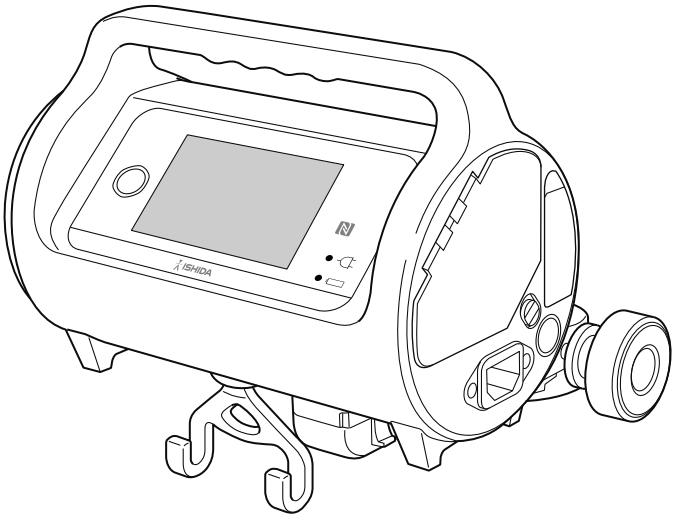
ISHIDA

Urine Measurement and Recording System

Uro Checker



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.

No.AA-1074-00

Introduction

Thank you very much for purchasing our “Uro Checker” (hereinafter referred to as “the product”).
Please read this document and the package insert carefully before use.

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

Requests for Users

- Unauthorized reproduction of the information contained in this document is strictly prohibited.
- Note that the information contained in this document may partly be inconsistent with the product due to improvements.
- The information contained in this document is subject to change without notice in the future.
- Although we made all possible efforts to ensure this document was perfectly prepared, if you find any error or questions about the contents, please contact us.
- The instruction manual with missing pages or binding errors will be replaced. Contact the nearest distributer of ISHIDA MEDICAL.
- We will deal with troubles with the devices and the main unit of the system in accordance with the individual maintenance contracts; however, we assume no responsibility for secondary troubles such as downtime caused by a trouble with the main unit.

Important Notice

Intended use of the product

- This product measures and displays the urine output per time in the urine bag connected patient in the profes sional healthcare facility environment.
- Urine bag is hung on a strain gauge load cell to measure weight, and the urine output per set time is measured as urine output per time.

Safety

- Be sure to read “1. Precautions for Safety (to be strictly observed)” 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.
- This document contains confidential information of ISHIDA MEDICAL, and the company possesses all copyrights on this document. Written consent of ISHIDA MEDICAL is required prior to disclose the confidential information to a third party, reproduce, or duplicate this document in whole or in part.
- 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

- WARNING: No modification of the product is allowed.
- WARNING: No modification of the IT-NETWORK settings and related connected devices is allowed.
  Other equipment connection of an IT-NETWORK could result in previously unidentified risks to patients, oper ators or third parties, the responsible organization should identify, analyze, evaluate and control these risks. Subsequent changes to the IT-NETWORK could introduce new risks and require additional analysis, and cha nges to the IT-NETWORK include: configuration, connection of additional items; disconnecting items; update of equipment; and upgrade of equipment.
- ISHIDA MEDICAL assumes no responsibility for any disassembly, modification, or alteration by users.

Disposal

- Dispose of the product in accordance with local ordinances.

Information security

- Users are responsible for the management and operation of the information security related to the product.
- Essentially, external connection of the product using a wired or wireless LAN, near field communication (NFC), or other wireless technology involves security vulnerability. Note in advance that it is your responsibility to take information security measures depending on the usage environment and give protection against information leakage.
- To connect the product or exchange information with another medical or general information system in the usage environment and for the intended purpose of the product, the agreement of the security manager and system administrator of the information system about the operation of the product should be obtained.

Table of Contents

Notes

1 Precautions for Safety (to be strictly observed)

Meaning of Markings

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

- Be sure to use the supplied AC power cable. Using an AC power cable other than the specified one may cause fire or electric shock, resulting in serious injury.
- Thoroughly check the AC power plug of the product and its surroundings, and main parts such as the display unit. If any area getting wet with a chemical solution is found, turn off the product and disconnect the AC power cable from the product and the outlet, and promptly wipe off the solution with a dry cloth. Using the product without drying its wet area may cause fire or electric shock, resulting in serious injury.
- Do not place the product in a place that interferes with the insertion and removal of the power cable.
- Do not insert or remove the power plug with wet hands. Doing so may cause electric shock, resulting in serious injury.
- Do not remove the battery during AC power cable plugin or plug in AC power cable without battery inside the device.
- Do not use the AC power cable if it is damaged. Doing so may cause fire, resulting in serious injury.
  To purchase the AC power cable, contact ISHIDA MEDICAL or our distributor.
- If you find any of the following, turn off the product 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.

