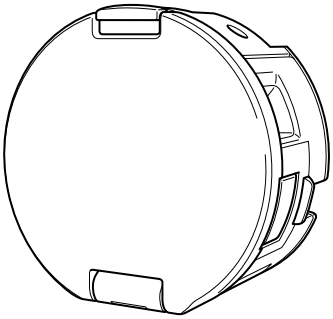
ISHIDA

Urine Measurement and Recording System

Hemato Check Module



Instruction Manual

- Do not install, operate, or maintain/inspect the product before understanding the information contained in this manual.
- Keep this manual with care so that you can read it anytime when installing, operating, and maintaining/inspecting the product.

ISHIDA MEDICAL CO., LTD.

A133208-1_2

Important Notice

Introduction

Thank you very much for purchasing our product "Hemato Check Module" (hereinafter referred to as "the product").

The product automatically measures the hemoglobin concentration in the tube of the urine bag attached to the patient for the doctor or nurse to check the patient's condition in the professional healthcare facility environment.

Please read this instruction manual carefully before using the product.

The product does not have the essential performance defined in IEC 60601-1.

Safety

- Please read "1 Precautions for Safety (to be strictly observed)" ☞ (p 4) before use. It contains important precautions for safe handling of the product.

Trademarks and copyrights

- Company names and product names mentioned in this document are the trademarks and registered trademarks of the companies.
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- ISHIDA MEDICAL exclusively possesses this document, etc. and the know-how about the product. ISHIDA MEDICAL grants the non-transferable and non-exclusive right to use the know-how only for the purpose of use and maintenance of the product under the conditions and within the scope specified in this document, etc.

Disassembly and modification

- Do not disassemble, modify, or alter the product. ISHIDA MEDICAL assumes no responsibility for any disassembly, modification, or alteration by users.

Disposal

- Dispose of the product in accordance with local ordinances.

Table of Contents

Meaning of Labels

Signal words

On the product and in the instruction manual, the important information is provided to prevent harms to users and other persons and property damage and to ensure safe and proper use.

Fully understand the following markings and graphic symbols, and then read this document and follow the instructions.

Marking	Description
WARNING	It indicates a potentially hazardous situation that can result in death or serious injury if the instructions given are not observed.
CONTRAINDICATIONS	It Indicates an act that must not be done. The use beyond performance of the product or improper use of the product can result in death or serious injury.
CAUTION	It indicates a possible situation that can result in minor or moderate injury if the instructions given are not observed.
! Notice	It indicates a possible situation that can cause failure of the product or physical damage to the product if the instructions given are not observed.

Other Notices

Symbol	Description
Notes	It indicates functions and reference information useful to know.
☞	It indicates the section to be referred to when the related information is given in this document.

Prohibitions/Instructions to Be Followed

⚠ WARNING

< Usage >

- **If you find any of the following, turn off Uro Checker immediately and disconnect the AC power cable from the outlet and contact ISHIDA MEDICAL or our distributor.**
  - **– Unusual sound**
  - **– An unusual odor**
  - **– Smoke emission from the main unit**

  If you keep using the product in an abnormal condition, electric shock or fire may be caused, resulting in serious injury.

< Maintenance and inspection >

- **Make sure to turn off the power of Uro Checker and unplug the AC power cable before cleaning. There is a risk of injury due to electric shock.**

CONTRAINDICATIONS

< Usage >

- **Do not use the product in an atmosphere where a flammable anesthetic gas, an active gas, or a high concentration of oxygen exists. Doing so may cause explosion or fire, resulting in serious injury.**
- **Do not bring this product into the MR environment when performing an MRI scan, as it may cause an accident due to the product being attached to the MRI machine, which is very dangerous.**

⚠ CAUTION

< Usage >

- **The product is a medical device to measure the urine hemoglobin concentration in patients with urinary catheter tube. Do not use for any other purposes.**
- **The product should be used by the following healthcare professionals experienced in handling the product: physicians, nurses, and clinical engineers.**

! Notice

< Usage >

- **Attach the tube of the urine bag to the tube clamp in such a way to prevent the tube from being bent or crushed.**
- **If blood is deposited in the urinary catheter tube of the urine bag, the hemoglobin concentration may not be measured properly.**
- **Since the product is sensitive equipment, do not use if it falls on to the floor, the transfusion stand topples over, or an impact is applied to the product by hitting it strongly against something.**
- **Use of non-recommended urine bag may result in incorrect measurement of hemoglobin concentration.**

