



**Miis Horus Scope  
Wound Care System**

**Smart Wound Carer**

**MPD 100**

**Wound Care Platform**

**SC 3**

User Manual

DOC. No. TBD

Ver. TBD

Date of issue: October. 2020

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# Preparations

## Before use

Prior to installation and start-up of the Horus Scope MPD 100 and SC 3, carefully read the user manual. As with all technical devices, the proper function and safety operation of this device depend on the user complying with the safety recommendations described in these operating instructions. In addition, please make sure that it does not appear damaged or broken. If there are breaks on the outer casing or other visual defects, please contact the manufacturer or a certified service facility.

△ Caution: Federal law restricts this device to sale by or on the order of a healthcare professionals, and other countries shall be follow.

### Indication for use

Intended for qualified healthcare professionals who trained in its use.

The device is intended to be used in hospital or clinic.

The device may be used on any human group.

The device does not provide a diagnosis or therapy.

The clinical benefit is for healthcare professionals, helping deliver state-of-the-art care to their patients.

### Contraindications

△ This instrument must not be used for the following patients:

- Patients who are hypersensitive to light.
- Patients who recently underwent photodynamic therapy (PDT).
- Patients taking medication that causes photosensitivity.
- Patients with a history of migraines.
- Patients with a history of photosensitive epilepsy.
- Patients with any kind of disease which could be induced by flash or strong light.

### Camera handling

Protect the camera from excessive vibration, force, or pressure.

△ Avoid using the camera under the following conditions, which may damage the lens, the monitor, or the control unit and may also cause

the camera to malfunction or prevent recording:

- Dropping or hitting the camera against a hard surface.
- Exerting excessive force on the lens or the monitor.

Once the smart card reader slot cover is removed, the camera is not dust resistant, splash resistant, or waterproof. Avoid using the camera in places with excessive dust or sand, or where water can come into contact with the camera.

△ Avoid using the camera under the following conditions, which present the risk that sand, water, or foreign material may enter the camera through the lens or gaps around buttons. Be especially careful because these conditions may damage the camera, and such damage may not be repairable:

- Operate in extremely dusty or sandy places
- Exposing the camera to rain or moisture

#### **Condensation** (When the lens or the monitor is fogged up)

△ Condensation may occur when the camera is exposed to sudden changes of temperature or humidity. Avoid these conditions because they may soil the lens or the monitor, cause mold, or damage the camera.

△ If condensation does occur, turn off the camera and wait for about two hours before using it. Once the camera adjusts to the surrounding temperature, the fogging will clear naturally.

#### **No compensation for missed shots**

△ We cannot compensate for missed shots if technical problems with the camera or card prevent recording.

## **Usage cautions and notes**

#### **When in use**

- △ The camera may become warm if used for long periods of time, but this is not its fault.
- △ Keep the camera as far away as possible from electromagnetic equipment (such as microwave ovens, TVs, video games, etc.).

- △ Do not use the camera near radio transmitters or high-voltage lines.
- △ Never leave the camera and the battery in a car or on a car hood in the summer. Doing so may cause leakage of the battery electrolyte, overheating, fire, or a battery explosion due to the high temperature.
- △ If the camera gets wet, do not attempt to dry with a heater, microwave, autoclave, or UV light.
- △ Do not extend the supplied cables. Do not keep the power cord near any heat source.
- △ Plug of the power adapter is the disconnect device from the Mains power source. When the camera is not in use, please disconnect the power plug and keep it in a safe place.
- △ The eye cannot be exposed to the illumination light at operation.
- △ Please remove the battery if the device is not in use for a long time.
- △ Before use the device, please make sure that the voltage of the power supply meets the product specifications.
- △ The product needs to be installed in a location where it can be easily unplugged its power.
- △ The performance criteria of the following description were accepted when operating the device: short-term function abnormal but can be resumed after restarting without operator intervention. Unless basic safety cannot be achieved.
- △ Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- △ Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019.



### **Charging the battery**

- △ The time required for charging varies depending on the conditions of battery usage. Charging takes longer at high or

low temperatures and when the battery has not been used for some time.

- △ The battery will get warm during charging and for some time thereafter.
- △ The battery will be drained completely if not used for long periods of me, even after being charged.
- △ Only use Li-ion Battery 3.7V / Capacity 3900mAh which shall be provided by the manufacturer or distributors. The battery has designed the protection circuit. To ensure the safety of the product operation, if the battery reaches its life time, please contact the manufacturer or distributor to buy the spare battery.

#### **NOTE**

***The battery cannot be affected by external force impact. Its appearance cannot be damaged. If the battery is broken or damaged by external force, DO NOT USE to avoid dangerous.***

#### **Memory cards**

- △ If you purchase different memory capacity of memory card, must be preceded format to FAT32.
- △ To prevent damage to cards and data:
  - Avoid high temperatures, direct sunlight, electromagnetic fields, and static electricity.
  - Do not bend, drop, or expose to strong impacts.
  - Do not touch the terminals or allow them to become dirty or wet.
  - When operating this device, please do not remove or insert the memory card.

When disposing of/transferring memory cards:

- △ If using the “format” or “delete” functions on your camera or computer, this only changes the file management information and does not completely delete the data from the memory card. When disposing of or transferring your memory cards, we recommend physically destroying them or using commercially available computer data erasing software to completely delete the data from the card. Data on memory cards should be

managed responsibly.

### **Protection**

- △ Do not attempt to remove the cover from the product to prevent the product from malfunctioning.
- △ No modification of this device is allowed. The performance would be subject to any modification and may cause hazardous radiation exposure.

