Haiim®

"Haiim" Vacuum-assisted blood collection system

User Manual

Please read this instruction manual carefully before operating this product.

A.【Product Description】

This product, "Haiim" Vacuum-assisted blood collection system (WH-001), is composed of two parts: 1) a main device (HD-001) and 2) a single-use disposable cassette (HC-001). The main device includes a pressure control system that generates negative pressure to create a vacuum effect for collecting blood. The intended purpose of the product is limited to IVD use only. When operating this product, it is necessary to use a blood lancet with a needle (diameter ≥ 0.8 mm, gauge number ≤ 21G) or a blade (width ≥ 1.5 mm) and a micro-collection tube (the information of compatible micro-collection tubes is provided in Section E, Cassette (HC-001) General Specifications).

B.【Intended Use】

"Haiim" Vacuum-assisted blood collection system is intended to use a vacuum to collect capillary blood from a puncture site. The product is composed of a cassette able to connect with a single-use micro-collection tube and a main device providing a pressure control function. When assembled and activated, the product collects blood from the puncture site to the micro-collection tube. This product is for professional use only.

C.【Contraindications】

1. Diseases that are associated with blood coagulation disorders or need to take any anti-coagulation medication/treatment may cause abnormal blood loss.
2. Areas of skin infection or skin conditions like cellulitis or abscess should be avoided because of the risks of inoculating the blood with bacteria, viruses, and any substance that caused infection.

D.【Warnings and Precautions】

1.Product Safety

1.1 Before starting to use this product, please confirm if the standard voltage of the country or region where you are going to use the product is in the range of the technical specifications of the power adapter provided in Section E of this user manual.
1.2 Before starting to use this product, please verify that the product has complete packaging shown in Section F. If there is any missing part, please kindly return the whole product to where you purchased it from for a replacement.
1.3 Do not apply any physical impact to the main device and avoid it from falling.
1.4 This product can be used in a professional healthcare environment.
1.5 This product is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
1.6 The product should not be used adjacent to or stacked with other equipment.
1.7 Do not insert anything into the connectors' holes or the outer case gaps of the main device.
1.8 Do not place the product in a location accessible to children or unauthorized users.

2.Electrical Safety

2.1 Only use a power adapter having the model stated in Section E of this user manual. Any power adapter having a model different from the aforementioned model is prohibited.
2.2 Please do not use any other cables or accessories not approved by the manufacturer in this user manual to avoid negative influence on electromagnetic compatibility.
2.3 Do not connect this product to electric sockets with wet hands.
2.4 If abnormal behavior is observed due to EM disturbances, please relocate the main device accordingly.
2.5 There may be an interaction between the product and an electric equipment due to electromagnetic radiation. It's recommended a safety distance of at least 30 cm between the product and electric equipment, especially sensitive equipment.
2.6 This Product is medical electrical equipment that needs special precautions regarding EMC and needs to be installed according to the EMC information provided.

3.Instructions for Safe Blood Drawing

3.1 Before starting to use this product, please read this user manual carefully and other documents provided along with the product.
3.2 This product has been designed for fingertip blood collection. Please do not give it any other uses.
3.3 Only medical or healthcare providers are eligible to operate this product in accordance with local regulations.
3.4 The main device can only be used with the cassettes. Please do not use any other goods similar to the cassettes.
3.5 The cassette is a single-use consumable. Please do not reuse it.
3.6 Do not use any cassette whose individual packaging is damaged or perforated to avoid any risks of contamination.
3.7 Do not start to operate this product until the cassette has been correctly installed.
3.8 For emergencies or accidents during blood drawing, please refer to the system operation setting stated in Section E of this user manual.
3.9 Users should prepare other items that may be required for blood drawing according to Section H (e.g., gloves, alcohol pads, etc.).
3.10 Since blood is a high-risk biological specimen, it is important to take proper precautions every time when performing the blood collection process. Users shall avoid directly touching the wounds or any areas with blood.
3.11 Do not inject the collected blood specimen back into anyone's body to avoid infection or further risks.
3.12 Usage of this product performing by a person unable to properly operate the product due to color blindness, blindness, or blurred vision shall be avoided.
3.13 Please comply with local authority regulations and use appropriate biological waste disposal protocols to dispose of used cassettes and other consumables that have been used or that have been in contact with blood specimens. Regarding the disposal of the main device, please follow your national requirements.