< Maintenance and inspection >

- **Do not use any disinfectant other than those compatible with the product. The product may be damaged or fail.**
- **Do not perform maintenance or inspection of the product while it is being used on patients.**

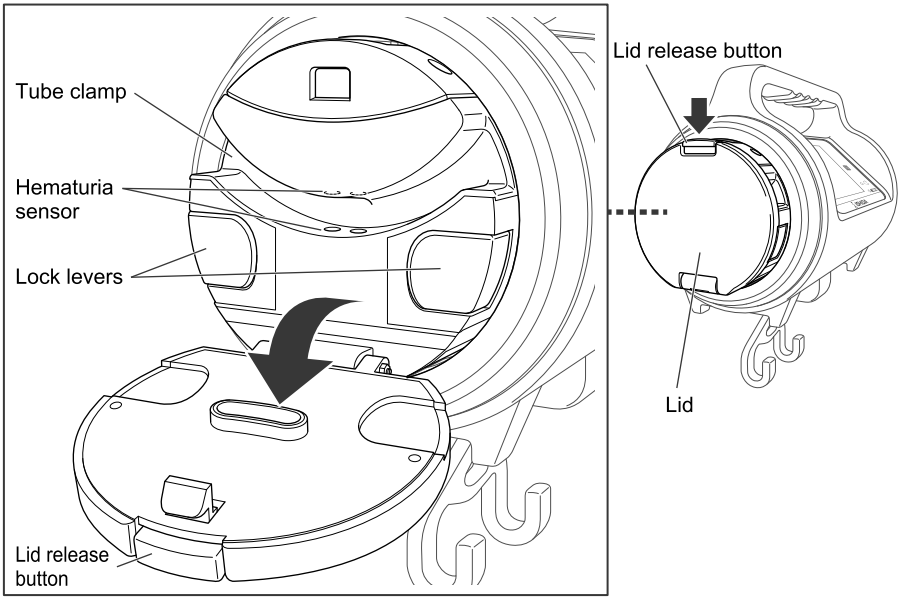
2 About Hemato Check Module

Overview of Hemato Check Module

The hemato check module is used by connecting into Uro Checker (URC-50M). The module measures the urine hemoglobin concentration flowing through the urinary catheter tube of the urine bag, and send the measurement result to Uro Checker.

Notes For the overview of the entire urine measurement and recording system, refer to the instruction manual of Uro Checker.
☞ "Functions" - "Using with other products"

Name and Function of Each Part

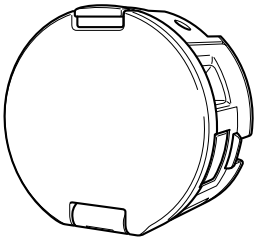


Name	Function
Tube clamp	The urinary catheter tube of the urine bag is passed through, and it is secured by closing the lid. The urine hemoglobin concentration in the urinary catheter tube passed through the tube clamp is measured.
Lid	The lid is opened when the urinary catheter tube is passed through the tube clamp.
Lock levers	It is used to attach and detach the hemato check module. Pushing both levers inward will release the inner lock and allow the module to be removed from the uro checker.
Lid release button	The button is used to open the lid.
Hematuria sensor	It has an optical sensor consisting of a projector and a receiver. The urine hemoglobin concentration is measured by absorptiometry.

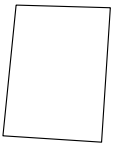
3 Preparing Hemato Check Module

Checking the Items

Check that the following items are included in the package. Contact ISHIDA MEDICAL or our distributor if you find any missing item or damaged item.



Hemato check module ×1



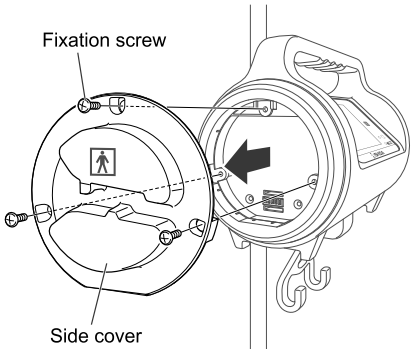
Instruction manual ×1

Connecting to Uro Checker

The procedure for attaching the hemato check module to Uro Checker is described below.

