

Warrior Blood and Fluid Warmer Model QiF-01-12



Instruction for Use (IFU)

PROPRIETARY AND CONFIDENTIAL

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TABLE OF CONTENTS

1.	Indications for Use	4
2.	Intended Use	4
3.	Package Contents	4
4.	System Description	5
5.	System Components	6
5.1	Base Unit	6
5.2	Compact Disposable Unit	6
5.3	Intended Users	7
5.4	Fluid Warming Capacity	7
6.	Preparing and Operating the System	8
6.1	Charging the Battery	8
6.2	Preparing the System for Warming	9
6.3	Connecting the Base Unit to the Compact Disposable Unit	10
6.4	Connecting the Warrior to the Fluid Bag and Patient	11
6.5	Warming Blood or Intravenous Fluid Products	13
6.6	General Operation Instructions	13
6.7	Self-Test	14
6.8	Stopping the Warrior device Fluid / Blood Warming	14
6.9	Battery Replacement during Administration	15
7.	System Notifications and Troubleshooting	17
8.	Specifications and Characteristics	19
8.1	Electrical Specifications	19
8.2	Physical Properties	19
8.3	Environmental Conditions	19
8.4	Electromagnetic Compatibility (EMC) Conditions	20
9.	Cleaning the System	24
9.1	Cleaning the Compact Disposable Unit	24
9.2	Cleaning and disinfecting the Base Unit and Battery	24
10.	System Precautions	25
11.	Warnings	26
12.	Disclaimer and Warranty	
12.1	Disclaimer	
12.2	Warranty	
13.	Symbols and Legends	
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Do not use the Warrior 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") 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** 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** is provided in a hand carry bag. The bag can contain one additional battery, and its top compartment can be used for carrying or up to 4 Compact Disposable Unit.

4. System Description

What is the Warrior Blood and Fluid Warmer?

The **Warrior Blood and Fluid Warmer** is an inline, battery-powered, lightweight and completely portable system, for warming blood, blood product and IV fluids. The Warrior 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 °C \pm 2 °C (100.4 °F \pm 3.6 °F). The Warrior provides both audio and visual notifications.

5. System Components

The **Warrior** includes a reusable Base Unit and a sterile, single patient use disposable cartridge, called the 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 2. Base Unit front and rear views

5.2 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 IV / blood administration set to the Compact Disposable Unit Inlet Luer. The Outlet Luer of the 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 Compact Disposable Unit.

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

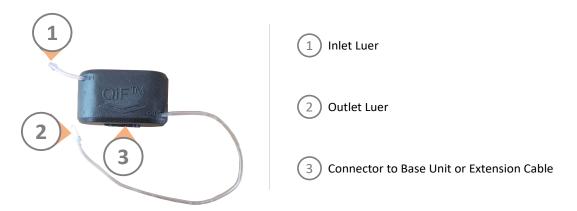


Figure 3. Compact Disposable Unit

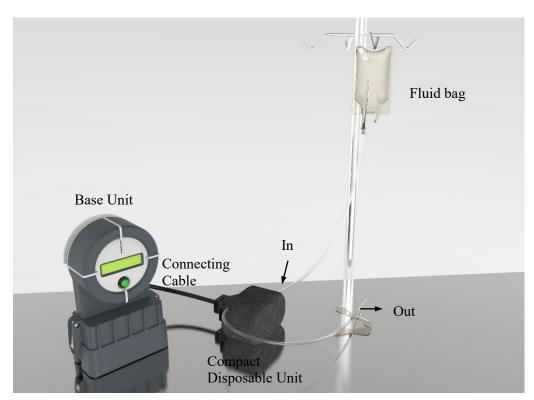


Figure 4. Base Unit connected to the Compact Disposable Unit

5.3 Intended Users

Who should use the Warrior Blood and Fluid Warmer?

The Warrior 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 warm using a fully charged battery?

The amount of fluid the Warrior 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 can warm up to three liters of parenterally administrated fluid with an inlet temperature of 4 $^{\circ}C$ (39.2 $^{\circ}F$).