4.Cleaning and Maintenance Considerations

4.1 Please avoid dust, dirt, or other contaminants enters the Cassette Connector of the main device (see section G, 1.4) or accumulated on the main device surfaces.
4.2 The main device shall be cleaned regularly, especially when it has been in contact with blood specimens, to prevent the risk of cross-contamination. For more details, please refer to the Section J of this user manual.
4.3 It is forbidden to disassemble or alter completely or partially both the main device and the cassette. If so, the functionality and safety of this product are not assured.
4.4 If the product requires maintenance, please contact the customer service provided by Winnoz Technology, Inc.

E.【Items and Specifications】

Item Name	Model	Remarks
"Haiim" Vacuum-assisted blood collection system	WH-001	
User Manual	HU-001	
Main Device	HD-001	
Cassette	HC-001	Accessory
Power adapter	GEM12I12-P1J	Accessory

"Haiim" Vacuum-assisted blood collection system
Main Device(HD-001) General Specifications

Dimension	Width: 62 mm/Length: 123 mm/Height: 62 mm
Weight	219 g (net weight)
System Operation Setting	- Press the Start-Button (Section G, 1.3) to start. - To stop the main device when functioning in case of emergency or accidents, press the Start-Button for one second. - Automatic cycle time: 2 min
Power Adapter Specifications	Model: GEM12I12-P1J Input Rating: 100-240 VAC, 50-60 Hz, 0.4-0.2A Output Rating: 12 Vdc/1A Cable Length: 1.8 m Weight: 118 g
Compatible Cassette	"Haiim" Vacuum-assisted blood collection system Cassette (HC-001)
Operating Conditions	Temperature range：0~40℃ Humidity range: 30~75% RH
Storage Conditions	Temperature range：0~40℃ Humidity range:30~75% RH Avoid direct exposure to sunlight
EMC Standards	· Conducted Emission (IEC 60601-1-2:2014) · Radiated Emission (IEC 60601-1-2:2014) · Harmonic distortion (IEC 60601-1-2:2014) · Voltage fluctuations and flicker (IEC 60601-1-2:2014) · ESD (IEC 60601-1-2:2014) · RS Radiated RF EM fields (IEC 60601-1-2:2014) · RS Proximity fields from RF wireless communications equipment (IEC 60601-1-2:2014) · EFT (IEC 60601-1-2:2014) · Surge (IEC 60601-1-2:2014) · CS (IEC 60601-1-2:2014) · PFMF (IEC 60601-1-2:2014) · Voltage dips and interruptions (IEC 60601-1-2:2014)

"Haiim" Vacuum-assisted blood collection system
Cassette (HC-001) General Specifications

Dimension	Width: 18 mm/Length: 32.5 mm/Height: 42 mm (excluding the height of the assembled micro-collection tube)
Weight	4 g (Net weight)
Recommended Micro-collection Tube Specification	1. BD Microtainer® Tube with BD Microgard™ Closure 0.5 mL (Without gel) 2. EV Single-use Containers for Human Capillary Blood Specimen Collection 0.5 mL (Without gel) It is not recommended to use a micro-collection tube with gel.
Compatible Device	"Haiim" Vacuum-assisted blood collection system. Main Device (HD-001)
Packaging	Single package (non-sterile)
Operating Condition	Temperature range：0~40℃ Humidity range: 30~75 % RH
Storage Conditions	Temperature range：0~40℃ Humidity range:30~75% RH Avoid direct exposure to sunlight
Shelf Life	3 years