1. **Loosen the fixation screws (× 3) on the left side of Uro Checker and remove the side cover.**

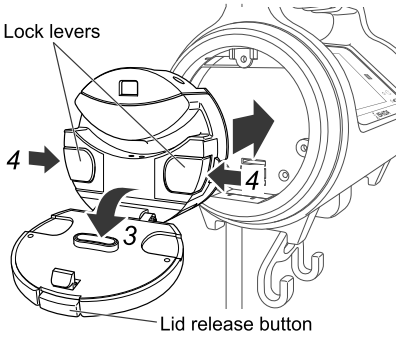
2. **Return the removed fixation screws to their original position and tighten them securely.**



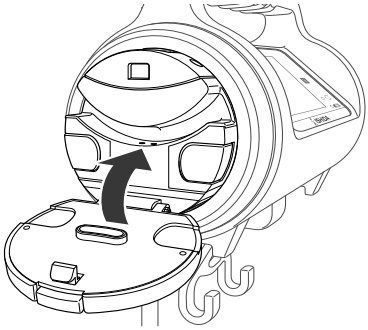
Notes Keep the cover removed from Uro Checker in an appropriate place so that it is not lost. This cover is reattached to Uro Checker when the hemato check module is not used.

3. **Press the lid release button on the hemato check module to open the lid.**

4. **While holding the lock levers of the hemato check module with fingers, connect the module to Uro Checker.**



5. **Close the lid.**



Settings of Hemato Check Module

Various settings required to use the hemato check module are described below.

List of various settings of hemato check module

The settings related to the hemato check module are configured using the touch panel display of Uro Checker after connecting the module to Uro Checker. The setting items are shown below. Before starting measurement, check and change the settings.

Setting item	Description
Display	Set the method of displaying the Measurement screen.
Time	Set the current time and the measurement time.
Notification	Set the settings for detection when the measured urine output exceeds the threshold.
Wi-Fi	Switch on/off the Wi-Fi. This setting is required only for integration with Vital Logger.
Hemato Check Module	Configure various settings for measurement of urine hemoglobin concentration. For details, see below. "Operation setting for measurement of urine hemoglobin concentration" ☞ (p 9)
Maintenance	Set the items related to maintenance of the product.
Vital logger	Switch on/off the integration with Vital Logger.
Current status	The current setting status is displayed as a list.

Notes For details of each setting, refer to the instruction manual of Uro Checker.
☞ "6 Details of Various Settings"

Operation setting for measurement of urine hemoglobin concentration

To perform the urine hemoglobin connection measurement, the module needs to be connected, and various notification settings need to be configured before starting the measurement.

Notes Uro Checker needs to be started and configured in advance. For the details, refer to the instruction manual of Uro Checker.
☞ "3. Preparing Uro Checker" - "Starting Uro Checker (when using for the first time)"
☞ "3. Preparing Uro Checker" - "Configuring Initial Setting"

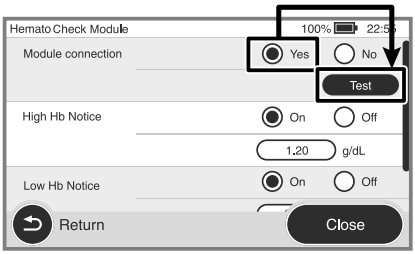
1. Tap [Setting] on the Preparation for measurement screen.

➡ The screen changes to the Setting screen.

2. Tap [Hemato Check Module].

➡ The screen changes to the Hemato Check Module settings screen.

3. Select [Yes] in the Module connection.



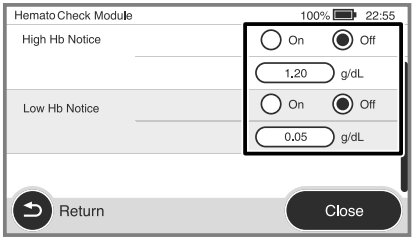
4. Confirm that there is nothing in the tube clamp and that the lid is closed, and tap [Test].

➡ When the module connection is confirmed, "OK" is displayed on the left side.

- When any abnormality is detected by the check, report to the administrator of the medical device, and address the cause of abnormality.

5. Change the settings for notification as needed.

- Please refer to the table below for the details of each setting.
- The notification setting may be changed during measurement.
- After changing the setting, tap [Close] to switch to the Preparation for measurement screen.



Setting item	Description	Initial value
High Hb Notice	The module can be configured to issue a notification when the urine hemoglobin concentration exceeds the specified value. When [On] is selected, specify the threshold. [On] : It is notified [Off] : It is not notified	Off (1.20g/dL)
Low Hb Notice	The module can be configured to issue a notification when the urine hemoglobin concentration falls below the specified value. When [On] is selected, specify the threshold. [On] : It is notified [Off] : It is not notified	Off (0.05g/dL)

Measurement result display settings

The steps to change the display method of the Measurement screen that appears during measurement are described below. There are the following 2 options.

