

NO MORE COLD BLOOD & FLUIDS

**Warrior / Warrior EXTREME
Blood and Fluid Warmer Operated
with AC Power Supply Module**



Instruction for Use (IFU)

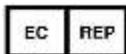
PROPRIETARY AND CONFIDENTIAL

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Do not use the Warrior Blood and Fluid Warmer system with AC power supply module before viewing training materials and carefully reading the following instruction for use (IFU)!

Training materials (IFU / Quick User Guide) are provided with the AC power supply module and are also available on QinFlow's designated online resource database for its distribution partners (for inquiries: info@qinflow.com or sales@qinflow.com).

Training shall be performed before using the AC power supply module. Operating the AC power supply module should be performed in accordance with the prevailing protocols in your organization. The training shall include carefully reading the IFU. Demonstrations for training purposes can be performed by a certified trainer. The company may release demonstration videos for training purposes.

1. Intended Use

QinFlow (QiF) Blood and Fluid Warmer (“Warrior / “Warrior EXTREME”) device is intended for warming blood, blood products, and intravenous fluids prior to administration. It is intended to be used by healthcare professionals in hospitals and other controlled medical environments, to help prevent hypothermia.

1.1 Indication for Use

Whenever parenteral introduction of normothermic fluid is required or indicated.

1.2 Intended Users

The Warrior Blood and Fluid Warmer 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.

2. Package Contents

The **Warrior Blood and Fluid Warmer AC Power Supply Module** package includes:

- a. One AC power supply module (“AC Module”)
- b. AC grounded cable
- c. Instruction for use (IFU)

3. Device Description

The **Warrior AC Module** (see figure 1 below) with the Base Unit* and Compact Disposable Unit* is an inline, AC-powered device for warming blood, blood products and IV fluids. The Warrior AC Module with the Base Unit* and Compact Disposable Unit * can be used to help prevent hypothermia.

* The Warrior Base Unit and Compact Disposable Unit are provided separately.

The system is positioned between the blood/IV tubing and the patient. The temperature set point of the system is $38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ ($100.4\text{ }^{\circ}\text{F} \pm 3.6\text{ }^{\circ}\text{F}$). The Warrior warmer provides both audio and visual notifications.

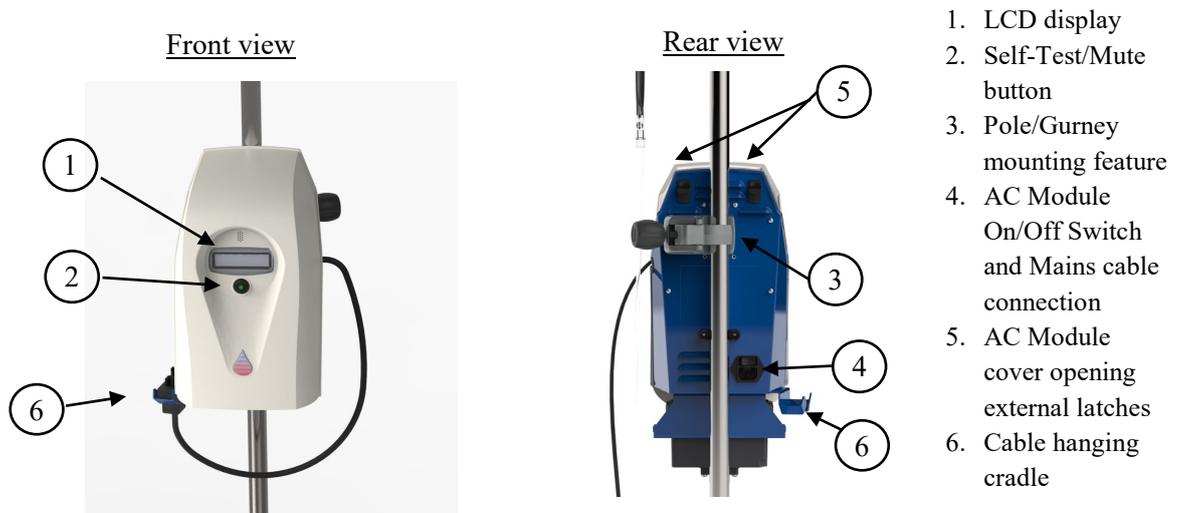


Figure 1. AC Power Supply Module front and rear views

3.1 Base Unit

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

The Base Unit can be connected to either a rechargeable battery or to an AC power supply. Connecting the Base Unit to AC power supply is performed through the Warrior AC Module. The Base Unit is connected to the AC Module through the opening at the bottom of the unit. Note: this connector is also used to connect a battery (supplied separately) for off-grid usage.