CONTRAINDICATIONS

- 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 the product into the hyperbaric oxygen therapy equipment. Doing so may cause a malfunction, damage, or explosion, resulting in serious injury.
- Do not bring the product into the examination room during a MRI examination. Doing so is very dangerous because adsorption of the product to the MRI device may induce an accident. Or, it may cause ignition or explosion, resulting in serious injury.

⚠ CAUTION

< Precautions about how to use >

- The product should be used by the following healthcare professionals experienced in handling the product: physicians, nurses, and clinical engineers.

! Notice

< Precautions for use in combination with other devices >

- When using a device that generates electromagnetic waves and high-frequency waves (defibrillator, electrosurgical knife, etc.), keep it away from the product as much as possible.

< Precautions related to installation >

- The product uses the mass measurement method for urine measurement.
  Please note the following during the measurement.
  - Ensure that you hang a urine bag on the urine bag hook.
  - Ensure that you attach the urinary catheter tube of urine bag through the tube clamp.
  - Do not place anything around urine bag avoid contact.
  - When attaching the urinary catheter tube, make sure that the tube does not pull or push the urine bag.
- To install the product to an IV stand, use the specified mounting bracket to fix the product securely and check stability of the stand.

< Precautions about how to use >

- Do not put anything on the product.
- When moving the IV stand with the product fixed to the stand, do not hold the handle of the product or apply force from above.
- When carrying the product after removing from the fixing bracket, be sure to hold the handle of the product. Prevent load from being applied to the urine bag hook.
- Since the product is sensitive equipment, do not use if it falls on to the floor, the IV stand topples over, or an impact is applied to the product by hitting it strongly against something.
- Do not install anything other than the optional items or accessories specified by ISHIDA MEDICAL to the product.
- Do not connect any device other than a barcode reader to the USB port.
- Do not connect any cable other than the network cable of the facility where the product is used to the LAN port.
- Please note the following when connecting the device powered by another source to the product.
  - When used in the patient environment, connect device that comply with IEC60601-1.
  - When used outside the patient environment, connect device that comply with IEC safety standards.
- Do not perform maintenance or inspection of the product while it is being used on patients.