### **EMC (electromagnetic compatibility)**

During installation and operation of the device, observe the following instructions:

- △ When operating the device simultaneously with other electronic equipment, please make sure the distance between the device and other electronic equipment is no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.
- △ Do not use or stack the device near, on, or under other electronic equipment to avoid electromagnetic interference with the operation of the device.
- △ Do not use the system with portable and mobile radio frequency communication systems because that may have an adverse effect on the operation of the device.
- △ Do not use cables or accessories that are not specified for the device because that may increase the emission of electromagnetic waves from the device and decrease the immunity of the device to electromagnetic disturbance.
- △ The product is not an RF electromagnetic energy medical product for the purpose of transmitting or receiving.

### **Cleaning and disinfection**

The device is a precision photo electronic instrument that shall be handled with specific care. Please note the following cleaning instructions:

- △ Turn off the device before cleaning it.
- △ Disinfect the camera with CaviWipes and maintain 3~5 mins. Wait for the cleaning liquid to dissolve before turning the power on and connecting USB cable or other device to the camera.

- △ It is recommended to clean the cover lens with a clean cloth and solvent (clean water with 75% alcohol)

**NOTE**

- △ ***The device is not intended to be sterilized. Disinfect the device with CaviWipes that is a commercial product and be manufactured by THORLABS Inc. ([www.thorlabs.com](http://www.thorlabs.com)).***

**Maintenance**

Please check MPD 100 once every 3 months.

It is the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on MPD 100 & SC 3 may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

Please note that the actual controls and components, menu items, and other information of your camera may differ from those in the illustrations provided in these instructions.

**Operating Environment**

- Ambient temperature: 10°C to +35°C
- Relative humidity: 30% to 90%
- Atmospheric pressure: 800hPa to 1013hPa
- Shock (without packing): 10G, duration 6ms

**Environment for Storage**

- Ambient temperature: -10°C to +55°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 700hPa to 1013hPa

**Environment for Transportation**

- Ambient temperature: -40°C to +70°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 500hPa to 1013hPa
- Vibration, sinusoidal: 10Hz to 500 Hz: 0.5G



- Shock: 30G, duration 6ms
- Bump: 10G, duration 6ms

### **NOTE**

***It is recommended to remove the battery if the device is stored over two weeks.***

### **Regulations**

- △ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- △ This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2: 2014. These limits are designed to provide reasonable protection against harmful interference in a standard medical installation. If this device does cause harmful interference to other devices, which can be determined by turning the system off and on, the user is encouraged to try to correct the interference through one or more of the following measures: Reorient or relocate the receiving device.
  - Increase the separation between the system and other devices.
  - Connect the device to an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer or field service technician for help.
- △ The International Electrotechnical Commission sets the essential requirements for electrical and electronic equipment that may disturb or be disturbed by other equipment. The device complies with these requirements as shown in the tables in “Symbols and standards: EMC”. Follow the guidance in the tables for use of the device in an electromagnetic environment.

### **IT Network Security**

Computers used to connect to the device should be note the following security instructions:

- △ Make sure anti-virus software is installed in personnel computer before connecting the device to it and keep the latest version.
- △ Recommended anti-virus software,
  - Android: Norton Mobile Security
  - Windows: Norton™ Internet Security

- △ The device can only be updated or processed by original factory or a legally authorized distributor. Do not allow unauthorized persons or users to update or process the software with any memory card.
- △ Users must keep patient information in a safe place.
- △ Physically destroyed the memory card when abandoned.
- △ Connection of SC 3 or MPD 100 to an IT-Network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.
- △ The responsible organization which operates SC 3 and MPD 100 should identify, analyze, evaluate and control the risks when the devices connect to an IT-Network.
- △ Subsequent changes to the IT -NETWORK could introduce new RISKS and require additional analysis. These changes include:
  - Changes in the IT-Network configuration.
  - Connection of additional items to the IT-Network.
  - Update of equipment connected to the IT-Network
  - Upgrade of equipment connected to the IT-Network.

## Names of components

### Scope of Delivery

Product Name		Model Name	Accessories
Wound Care System	Smart Wound Carer	MPD 100	1. Battery 2. Power adapter 3. USB (Type C) cable 1.0m (Shielded)
	Wound Care Platform	SC 3	N/A

### **NOTE**

- △ ***The Wound Camera MPD series can only be used with SC 3 platform for wound care.***

**Intended for use**

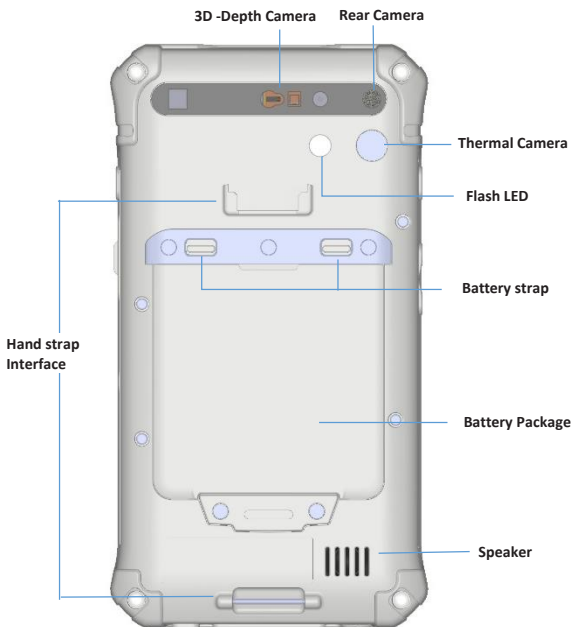
Wound Care System comprised a digital hand-held wound care device and proprietary software used to record digital photographs, inspect dimensions, area, depth and the condition of wound, determine the boundary of the wound and classify the tissue types of wound and manage the wound care information.

