the cables provided by the manufacturer. Base Unit cable length is 90cm (approximately 34 in.);

Portable and mobile RF communications equipment can affect the QiF device.

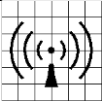
The system may recognize the disturbance and initialize a self-test.

**Table 7. Electromagnetic interference resistance**

<b>Guidelines and manufacturer's declaration – electromagnetic interference resistance</b>			
The QiF Warrior Extreme blood and fluid warmer is intended for use in the electro-magnetic environment specified below. The customer or the user of the QiF Warrior Extreme blood and fluid warmer should assure that it is used in such an environment.			
<b>Interference resistance test</b>	<b>IEC 60601-test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guideline</b>
Electrostatic discharge IEC 61000-4-2	$\pm 8 \text{ kV}$ contact  $\pm 15 \text{ kV}$  air	$\pm 8 \text{ kV}$ contact  $\pm 15 \text{ kV}$  air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Fast transient /electrical bursts acc. to IEC61000-4-4	Not applicable	Not applicable	Power supply for the system is the battery.
Surges as per IEC 61000-4-5	Not applicable	Not applicable	The mains power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations of the supply voltage acc. to IEC 61000-4-11	Not applicable	Not applicable	The mains power supply quality should be that of a typical commercial or hospital environment.

Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at this power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Table 8. Electromagnetic interference resistance**

<b>Guidelines and manufacturer's declaration – electromagnetic interference resistance</b>			
The QiF Warrior Extreme blood and fluid warmer is intended for use in the electro-magnetic environment specified below. The customer or the user of the QiF Warrior Extreme blood and fluid warmer should ensure that it is used in such an environment.			
<b>Interference resistance test</b>	<b>IEC 60601-test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment -guidelines</b>
			Portable and mobile RF communications equipment should be used no closer to any part of the QiF Warrior Extreme blood and fluid warmer, including cables, than the recommended protection distance calculated from the equation applicable to the frequency of the transmitter: <b>Recommended protection distance:</b>
Conducted RF disturbance variables acc. to IEC 61000-4-6	3 Veff150 kHz to 80 MHz	3 → V1 in V	$d = \left(\frac{3.5}{V1}\right) * \sqrt{P}$
Radiated RF disturbance variables according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 → E1 in V/m	$d = \left(\frac{3.5}{E1}\right) * \sqrt{P}$ for 80 MHz to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended protection distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following  symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.  
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people  
 a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the QiF Warrior Extreme blood and fluid warmer is used exceeds the applicable RF compliance level above, the QiF Warrior Extreme blood and fluid warmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the QiF Warrior Extreme blood and fluid warmer.  
 b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.


**Table 9. Recommended safety distances between portable and mobile RF telecommunications devices**

<b>Recommended safety distances between portable and mobile RF telecommunications devices and the QiF Warrior Extreme blood and fluid warmer</b>			
The QiF Warrior Extreme blood and fluid warmer is intended for use in an electromagnetic environment in which radiated RF disturbance variables are controlled. The customer or user of the QiF Warrior Extreme blood and fluid warmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the QiF Warrior Extreme blood and fluid warmer as recommended below, according to the maximum output power of the communications equipment.			
<b>Rated maximum output power of transmitter W</b>	<b>Protection distance according to transmitter frequency m</b>		
	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.			

## 9. Cleaning the System

### 9.1 Cleaning the Disposable Unit / Compact Disposable Unit

- a STERILE EO The Disposable Unit / Compact Disposable Unit is provided sterile and ready for use.
- b If cleaning during use is necessary, wipe the external covering of the unit with water or alcohol (Iso-Propanol/Ethanol), using a damp cloth.

- c  The Disposable Unit / Compact Disposable Unit is a single patient use item; do not reuse it!
- d Do not submerge, sterilize or autoclave the Disposable Unit / Compact Disposable Unit

## 9.2 Cleaning the Base Unit and Battery

The Warrior Extreme Base Unit, battery, battery charger and charger adapter can be reused.




- a Clean the Base Unit and Battery after each use.
- b Cleaning should consist of wiping the external covering of the Base Unit with a damp cloth using Deconex® SOLARSEPT (by Borer Chemie AG) solution.
- c Do not submerge, sterilize or autoclave the Warrior Extreme Base Unit and/or Battery.

## 10. System Precautions

- a Do not use the Warrior Extreme if the audio and/or 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 Disposable Unit / Compact Disposable Unit
- e Always position the Disposable Unit/ Compact Disposable Unit between the IV bag and patient, and connect it using a standard IV / blood administration set.
- f In case of a problem or error (“system error” or “malfunction” notification) that is not resolved following the troubleshooting instructions, contact the manufacturer or its representative.
- g Do not use this system until it is repaired or replaced by Quality in Flow Ltd., or one of its representatives
- h Always replace the Disposable Unit / Compact Disposable Unit when replacing a blood IV administration set.
- i Charge the rechargeable battery only with the supplied Fuyuang 2552000 Battery Charger.
- j The following components are reusable: Base Unit, battery, battery charger and charger adapter.
- k The Warrior Extreme requires a fully charged battery for its operation. 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 the manufacturer for purchasing a new battery.



## 11. Warnings

- a Never throw the Warrior Extreme battery into the trash. The batteries contain toxic materials and need to be disposed of at a designated battery disposable collection point.
- b Warming IV fluids/blood at flow rates higher than 200 ml/min (for example by using a pressure infusion bag or fluid pump) may result in an output temperature lower than  $38 \pm 2$  °C.
- c Do not use the Warrior Extreme in MRI, X-ray and CT environments.
- d Warming medications through the Warrior Extreme was not validated!
- e No modification of this equipment is allowed!
- f Use of the Warrior Extreme not according to its instructions may result in failure of the system or injury to patient.
- g  Do not use the Disposable Unit / Compact Disposable Unit if the sterile package is damaged.
- h  The Disposable Unit / Compact Disposable Unit is for single use only and does not require any calibration or maintenance. Do not reuse it!
- i  Do not re-sterilize the Disposable Unit / Compact Disposable Unit

## **12. Disclaimer and Warranty**

### **12.1 Disclaimer**








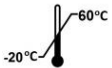

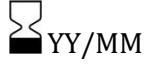







Quality in Flow Ltd. shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of the Warrior Extreme, other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto.

### **12.2 Warranty**

The Warrior Extreme 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.

For support & service and information contact: [support@qinflow.com](mailto:support@qinflow.com).

## 13. Symbols and Legends

Symbol	Description
	Manufacturer
	Authorized representative in the European community
	Catalogue number
	Serial Number
	Warning
	Refer to instruction manual/booklet
	Defibrillation proof BF applied part
	Temperature limitation
	Do NOT reuse
	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
	Contains approximately 2% (weight) of Bis (2-ethylhexyl) phthalate (DEHP)
IP56	Water and particles ingress rate
	Non pyrogenic fluid path - the Disposable Unit / Compact Disposable Unit 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)