- [1 item]: Only the urine output per time or the urine hemoglobin concentration is displayed on one screen. (Default setting)
- [All in 1]: Both the urine output per time and the urine hemoglobin concentration are displayed on one screen.

1. **Tap [Settings] on the Preparation for measurement screen or the measurement screen.**

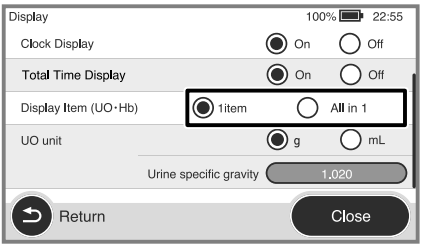
➡ The screen changes to the Setting screen.

2. **Tap [Display].**

➡ The screen changes to the Display setting screen.

3. **Scroll down the screen.**

4. **Select [1 item] or [All in 1] for the Display items.**



4 Attaching Hemato Check Module

Compatible Urine Bags

In case of installing the hemato check module, please use the recommended urine bag. The recommended urine bags are as follows.

Manufacturer	Name of urine bag
BARD	Latex-Free Urinary Drainage Bag REF154002
BARD	Closed System Urinary Drainage bag Reorder802001
MedLINE	Urinary Drainage Bag
Teleflex	RUSCH Urinary Drainage bag

Inspection before Use and Precautions during Attachment of Module

Before using the hemato check module, perform the following inspections.

Inspection point	Detail of inspection and actions
Hemato Check Module (main unit)	Check that it is correctly connected to Uro Checker. For the connection method, see below. "Connecting to Uro Checker" ☞ (p 8)
	Check for dirt and damage. Clean them if you find dirt or chemicals on them. "Care after Use (cleaning)" ☞ (p 19)
Urinary catheter tube (urine bag)	Is the urinary catheter tube of the urine bag clean? If the tube at the receiver of the sensor is not clean, measurement may not be performed properly. Please use a clean urine bag.

⚠ CAUTION

Install the product in such a way that the tube clamp is lower than the waist level of the target patient. If it is accidentally placed higher than the waist level, backflow of urine or stagnation of urine flow may occur.

Operation Check before Start of Measurement

When Uro Checker is turned on, the Pre-Use Operation Check screen appears.

Notes

- If the Pre-Use Operation Check screen is not displayed, the module settings of the hemato check module may not be configured. Refer to "Settings of Hemato Check Module" ☞ (p 9) to configure the settings.
- To skip the check, tap [Next] in the step 3.
- For the steps to start measurement after displaying the Preparation for Measurement screen in the step 5, refer to the instruction manual of Uro Checker.
  ☞ "5 Performing Measurement" - "Starting Measurement"

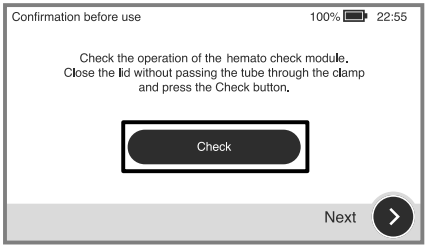
1. **Press the power button on Uro Checker.**

➡ The pre-use operation check screen appears.

2. **Check that the urinary catheter tube is not attached and that the lid is closed.**

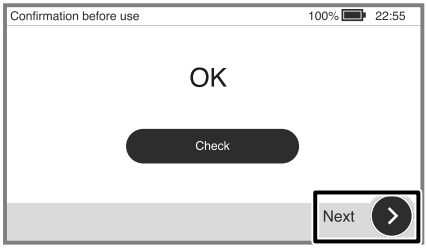
3. **Tap [Check].**

➡ The operation check starts.



4. **Check the result of the operation check.**

- "OK": The module is functioning normally.
- "NG": Report to the person in charge of management of the medical device, and address the cause of NG. When the problem is solved, repeat the procedure from Step 3.



5. **Tap [Next].**

➡ The Preparation for Measurement screen appears.

Attaching Urinary Catheter Tube to Hemato Check Module

The steps for attaching the urinary catheter tube after hanging the urine bag on the urine bag hook are described below.

Notes

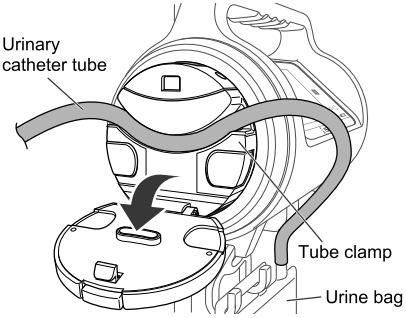
For the steps for installation of Uro Checker and urine bag and the steps to start measurement after passing the urinary catheter tube, refer to the instruction manual of Uro Checker.

