Haiim

"Haiim" Vacuum-assisted blood collection system

WH-001

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. 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 (*In Vitro* Diagnositcs) 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).

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.

D. Warnings and Precautions

Product safety

- Please verify that the product has complete components as shown in Section F.
- ⚠ **Do not** apply any physical impact to the Main Device and avoid it from falling.
- The product should not be used adjacent to or stacked with other equipment.
- It is recommended to place this product on a level platform during operation and avoid placing it on uneven surfaces.
- ⚠ **Do not** insert anything into the Cassette Connector or the outer case gaps of the Main Device.
- ⚠ **Do not** place the product in a location accessible to children or unauthorized users.

Electrical safety

- Please confirm that the standard voltage of the provided power adaptor is suitable for your area.
- ⚠ **Do not** use any other cables, power adapter or accessories that are **NOT** approved by the manufacturer.
- ⚠ **Do not** connect this product to electric sockets with wet hands.
- This product needs to be installed according to the EMC information provided (Section M). A safety distance of at least 30 cm between the product and other electrical equipment.
- This product can be used in a professional healthcare environment.
- This product is not intended for use in residential environments and may not provide adequate protection for radio reception in such environments.

Instructions for safe blood drawing

- Please read this user manual carefully and other documents provided along with the product.
- This product has been designed for capillary blood collection. **Do not** give it any other uses.
- Only a medical or healthcare provider or an eligible person in accordance with local regulations is the user of this product.
- The Cassette is a single-use consumable. Please **do not** reuse it.
- ⚠ **Do not** use a Cassette with damaged packaging.
- ⚠ **Do not** use a Cassette if the membrane of the Cassette is loosened from its original position.
- ⚠ **Do not** start to operate this product until the Cassette has been correctly installed.
- For emergencies or accidents during blood drawing, press the Start-Button for 1 second to stop the operation of the Main Device.
- Users shall avoid directly touching the wounds or any areas with blood when performing the blood collection process.
- ⚠ **Do not** inject the collected blood specimen back into anyone's body.
- A person with color blindness, blindness, or blurred vision may need assistance to operate this product properly.
- When disposing of the Main Device, used Cassettes, and other consumables, please comply with local authority regulations and biological waste disposal protocols.

Cleaning and maintenance considerations

- Please avoid dust, dirt, or other contaminants entering the Cassette Connector part of the Main Device or accumulated on the Main Device surfaces.
- The Main Device shall be cleaned regularly, especially when it has been in contact with blood specimens. For more details, please refer to the Section J of this user manual.
- ⚠ **DO NOT** disassemble or alter completely or partially the Main Device or the Cassette.
- If the product requires maintenance, please contact the customer service provided by Winnoz Technology, Inc.

E. Items and Specifications

Item Name	Model
"Haiim" Vacuum-assisted Blood Collection System	WH-001
User Manual	HU-001
Main Device	HD-001
Cassette	HC-001
Cassette-L	HC-002
Power Adapter	GEM12I12-P1J

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) to start. - In case of emergency or accidents, press the Start-Button for 1 second to stop the Main Device. - 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) or Cassette-L (HC-002)
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+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · Radiated Emission (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · Harmonic distortion (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · Voltage fluctuations and flicker (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · ESD (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · RS Radiated RF EM fields (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · RS Proximity fields from RF wireless communications equipment (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · EFT (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · Surge (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · CS (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · PFMF (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021) · Voltage dips and interruptions (IEC 60601-1-2:2014+A1:2020 CSV and EN 60601-1-2:2015+A1:2021)

Cassette (HC-001) General Specifications

Dimension	Width: 18 mm Length: 33 mm Height: 39 mm (excluding the height of the assembled micro-collection tube)
Weight	2.8 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

Cassette-L (HC-002) General Specifications

Dimension	Width: 18 mm Length: 33 mm Height: 39 mm (excluding the height of the assembled micro-collection tube)
Weight	2.8 g (net weight)
Recommended Micro-collection Tube specification	1. Greiner MiniCollect® Blood Collection Tubes 2. BD Microtainer ® Tube with BD Microgard™ Closure 0.5 mL (Without gel) 3. 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 components of the "Haiim" Vacuum-assisted blood collection system are shown below. If there is any missing part for your order, please contact Winnoz Technology, Inc. for further actions.