## MPD 100 - Outline



**\*\* One the plus is removed, the smart reader slot cannot be waterproof anymore.**

## Rear View



**\*\* Please do not look the 3D depth camera and Flash LED directly.**

## Battery

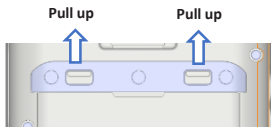
### Always charge before first use

Prior to first use, insert the battery into the control unit and close the battery cover referred to the below section. Connect USB connector to the power adapter. Let the battery charged for at least five hours.

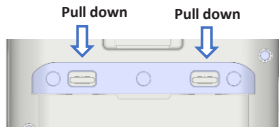
### Battery replacement

Please do not touch the electrode with a finger or something pointed.

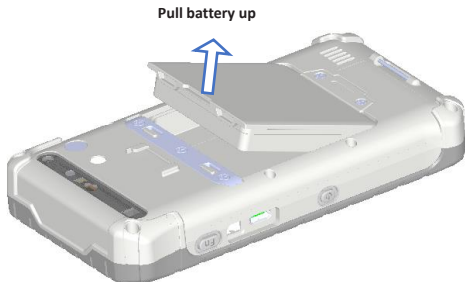
- Remove: Pull the battery strap up and remove the battery from battery room.
- Installation: Place the battery into battery room and lock the battery strap to secure it.



Battery buckle Released



Battery buckle Locked



# MPD 100 Operation


## Getting start

### Start up the APP “WoundCareRTC”




### Log in



- Type in your user name and password.
- Select login time. (8 hrs. / 1 day. / 3 days.)



UserName

 Enter username

Password [Change Password](#)

 Enter password 

Time Setting

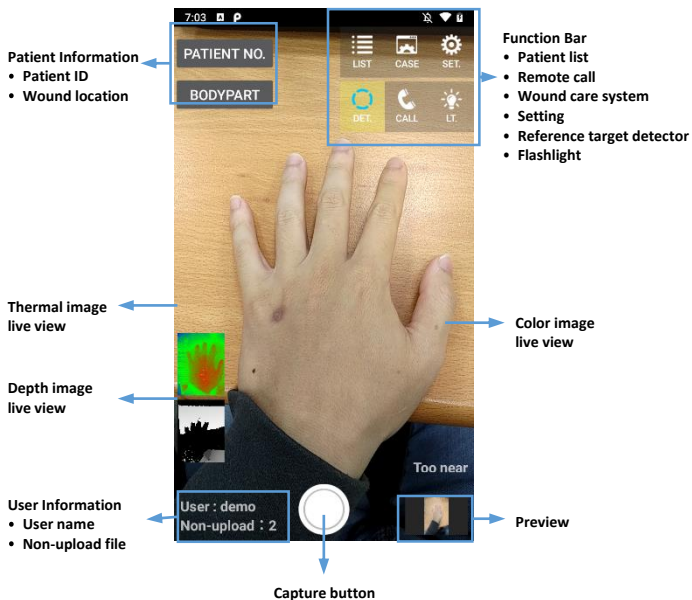
8 hours  1 day  3 days

[LOGIN](#)

### Note:

- In order to secure the personal information, please logout after using the device.
- The device will return to the access page after logout successfully.

## User interface





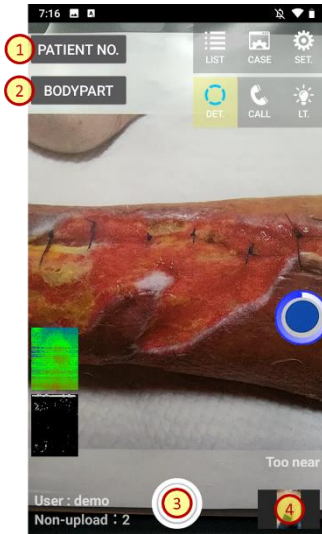
## Taking wound image and analysis

Step 1. Select patient ID.

Step 2. Select wound location.

Step 3. Capture wound image.

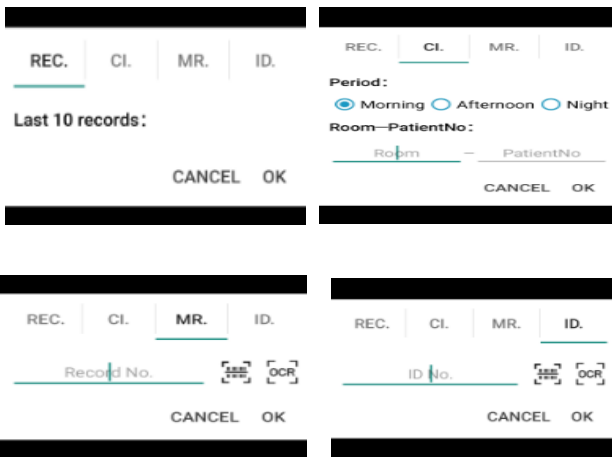
Step 4. Wound analysis and data management.



### Select Patient ID

Users can enter/select patient IDs by the following ways.

- Past records: the last 10 patient IDs.
- Consultation number.
- Medical record number.
- Identity card number.