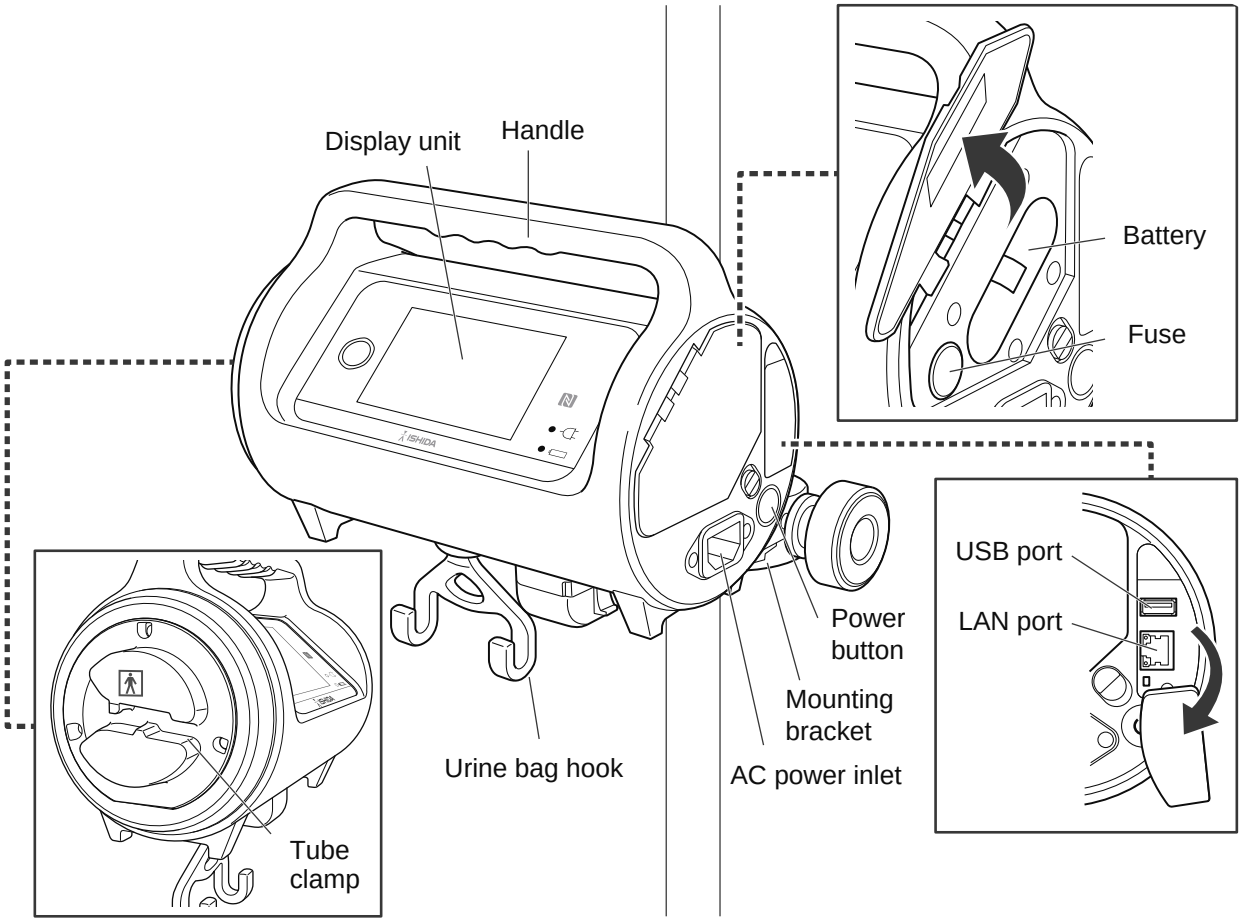
< Precautions related to battery >

- Inspect the product periodically to check that the battery is not deteriorated.
- To charge the battery, ensure that you follow the charging procedure described in this manual.
- If you do not use this product for a long time, remove the battery.

2 Functions

Name and Function of Each Part

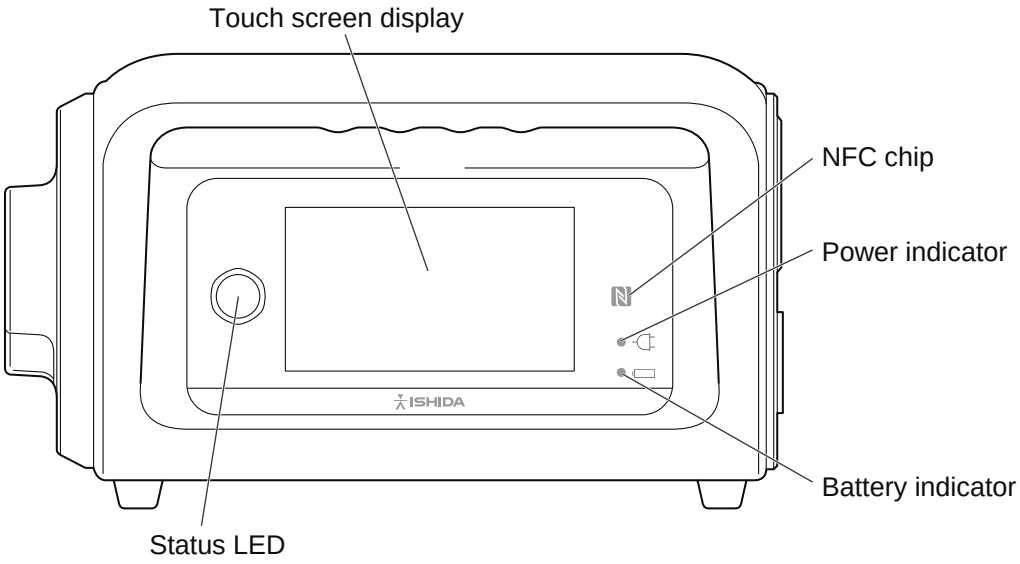
Uro Checker (overall)



Name	Function
Display unit	Operate Uro Checker and displays various data.
Handle	It is a handle to be held when Uro Checker is carried alone. Be sure to hold the handle when carrying Uro Checker to prevent failure of or damage to the product.
Urine bag hook	Hang a urine bag.
Mounting bracket	Fix Uro Checker to an IV stand.
Battery (and battery slot)	It is the supplied battery and battery slot.
Fuses (and fuse boxes)	It is the fuse and fuse box of the product.
USB port	It is used to connect the bar code reader (Option).

