



## **QiF Blood and Fluid Warmer**



### **AC Power Supply Module Instruction for Use (IFU)**

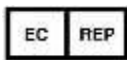
PROPRIETARY AND CONFIDENTIAL

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Do not use the QiF 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](mailto:info@qinflow.com) or [sales@qinflow.com](mailto: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

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

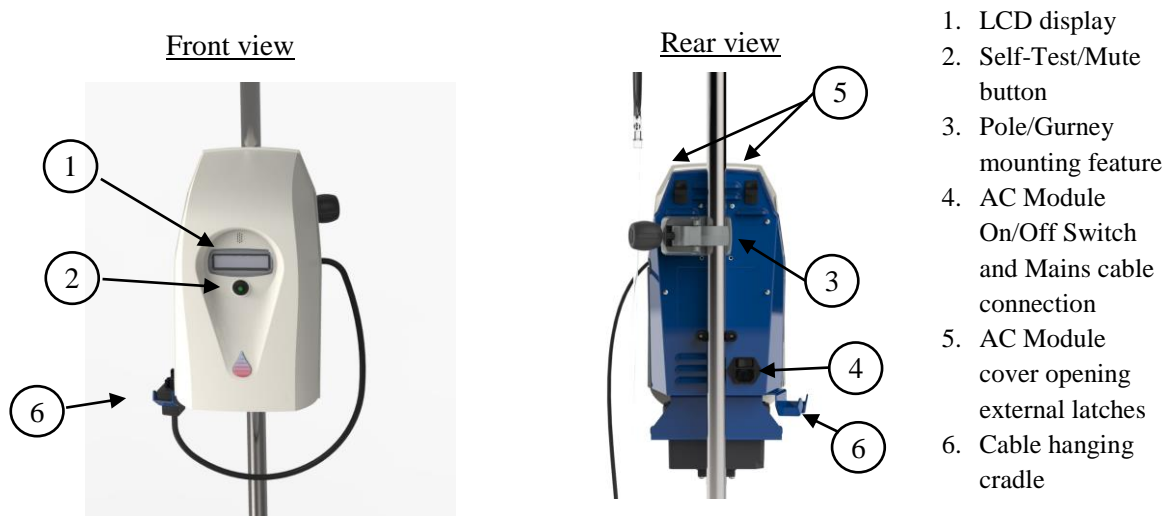
- a. One QiF AC power supply module ("AC Module")
- b. QiF AC grounded cable
- c. Instruction for use (IFU)

## 3. Device Description

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

\* The QiF Base Unit and 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 QiF warmer provides both audio and visual notifications.



**Figure 1. AC Power Supply Module front and rear views**

### 3.1 Base Unit

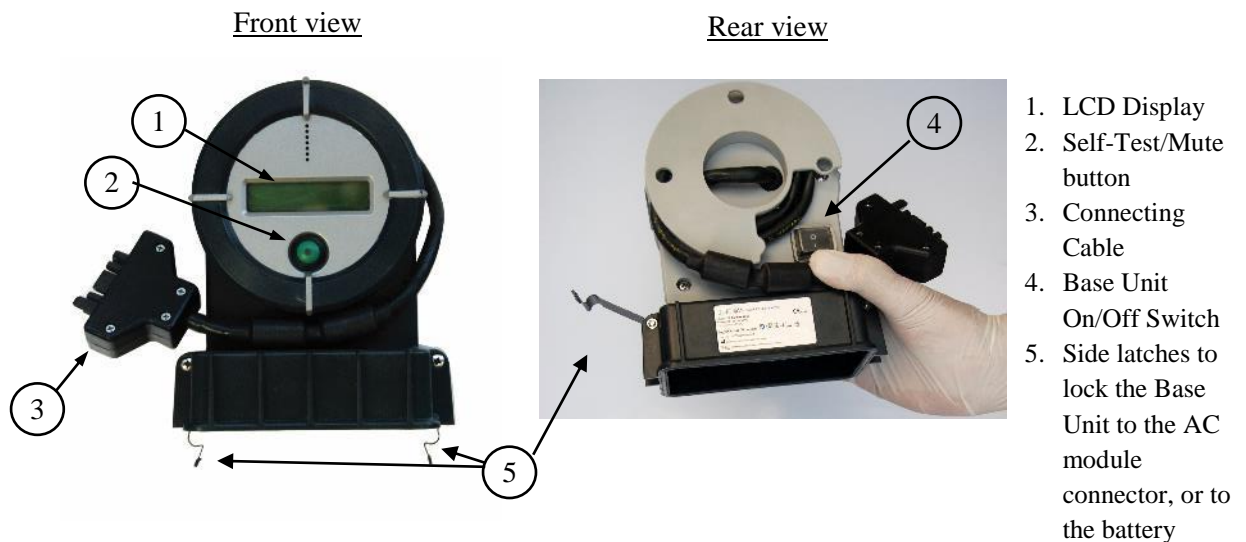
The Base Unit comprises an LCD, On/Off switch, speaker and a green pushbutton. It also includes a connecting cable that when not in use, is wrapped around its back side.