■ **Main Device(HD-001), including Power Adapter (GEM12I12-P1J)**

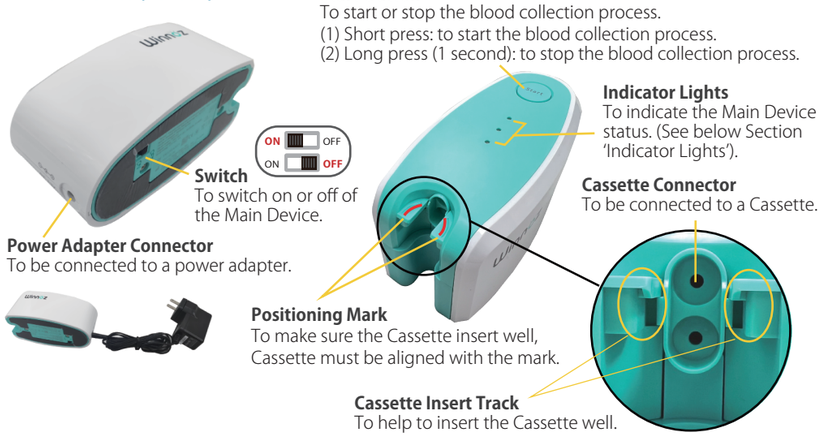
■ **Cassette (HC-001) / Cassette-L (HC-002)**

HC-001 HC-002

G. Description of Key Items

The function of each key item of the product is labeled and briefly described below:

■ **Main Device (HD-001)**



Start-Button
To start or stop the blood collection process.
(1) Short press: to start the blood collection process.
(2) Long press (1 second): to stop the blood collection process.

Indicator Lights
To indicate the Main Device status. (See below Section 'Indicator Lights').

Switch
To switch on or off of the Main Device.

Cassette Connector
To be connected to a Cassette.

Power Adapter Connector
To be connected to a power adapter.

Positioning Mark
To make sure the Cassette insert well, Cassette must be aligned with the mark.

Cassette Insert Track
To help to insert the Cassette well.

■ **Indicator Lights**

White light	Green light	Yellow light	Blue light
			
Initiation mode It indicates that the Main Device is initiating.	**Standby mode** It indicates that the Main Device is standby.	**Alarm mode** It indicates that the vacuum pressure has not reached the preset value yet.	**Blood collection mode** It indicates that the Main Device is in the blood collection process and the vacuum pressure reaches the preset value.

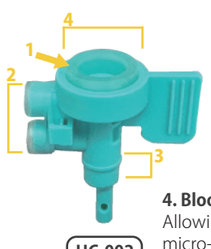
■ **Cassette (HC-001) or Cassette-L (HC-002)**

HC-001

1. Finger Pad
A soft pad where a fingertip should be placed.

2. Main Device Connector
To be connected to the Cassette Connector on the Main Device.

3. Tube Connector
A specific design part to connect to a commercial micro-collection tube.



HC-002

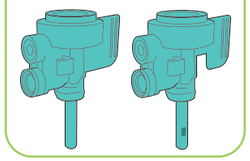
4. Blood Collection Hole
Allowing blood flow into a micro-collection tube.