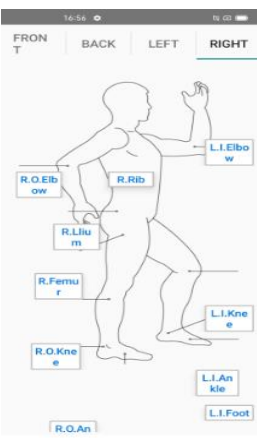
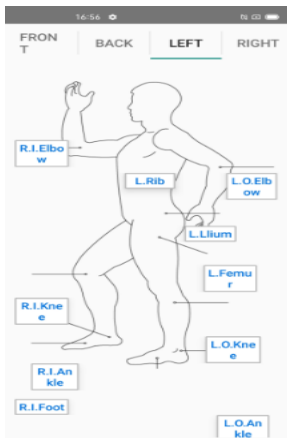
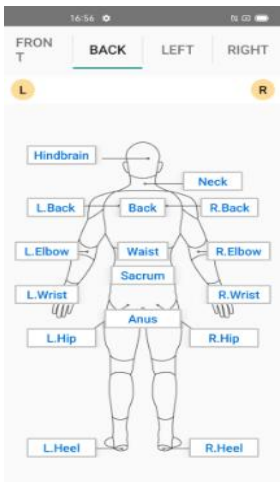
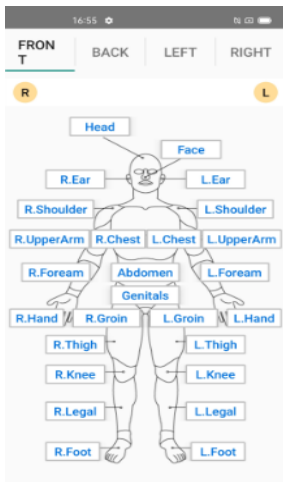


Note:

The device provides Barcode scanning and OCR to identify the medical record number and ID card number directly.

### **Select wound location**

User can select the location of the wound by tapping the icon of the human model.



### Capture wound image

- Move the device to let the wound image in the center of screen and make all the necessary areas visible.
- Check the distance between the device and the wound is around 30cm ~ 60cm.
- Click “capture” button to get color, thermal, and depth image at the same time.
- The image will show in the preview window after capturing.



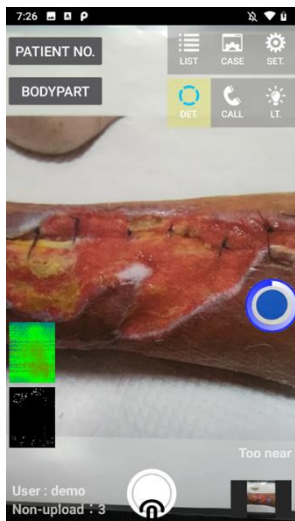
#### Note:

- All dressings and coverings should be removed before capturing the image.
- The distance between device and the wound should be around 30cm ~ 60cm.
- The most accurate condition for image analysis is indoors (without

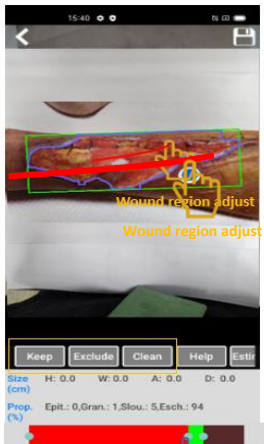
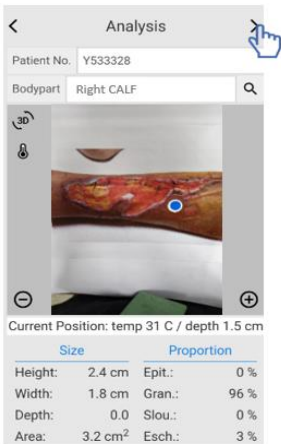
sunlight impact) and has adequate lighting.

### Wound analysis and data management

- Click “preview” at the bottom right corner of the screen and get into the preview page. The wound image will be in groups according to patient ID and sorted by date.



- Select the image, and the APP will get into detail information page. User can check and modify the patient information and wound position in this page.
- Click “wound analysis” at the top right corner of the screen to get into the wound analysis page.
- The APP will mark the wound region automatically, and user can re-adjust the region manually.
- The wound dimensions, area and tissue distribution ratio will show at the lower side of the screen, user can re-adjust the result manually.



Tissue distribution adjust

- If the device is connected to SC 3, user can also select the “AI” button to calculate the wound region and tissue distribution by the online AI model.
- Click “done” to save the result and finish the analysis.

Note:

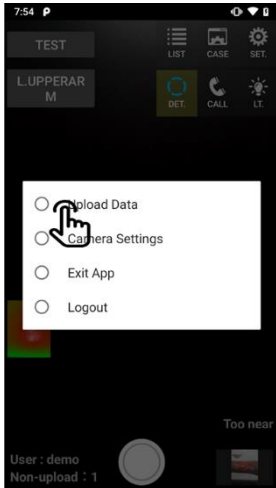
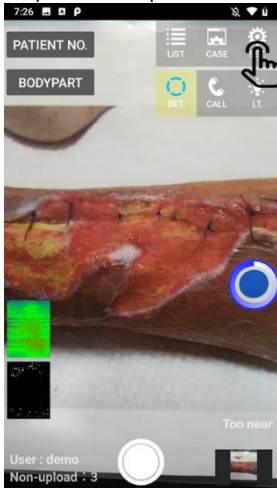
The AI wound analysis only works when the log-in account has the access authority and the device is connected to the internet.

## Data upload

Step 1. Check WIFI is connected.

Step 2. Click setting button.

Step 3. Select “upload wound information”.

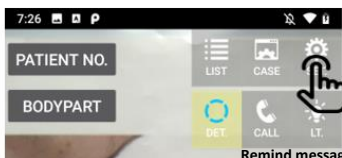


- After the upload process is completed, the number of unuploaded files will become 0.
- User can check the uploaded file in SC 3 wound care platform.

## Online diagnostic

### Case reminder

User can tap the remote call button to send a reminding message with patient information to notify the SC 3 wound care platform user (doctor or nurse) and get the medical suggestions.