F.【Product Images】

The complete packaging of "Haiim" Vacuum-assisted blood collection system is shown below:

1. Main device (HD-001), including Power Adapter (GEM12I12-P1J)

2. Cassette (HC-001)

G.【Description of Key Items】

The function of each key item of the Product as labeled and briefly described below:

1. Main Device (HD-001)

1.1. Power Adapter Connector: a connector shall be connected to a power adapter (GEM12I12-P1J) to have power input before blood collection.
1.2. Switch: the switch of the main device. By moving Switch, the main device could be turned on or off.
1.2.1. ON position.
1.2.2. OFF position.
1.3. Start-Button: a button for starting a blood collection process by gently press. In case of emergency or accidents, press again the Start-Button for 1 second to stop the blood collection process.
1.4. Cassette Connector: a connector for connecting to the Main Device Connector.
1.5. Indicator Lights: the indicator lights consist of three LED lights, showing different colors corresponding to different status as described below:

- White light:

The Indicator Lights show the white color right after powering on the main device. Then, the Indicator Lights will turn to the green color and go into standby mode.

- Green light:

Standby mode.
The Indicator Lights are green when the main device is in a normal condition, and is not collecting blood.

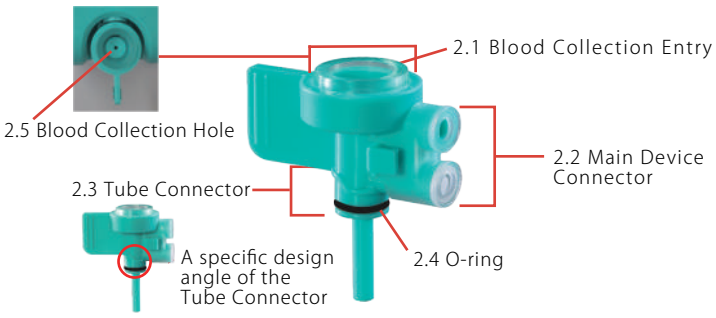
- Yellow light:

The yellow color means negative pressure does not reach the preset value.
The Indicator Lights first show the yellow color once pressing the Start-Button. If the pressure does not reach the preset value within 10 seconds, the Indicator Lights will turn to the green color, and the main device will go back to the standby mode. Please refer to Scenario 1 of Section L for troubleshooting.

- Blue light:

Blood collection mode. When the negative pressure reaches the preset value, the Indicator Lights will turn from the yellow color to the blue color and maintain at blue for 2 minutes to complete the blood collection process.
If the Indicator Lights turn from the blue color to the yellow color during the blood collection process, please refer to Scenario 2 of Section L for troubleshooting.

2. Cassette (HC-001)



2.1 Blood Collection Entry: an open end of the cassette on where a fingertip should be placed.
2.2 Main Device Connector: a connector for connecting to the Cassette Connector.
2.3 Tube Connector: a connector with a specific design angle for connecting to a commercial micro-collection tube recommended in this user manual.
2.4 O-ring.
2.5 Blood Collection Hole: the top entry of the capillary structure of the cassette for receiving blood specimens from a fingertip.

H.【Preceding Operation】

Before starting, please prepare the following items:


(1) Main Device


(2) Cassette


(3) Micro-collection tube


(4) Lancet


(5) Wrist pad


(6) Gloves


(7) Alcohol pad, or other consumables for disinfection


(8) Cotton swab

(9) Cotton ball, or other hemostatic consumables

I.【System Operation】

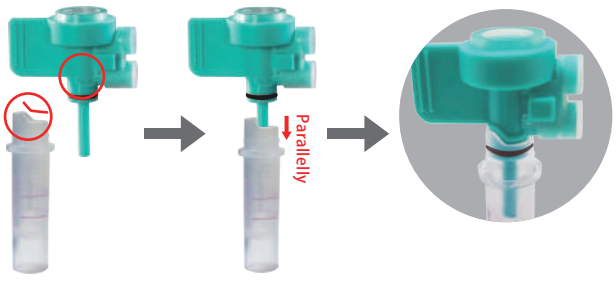
In order to well operate this product, please read the following instructions and corresponding pictures carefully:

1. Turning on a main device

1.1 Connecting a main device and a power adapter (GEM12I12-P1J) through the Power Adapter Connector.
1.2 Connecting the power adapter to a power outlet having a suitable range of Input Rating stated in Section E.
1.3 Moving the Switch to the ON position.

2. Assembling steps

2.1 Connecting a cassette to a commercial micro-collection tube recommended in this user manual. Please refer to the pictures below:



- To ensure airtight during the blood collection process, please confirm that the angle of the micro-collection tube open end is correctly aligned with the specific design angle of the Tube Connector of the cassette. Please note that the O-ring should not be deformed when assembling.

2.2 Connecting the cassette to the main device. Please refer to the picture below:

(1) Please insert the cassette into the main device and do not tilt the cassette when inserting.
(2) To ensure the cassette is installed firmly, please push the cassette inward to the main device.

3. Checking airtight of the system

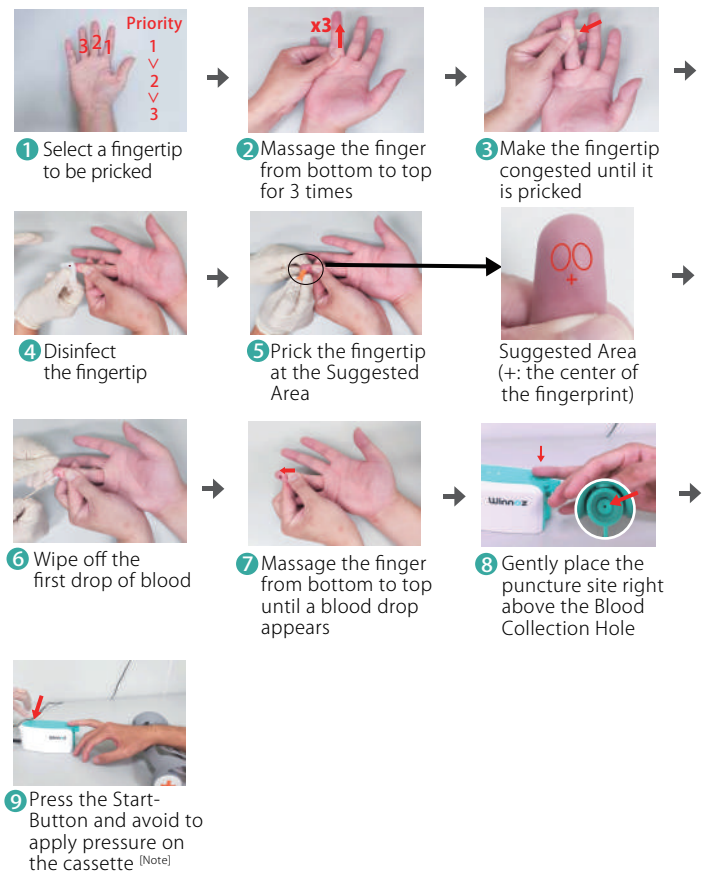
Before conducting the blood collection process, the user shall check the airtight of the system by inspection if the micro-collection tube along with the cassette is correctly installed on the main device per the following instructions:

(1) Wash and dry your hands.
(2) Select a finger to be pricked and put on the Blood Collection Entry (Section G, 2.1). Please keep relaxing your finger to avoid unnecessary pressure enforced on the cassette and resting your wrist and arm on a desk or a supportable object. Please note that the user does not need to prick the finger at this step. For choosing a finger to be pricked, please refer to step 4 of this Section.
(3) Press the Start-button, and you would hear machinery sound, feel suction at your fingertip, and observe that the Indicator Lights changes from green to yellow and then to blue in 3-10 seconds, indicating the system has successfully entered into the blood collection mode. If succeed, please press the Start-button again for 1 second to stop the process and proceed step 4 to step 6 of this Section for the blood collection. Otherwise, please refer to Scenario 1 of Section L for troubleshooting.