H. Preceding Operation

Before starting, please prepare the following items:

1) Main Device

2) Cassette/ Cassette-L



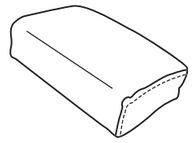
3) Micro-collection Tube

The information of compatible micro-collection tubes is provided in Section E

4) Lancet / Blade

Lancet with a needle (diameter ≥ 0.8 mm, gauge number ≤ 21G) blade (width ≥ 1.5 mm)

5) Blood Collection Pillow/ Wrist Pad

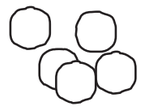


6) Gloves

7) Alcohol Pad
or other consumables for disinfection

8) Cotton Swab

9) Cotton Ball
or other hemostatic consumables



10) Disinfectant

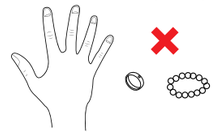
For device clean & disinfection, please refer to **Section J** for more details.

I. System Operation

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

1) Prepare patient's finger for blood collection

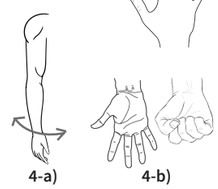
1. Take off rings or other jewelry



2. Recommend to drink 200-300 ml of water before blood collection

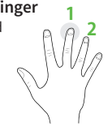
3. Wash and dry hands

4-a) Hang the entire arm by your side, and then 4-b) perform grasping-relaxing movements with your hands 25 to 30 times.



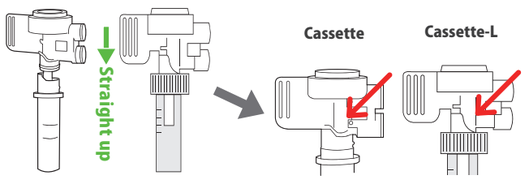
4-a) 4-b)

5. Choose a finger
Recommended Priority 1>2



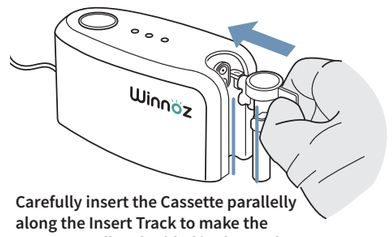
2) Turn on a Main Device

3) Assemble Cassette & Microtube



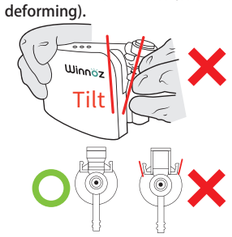
***NOTE**
Please confirm that the Cassette (HC-001) and Cassette-L (HC-002) are totally well-matched with the microtubes as above images.

4) Connect the Cassette to the Main Device

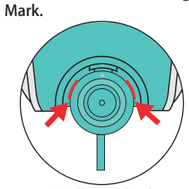


Carefully insert the Cassette parallelly along the Insert Track to make the Cassette well embedded in the track.

***NOTE-1**
DO NOT tilt the Cassette (to avoid deforming).



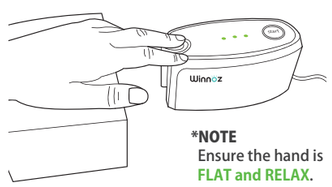
***NOTE-2**
Cassette must be aligned with and fit with the Positioning Mark.



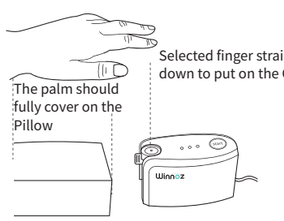
Well-matched

5) Pre-test (Checking airtight of the system)

1. Patient places the palm on the pillow and gently put the finger on the Cassette

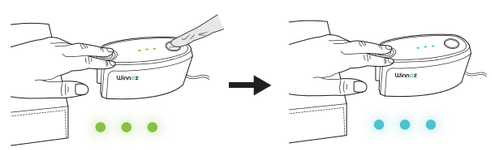


***NOTE**
Ensure the hand is **FLAT and RELAX**.



2. Operator presses the start button to activate the pre-test

The patient can slightly move the fingertip to the correct position to make sure the fingertip fully covers the Cassette Hole. (However, **DO NOT** apply any pressure to the Cassette.)