☞ "4 Installing Uro Checker" - "Installing to IV Stand"
☞ "5 Performing measurement" - "Starting Measurement"

1. **Press the lid release button on the hemato check module to open the lid.**

2. **Attach the urinary catheter tube to the tube clamp.**

- Allow some slack so that the urinary catheter tube is not under tension.
- Make sure that the urinary catheter tube is not kinked.



3. **Close the lid.**

- If the lid is not closed, the hemoglobin concentration may not be measured correctly.

How to Interpret Measurement Screen

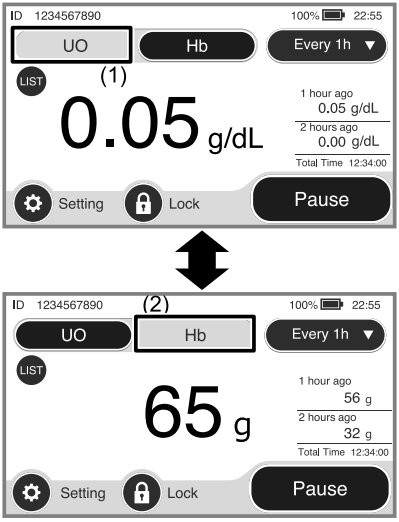
This section describes how to interpret the measurement screen for urine hemoglobin measurements.

Display method of screen

For the method for displaying the urine output per time and the urine hemoglobin concentration, either the "1 item" or the "All in 1" can be selected.

Notes For the steps to switch the display method, refer to the instruction manual of Uro Checker.
☞ "6. Details of Various Settings" - "Display setting"

1 item	All in 1
The urine output per time and the urine hemoglobin concentration are individually displayed.	The values and measurement periods of both of the urine output per time and the urine hemoglobin concentration are displayed on the same screen.

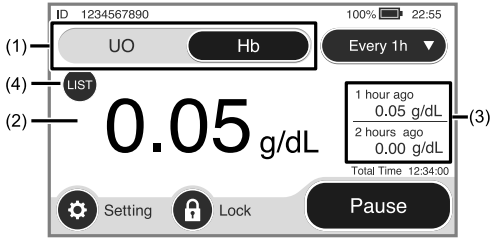


(1) When [UO] is tapped on the screen displaying the urine hemoglobin concentration, the screen changes, and the urine output per time and its measurement period are displayed.
(2) When [Hb] is tapped on the screen displaying the urine output per time, the screen changes, and the urine hemoglobin concentration value and its measurement period are displayed.

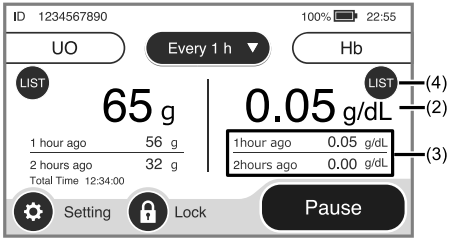
Description of display items

When the hemato check module is used, the measurement result of urine hemoglobin concentration is displayed on the measurement screen of Uro Checker. Only the display items related to urine hemoglobin concentration measurement are described here.

<1 item>



<All in 1>



No.	Name of button/display item	Description
(1)	[Hb] (urine hemoglobin) display button/ [UO] (urine output) display button	The measurement result for the highlighted button is displayed. Tap the other button to switch to the measurement result screen.
(2)	Measurement result (latest)	The latest measurement result (urine hemoglobin concentration) is displayed.
(3)	Measurement results (past two measurements)	The results for the past 2 measurements (urine hemoglobin concentration) are displayed.
(4)	[LIST] button	Tap this button to display the Hb history as a list. When the measurement interval is crossed on the history screen, the screen is automatically reloaded and the measured value is reflected. Up to 12 items can be displayed for Hb history.

Notes

- For details of the display items not related to urine hemoglobin concentration measurement, refer to the instruction manual of Uro Checker.
  ☞ "5. Performing measurement" - "How to Interpret Measurement Screen" - "Common display items"
- When the display setting is “all in 1”, the measurement results of both (UO and Hb) are displayed side by side. For the details, refer to "Display method of screen" ☞ (p 15).

Switching screens by measurement period

The user can switch the measurement screen by the preset measurement period. Press the screen switch button, and select the time interval from the pull-down menu to switch the display. For the measurement period, in addition to the 24-hour interval, 2 other intervals can be selected.