The LCD, located on the front of the Base Unit, displays the fluid outflow and inflow temperature, the battery charging level (which when connected to the AC Module is steady on 3 bars out of 4 bars), and additional notifications described in Chapter 5 below.

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

Note: when using the Base Unit with the AC Module, the Base Unit On/Off switch is not used, and it is replaced by the AC Module On/Off switch, which is located on the rear side of the AC module.

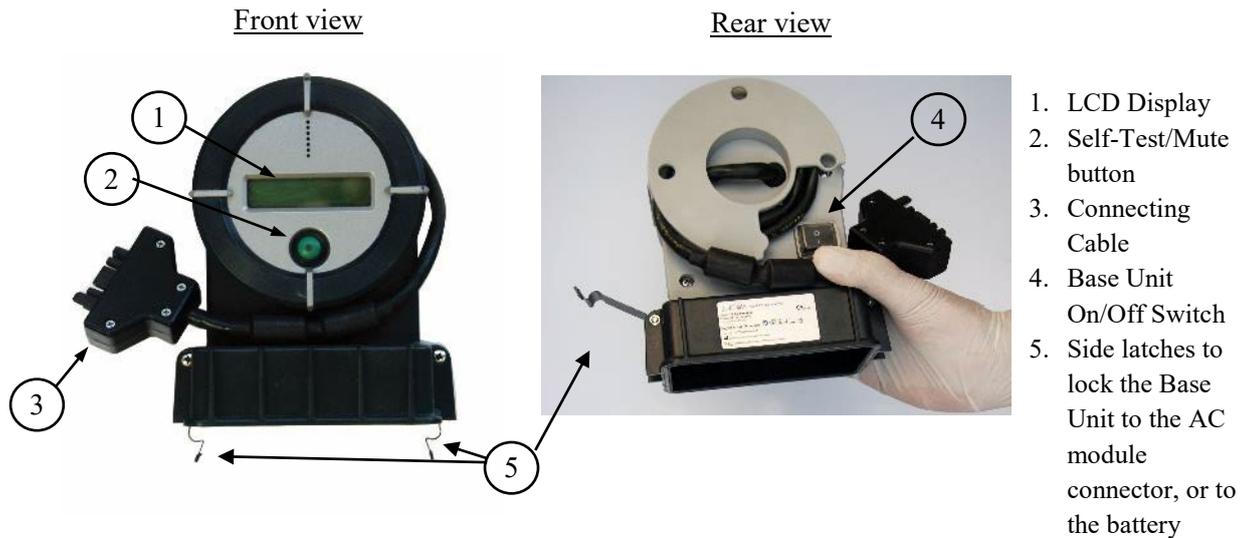


Figure 2. Base Unit front and rear views

3.2 Compact Disposable Unit

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

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

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

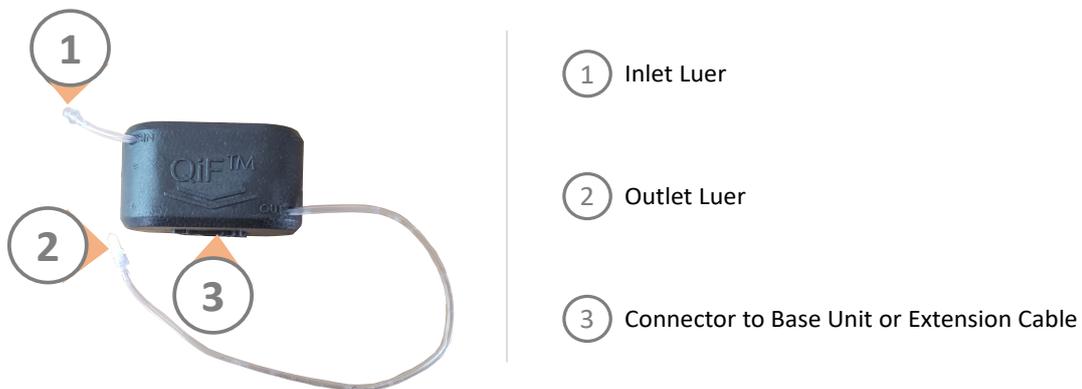


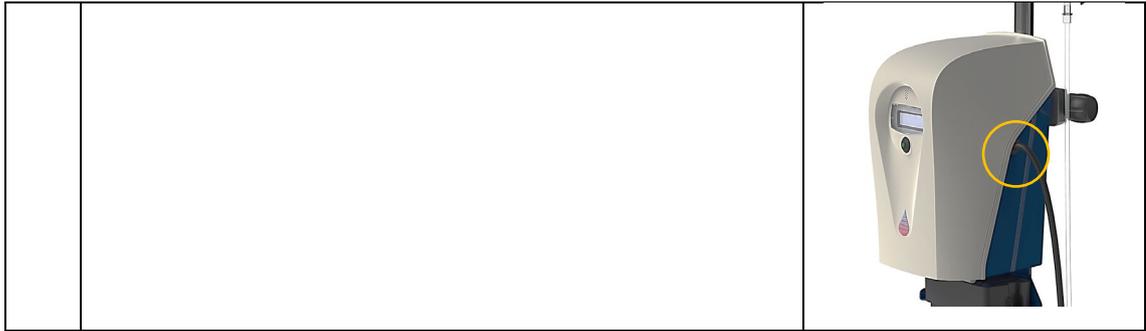
Figure 3. Compact Disposable Unit Cartridge

4. Preparing and Operating the System

4.1 Connecting the Base Unit to the AC Module

The Warrior Blood and Fluid Warmer is powered by an AC power supply, encased in a plastic housing. The power supply requires 120/240 [VAC], 50-60 Hz mains connection.

<p>a.</p>	<p>The AC module is provided with a pole/gurney mounting fixture.</p> <p>The mounting fixture is provided in the orientation of pole mounting. Install the AC Module on an IV pole using the mounting fixture knob on its back side: open the mounting clamp by turning the knob counterclockwise (CCW). Position the clamp around the pole and turn the knob clockwise (CW) to tighten.</p> <p>In case you would like to install the AC module on a rail, unscrew the mounting fixture from the back side, rotate the fixture in 90 degrees CW and screw back the screws.</p>	
	<p>Note: The AC Module shall be positioned only in an upright position as illustrated.</p>	