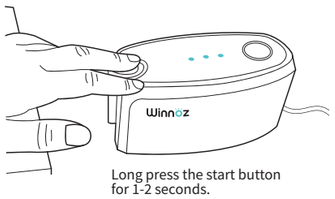


When the indicator ights turn from GREEN to BLUE, the system is airtight and will perform as required.

***NOTE:** If you **do not feel suction** or **the Indicator Lights does not change**, please **refer to problem 1 of Section L**, Troubleshooting part.

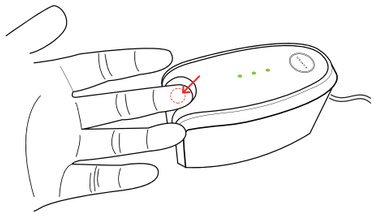
5) Pre-test (Checking airtight of the system)

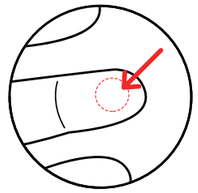
3. Operator stops the system



Long press the start button for 1-2 seconds.

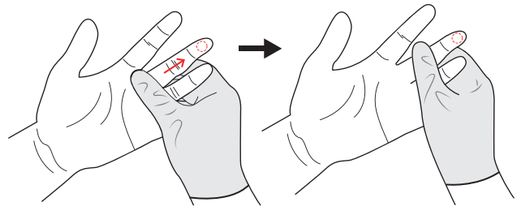
4. Move out your finger from the cassette

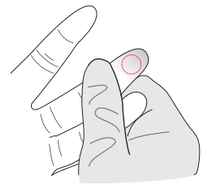




There will be a circular imprint on the patient's fingertip.

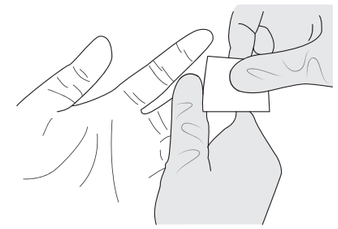
6) Operator holds the patient's hand and massage the testing finger



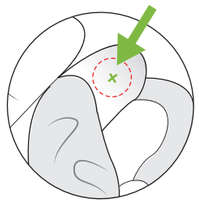


***NOTE:** .Operator should gently apply **intermittent pressure** to the patient's fingertip to stimulate blood flow.

7) Operator disinfects the patient's fingertip



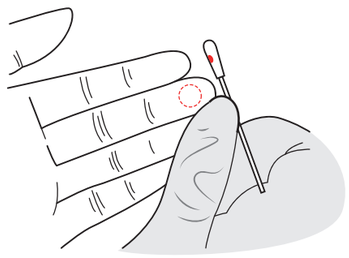
8) Operator pricks the patient's fingertip

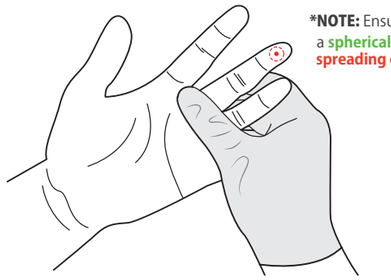


Pricking area should be at the center of the circular imprint.

***NOTE:** Make sure the fingertip is **dry** before pricking.

9) Operator wipes off the first drop of blood and helps the patient squeeze out 1 more drop of blood

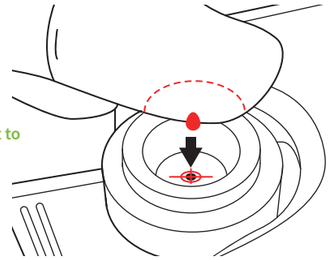




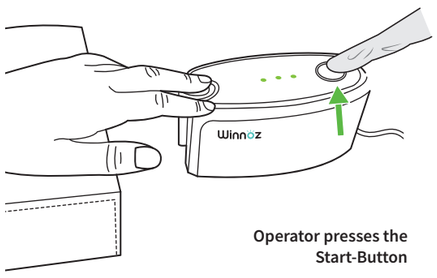
***NOTE:** Ensure the blood drop maintains a **spherical shape** and **not flowing or spreading out**.