Notes

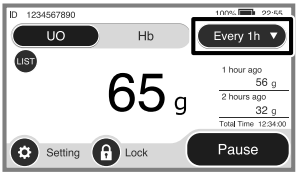
For the steps to change the measurement unit and the measurement period, refer to the instruction manual of Uro Checker.

- Change of unit display ☞ "6. Details of Various Settings" - "Display setting"
- Change of measurement period ☞ "6. Details of Various Settings" - "Time setting"

For “1 item”

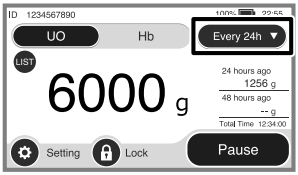
<Measurement result of urine output per time>

Every 1 hour (example)



Every 8 hours (example)

Every 24 hours



<Measurement results of urine hemoglobin concentration>

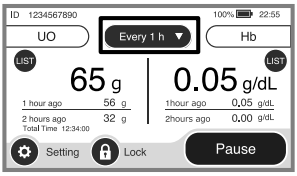
Every 1 hour (example)

Every 8 hours (example)

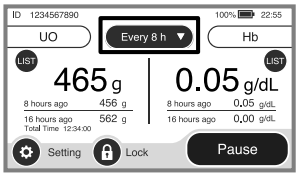
Every 24 hours

For “all in 1”

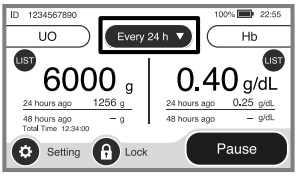
Every 1 hour (example)



Every 8 hours (example)



Every 24 hours



Notification

When a notification occurs, the Uro Checker will buzz repeatedly and the LED will blink green.

Item	Conditions/measures
Hemato Check Module is not connected	The hemato check module is not properly connected. Please check the connection.
High Hb in urine	The value is exceeded the threshold of urinary Hb notification (high) specified in "Hemato Check Module" ☞ (p 9)
Low Hb in urine	The value is below the threshold of urinary Hb notification (low) specified in "Hemato Check Module" ☞ (p 9).

Terminating the Measurement

For the steps to terminate measurements and to remove Uro Checker from the patient after termination, refer to the instruction manual of Uro Checker.

☞ “5. Performing measurement” - “Terminating Measurement/Removing Uro Checker”

6 Care and Inspection

This section describes cleaning and periodic inspection of the Hemato Check Module.

Care after Use (cleaning)

To use the product safely, make sure to clean the main unit after each use.

! Notice

- **Do not use disinfectants to clean the hematuria sensor. This may cause a product failure.**
- **Do not use autoclaves or other sterilizers. This may cause a product failure.**
- **Do not use drying equipment such as a hair dryer. The product may be damaged or fail.**
- **Avoid ingress of fluids into the product. The product may fail.**
- **Do not use aerosol products for cleaning. Doing so may result in damage or malfunction.**

■ Compatible disinfectants

Some examples of compatible disinfectants (ingredients) are shown below. For use of disinfectants, follow the information described in the package insert of each disinfectant (dilution concentration, etc.).

Disinfectant (ingredient)	Concentration
Ethanol for disinfection	76.9 to 81.4vol %
Sodium hypochlorite solution for disinfection	Chlorine concentration: 0.02 to 0.1 %
Chlorhexidine gluconate	to 5 %
Cresol soap solution	–
Benzalkonium chloride	to 5 %
Isopropyl alcohol	to 17 %

■ Cleaning method

1. **Wring out a disinfectant-soaked gauze pad, and then gently wipe the main unit.**
2. **Wring out a water- or lukewarm water-soaked gauze pad, and then wipe off the disinfectant.**
3. **Wipe off water thoroughly with a dry soft cloth.**

■ Cleaning of hematuria sensor

1. Wring out a water- or lukewarm water-soaked gauze pad, and then wipe off dirt.

2. Wipe off water thoroughly with a dry soft cloth.

Periodical Inspection

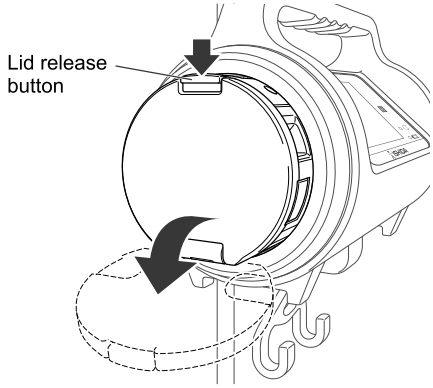
In order to ensure safety and longevity of use, please perform inspections every six months as a guideline. If any abnormality is identified during inspection, immediately stop using the product and contact ISHIDA MEDICAL or our distributor.