<p>b.</p>	<p>Open the AC Module by pressing the two external latches on the back side (no. 5 in figure 1).</p> <p>Unroll the Base Unit cable to its full length.</p> <p>If the Base Unit is connected to a battery, remove the battery from the bottom edge of the Base Unit.</p> <p> WARNING! Make sure that the AC Module interior part is free of fluids and foreign objects</p> <p>Insert the Base Unit into the AC Module and properly attach the side latches (item 5 in figure 2) of the Base Unit to the AC connector.</p>	
<p>c.</p>	<p>Route the cable outside of the AC Module through its designated cable routing guide.</p> <p>Close the AC Module cover, until it is adequately secured by the external latches.</p> <p>Plug the AC Module to mains electricity using the grounded cable provided with the AC Module.</p> <p> WARNING! use only the grounded cable provided with the Warrior AC Unit Module</p>	



4.2 Preparing the System for Warming



WARNING: follow all the instructions provided by the manufacturer of the blood/intravenous fluid administration set and the protocols of your organization when administrating blood or fluid through the Warrior Blood and Fluid Warmer.

a.	<p>The Warrior Blood and Fluid Warmer Compact Disposable Unit cartridge is provided sterile, packaged in a sterile bag. Visually inspect the Compact Disposable Unit package before opening to ensure that there is no damage to the packaging or to the product.</p> <ul style="list-style-type: none">  Do not use the Compact Disposable Unit if the sterile package is damaged or is not fully sealed.  Do not reuse the Compact Disposable Unit. 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. 2020/03, valid until 31st of March 2020).  Do not re-sterilize the Compact Disposable Unit. 	
b.	Open the Compact Disposable Unit sterile package.	