# SC 3 Operation

## System requirement

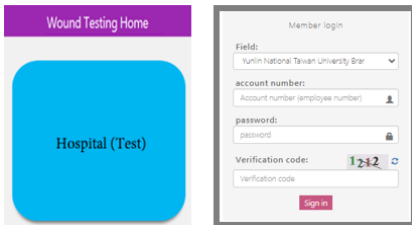
Before SC 3 installation and operation, please make sure the system meets the following minimum hardware requirements:

Hardware	CPU	Intel i7 (Intel VT-x supported)
	RAM	8GB
	GPU	Nvidia Geforce (RTX 2060 ~ RTX 2080TI)
	Hard Disk	2.5TB (2MB/per image)
Software	Operating system	MS Windows 10 Pro/Server (or Ubuntu 16.04)
	Browser	Chrome 、 Firefox
	Programming language	Java 1.7 Spring framework, Tomcat, Video Conference Docker, python-based AI
	Server	Tomcat 7.x
	Software version control	TortoiseSVN 1.13.x
	Database	SQL Server 2012 1.
Network	WLAN	802.11 a/b/g/n/ac
	Bluetooth	Bluetooth 5.0
	IP	Open ports: 8080, 443, 8007, 8180

\*\* The hardware system is suggestion specification.

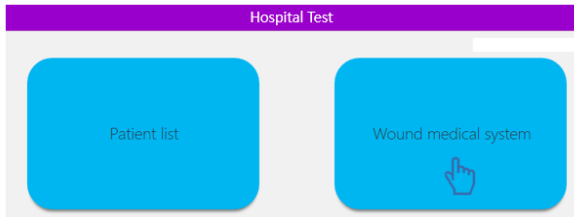
## Getting start

### Enter the SC 3 wound care platform.



### Log in

- The system will guide to hospital's user interface.
- Tap wound care platform (SC 3).



## Main page

The screenshot displays a web-based patient care information system interface. It is divided into several sections:

- 1**: A status bar at the top left with buttons for "Not Closed", "Closed", and "Logout".
- 2**: A "Patient information" section containing a search bar with "A4321" and "Search", and fields for "A4321 / 843213" and "AAA / 11 / 120". Below this is a "Notice" section with the text "Renovant information of patient".
- 3**: A "Wound records" section with a table header: "Status Date Bodypart L-Hand". Below the header is a table with one row: "N" in the "Status" column. Navigation buttons "Prev" and "Next" are visible.
- 4**: A central area with a date "2020-11-09" and a large greyed-out image of hands on a keyboard.
- 5**: A text prompt: "If you need to compare photos, please choose one of the visit dates above." Below this is a date range selector: "2020-11-09 09:55:22 443\_2020-11-09 11:09\_L.jpg.jpg" with "From" and "To" labels, and a "Sub info" button.
- 6**: A navigation bar with buttons for "Data", "Education", "Order", "Radial Chart", "Report", "Upload files", "AI analysis", and "Save".
- 7**: A section on the right with a date "2020-11-09" and a line graph showing "Wound Status" over time. The graph has points for "Wound Status" and "Wound Status" with values "0.0000" and "0.0000".

The view of patient care information

No.	Function	Description
1	Patient / image list	This provides a list of untreated / closed patients, and a list of wound images of unclassified patients.
2	Basic patient information	According to the patient number, the corresponding basic information is displayed. (including name, ID number, age, gender, etc.)
3	Patient wound location	This provides a list of wound records of multiple parts of the patient, and the medical staff can choose one part to view the detailed information.
4	Visit date selection	According to the wound location, a menu of records corresponding to the date of visit is provided, and the medical staff can view the detailed record information at any point.
5	Wound image browsing	The left and right blocks each provide an image preview function of the wound, and the user can slide/enlarge the image at will to grasp the current healing state of the wound.
6	Main function buttons	The left block is an additional function button, which corresponds to the related chart information of the daily medical record, and the right button of the right block contains the export of electronic drawing files, wound analysis and storage.
7	Wound information / graph display	This displays the wound information, recovery process radar chart, health education information and treatment methods of each medical record.

## **Search Patient care information**

Search by the patient identification number.

Step 1. Input the searching content such as medical record number, identity card number, and visit number in English letters and numbers only.

Step 2. Click the “search” button.

Note:

If there is no existing data in the platform, the notification window will jump out and inform the user to create the new patient information. After the patient information is created and saved, the system will display the information on the platform screen automatically.

Patient Information

Patient No.

A4321 / 843213

AAA / M / 120

Notice

Relevant information of patient

Patient Information

A4321 / 843213

AAA / M / 120

Notice

Relevant information of patient

New patient data

Sex:

Age:

Address:

Medical history:

Admission date:

Death date:

Death cause:

1 Enter patient number/ID number)

2 Entered correctly Show basic information

3 Entered incorrectly show new patient information

The view of patient information search

## **Basic patient information preview and edit**

User can see and edit basic patient information, including medical record number (uncorrectable), ID card, name, age, related disease history, and other notes. Because the medical record number is the key value (search condition), when the user updates the patient data, the system is forced to edit it to ensure the integrity and consistency of the data. After the patient's basic data is updated and saved, the screen will display the latest information simultaneously. The operation sequences are as follows:

Step 1. Click the “Edit” button.

Step 2. Fill in/update the contents of the field (only the medical record number can't be modified). Confirm the update information, and click the “Save” button. If the contents are not updated, click the “Cancel” button.

Step 3. The system displays the updated basic patient information automatically.