10) Patient places the fingertip on the cassette

Target the blood drop right to the hole in the Cassette

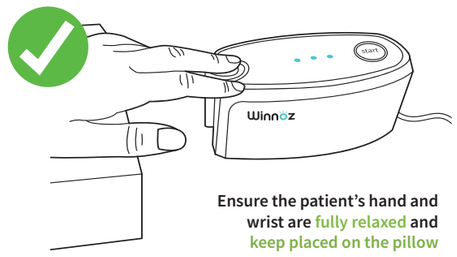


11) Start blood collection



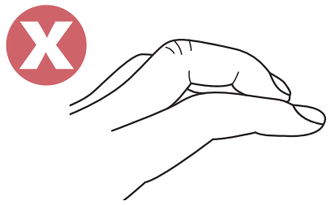
Operator presses the Start-Button

Blood Collection Time 2 min

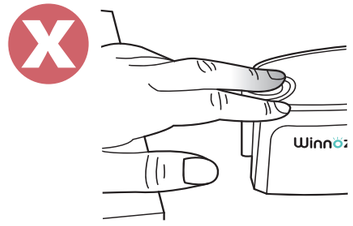


Ensure the patient's hand and wrist are fully relaxed and keep placed on the pillow

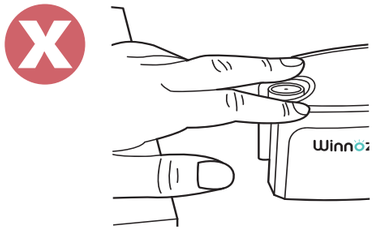
During the blood collection process, the patient...



DO NOT BEND THE FINGER



DO NOT PRESS ON CASSETTE

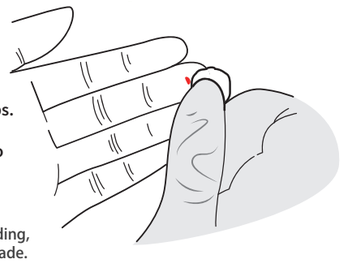


DO NOT MOVE THE FINGER

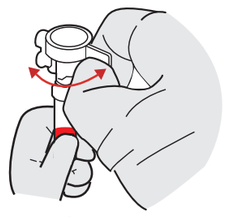
12) Complete the blood collection process

Patient removes the finger from the Cassette after the device stops. Operator uses a Cotton Ball or other hemostatic consumables to stanch bleeding.

***NOTE**
If the patient's fingertip is still bleeding, a second blood collection can be made.



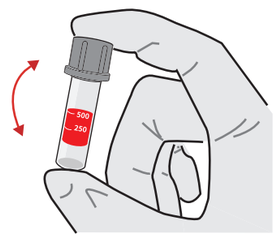
13) Retrieve the cassette and disconnect the micro-collection tube



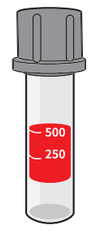
***NOTE**
When disconnecting the cassette, you should hold the tube firmly and slightly twist the cassette.

14) Cover the cap of the tube

If applicable, mix the specimen with the anticoagulant gently.



15) Blood sample collected



After completing the blood collection you must perform the cleaning and disinfection procedure (Refer to **Section J** on next page)

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.