4.3 Connecting the Base Unit to the Compact Disposable Unit

	<p>Note: When connecting the cable to the Compact Disposable Unit, verify the engraved (top) side of the cable connector is next to the engraved side of the</p>
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	<p>Compact Disposable Unit, as shown in the image on the right.</p>	
	<p>➔ Note: the disconnections of the cable shall be performed by holding and pulling the designated connector (top image on the right), and NOT by holding and pulling the cable or holding and pulling the ferrites on the cable (bottom image on the right).</p> <p>➔ Important! Disconnect the cable from the Compact Disposable Unit only by pulling the designated connector.</p>	

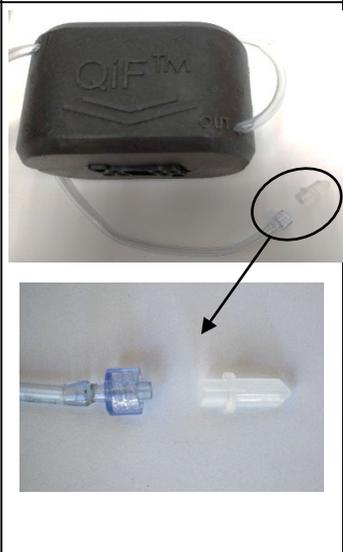
4.4 Connecting the WARRIOR Warmer to the Fluid Bag and Patient

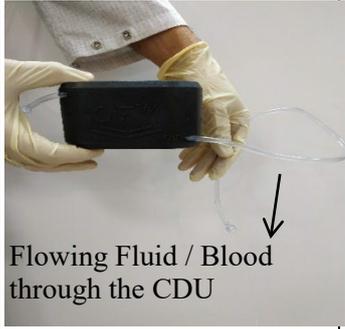
The Warrior Blood and Fluid Warmer Compact Disposable Unit is compatible with any standard IV administration set that utilizes standard Luer connections.



WARNINGS:

- Warming IV fluids/blood at flow rate higher than 290 ml/min (for example by using a pressure infusion bag or fluid pump) may result in output temperature lower than 38 ± 2 °C.
- Do not use Warrior Blood and Fluid Warmer in MRI, X-ray and CT environments!
- Warming medications through the Warrior Blood and Fluid Warmer was not validated!
- No modification of this equipment is allowed!
- Use of the Warrior Blood and Fluid Warmer in a manner that is inconsistent with the instructions may result in failure of the system or injury to patient or to the caregiver.

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

	<p>⚠ WARNING: Always flush the line with intravenous fluid / blood / blood product before administrating to patient.</p> <p>⚠ WARNING: Warming medications through the Warrior Blood and Fluid Warmer was not validated!</p> <p>Note: The Warrior Blood and Fluid Warmer 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 Warrior warmer with a damp cloth with water or alcohol (Iso-Propanol/Ethanol).</p>	
d.	Connect the blood/IV line to the fluid bag and flush the line with the intravenous fluid/blood.	 <p>Flowing Fluid / Blood through the CDU</p>

4.5 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 AC Module by moving the On/Off switch on the rear side of the AC module to “On”.</p> <p>The On/Off switch green led will light and you would hear the AC unit fan.</p> <p>The Base Unit LCD displays the “Initializing...” message and you will hear a steady beep.</p>	
b.	<p>Start flowing IV fluid / blood through the Compact Disposable Unit.</p> <p>The system will reach the set-point temperature within a few seconds.</p> <p>During this time the LCD displays:</p> <p>Heating</p> <p>Tout: outflow temp °C (inflow temperature °C). The temperature is presented in Celsius degrees (°C).</p> <p>For example: “Tout: 38°C (8°C)”.</p> <p>Note: Tout means "Temperature Out", or the temperature of the warmed fluids.</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>	
	<p>Note: When there are extreme changes in the flow rate or the inlet fluid temperature, the Warrior warmer 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.</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 the protocols of your organization.</p>	
	<p>Note: You can administer several fluid bags using the same Compact Disposable Unit. The Warrior warmer does not need to be shut off while replacing the fluid bag.</p>	