Not Closed

Patient Information ✎

A4321 / 843213

AAA / M / 120

Closed

Notice 📄

Relevant information of patient

Logout

Wound records 🗑️ ✎ +

Status	Date	Bodypart
N		L.Hand

**1 Show edit buttons**

New patient data

Medical record number:	<input type="text" value="556699"/>
ID number:	<input type="text"/>
Name:	<input type="text"/>
gender:	<input type="text" value="please choose"/>
birthday:	<input type="text"/>
age:	<input type="text"/>
Contact number:	<input type="text"/>
Contact Address:	<input type="text" value="Counties"/> <input type="text" value="Township"/> <input type="text"/>
History of related diseases:	<input style="width: 100%; height: 30px;" type="text" value="Please enter related disease history"/>
Date of hospitalization:	<input type="text"/>
Date of discharge:	<input type="text"/>
Death case closed:	<input type="text" value="please choose"/>

**2 Edit (update) patient data**

### **Wound location tracking list**

User can see a list of the wound sites closed and not closed, and click the wound image to view the full course of treatment information. The column in the list shows whether the case is closed, the date of the wound image and the wound location. Click the icon on the up-right corner of the list, then user can delete /edit /add the contents of the fields in the following format:

- (1) Common parts:** user can select the wound location.
- (2) Date of Occurrence:** the date can be selected through the calendar.
- (3) Case closed:** user can select whether the case is closed.

The operation procedure of the wound location list (take patient wound list management as an example) is as follows:

Step 1. Check the initial screen of patient wound list

Step 2. Click one column of the wound list and click the Add/Edit/Delete button.

Step 3. Fill in / update the contents of the field (common parts, date of occurrence and whether the case is closed).

Step 4. Confirm that the update information is correct, and then click the "Save" button. If not updated, click the "Cancel" button. The system will automatically display update / addition records on the wound location list.

Case closed	Date of occurrence	Location
no		Back
no		Right ankle

last page 1 next page

**1** Initial screen of patient wound list

Wound location record		
Case closed	Date of occurrence	Location
no		Back
no		Right ankle

last page 1 next page

**2** Click wound site for **Add/Edit/Delete** button

Add wound location

Common parts:

Date of occurrence:

Case closed:

**3** Click the **Save** button to update

The view of wound location **tracking** list.

### Wound image preview side by side

User can check images in different consultation dates of the same wound side by side. In addition, User can browse the wound images by switching left and right pictures, and see the detailed wound images under the zoom view. The operation procedure of wound image browsing is as follows:

Step 1. Select the wound image to be viewed by the capturing date. After the date is selected, the thumbnail and enlarged image will be displayed on the screen.



Note: for the first time open the wound site during the course of medical information than the region will text mode informs the user must click to see the doctor dates to display than the control sheet).

Step 2. Select one of the thumbnail images. The enlarged image of the selected one will show on the screen.

\*\* Slip rat placed in a large region inside may be utilized Movies roller zoom image.



The view of wound images presented side by side.



The view of wound images presented side by side (different dates).

# Wound record form

1 Click Wound Record button

Wound record Health Education information  
Disposal (doctor's order) Radar chart

4 Save record

Export report Attached drawings AI analysis Save record

2 Check/enter wound related information

Wound history and symptom report information 2020-10-14 10:15:42.76 #平安

Wound size length:  Cm width:  Cm depth:  Cm area:  Square centimeters

Organization ratio Epithelium:  % Granulation:  % carrion:  % Scorch:  %

Wound category (acute wound)  Surgical wound  Bruise  contusion  Laceration  Burns  
 other

Wound category (chronic wound)  Diabetic ulcer  Stress injury  Stagnation ulcer  Ischemic ulcer  
 other

Wound staging  Stage 1  Stage 2  Stage 3  Stage 4  Stage X

Wound staging (other)  Superficial skin damage  Part of the cortex is damaged  Full-thickness cortex damage

Exudate volume  5%  25%  50%  75%  100%

Exudate color  Pink  red  yellow  green  black

Healing condition	direction	depth	Function bar
<input type="text" value="please"/>	<input type="text"/> O'clock direction	<input type="text"/> Cm	<input type="button" value="Create"/> <input type="button" value="clear"/>
no data			

3 (creation/editing/deletion)

last page next page

The view of wound record form.

## Wound record form

In all fields in the record form, users can manually check / fill in and store relevant measurement data according to the wound detection situation of the patient on the current day (except for the wound size and tissue ratio can be obtained by the system performing wound circle analysis Out of results ).

Step 1: Click the Wound Record button.

Step 2: Check/enter wound related information (Size and organization can be brought in by APP)

Step 3: Fill in sneaky deep hole records (with functions such as creation/editing/deletion)

Step 4: After confirming that the information is filled in correctly, click the Save button to save the data.

## The health information

1 Click the health education information button

Wound record **Health Education Information** Disposal (doctor's order)

Radar chart

2 Choose health education category

Skin cleansing Skin moisturizing Skin protection Skin care stress reliever Note when changing dressing Life attention Referral to Specialty other

Clean skin, use neutral or weak acid detergent

Clean the skin, avoid rubbing to clean the skin, but use gentle pressure to wipe clean

Clean skin, avoid using disinfectant every time

Clean the skin, use zinc oxide, and then apply after it comes off naturally during washing. Do not rub off forcefully

3 Check the required health education

### The health information

Step 1: Choose health education category.

Step 2: Choose health education category.

Step 3: Check the required health education method as a follow-up key item of wound attention.

## The medical order

1 Click the Disposal (medical order) button

2 Provide fields for treatment content

3 Display the current disposal method

The screenshot shows a web interface for medical orders. At the top, there are navigation tabs: 'Wound record', 'Health Education information', and 'Disposal (doctor's order)'. The 'Disposal (doctor's order)' tab is highlighted with a red box and an arrow pointing to it from step 1. To the right of the tabs are buttons for 'Export report', 'Attached drawings', 'AI analysis', and 'Save record'. Below the tabs is a form area. Step 2 points to the form's header and input fields. The form has a table with columns: 'Method of application', 'Application method (other)', 'size', 'Quantity', 'frequency', and 'Function bar'. Below the table are input fields: 'Please choose the method of a', 'Please choose other', 'Please select size', and 'Please select frequer'. To the right of these fields are 'Create', 'bring-in', and 'clear' buttons. Below the form, there is a 'no data' message and 'last page' and 'next page' buttons. Step 3 points to the 'no data' message.