When there are extreme changes in the flow rate or the inlet fluid temperature, the Warrior 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 is powered by a researchable 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.	 Plug the Battery into the Battery Charger using the charger adapter, and plug the Battery Charger into an AC electrical outlet. Note: the battery shall be charged using only its designated charging adapter. 	
	Note: the battery charger adapter shall be attached to the battery in the correct orientation: the charger adapter label in on the opposite side of the battery label, as shown in the picture on the right	
b.	Allow the battery to charge until the battery is fully charged. When the battery is fully charged, the battery charger green LED lights. (This is expected to be approximately 4—5 hours if the battery is empty). 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.	
	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.	

• 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 battery into the trash. The battery should be disposed of at a designated battery disposable collection point.

Preparing the System for Warming

6.2

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

Note: The following instruction show the Compact 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 Compact Disposable Unit connections. See section 5.2 for more details.

a.	 The Compact Disposable Unit cartridge is provided sterile 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. 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. 20/03, valid until 31st of March 2020). Do not re-sterilize the Compact Disposable Unit 	energies of the second se
b.	Insert the battery into the Base Unit and close the side latches. 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 . For more instructions on how to replace the battery during administration, see section 6.9.	

c.	Open the Compact Disposable Unit sterile package.	

6.3 Connecting the Base Unit to the Compact Disposable Unit

	Note: When connecting the cable to the Compact Disposable Unit, verify the top side of the cable connector is next to the protrusions on top of the Compact Disposable Unit	
d.	Connect the Base Unit cable to the Compact Disposable	
	Unit	
	► 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).	
	Important! Disconnect the cable from the Compact Disposable Unit only by pulling the designated connector.	- Contraction

6.4 Connecting the Warrior to the Fluid Bag and Patient

The Warrior 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 Warrior in MRI, X-ray and CT environments!
- Warming medications through the Warrior was not validated!
- No modification of this equipment is allowed!
- Use of the Warrior 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 Compact 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.	
с.	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.	

	WARNING: Always flush the line with intravenous fluid / blood / blood product before administrating to patient.	
	WARNING: Warming medications through the Warrior was not validated.	
	Note: The 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 Compact Disposable Unit with a damp cloth with water or alcohol (Iso- Propanol/Ethanol).	
d.	Connect the IV line to the fluid bag and flush the line with the intravenous fluid/blood.	Priming the

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.	Switch on the Base Unit, by moving the On/Off switch on the back side of the system to "I" position. The LCD displays the "Initializing" message and you will hear a steady beep.	
b.	Start flowing IV fluid / blood through the 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)".	
с.	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. Read the notification on the LCD display following each audio notification (short or steady beep).	
d.	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.	
	Note: You can administer several fluid bags using the same Compact Disposable Unit. The Warrior does not need to be shut off while replacing the fluid bag.	

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 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 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 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 2. 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 device Fluid / Blood Warming

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 system 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—d is section 6.4 above.

Dispose of the 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.

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.

Table 1. Battery Indications

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.

	WARNING: While the Base Unit is in the "Off" position the fluid/blood continues flowing through the system without being warmed until the system is turned on, completes initialization and starts warming again.	
a.	Shut off the Warrior Base Unit by pressing the On/Off switch on the back of the system to "0" position.	
b.	Remove the empty battery from the Warrior by opening the two side latches and pulling out the battery.	

c.	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 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 .	
d.	Switch on the Base Unit. The LCD displays the "Initializing" message and a steady beep is sound.	
	Start flowing IV fluid / blood through the 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)".	
e.	Follow the fluid or blood administration instructions provided by the manufacturer of the IV/blood administration set and your facility protocols.	

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.

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 the 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 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 until repaired by the manufacturer or by its representative.
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.
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.