Inspection item

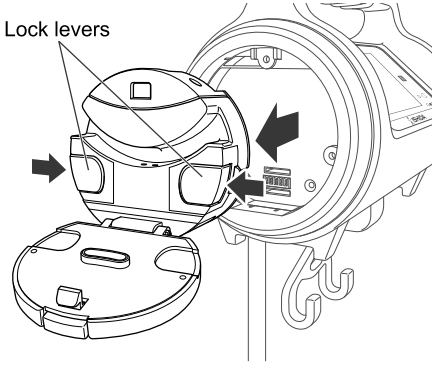
Inspection item	Inspection method/reference
Check for damage and dirt	1. Remove the product from Uro Checker in advance. "Removing from Uro Checker" ☞ (p 21) 2. Promptly wipe off any spilled drug solution, etc. "Care after Use (cleaning)" ☞ (p 19)
Hematuria sensor operation check	1. Connect the product to Uro Checker in advance. "Connecting to Uro Checker" ☞ (p 8) 2. Check if the output value of the hematuria sensor is normal on the maintenance screen. "Maintenance screen" ☞ (p 22)
Hematuria sensor light intensity adjustment	1. Connect the product to Uro Checker in advance. "Connecting to Uro Checker" ☞ (p 8) 2. Adjust the light intensity of hematuria sensor on the maintenance screen. "Maintenance screen" ☞ (p 22)

Removing from Uro Checker

1. **Press the lid release button on the hemato check module to open the lid.**



2. **While holding the lock levers with fingers, remove the hemato check module from Uro Checker.**



Maintenance screen

The maintenance screen allows you to check the operation of the hematuria sensor and adjust the light intensity.

1. **Tap [Setting] on the Preparation for measurement screen.**

➡ The screen changes to the Setting screen.

2. **Tap [Maintenance].**

➡ The screen changes to the Maintenance screen.

3. **Tap [Hemato Check Module check].**

➡ The "Hemato Check Module check" screen appears.

- The module name and the version number are displayed.

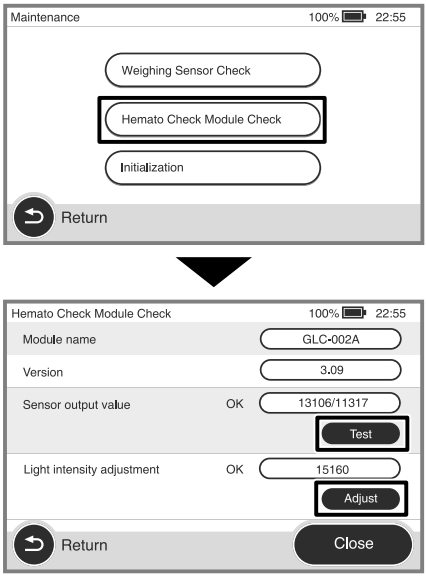
4. **Tap [Test] for "Sensor output value".**

➡ If there is no issue with the sensor output value, "OK" is displayed.

5. **Tap [Adjust] for "Light intensity adjustment".**

➡ When the light intensity adjustment is completed without any problem, "OK" is displayed.

- Do not attach the tube and close the lid before proceeding the test.
- After confirmation, tap [Close] to switch to the Preparation for measurement screen.



Notes When the sensor output fails the check, it is possible that the hematuria sensor is dirty. Open the lid and clean the sensor light emitting part and the light receiving part.

For cleaning, refer to "Care after Use (cleaning)" ☞ (p 19).

Precautions for storage

Store the hemato check module without disconnecting from Uro Checker. For the details of storage conditions, refer to the instruction manual of Uro Checker.

☞ "9 Specifications" - "General Specifications" - "Transportation/storage environment"

7 Specifications

■General specifications

Item	Description
Model	HCM-50M
External dimensions	W95 × H90 × D55 mm or smaller (Excluding the connector part)
Weight of main unit	250 g or less
Interface/power supply	Communication method : UART Power supply voltage : 5VDC Power consumption : ≤ 0.25 W
Use environment	Operating temperature : 41 to 95°F (5 to 35°C) Operating humidity : 10 to 85% RH (No condensation)
Transportation/storage environment	Transport and storage temperature : 23 to 140°F (-5 to 60°C) Transport and storage humidity : 10 to 85% RH (No condensation)
Degree of protection	IP24 (Lid is in closed position)
Service life	5 years (based on self-certification) If the specified maintenance, inspection, and replacement of consumables are performed and the product is used in a standard manner.
Measuring range	Hemoglobin concentration: 0.00 to 1.20 g/dL
Output scale interval	0.05 g/dL
Measurement accuracy	Low concentration (0.00 to 0.40 g/dL) : ± (20% + 0.05 g/dL) High concentration (0.40 to 1.20 g/dL) : ± (50% + 0.05 g/dL)
Classification by type of protection against electric shock	Class II device
Classification of applied part by degree of protection against electric shock	Type BF applied part