Name	Function
LAN port	Connect the LAN cable connector for wired connection to the network.
Power button	The power button of the product.
AC power inlet	Connect the supplied AC power cable to supply power to Uro Checker.
Tube clamp	Attach the urinary catheter tube to the clamp and fix it. (APPLIED PARTS)

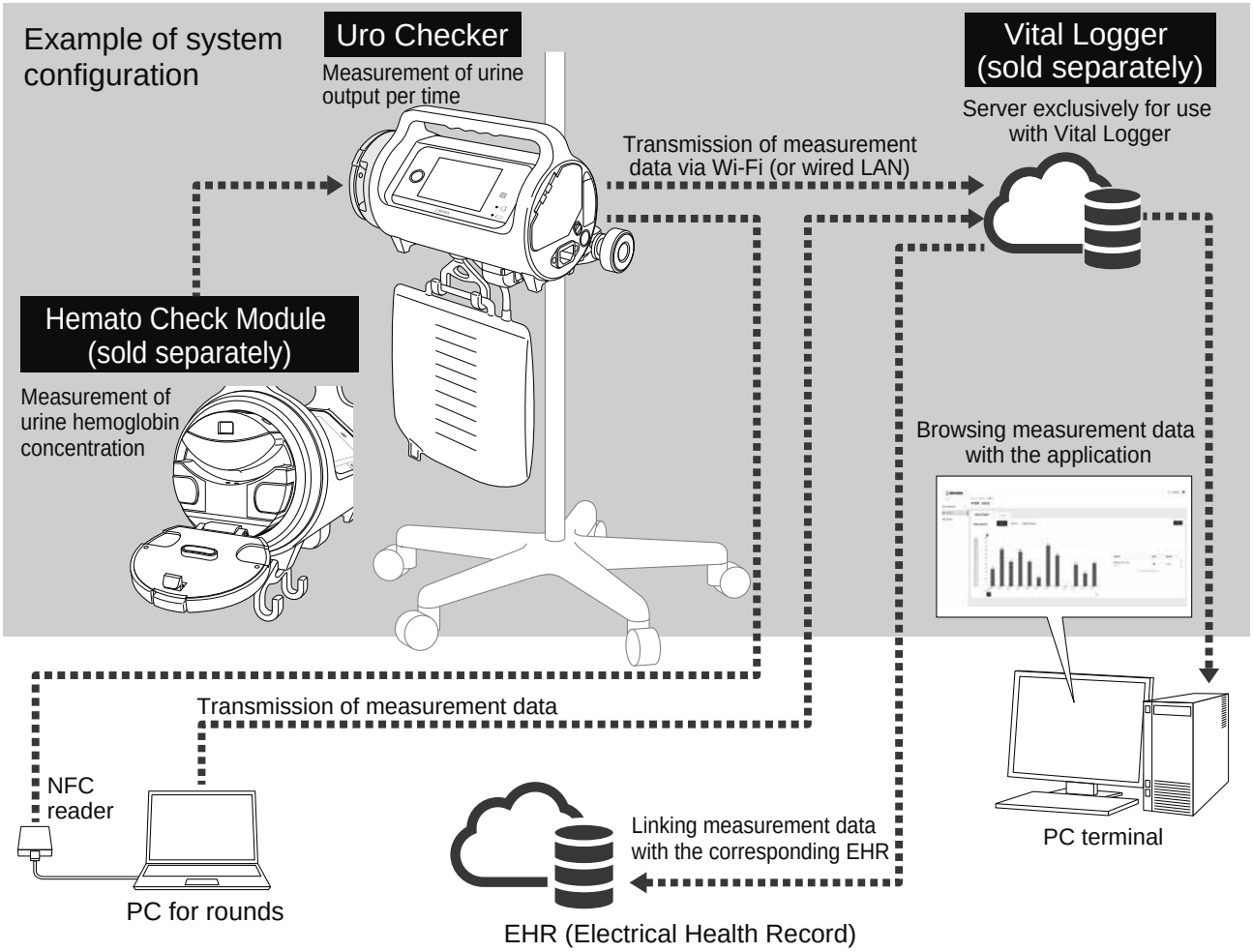
Display unit



Name	Function
Status LED	It lights up in green during measurement. The LED blinks in green when a notification or error occurred. "List of Messages" ☞ (p 51)
Touch screen display	Touch screen display is a screen to display the measurement data and allows users to configure various settings. "How to Interpret Measurement Screen" ☞ (p 24)
NFC chip	Touch a NFC reader to read the measurement data recorded on Uro Checker. The read measurement data can be displayed on the Vital Logger (sold separately).
Power indicator	It lights up in green when power is supplied by the AC power cable.
Battery indicator	It lights up in green when power is supplied by the battery. It turns off when the remaining battery level becomes 10% or lower.