4.6 General Operation Instructions

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

 **WARNING:** Do not cover the display or the speaker of the AC Module.

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

 **WARNING:** Make sure that the AC Module interior part is free of fluids and foreign objects.

During administration keep track of the display and sound notifications. For details on system notifications and troubleshooting, see Chapter 5.

When the AC unit lid is open, the Base Unit does not get any power and does not warm the fluids.

4.7 Self-Test

To check the Base Unit is properly communicating with the 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; this will reset the system. If needed, you can reset the system by shutting off the AC unit and then turning it ON again.



Figure 4. Self-Test/Mute Button

In “Self-Test” mode, the blood or fluid may continue to flow through the system but are not warmed.

See additional details in the troubleshooting chapter (Chapter 5).

4.8 Additional Operating and Ceasing Operation Guidelines

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

You do not have to shut off the **Warrior Blood and Fluid warmer AC Module** when replacing the fluid bag.

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

Always replace the **Compact Disposable Unit** when replacing the blood IV administration set, and repeat stages a to d in section 4.4 above.

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

Shut off the AC Module by switching Off the On/Off switch on the Rear side of the AC Module. The Base Unit can remain inside the AC Module for the next use.



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

4.9 Removing the Base Unit from the AC Module

If you wish to remove the Base Unit from the AC Module and continue to use it off-grid with the Warrior battery, then:

- a. Open the AC Module cover by pressing the two latches on the AC Module back.
- b. Open the Base Unit side latches and remove it from the AC Module.
- c. Switch off the Base Unit (by pressing "0" on the Base Unit on/off switch on the back side) and close the AC Module cover.
- d. Connect the battery to the Base Unit, switch on the Base Unit and continue to heat fluid/blood.

Note: While the Base Unit is not connected to the AC Module or battery, the fluid/blood continue to flow but are not warmed.

Note: When using the Base Unit with battery, please refer to the relevant instruction for use document QPORT1700.

If you wish to remove the Base Unit from the AC Module for storage, then follow steps a to c above. Thereafter, roll the Base Unit cable into its designated position on the Base Unit rear side and store the unit.

5. 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 1. 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 Compact Disposable Unit connection	System is Ready Connect the DU	No	Connect the Base Unit to a flushed Compact Disposable Unit 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	Open the IV set roller clamp until the required flow is reached. Look for IV kink and release it. Replace the IV tubing if necessary.
No display on LCD, though the AC module is switched "ON"	No display	Standard audio or audio notifications do not play	Check if the AC module is On and that the Warrior AC Module power cable is plugged into a mains outlet. Check that the Base Unit is properly installed inside the AC module and the side latches are fastened. Check that the AC Module cover is properly closed. If the problem is not resolved, do not use the system; contact the manufacturer or its representative.

Description	LCD Notification	Audio Notification	User Action (if required)
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 Warrior Blood and Fluid Warmer AC Module and replace the 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) Keep track of the LCD display.
System malfunction (HW/SW)	System Error	Steady beep	Make Sure that the 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 AC module, replace the Compact Disposable Unit with a new one, flush the air out of the Compact Disposable Unit, and turn the AC module back on. If the problem is not resolved contact the manufacturer or its representative.

6. Specifications and Characteristics

Note: Operation outside the limits of the design specifications may result in a lower outflow temperature and/or damage the system.