Materials for Cleaning and Disinfection

1. 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**, Super Sani-Cloth Plus, CaviWipes, 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	CaviWipes 2.0	MEDASEPT® 100	Super Sani-Cloth Plus
Bactericidal				
Pseudomonas aeruginosa	3 min.	2 min.	30 sec.	1 min.
Staphylococcus aureus	3 min.	2 min.	30 sec.	1 min.
Enterococcus spp. (incl. VRE)	3 min.	2 min.	30 sec.	N.A.
MRSA	3 min.	2 min.	30 sec.	2 min.
Fungicidal				
Candida albicans	1 min.	2 min.	30 sec.	1 min.
Aspergillus brasiliensis	1 min.	N.A.	5 min.	N.A.
Trichophyton mentagrophytes	3 min.	N.A.	N.A.	N.A.
Virucidal				
HBV/HCV/HIV	2 min.	2 min.	30 sec.	15 sec.
Influenza A2/H1N1/H5N1	2 min.	2 min.	30 sec.	15 sec.
Vaccinia virus	2 min.	2 min.	30 sec.	15 sec.
Coronavirus	2 min.	2 min.	30 sec.	15 sec.
HSV-1/HSV-2	2 min.	2 min.	30 sec.	N.A.
BVDV	2 min.	2 min.	30 sec.	N.A.
Mycobactericidal/ Tuberculocidal				
Mycobacterium terrae	1 min.	2 min.	3 min.	30 sec.
Mycobacterium avium	1 min.	2 min.	3 min.	N.A.
Mycobacterium bovis	3 min.	2 min.	N.A.	N.A.

Note N.A. is for Not Available.

2. Cleaning and disinfection procedure for the Main Device:
   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 2.b. or 2.c. with a new cleaning material.
   e. Stand and air-dry the cleaned area.

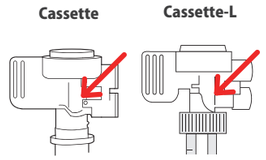
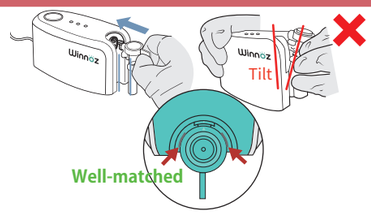
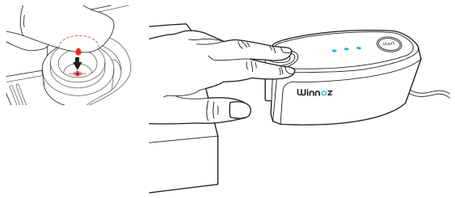
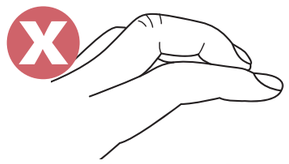
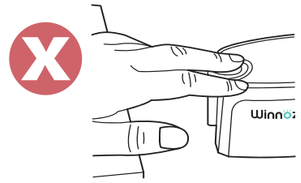
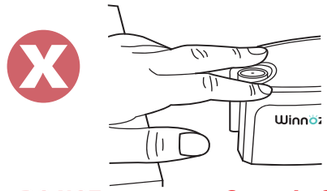
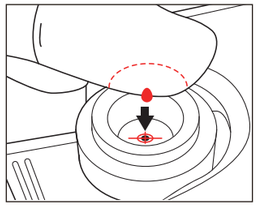
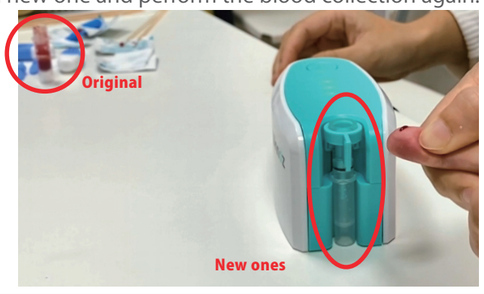
3. **CAUTIONS** of the cleaning and disinfecting procedure
   - Before using any cleaning materials aforementioned, please carefully Read the IFU of the cleaning material to be used.
   - ⚠ **AVOID** getting any moisture or dirt into any openings of the Main Device.
   - ⚠ **DO NOT** spray any cleaning agent directly onto the Main Device.
   - ⚠ **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