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 QiF 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.



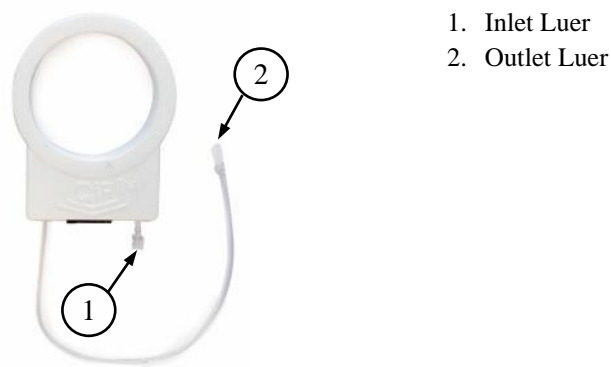
**Figure 2. Base Unit front and rear views**

## 3.2 Disposable Unit

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

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









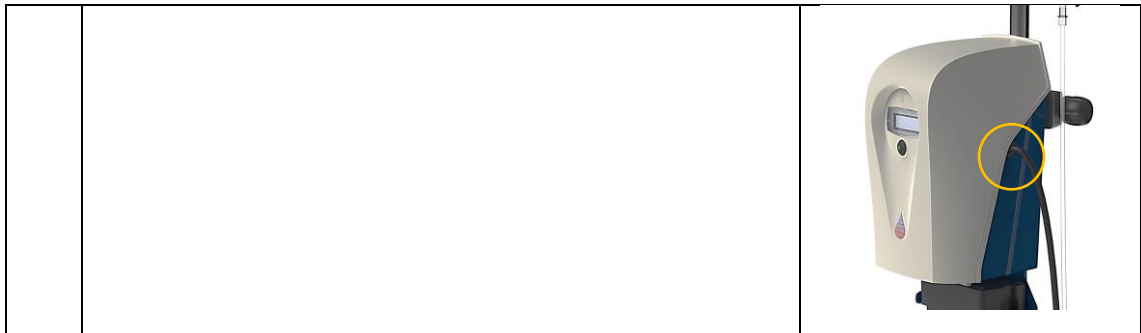
**Figure 3. Disposable Unit Cartridge**

## 4. Preparing and Operating the System

### 4.1 Connecting the Base Unit to the AC Module

The QiF 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.







a.	<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>➡ <b>Note:</b> The AC Module shall be positioned only <b>in an upright position as illustrated.</b></p>	
b.	<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> <b>WARNING!</b> 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>	
c.	<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> <b>WARNING!</b> use only the grounded cable provided with the QiF AC Unit Module</p>	



## 4.2 Preparing the System for Warming

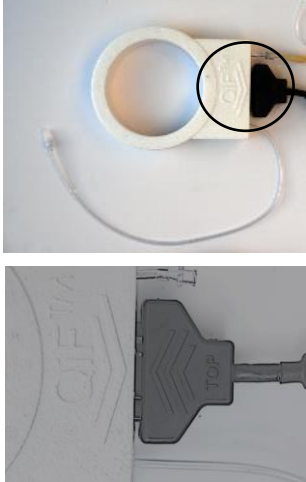



**WARNING:** follow all the instructions provided by the manufacturer of the blood/intravenous fluid administration set and the protocols of your organization when administering blood or fluid through the QiF Blood and Fluid Warmer.

a.	<p>The QiF Blood and Fluid Warmer Disposable Unit cartridge is provided sterile, packaged in a sterile bag. Visually inspect the 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 if the sterile package is damaged or is not fully sealed.</p> <p> Do not reuse the 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. 2018/03, valid until 31st of March 2018).</p> <p> Do not re-sterilize the disposable unit.</p>	
b.	Open the Disposable Unit sterile package.	



### 4.3 Connecting the Base Unit to the Disposable Unit

	<p>➡ <b>Note:</b> When connecting the cable to the Disposable Unit, verify the engraved (top) side of the cable connector is next to the engraved side of the Disposable Unit, as shown in the image on the right.</p>	
a.	<p>Connect the Base Unit cable to the Disposable Unit.</p>	

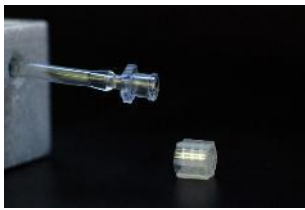

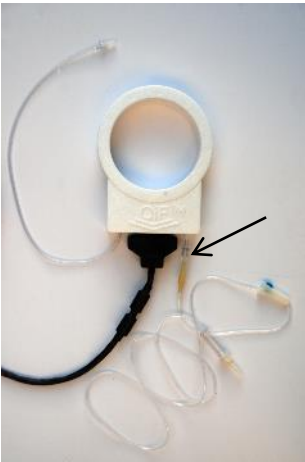
## 4.4 Connecting the QiF Warmer to the Fluid Bag and Patient

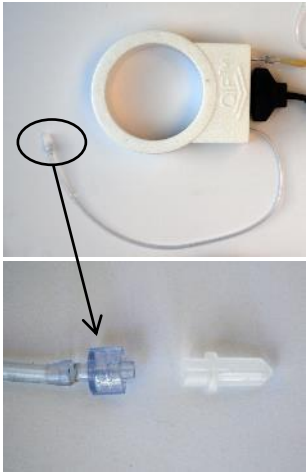
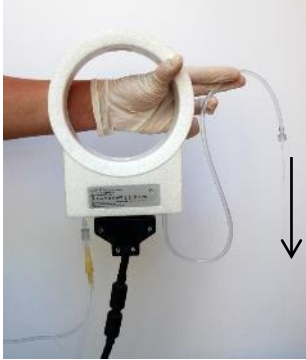
The QiF Blood and Fluid Warmer Disposable Unit is compatible with any standard IV administration set that utilizes standard Luer connections.



### 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  $38 \pm 2$  °C.
- Do not use QiF Blood and Fluid Warmer in MRI, X-ray and CT environments!
- Warming medications through the QiF Blood and Fluid Warmer was not validated!
- No modification of this equipment is allowed!
- Use of the QiF 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.	Remove the Inlet Luer cap from the inlet tube of the QiF warmer Disposable Unit (marked as "IN" on the DU casing). The inlet tube connects to the blood/IV set outlet.	
	 <b>Note:</b> 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).	
b.	Connect blood/IV tubing to the Inlet Luer, and tighten until resistance is met.	

c.	<p>Remove the Outlet Luer cap from the outlet end of the blood/IV extension tube (marked as "OUT" on the DU casing).</p> <p>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 QiF Blood and Fluid Warmer was not validated!</p> <p><b>➡ Note:</b> The QiF Blood and Fluid Warmer 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 QiF warmer with a damp cloth with water or alcohol (Iso-Propanol/Ethanol).</p>	
d.	<p>Connect the blood/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>

## 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 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>➡ <b>Note:</b> When there are extreme changes in the flow rate or the inlet fluid temperature, the QiF 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>➡ <b>Note:</b> You can administer several fluid bags using the same Disposable Unit. The QiF warmer does not need to be shut off while replacing the fluid bag.</p>	

## 4.6 General Operation Instructions

The 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 QiF 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 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 **QiF Disposable Unit** when replacing the fluid or blood bag. You can administer several fluid bags using the same Disposable Unit.

You do not have to shut off the **QiF 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 **Disposable Unit** outlet from intravenous catheter.

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

Dispose of the **QiF 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 QiF battery, then:

- Open the AC Module cover by pressing the two latches on the AC Module back.
- Open the Base Unit side latches and remove it from the AC Module.
- 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.
- 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.

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 Disposable Unit connection	System is Ready Connect the DU	No	Connect the <b>Base Unit</b> to a flushed <b>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

Description	LCD Notification	Audio Notification	User Action (if required)
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 QiF 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.
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 QiF Blood and Fluid Warmer AC Module and replace the 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 Disposable Unit is flushed and filled with fluid and


Description	LCD Notification	Audio Notification	User Action (if required)
General malfunction	*MALFUNCTION!!* Tout: XX °C (YY °C)  The LCD blinks	Steady beep	restart the system by shutting it off and then on again.  If the problem is not resolved shut off the AC module, replace the Disposable Unit with a new one, flush the air out of the 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 1. 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 QiF Blood and Fluid Warmer Disposable Unit is safe to be used when joined with a defibrillator



## 6.2 Physical Properties

**Table 2. Physical Properties**

Parameter	Value
Weight of AC Module with Base Unit	Approximately 3600 g (8 lb)
Weight of Disposable Unit in sterile bag	Approximately 140 g (0.3 lb)
Dimensions of AC Module H × W × L	Approximately 300×190×180 mm (11.8×7.5×7.1 in)
Dimensions of Disposable Unit H × W × L	Approximately 210×160×45 mm (8.3×6.5×1.8 in)

## 6.3 Environmental Conditions

**Table 3. 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)
Disposable Unit Shelf Life	3 years
Base Unit and AC Module Service Life*	5 years
Water and particles Ingress rate	IP22

\* The QiF 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 4. Electromagnetic Compatibility Conditions**

Emission Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	NA
RF emissions CISPR 11	Class A	The QIF 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

## 7. Cleaning the System

### 7.1 Cleaning the Disposable Unit

- a  The QiF Blood and Fluid Warmer 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 QiF Blood and Fluid Warmer Disposable Unit is a single patient use item; do not reuse it!
- d Do not submerge, sterilize or autoclave the QiF Blood and Fluid Warmer Disposable Unit.

### 7.2 Cleaning the Base Unit and AC Module

The QiF Blood and Fluid Warmer Base Unit and AC Module can be reused.

- e Clean the AC Module externally after each use.
- f Cleaning should consist of wiping the external covering of the AC Module with a damp cloth using Deconex® SOLARSEPT (by Borer Chemie AG) solution.
- g Do not submerge, sterilize or autoclave the QiF Blood and Fluid Warmer Base Unit and/or AC Module.

## 8. System Contraindications and Precautions




### 8.1 QiF Blood and Fluid Warmer System Contraindications

- a Warming medications through the QiF Blood and Fluid Warmer was not validated.

### 8.2 QiF Blood and Fluid Warmer 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 QiF Blood and Fluid Warmer Disposable Unit.
- d Always position the QiF Blood and Fluid Warmer 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 Disposable Unit when replacing the blood administration set.

## 9. Warnings

- a Do not use the QiF Blood and Fluid Warmer if the audio and/or visual indications are not functioning.
- b 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  $38 \pm 2$  °C.
- c Do not use the QiF Blood and Fluid Warmer in MRI, X-ray and CT environments.
- d No modification of this equipment is allowed!
- e Use of the QiF Blood and Fluid Warmer not according to its instructions may result in failure of the system or injury to patient.
- f  Do not use the Disposable Unit if the sterile package is damaged.
- g  The Disposable Unit is for single use only and does not require any calibration or maintenance. Do not reuse it!
- h  Do not re-sterilize the Disposable Unit.
- i Make sure that the AC Module interior part is free of fluids and foreign objects.
- j Use only the cable provided with the QiF AC Unit Module.
- k Connect the AC Module only to a grounded power source.

## **10. Disclaimer and Warranty**

### **10.1 Disclaimer**








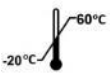








Quality in Flow Ltd. shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of this QiF Blood and Fluid Warmer AC Module, other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements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

### **10.2 Warranty**

The QiF 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](mailto: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., 18/03 is valid until March 2018)
	Do NOT re-sterilize
	Sterilized using Ethylene Oxide
	Do NOT use if package is damaged
	Keep away from sunlight
	Contains approximately 2% (weight) of Bis (2-ethylhexyl) phthalate (DEHP)
IP22	Water and particles ingress rate
	Pyrogenic Free. The QiFDisposable 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)