Table 2 System	Notifications and	Troubleshooting
Table 2. System	1 ouncations and	Troubleshooting

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
Fluid is warmer than 42 °C	Fluid is hot!!! Tout: XX °C (YY °C) The LCD blinks	Steady beep	 (e.g. changing from 180 ml/min to 40 ml/min). If none of the above conditions is apparent, turn off the Base Unit 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) and check the battery status. 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
General malfunction	*MALFUNCTION!!* Tout: XX °C (YY °C) The LCD blinks	Steady beep	with fluid and restart the system by shutting it off and then on again. If the problem is not resolved shut off the system, replace the Compact Disposable Unit with a new one, flush the air out of the 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	D 100–220 VAC 50–60 Hz Max 0.9 A
Defibrillation Proof type CF Applied Part	The 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 Compact Disposable Unit in sterile bag	Approximately 117 g (0.26 lb)
Dimensions of Base Unit with battery $H \times W \times L$	Approximately 232×156×78 mm (9.13×6.14×3.07 in)
Dimensions of Compact Disposable Unit $H \times W \times L$	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)
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)
Compact Disposable Unit Shelf Life	3 years
Base Unit Service Life*	5 years
Water and particles Ingress rate****	IP33

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 is suitable for use in all establishments, including domestic
Harmonic Emissions	NA	establishments and those directly connected to the public low voltage power
Voltage Fluctuations	NA	supply network that supplies buildings used for domestic purposes.

The following EMC conditions are relevant to Base Unit S/N BU01000 and forward.

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.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Warrior, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

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

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 5 %.
Electrical fast transient/burst, IEC 61000-4-4	2 kV for power supply lines 1 kV for SIP/SOP lines	Not required	The Warrior is battery powered equipment.
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	Not required	The Warrior is battery powered equipment.
Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	Not required	The Warrior is battery powered equipment.
Power frequency magnetic field, IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

 Table 7. Electromagnetic interference resistance

	~ .		
NOTE: UT	is the AC mains v	oltage prior to application	on of the test level.

Table 8. Electromagnetic interference resistance

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6	3 Vrms	[V] = 3 Vrms
Conducted RF	150 kHz to 80 MHz	
	6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz)	[V] = 6 Vrms
IEC 61000-4-3	10 V/m	[E] = 10 V/m
Radiated RF	80 MHz to 2.7 GHz	
Proximity fields from RF wireless	385 MHz	27 V/m
communications equipment	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	
	1845 MHz	
	1970 MHz	
	2450 MHz	

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

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

Recommended safety distances between portable and mobile RF telecommunications devices and the QiF Warrior blood and fluid warmer

The QiF Warrior 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 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 blood and fluid warmer as recommended below, according to the maximum output power of the communications equipment.

Rated	Protection distance according to transmitter frequency m		
maximum output power of transmitter W	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.

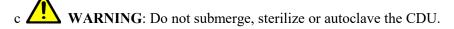
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. Cleaning the System

9.1 Cleaning the Compact Disposable Unit

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

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



9.2 Cleaning and disinfecting the Base Unit and Battery

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

Before cleaning, disconnect the BU from the Battery.

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 reusable parts.

10. System Precautions

- a Do not use the Warrior 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 Compact Disposable Unit
- e Always position the 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 Compact Disposable Unit when replacing a <u>blood</u> 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 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. **A** Warnings

- a Never throw the Warrior 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 Warrior in MRI, X-ray and CT environments.
- d Warming medications through the Warrior was not validated!
- e No modification of this equipment is allowed!
- f Use of the Warrior not according to its instructions may result in failure of the system or injury to patient.
- g Do not use the Compact Disposable Unit if the sterile package is damaged.
- h 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.
 - Do not re-sterilize the 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, other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto.

12.2 Warranty

The Warrior 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
EC REP	Authorized representative in the European community
REF	Catalogue number
SN	Serial Number
	Warning
2	Refer to instruction manual/booklet
┥♥	Defibrillation proof CF applied part
-20°C	Temperature limitation
\otimes	Do NOT reuse
YY/MM	Use by YY/MM (meaning the end of the indicated month. i.e., 20/03 is valid until March 2020)
STERNIZE	Do NOT re-sterilize
STERILEEO	Sterilized using Ethylene Oxide
8	Do NOT use if package is damaged
×.	Keep away from sunlight
X	Do NOT throw to trash
IP33	Water and particles ingress rate
X	Non pyrogenic fluid path - the 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)