Problem	Causes / Solutions
1. The Main Device cannot enter the blood collection (blue-light) mode.	**Cause 1 - The system is not airtight.** **Solution:**  Retrieve the Cassette and check if the membrane is out of its original position or the snaps are deformed. **If YES**, change a new Cassette.  Re-assemble the Cassette and the micro-collection tube (See Section I-3)  Re-assemble the Cassette and the Main Device (See Section I-4)  Make sure the patient's finger **fully covers** the Cassette Finger Pad. **Cause 2 - The pump in the Main Device is malfunctioning.** **Solution:** Contact the customer service provided by Winnoz Technology, Inc.
2. The Main Device changes to alarm (yellow-light) mode during blood collection process and then stops.	**Cause 1 - The patient moves his/her finger or applies pressure on the Cassette during blood collection** **Solution:**  **Keep your hand relax and rest your wrist & arm on a supportable object**  **DO NOT bend your finger**  **DO NOT apply any pressure on the cassette**  **DO NOT move your finger before the process complete** **Cause 2 - The pump in the Main Device is malfunctioning.** **Solution:** Contact the customer service provided by Winnoz Technology, Inc.
3. You observe many rising air bubbles during blood collection.	**Cause 1 - The patient moves his/her finger or the patient's finger does not fully cover the cassette finger pad.** **Solution:** Adjust the finger position and make sure the patient's finger covers the Cassette Finger Pad fully.  
4. You cannot feel suction during the blood collection process (blue-light mode). The LED Indicator Lights change from blue to white, and then to green, and after that, the Main Device stops.	**Cause 1 - The blood splashed upwards and sealed the Main Device Connector part of the Cassette.** **Solution:** Replace the Cassette and the micro-collection tube with a new one and perform the blood collection again.  Cannot feel suction or the Main Device stops. 
5. Collected blood volume does not meet the fill volume of the micro-collection tube.	**Cause 1 - The blood collection volume is insufficient or excessive.** **Solution-**If the blood collection volume is insufficient: 1. Perform blood collection again (Section I, step 9 - 12) with the original set of the cassette and micro-collection tube if the blood on the puncture site has not coagulated yet. 2. Use a new cassette with the original micro-collection tube, and repeat steps (Section I, steps 3-12, choose another finger) if the blood on the puncture site has coagulated. **Solution-**If the blood collection volume is excessive: 1. Use a new cassette and a new micro-collection tube, and repeat steps (Section I, steps 3-12, choose another finger). 2. If the blood collection volume is near the upper limit of the micro-collection tube fill volume, the operator can stop the collection by pressing the Start-Button for 1 second. **Cause 2 - The blood circulation of patient's finger needs improvements.** **Solution:** 1. Ensure that the instructions in the "Prepare Your Finger" (Section I, step 1) are followed completely. 2. Use a new Cassette (and a new micro-collection tube, if necessary) and perform blood collection again (Section I, steps 3-12, choose another finger).

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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV line(s) to line(s) ±0.5kV, ±1kV, ±2kV line(s) to earth	±0.5kV, ±1kV 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 for 0.5 cycle 0% U_T for 1 cycle 70% U_T 25/30 cycles Voltage interruptions: 0% U_T 250/300 cycle	Voltage dips: 0% U_T for 0.5 cycle 0% U_T for 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	3 A/m 50 Hz or 60 Hz	3 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	3 Vrms: 0.15 MHz - 80 MHz 6 Vrms: in ISM bands between 0.15 MHz and 80 MHz	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	80 % AM at 1 kHz 3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	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.

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 metres (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.
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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
	Caution
	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
	Mandatory: Refer to instruction manual/ booklet
	Please read the IFU before use

Symbol	Definition
REP	European Authorized Representative
IVD	*In Vitro* Diagnostic Medical Device
UDI	Unique Device Identification System

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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
810 870 930	800-960	GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28	28
1720 1845 1970	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
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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9	9

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.

Winnoz

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Website: https://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

EC REP MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster, Germany

CE IVD