Symbol

Mark or sign	Description
	This mark provided on the product indicates the degree of protection against external current entry (type BF applied part).
IP24	This mark indicates the degree of protection against ingress of water and dust as specified in IEC60529.
	This mark prompts users to carefully read the instruction manual (this document).

Mark or sign	Description
	KEEP AWAY FROM SUNLIGHT
	TEMPERATURE LIMITS
	KEEP AWAY FROM RAIN
	FRAGILE, HANDLE WITH CARE

EMC Technical Specifications

The product complies with the EMC (electromagnetic compatibility) standard IEC 60601-1-2:2014/JIS T 0601-1-2:2018 required for the safe use of medical electrical equipment. The compliance information is provided below. The product is a medical electrical device requiring special precautions for EMC and must be installed and used in accordance with the following EMC information.

What is EMC (electromagnetic compatibility)?

It is the ability to meet the following 2 conditions.

- The device does not generate any noise that would cause unacceptable failures in other surrounding electronic equipment. (Emission)
- The device functions normally without being affected by the surrounding electromagnetic environment such as noise generated by other surrounding electronic devices. (Immunity)

Technical descriptions related to EMC (electromagnetic compatibility)

Medical electrical device requires special precautions for EMC and must be used in accordance with the following EMC information.

- 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 Hemato Check Module HCM-50M, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of devices other than accessories or options may result in increased emissions or decreased immunity.
- Do not use the product adjacent to or stacked with other device. If it is to be used adjacent or stacked, check that it operates correctly in their placement.

■ Guidance and manufacturer's declaration (electromagnetic emission)

The product is intended for use in the electromagnetic environment specified below.
The user of the product should ensure that it is used in the following environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR11	Group 1	The product uses the RF energy only for its internal function. Therefore, its RF emissions are very low, and the possibility of interfering with nearby electronic devices is low.
RF Emissions CISPR11	Class B	The product is suitable for use in all facilities that include the facilities directly connected to public low-voltage power distribution networks, providing power to residential facilities and for domestic purposes.

■ Guidance and manufacturer's declaration (electromagnetic immunity) (1)

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

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with a synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	30A/m	30A/m	The power frequency magnetic field should be at the same level as typical locations in a typical commercial or hospital environment.

■ Guidance and manufacturer's declaration (electromagnetic immunity) (2)

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

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - Guidance
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.7GHz Near-field transmission from wireless communication device a)	3V/m 80MHz to 2.7GHz Near-field transmission from wireless communication device a)	Portable and mobile RF communications devices should not be used closer to any part of the product, including cables, than the recommended separation distance calculated using the equation applicable to the frequency of the transmitter. Recommended separation distance $d=6/E * \sqrt{P}$ where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the radiation electromagnetic field level in volts/meters (V/m).

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2 These guidelines do not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) The near-field transmissions from wireless communication devices are as shown in the table below.

Test frequency [MHz]	Band [MHz]	Equipment	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ±5kHz 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN820 CDMA850 LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

Test frequency [MHz]	Band [MHz]	Equipment	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11a	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

■ Recommended separation distance between portable and mobile RF communication devices and the product

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help reduce electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters) and the product as recommended below, based on the maximum output power of the transmitters.

Maximum rated output power of transmitter (W)	Separation distance according to frequency of transmitter (m)
	80MHz to 2.7GMHz $d = 0.6\sqrt{P}$
0.01	0.06
0.1	0.19
1	0.6
10	1.9
100	6

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation corresponding to the frequency of the transmitter. Where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines do not apply to all situations. It is affected by absorption and reflection from structures, objects and people.

ISHIDA MEDICAL CO., LTD.

Address: 60-1 Shogoin Rengezo-cho, Sakyo-ku, Kyoto-shi, 606-8357 JAPAN

Manufacturer: NIHON SEIMITSU SOKKI CO., LTD.
Address: 2508-13 Nakago, Shibukawa, Gunma, 377-0293 JAPAN

Distributor: