



QiF™ Blood and Fluid Warmer Model 01



Instruction for Use (IFU)

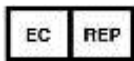
PROPRIETARY AND CONFIDENTIAL

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Do not use the QiF™ Blood and Fluid Warmer system before viewing training materials and carefully reading the following instruction for use!

1. Indications for Use

The **QiF™ Blood and Fluid Warmer** device is intended for warming blood, blood products (i.e., Red Blood Cells (RBC) and whole blood), 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 **QiF™ Blood and Fluid Warmer** 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 **QiF™ Blood and Fluid Warmer** 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).

4. System Description

What is the QiF™ Blood and Fluid Warmer?

The **QiF™ Blood and Fluid Warmer** (model 01) is an inline, battery-powered, lightweight and completely portable system, for warming blood, blood product and IV fluids. The QiF™ Blood and Fluid Warmer 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 QiF™ warmer provides both audio and visual notifications.



Figure 2. QiF Blood and Fluid Warmer (illustrated set-up)

5. System Components

The **QiF™ Blood and Fluid Warmer** includes a reusable Base Unit and a sterile, single patient use disposable cartridge, called the Disposable Unit.

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.

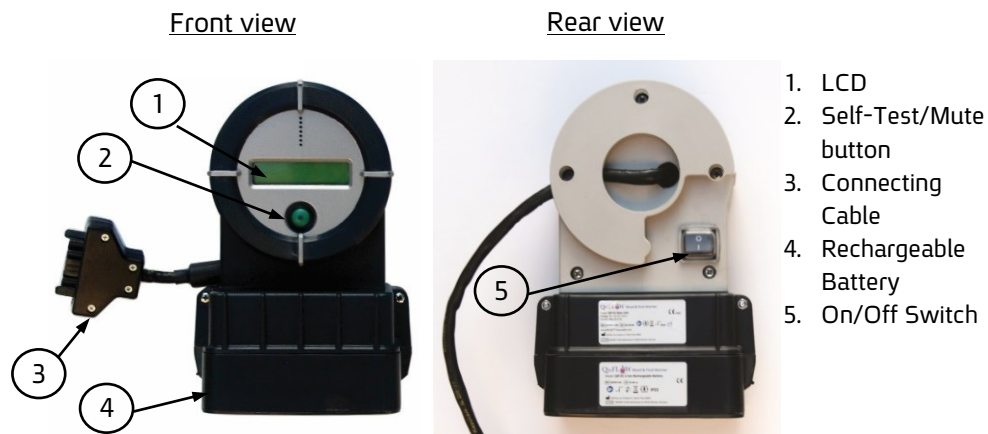


Figure 3. Base Unit front and rear views

5.2 Disposable Unit

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 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**.

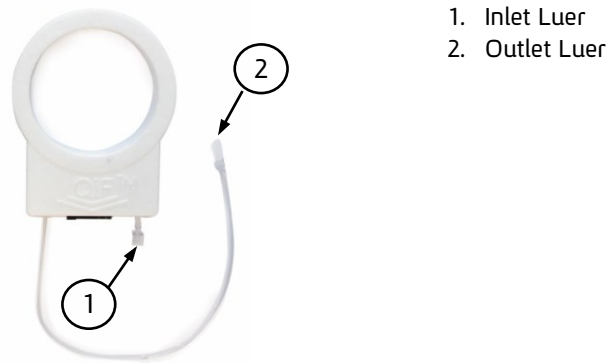


Figure 4. Disposable Unit Cartridge

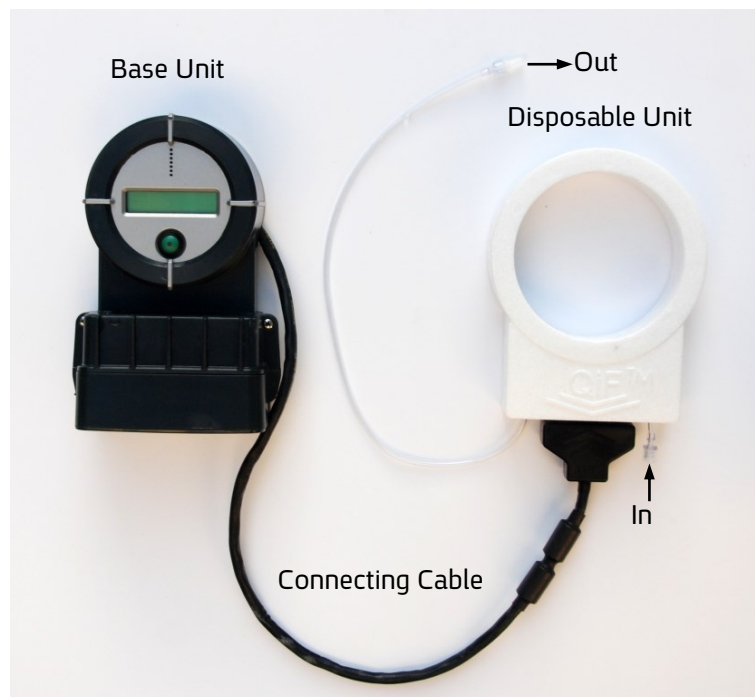


Figure 5. Base Unit connected to the Disposable Unit

5.3 Intended Users

Who should use the QiF™ Blood and Fluid Warmer?

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.

5.4 Fluid Warming Capacity

How much fluid can the product warm using a fully charged battery?

The amount of fluid the QiF™ warmer 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 QiF™ warmer 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 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.

6. Preparing and Operating the System

6.1 Charging the Battery

The QiF™ Blood and Fluid Warmer 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.




a.	<p>Plug the Battery into the Battery Charger using the charger adapter, and plug the Battery Charger into an AC electrical outlet.</p> <p>Note: the battery shall be charged using only its designated charging adapter.</p>	
b.	<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>➡ Note: 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 before each use.




⚠ **WARNING:** Never throw the QiF™ Blood and Fluid Warmer 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 QiF™ Blood and Fluid Warmer.

a.	<p>The QiF™ Blood and Fluid Warmer Disposable Unit cartridge is provided sterile 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.	<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 Base Unit label. If you insert the battery in the wrong orientation, the battery will not dock with the Base Unit. If this happens, remove the battery, turn it 180 degrees and reinsert into the Base Unit.</p> <p>For more instructions on how to replace the battery during administration, see section 6.9.</p>	
c.	<p>Open the Disposable Unit sterile package.</p>	

6.3 Connecting the Base Unit to the Disposable Unit

	 Note: When connecting the cable to the Disposable Unit, verify the top side of the cable connector is next to the engraved side of the Disposable Unit.	
d.	Connect the Base Unit cable to the Disposable Unit.	

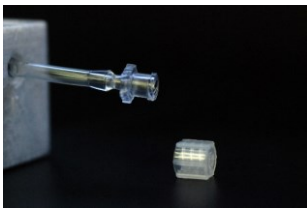

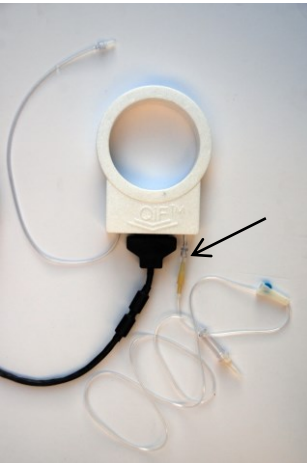
6.4 Connecting the QiF™ Warmer to the Fluid Bag and Patient

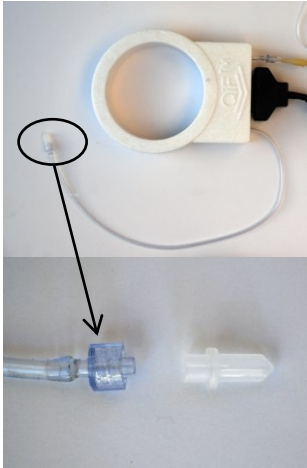
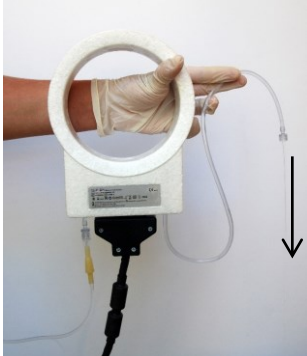
The QiF™ Blood and Fluid Warmer is compatible with any standard IV administration set that utilizes standard Luer connections.



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 ± 2 °C.
- Do not use QiF™ Blood and Fluid Warmer in MRI, X-ray and CT environments!
- Never flow medicines through the QiF™ Blood and Fluid Warmer!
- No modification of this equipment is allowed!
- Use of the QiF™ Blood and Fluid Warmer inconsistent with its instructions may result in failure of the system or injury to patient.




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 IV set outlet.	
	 Note: 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).	
b.	Connect 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 IV extension tube (marked as "OUT" on the DU casing). 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: Never flow medicines through the QiF™ Blood and Fluid Warmer.</p> <p>➡ Note: 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 water or alcohol (Iso-Propanol/Ethanol) using a damp cloth.</p>	
d.	<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".</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. 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>➡ Note: 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>	

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 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 QiF™ Blood and Fluid Warmer 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 (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 6. 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 QiF Device Fluid / Blood Warming

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** 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** outlet from intravenous catheter.

Always replace the **QiF™ disposable Unit** when replacing the blood IV administration set, and repeat stages a–d is section 6.4 above.

Dispose of the **QiF™ 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.

	<p>⚠ WARNING: While the QiF™ 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.</p>	
a.	<p>Shut off the QiF™ Blood and Fluid Warmer Base Unit by pressing the On/Off switch on the back of the system to "0".</p>	
b.	<p>Remove the empty battery from QiF™ Blood and Fluid Warmer by opening the two side latches and pulling out the battery.</p>	
c.	<p>Replace the empty battery with a fully charged battery and close the side latches.</p> <p>Pay attention to the correct battery insertion orientation: the battery label should be alongside the Base Unit label. If you insert the battery in the wrong orientation, the battery will not dock with the Base Unit. If this happens, remove the battery, turn it 180 degrees and reinsert into the Base Unit.</p>	
d.	<p>Switch on the Base Unit. The LCD displays the "Initializing..." message and a steady beep is sound.</p> <p>Start flowing IV fluid / blood through the 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>	
e.	<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 connection	System is Ready Connect the DU	No	Connect the Base Unit to the 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	<ul style="list-style-type: none"> • 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 system is turned on	No display	No	<p>Check the On/Off switch is turned on. If it is, replace the battery.</p> <p>If after replacing the battery the display is still not working, do not use this QiF™ warmer until repaired by the manufacturer or by its representative.</p>
Battery energy status is at 25-30% capacity	Note: Battery is Getting Low! The LCD blinks	Steady beep	<p>Pay attention, a "Battery Empty" message will follow.</p> <p>You can Mute the audio notification with a short press on the Self-Test/Mute button.</p>
Battery is critically low	Battery Empty Tout: XX °C (YY °C)	Steady beep	<p>Replace the empty battery with a fully charged, battery (see section 6.9 for instructions).</p> <p>You can Mute the audio notification with a short press on the Self-Test/Mute button.</p>



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 40 ml/min to 180 ml/min). If none of the above conditions is apparent, turn off the QiF Blood and Fluid Warmer Base Unit 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 is warmer than 42 °C	Fluid is hot!!! Tout: XX °C (YY °C) The LCD blinks	Steady beep	
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	Shut off the system, replace the Disposable Unit with a new one, and turn the system back on. If the error message still appears, turn off the system and send it for repair. Do not use this system until it is repaired or replaced by Quality in Flow Ltd., or one of its representatives.
General malfunction	*MALFUNCTION!!* Tout: XX °C (YY °C) The LCD blinks	Steady beep	

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 2. 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
Mascot Charger 9940Li	 100-220 VAC 50-60 Hz Max 0.9 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

8.2 Physical Properties

Table 3. Physical Properties

Parameter	Value
Weight of Base Unit with battery	Approximately 1650 g (3.64 lb)
Weight of Disposable Unit in sterile bag	Approximately 140 g (0.3 lb)
Dimensions of Base Unit with battery H × W × L	Approximately 235×160×75 mm (9.25×6.5×2.9 in)
Dimensions of Disposable Unit H × W × L	Approximately 210×160×45 mm (8.3×6.5×1.8 in)

8.3 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)	620 to 1,060 hPa (-400 to 3,962 meters); (-1312 to 13,000 ft)
Disposable Unit Shelf Life	3 years
Base Unit Service Life*	5 years
Water and particles Ingress rate	IP22

* The QiF™ Blood and Fluid Warmer 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.



8.4 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 B	The QiF™ Blood and Fluid Warmer 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	

9. Cleaning the System

9.1 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.

9.2 Cleaning the Base Unit and Battery

The QiF™ Blood and Fluid Warmer 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 QiF™ Blood and Fluid Warmer Base Unit and/or Battery.

10. System Contraindications and Precautions




10.1 QiF™ Blood and Fluid Warmer System Contraindications

- a Do not use the QiF™ Blood and Fluid Warmer if the audio and/or visual indications are not functioning.

10.2 QiF™ Blood and Fluid Warmer System Precautions

- a For blood / blood product / intravenous fluid infusion instructions, refer to your facility/organization protocol.
- 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), shut off the system, replace the Disposable Unit with a new one, and turn the system back on. If the error message still appears, turn off the system and send it for repair.
- f Do not use this system until it is repaired or replaced by Quality in Flow Ltd., or one of its representatives
- g Always replace the Disposable Unit when replacing a blood IV administration set.
- h Charge the rechargeable battery only with the supplied Fuyuang 2552000 Battery Charger.
- i The following components are reusable: QiF™ Blood and Fluid Warmer Base Unit, battery, battery charger and charger adapter.
- j The QiF™ Blood and Fluid Warmer 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 QiF™ Blood and Fluid Warmer 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 ± 2 °C.
- c Do not use the QiF™ Blood and Fluid Warmer in MRI, X-ray and CT environments.
- d Do not flow medications through the QiF™ Blood and Fluid Warmer.
- e No modification of this equipment is allowed!
- f Use of the QiF™ Blood and Fluid Warmer not according to its instructions may result in failure of the system or injury to patient.
- g  Do not use the Disposable Unit if the sterile package is damaged.
- h  The 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.

12. Disclaimer and Warranty

12.1 Disclaimer








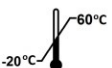









Quality in Flow Ltd. shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of this QiF™ Blood and Fluid Warmer, other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto.

12.2 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.

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., 15/03 is valid until March 2015)
	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)
IP22	Water and particles ingress rate
	Non pyrogenic fluid path - QiF™ 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)