Using with Other Products

When the hemato check module is attached to Uro Checker, it can measure the hemoglobin concentration in urine. In addition, the measurement data of Uro Checker can be remotely checked with a web browser on the PC terminal by transmitting the data to Vital Logger.



Notes

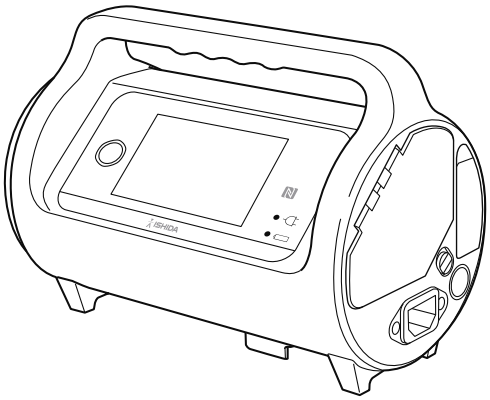
- The NFC reader, PC for rounds, PC terminal, and EHR (Electrical Health Record) are not included in the product configuration of this system.
- The hemato check module is used connected to into Uro Checker. For usage, refer to the instruction manual of the hemato check module.

3 Preparing Uro Checker

Checking the Items

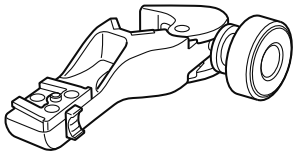
Accessories

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.

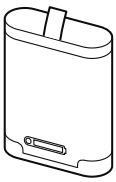


Uro Checker (main unit) ×1

Urine bag hook ×1

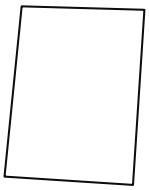


Mounting bracket ×1



Battery ×1

AC power cable ×1



Instruction manual ×1

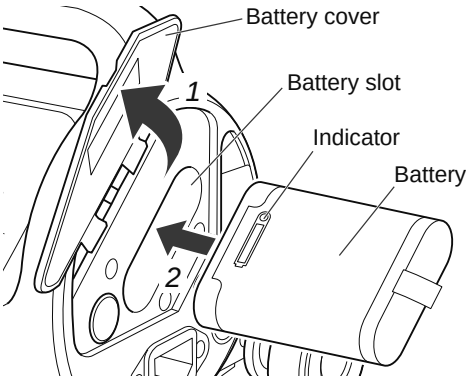
Starting Uro Checker (when using for the first time)

To use Uro Checker, preparations such as installation of the battery and initial setting for measurements should be made first. This section describes how to install the battery and turn the power on.

1. Open the battery cover of Uro Checker.

2. Insert the battery in the battery slot.

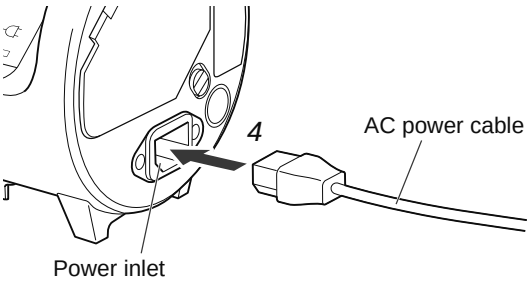
- Install the battery in the orientation that allows the indicator on the battery to be on the display unit side of Uro Checker.



3. Close the battery cover.

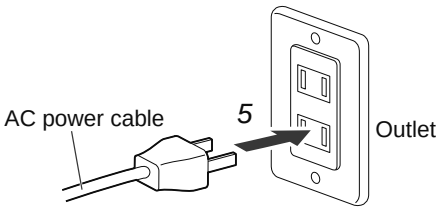
4. Plug the AC power cable into the AC power inlet of Uro Checker.

5. Plug the connector of the AC power cable into an outlet.



Notes

The battery is charged by connecting it to an outlet. When the battery level is very low, it requires approximately 6 hours to fully charge the battery.