6.1 Electrical Specifications

Table 2. Electrical Specifications

Parameter	Value
Input	110VAC 7A RMS 240VAC 3.5A RMS 50-60 Hz
Output	24 VDC; 26.5 A
Defibrillation Proof type BF Applied Part	 The Warrior Blood and Fluid Warmer Compact Disposable Unit is safe to be used when joined with a defibrillator

6.2 Physical Properties

Table 3. Physical Properties

Parameter	Value
Weight of AC Module with Base Unit	Approximately 3600 g (~8 lb)
Weight of Compact Disposable Unit in sterile bag	Approximately 117 g (0.26 lb)
Dimensions of AC Module H × W × L	Approximately 300×190×180 mm (11.8×7.5×7.1 in)
Dimensions of Compact Disposable Unit H × W × L	Approximately 72.2x68.5x117.5 mm (2.84x2.70x4.63 in)

6.3 Environmental Conditions

Table 4. Environmental Conditions

Parameter	Value
Storage & Transport conditions	-20 °C to 60 °C & 93% RH (-4 °F to 140 °F & 93% RH)
Operation Temperature & Humidity	5 °C & 15% RH to 40 °C & 93% RH (41 °F & 15% RH to 104 °F & 93% RH)
Atmospheric Pressure/(Altitude)	700 to 1060 hPa (-400 to 3200 meters); (-1312 to 10,499 ft)
Compact Disposable Unit Shelf Life	3 years
Base Unit and AC Module Service Life*	5 years
Water and particles Ingress rate	IP22

* The Warrior Blood and Fluid Warmer Base Unit and AC Module does not require any calibration or maintenance. At the end of the service life period turn to the manufacturer for Base Unit/AC Module refurbishing options.

6.4 Electromagnetic Compatibility (EMC) Conditions

Table 5. Electromagnetic Compatibility Conditions

Emission Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	NA
RF emissions CISPR 11	Class A	The WARRIOR Blood and Fluid Warmer AC Module 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 IEC 61000-3-2	Class A	NA
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	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 Warrior 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 Warrior device is that the outflow temperature stabilizes on $38 \pm 2 \text{ }^\circ\text{C}$ ($100.4 \pm 3.6 \text{ }^\circ\text{F}$).

Warrior device and the AC power supply module shall only be used with the cables provided by the manufacturer. Base Unit cable length is 90cm (approximately 34 in.); AC power supply module cable length is 3.0 Meter (118 in.).

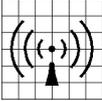
Portable and mobile RF communications equipment can affect the Warrior device. The system may recognize the disturbance and initialize a self-test.

Table 6. Electromagnetic interference resistance

Guidelines and manufacturer's declaration – electromagnetic interference resistance			
The Warrior blood and fluid warmer operated with the AC power supply module is intended for use in the electro-magnetic environment specified below. The customer or the user of the Warrior blood and fluid warmer operated with the AC power supply module should assure that it is used in such an environment.			
Interference resistance test	IEC 60601-test level	Compliance level	Electromagnetic environment - guideline
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	$\pm 2 \text{ kV}$ for power supply lines $2 \text{ kV} \pm 1 \text{ kV}$ for input/output lines	$\pm 2 \text{ kV}$ for power supply lines Not applicable	The mains power supply quality should be that of a typical commercial or hospital environment.
Surges as per IEC 61000-4-5	$\pm 1 \text{ kV}$ differential mode $\pm 2 \text{ kV}$ common mode	$\pm 1 \text{ kV}$ differential mode $\pm 2 \text{ kV}$ common mode	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	$< 5 \%$ UT ($> 95 \%$ fall in UT)for $\frac{1}{2}$ period 40% UT (60% fall in UT)for 5 periods 70% UT	$< 5 \%$ UT ($>95 \%$ fall in UT) for $\frac{1}{2}$ period 40% UT (60% fall in UT) for 5 periods 70% UT (30% fall in UT)	The mains power supply quality should be that of a typical commercial or hospital environment. If the user of the Warrior blood and fluid warmer operated with the AC power supply module requires continued operation even in the case of power supply interruptions it is recommended to connect the Warrior blood and fluid warmer operated with the AC power supply

	(30 % fall in UT)for 25 periods < 5 % UT (> 95 % fall in UT) for 5 s	for 25 periods < 5 % UT (> 95 % fall in UT) for 5 s	module to an uninterruptible power source.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at this power frequency 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 7. Electromagnetic interference resistance