Method of application	Application method (other)	size	Quantity	frequency	Function bar
Please choose the method of a	Please choose other	Please select size		Please select frequer	Create bring-in clear

no data

last page next page

The view of medical order.

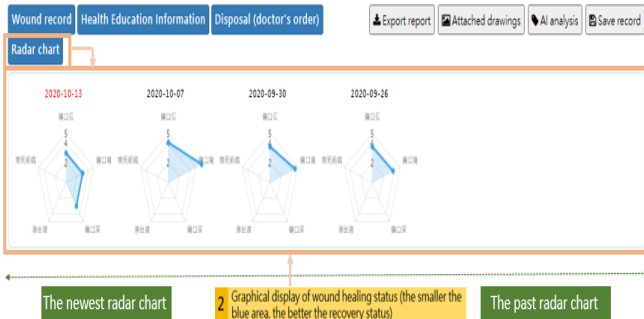
Step 1: Click the Disposal (medical order) button.

Step 2: Provide fields such as application method, other methods, size, quantity and frequency for the user to record the treatment content.

Step 3: Display the current disposal method (can also be used to count the use of dressing), and provide users to edit / delete.

## Wound radar chart

1 Click on the Wound Progress **Radar Chart** button



The view of wound process radar chart.

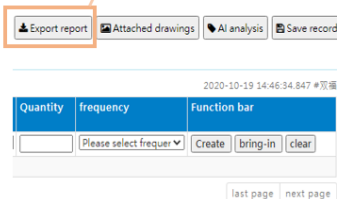
User can see several days wound quantitative data radar chart, showing the way mining display recently four times the state back to the clinic; the date on the top of the radar chart for each data analysis represents the date. The radar chart browsing process is as follows:

Step 1: User can click the radar chart button in the function list of the wound history page.

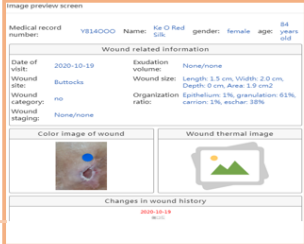
Step 2: User can see the recovery radar chart of the patient's wound site. Graphical display of wound recovery status.

## Wound summary export

**1 Click the Export Electronic File button**



**2 Display image file output preview screen**



The view of wound summary export.

Step 1: Click the Export Electronic File button to open the image preview screen.

Step 2: After confirming that the report content is correct, click Download.

Step 3: Get the downloaded PNG image file in the local default download folder.

Step 4: Place the picture in the patient report record of the hospital standard, and provide follow-up processing for health insurance application.

\*\* Users can export the wound information to wound summary report file formats (PNG).

# Miscellaneous

## Technical description

### MiiS Horus Scope MPD 100

Display	- 5" (1280*720), TFT LCD - 500 nit (typ.) With Direct optical bonding for sunlight readable - Projective Capacitive Multi-touch
Processor	Qualcomm Kryo 260CPU,Octa-core,up to 2.2GHz
System Memory	3GB SDRAM
Storage	32GB eMMC, Additional storage available with optional storage card.
Wireless	WLAN: 802.11 a/b/g/n/ac
External I/O	1 x Micro SD card slot 1 x USB-C 3.0 (Spec. TBD) 1 x Audio Jack 1 x Smart card reader slot
Control Button	1 x Volume +/- 1 x Power button 2 x Function button 4 x Front Key
Touch Panel	10-Point multi touch, support /Hand/Gloves and Rain Mode on, On-screen QWERTY keyboard
LED indicator	1 x LED indicator <ul style="list-style-type: none"><li>• Orange: The battery is charging.</li><li>• Green: The battery is full charged.</li><li>• No light: The battery is not in charging status.</li></ul>
Audio	2 x Built-in Microphone 1 x Speaker 1 x Front Receiver

Battery	3.7V 3900mAh Li-ion removable battery
Power Adapter	Input Spec.: 100-240Vac, 0.6-0.3A, 50-60Hz; Output Spec.: 5V DC, 1.2A
External Power	Source: 100~240 VAC, 50/60 Hz
Working Range	30cm~60cm.
Viewing area	Typ. 24.5 x 18.5 cm at 30cm working distance. Typ. 49.1 x 36.9 cm at 60cm working distance.
Thermal image	Scene range 28°C ~ 40°C
Tissue classification	4 type (epithelium/granular/slough/eschar)
3D wound measurement	Accuracy $\pm$ 2.5mm
Dimensions (W x L x H)	85.9 x 163.2 x 26 mm (Typ.)
Weight (g)	340g +/- 5%
Expected service life (defined by manufacturer)	5 years from the date of initial operation *Proper maintenance is necessary.



## Liability

Manufacturer considers itself responsible for the effects on safety, reliability, and performance of the device only if











- △ The device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.
- △ Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized.
- △ The electrical installation of the relevant room complies with the requirements.
- △ The equipment is used in accordance with these instructions for use.












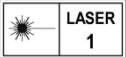
## Disposition









- △ Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components, especially when disposing of the lithium ion battery, circuit board, plastic parts that contain brominated flame retardant, LCD, or power cord.
- △ Follow the local governing ordinances and recycling plans when disposing of the circuit board with the lithium battery. Inappropriate disposal may contaminate the environment.
- △ When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.
- △ Inappropriate disposal may contaminate the environment.
- △ When disposing of eyecup, follow the disposal procedures for medical waste such as needles, infusion tubes, and metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution.