4. Finger selection priority

The recommended priority of fingers for blood drawing are follows: ring finger > middle finger > index finger. Please note that the fingertip's size and elasticity will affect the efficacy of blood collection. The fingertip's size is larger and the fingertip is more pliable, the efficacy of blood collection will be improved. The general order of fingertip size is as shown: middle finger > index finger ≈ ring finger. It is not recommended to use a fingertip having calluses. Users can choose fingers dependent on their physical conditions.

5. Blood collection procedure



1 Select a fingertip to be pricked
2 Massage the finger from bottom to top for 3 times
3 Make the fingertip congested until it is pricked
4 Disinfect the fingertip
5 Prick the fingertip at the Suggested Area
Suggested Area (+: the center of the fingerprint)
6 Wipe off the first drop of blood
7 Massage the finger from bottom to top until a blood drop appears
8 Gently place the puncture site right above the Blood Collection Hole
9 Press the Start-Button and avoid to apply pressure on the cassette [Note]

[Note]: Please relax your finger and rest your wrist and arm on a desk or a supportable object.

6. After completing blood collection

1 Remove the fingertip from the cassette
2 Retrieve the cassette and disconnect the micro-collection tube
3 Cover the cap. If applicable, mix the specimen with the anticoagulant
4 Proceed with a specimen testing based on needs

J.【Cleaning and Disinfecting】

Cassette

The cassette is single-use disposable. Please discard it as a biological waste according to local authority regulations.

Main Device

1. Although the user needs to operate the main device with clean disposable gloves, it is still recommended to clean and disinfect the main device.
2. Please confirm that the main device is not connected to any power source before cleaning and disinfecting it.
3. Please clean and disinfect the main device before and after each user's use, and once there is any dirt or blood on the main device.
4. Please use one of the following cleaning materials:
   (a) A clean gauze, cotton swab, or any functional analogue, moistened with a cleaning agent, including but not limited to, CaviCide, MEDASEPT® 100 or any similar CE-marked medical device (without hypochlorous acid and its derivatives) applying to disinfection.
   (b) An available commercial disinfection product, including but not limited to, CaviWipes, Super Sani-Cloth Plus or any similar CE-marked medical device (without hypochlorous acid and its derivatives).
   (c) Activity spectrum of the recommended cleaning agents:

Activity Spectrum	Recommended reaction time		
	CaviCide/ CaviWipes	MEDASEPT® 100	Super Sani-Cloth Plus
Bactericidal			
Pseudomonas aeruginosa	3 min.	30 sec.	1 min.
Staphylococcus aureus	3 min.	30 sec.	1 min.
Enterococcus spp. (incl. VRE)	3 min.	30 sec.	N.A.
MRSA	3 min.	30 sec.	2 min.
Fungicidal			
Candida albicans	1 min.	30 sec.	1 min.
Aspergillus brasiliensis	1 min.	5 min.	N.A.
Trichophyton mentagrophytes	3 min.	N.A.	N.A.
Virucidal			
HBV/HCV/HIV	2 min.	30 sec.	15 sec.
Influenza A2/H1N1/H5N1	2 min.	30 sec.	15 sec.
Vaccinia virus	2 min.	30 sec.	15 sec.
Coronavirus	2 min.	30 sec.	15 sec.
HSV-1/HSV-2	2 min.	30 sec.	N.A.
BVDV	2 min.	30 sec.	N.A.
Mycobactericidal/ Tuberculocidal			
Mycobacterium terrae	1 min.	3 min.	30 sec.
Mycobacterium avium	1 min.	3 min.	N.A.
Mycobacterium bovis	3 min.	N.A.	N.A.