Guidelines and manufacturer's declaration – electromagnetic interference resistance			
The Warrior blood and fluid warmer operated with the AC power supply module is intended for use in the electro-magnetic environment specified below. The customer or the user of the Warrior blood and fluid warmer operated with the AC power supply module should ensure that it is used in such an environment.			
Interference resistance test	IEC 60601-test level	Compliance level	Electromagnetic environment -guidelines
			Portable and mobile RF communications equipment should be used no closer to any part of the Warrior blood and fluid warmer operated with the AC power supply module, including cables, than the recommended protection distance calculated from the equation applicable to the frequency of the transmitter: Recommended protection distance:
Conducted RF disturbance variables acc. to IEC 61000-4-6	3 Veff150 kHz to80 MHz	3 → V1 in V	$d = \left(\frac{3.5}{V1}\right) * \sqrt{P}$
Radiated RF disturbance variables according to IEC61000-4-3	3 V/m80 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 a 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 Warrior blood and fluid warmer operated with the AC power supply module is used exceeds the applicable RF compliance level above, the Warrior blood and fluid warmer operated with the AC power supply module should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Warrior blood and fluid warmer operated with the AC power supply module.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 8. Recommended safety distances between portable and mobile RF telecommunications devices

Recommended safety distances between portable and mobile RF telecommunications devices and the Warrior blood and fluid warmer operated with the AC power supply module

The Warrior blood and fluid warmer operated with the AC power supply module is intended for use in an electromagnetic environment in which radiated RF disturbance variables are controlled. The customer or user of the Warrior blood and fluid warmer operated with the AC power supply module can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Warrior blood and fluid warmer operated with the AC power supply module 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.

7. Cleaning the System

7.1 Cleaning the Compact Disposable Unit

- a  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.

7.2 Cleaning and disinfecting the Base Unit and AC module

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

Before cleaning, disconnect the BU from the AC module.

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 solution/ Deconex® SOLARSEPT, 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/Warrior Extreme Blood and Fluid Warmer Base Unit and/or AC Module.

8. System Precautions

- a For blood / blood product / intravenous fluid infusion instructions, refer to your facility/organization protocols.
- b Always use with a designated standard blood / intravenous fluid administration set.
- c Follow all the instructions provided with the blood / intravenous fluid administration set when infusing blood / blood product / intravenous fluid through the Warrior Blood and Fluid Warmer Compact Disposable Unit.
- d Always position the Warrior Blood and Fluid Warmer Compact Disposable Unit between the IV bag and patient, and connect it using a standard IV / blood administration set.
- e 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.
- f Always replace the Compact Disposable Unit when replacing the blood administration set.

9.



Warnings

- g Do not use the Warrior Blood and Fluid Warmer if the audio and/or visual indications are not functioning.
- h Warming IV fluids/blood at flow rate higher than 290 ml/min (for example by using a pressure infusion bag or fluid pump) may result in lower output temperature than 38 ± 2 °C.
- i Do not use the Warrior Blood and Fluid Warmer in MRI, X-ray and CT environments.
- j Warming medications through the Warrior Blood and Fluid Warmer was not validated!
- k No modification of this equipment is allowed!
- l Use of the Warrior Blood and Fluid Warmer not according to its instructions may result in failure of the system or injury to patient.
- m  Do not use the Compact Disposable Unit if the sterile package is damaged.
- n  The Compact Disposable Unit 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.
- o  Do not re-sterilize the Compact Disposable Unit.
- p Make sure that the AC Module interior part is free of fluids and foreign objects.
- q Use only the cable provided with the Warrior AC Unit Module.
- r Connect the AC Module only to a grounded power source.

10. Disclaimer and Warranty

10.1 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 this Warrior Blood and Fluid Warmer AC Module, other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto.

10.2 Warranty

The Warrior Blood and Fluid Warmer 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.

11. 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
	Storage 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
IP22	Water and particles ingress rate
	Pyrogenic Free. The Warrior 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)