## Symbols and standards

### Symbols

	<b>CAUTION</b> The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.
	Operating Instructions for Use.
	Manufacturer
	Date of Manufacture
	CE-mark Note: Minimum height of CE is 5mm.
	Non-ionizing electromagnetic radiation
	The identification number assigned by the Federal Communication Commission 2AFB3M-MPD100
	Certification for Taiwan NCC ID: CCXXxxYYyyyZxW
	European Authorized Representative
	Catalogue Number

	Global Trade Item Number
	Lot number
	Serial Number
	GS1 Data Matrix
	Medical Device
	Direct current
	Power button
	Recycling lithium-ion batteries
	Specific Battery Recycling
	Disposal of noncontaminated electrical and electronic equipment
	This product had an internal rechargeable battery with a Class II power supply.
	CLASS 1 LASER PRODUCT

	Keep away from sunlight
	Hand with care
	Fragile
	This side up
	Fragile, handle carefully
	Lithium-ion battery
	Flammable material
	Follow instructions for use

## Standards

Electrical safety	IEC 60601-1:2005+A1:2012 (EN 60601-1:2006+A1:2013)
EMC and regulatory compliance	IEC 60601-1-2:2014 (EN 60601-1-2:2015)
Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	ISO 15004-1:2006
General radio compliance	Federal Communications Commission (FCC) National Communications Commission (NCC)

- △ Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output-part configures a medical system and is therefore responsible for the system complying with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

### **NCC**

取得審驗證明之低功率射頻電機，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

低功率射頻器材之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前述合法通信，指依電信管理法規定作業之無線電通信。低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

應避免影響附近雷達系統之操作。

高增益指向性天線只得應用於固定式點對點系統。

## **Federal Communications Commission (FCC)**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the distance between the equipment and the receiver
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

## **SAR**

The device is designed and tested to meet the applicable limits for radio frequency (RF) exposure established by the Federal Communications Commission (U.S.A.) Specific Absorption Rate; (SAR) refers to the rate at which the body absorbs RF energy.

The minimum allowable SAR distance is 5 mm, and the maximum allowable SAR limit is 4.0 W/kg, averaged over 10 gram of tissue for the device. The following SAR values were measured during product certification, 1.060 W/kg with a (0mm gap) a value well below the maximum allowable limit of 4.0 W/kg.

L'appareil est conçu et testé pour respecter les limites applicables aux fréquences radio (RF) exposition établie par la Federal Communications Commission (États-Unis).

Taux d'absorption; (SAR) fait référence à la vitesse à laquelle le corps absorbe de l'énergie RF.

La distance DAS minimale autorisée est de 5 mm et la limite DAS maximale admissible est de 4,0 W / kg, avec une moyenne de 10 grammes de tissu pour le périphérique. Les valeurs de DAS suivantes ont été mesurées lors de la certification du produit, à 1,060 W / kg avec un (écart de 0 mm), une valeur bien inférieure à la limite maximale autorisée de 4,0 W / kg.

### **EMC (Electromagnetic Compatibility)**

The device complies with the International Electrotechnical Commission standards (IEC 60601- 1-2: 2014) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in a Professional Healthcare Environment.

## EMC (IEC 60601-1-2: 2014)

<b>Guidance and manufacturer's declaration - electromagnetic emissions</b>		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A *1	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	*2	

\*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

\*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard.

For the regions where the rated voltage is 127 V or less, this standard is not applicable.



**Guidance and manufacturer's declaration - electromagnetic immunity**


The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floor 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 ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% $U_T$ for 0.5 cycle (1 phase) 0% $U_T$ for 1 cycles 70% $U_T$ for 25/30 cycles (50/60 Hz) 0% $U_T$ for 250/300 cycles (50/60Hz)	0% $U_T$ for 0.5 cycle (1 phase) 0% $U_T$ for 1 cycles 70% $U_T$ for 25/30 cycles (50/60 Hz) 0% $U_T$ for 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m at 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

**Guidance and manufacturer's declaration - electromagnetic immunity**

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	3 Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance  $E = \frac{6}{d} \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> 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.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above 3V/m., the device should be observed to verify normal operation. If

abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Test specifications for enclosure port immunity to RF wireless communications equipment**

Test frequency (MHz)	Band <sup>a</sup> MHz	Service <sup>a</sup>	Modulation <sup>b</sup>	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA400	Pulse modulation <sup>b</sup> 18 Hz	1.8	0.3	27
450	430-470	GMRS460, FRS460	FM <sup>c</sup> ±5kHz deviation 1 kHz sine	2	0.3	28
710	704 -787	LTE band 13,17	Pulse modulation <sup>b</sup>	0.2	0.3	9

**Test specifications for enclosure port immunity to RF wireless communications equipment**

745			217 Hz			
780						
810	800-960	GSM 800/900, TETRA800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b</sup> 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation <sup>b</sup> 217 Hz	2	0.3	28
1845						
970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b</sup> 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/ n	Pulse modulation <sup>b</sup> 217 Hz	0.2	0.3	9
5500						
5785						

<sup>a</sup> For some services, only the uplink frequencies are included.

<sup>b</sup> The carrier shall be modulated using a 50 percent duty cycle square wave signal.

<sup>c</sup> As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.



**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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The minimum separation distance for higher immunity test levels shall be calculated using the following equation:

$$E = \frac{6}{d} \sqrt{P}$$

(W), d is the minimum separation distance in meters (m), and F is the immunity test level in V/m.

Please visit [www.miis.com.tw](http://www.miis.com.tw) for more information.



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# horus

SCOPE