Note N.A. is for Not Available.

5. Cleaning and disinfecting procedure:
   (a) Wear clean disposable gloves.
   (b) Clean the exterior surface with a cleaning material aforementioned.
   (c) Clean the Cassette Connector using a cotton swab moistened with a cleaning agent aforementioned.
   (d) If the cleaning material is stained, repeat above step 5(b) or 5(c) with a new cleaning material.
   (e) Stand and air-dry the cleaned area.
6. CAUTIONS of the cleaning and disinfecting procedure
   (a) Before using any cleaning materials aforementioned, please carefully read the IFU of the cleaning material to be used.
   (b) AVOID getting any moisture or dirt into any openings of the main device.
   (c) DO NOT spray any cleaning agent directly onto the main device.
   (d) DO NOT use any organic solvents to clean the main device.

K.【Adverse Event Notification】

In the event that there is an unexpected accident or defective product, please notify the European authorized representative of Winnoz Technology, Inc.: MedNet EC-REP GmbH: Tel: +49 (0) 251 322 66-64; Fax: +49 (0) 251 322 66-22; Email: ecrep@medneteurope.com; Address: Borkstrasse 10, 48163 Muenster, Germany.

L.【Troubleshooting】

1. If the system does not run properly

Generally, once a fingertip is properly placed on the Blood Collection Entry of a cassette and the Start-Button is pressed, the Indicator Lights will first turn from the green color to the yellow color, indicating that the main device will start to produce negative pressure. In 3-10 seconds, the Indicator Lights will turn from the yellow color to the blue color, stating that the negative pressure reaches the preset value and the blood collection process starts. The Indicator Lights will maintain at blue color for 2 minutes to complete the blood collection process, and then the main device will go back to the standby mode.
If the colors of Indicator Light do not change according to the above statements or the main device stops during the blood collection process, please refer to the following scenarios for troubleshooting.

Scenario 1 The Indicator Lights do not turn from yellow to blue in 3-10 seconds after pressing the Start-Button.

1. Cause of issue: there is no airtight at the interfaces stated below
   (a) The cassette and the micro-collection tube.
   (b) The Main Device Connector of the cassette and the Cassette Connector of the main device.
   (c) User's fingertip and the Blood Collection Entry of the cassette.
2. Troubleshooting:
   (a) Please confirm that the micro-collection tube is correctly aligned with the cassette, and the O-ring of the cassette should not be deformed.
   (b) Please check if the cassette is secured accurately and firmly to the main device. It is recommended to re-insert the cassette into the main device and push the cassette inward to the main device slightly.
   (c) Please adjust the position of your fingertip to make sure the Blood Collection Entry is correctly covered. If your fingertip cannot cover the Blood Collection Entry, it is suggested to try other fingers.
   (d) A wet finger will affect the airtight of the system. Please dry your finger before the blood collection process if you washed your hands or use an alcohol pad to disinfect your fingertip.
   (e) Please make sure that your fingertip does not apply pressure on the cassette. It is recommended to rest your arm and wrist on a desk or a support object.
   (f) If the issue cannot be solved after the above procedures, please contact the customer service provided by Winnoz Technology, Inc.

Scenario 2 During the blood collection process, the Indicator Lights turn from the blue color to the yellow color.

1. Cause of issue: a not airtight status suddenly caused between the fingertip and the assembled cassette.
2. Troubleshooting:
   (a) Please adjust the position of your fingertip to make sure the Blood Collection Entry is correctly covered. If your fingertip cannot cover the Blood Collection Entry, it is suggested to try other fingers.
   (c) Please make sure that your fingertip does not apply pressure on the cassette. It is recommended to rest your arm and wrist on a desk or a support object.
   (d) If the issue cannot be solved after the above procedures, please contact the customer service provided by Winnoz Technology, Inc.
   (e) If you need to stop the process, please press the Start-Button for 1 second.

2. If the user could not collect enough blood volume or quality blood

Due to multiple heterogeneous factors such as age, microvascular distribution, blood circulation, atmospheric pressure, etc., the blood volume collected with the product could vary in different scenarios. Notwithstanding, when sufficient blood specimens cannot be collected, please try the following methods to obtain more blood or seek specialized medical assistance or try other blood collection methods.

(a) Before blood collection, it is recommended that you warm and massage your fingers properly.
(b) According to experimental data, hyperhidrosis and hypotension may affect the blood volume collected because a wet finger will affect the airtight of the system. Please dry your finger before the blood collection process if you washed your hands or use an alcohol pad to disinfect your fingertip.
(c) If you had applied hand cream on your hand, please wash it away and dry your fingers as it may contaminate the blood specimen.
(d) The airtight of the system affects the collected blood volume. Please confirm the system is airtight before blood collection by following the instructions in the scenario 1 of Section L.
(e) When operating this product, it is necessary to use a blood lancet with a needle (diameter ≥ 0.8 mm, gauge number ≤ 21G) or a blade (width ≥ 1.5 mm). In addition, using a lancet whose diameter or width is smaller than that of 21G would increase hemolysis risk.
(f) Suppose blood cannot be successfully collected after following the customer service's guidance and confirming that the product functions normally and has been operated correctly, the product may not be applicable to this user.

M.【MANUFACTURER'S declaration – Electromagnetic Compatibility – for all ME EQUIPMENT and ME SYSTEMS】

Manufacturer's declaration-electromagnetic immunity

The WH-001 is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the WH-001 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment-guidance (for professional healthcare environment)
Electrostatic discharge(ESD) IEC 61000-4-2	Contact: ±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Contact: ±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±0.5 kV, ±1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0.5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: 0 % U_T; 0.5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical professional healthcare environment. If the user of the WH-001 requires continued operation during power mains interruptions, it is recommended that the WH-001 be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The WH-001 power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity

The WH-001 is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the WH-001 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment-guidance (for professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0.15 MHz - 80 MHz 6 Vrms: in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0.15 MHz - 80 MHz 6 Vrms: in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the WH-001 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). 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 propagation is affected by absorption and reflection from structures, objects and people.

IFU-1801
EN 2020-09 rev.5.7

Recommended separation distance between portable and mobile RF communications equipment and the WH-001

The WH-001 is intended for use in an electromagnetic environment (for professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the WH-001 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WH-001 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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 separation distance for 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.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The WH-001 is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the WH-001 should assure that it is used in such an environment.

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m) (for professional healthcare)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28	28
870							
930							
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation [b] 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
5500							
5785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

N.【Symbols Description】

The warning signs or patterns marked on the label of this manual or the outer box are intended to maintain the safety of its use and to prevent the user or others from being injured or property damage in advance.

Symbol	Definition
SN	Serial number
REF	Catalogue number
LOT	Manufacturing batch number
	Remark: Please check the warnings and precautions
	Single-use only and used it for sterilization bag of cassette (Do not reuse it)
	Contact with electric shock protection (Do not contact with the heart)
	Double insulation
	Non-general household waste
	Manufacturer name and address
	Date of manufacture (year/month/day)
	Do not use if the package is damaged
	Maximum and minimum temperature
	Please read the instructions before use
REP	European Authorized Representative

Winnoz®

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Email: service@winnoz.com

Winnoz Technology, Inc. has entrusted Gigatek Inc. for manufacturing.
Made in Taiwan

R.O.C. (Taiwan) Patent： I652463
U.S. Patent：10,136,848
European Patent：EP3445311

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CE IVD

IFU-1801
EN 2020-09 rev.5.7