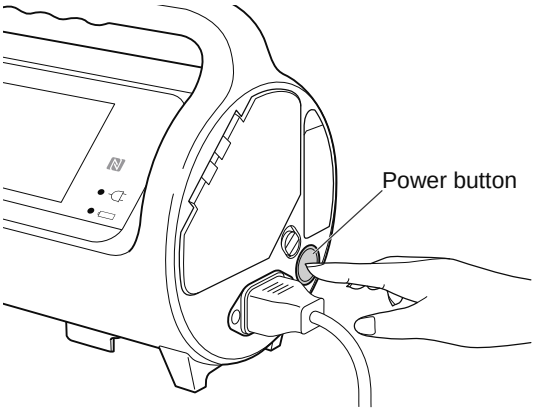


6. Press and hold the power button on Uro Checker.

➡ Uro Checker is turned on and the Initial Setting screen appears on the touch screen display.

Notes

- When Uro Checker is turned on for the first time, the Initial Setting screen appears. ☞ (p 9)
- When the initial setting is completed, the Preparation for Measurement screen appears from the next time the device is turned on.



Configuring Initial Setting

When Uro Checker is turned on for the first time, the Initial Setting screen appears. In initial setting, the user sets up language, PIN, time, and integration with Vital Logger.

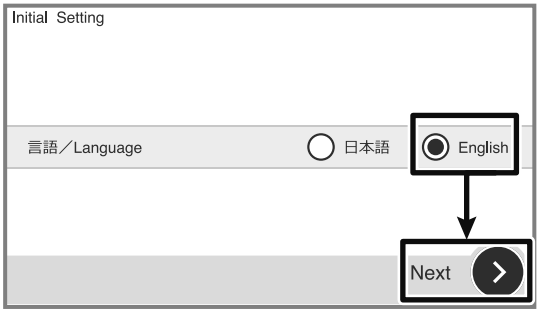
Notes

- The language and PIN settings cannot be changed before or during measurement. To change these settings, initialize Uro Checker on the Maintenance screen. ☞ (p 43)
- After the initial setting is completed, the Preparation for measurement screen appears from the next time the device is turned on.

1. Select the language to use.

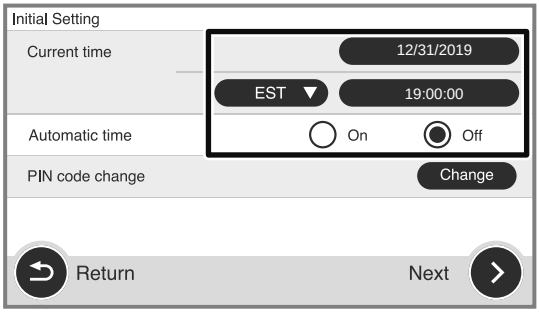
- Select either of [日本語] (Japanese) or [English] and tap [Next].

➡ The screen changes to the screen for the list of initial settings.



2. Set the current time.

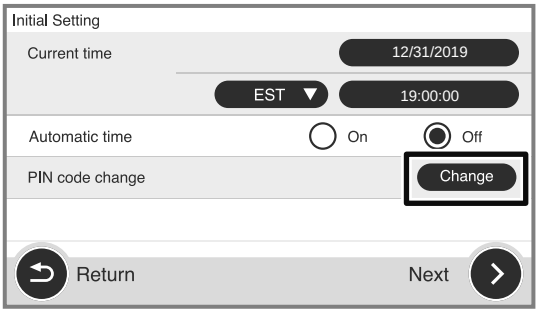
- Tap the input area and type the current time.
- When time synchronization is set to [On], the current time will be synchronized with the clock of the Vital Logger.

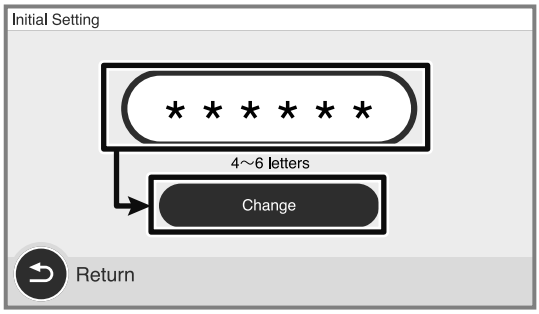


3. Change the PIN for initialization.

- Tap [Change] and type a PIN (half-width alphanumeric 4 to 6). If you do not change the PIN, the default value is "000000".
- After the PIN is entered, tap [Change] to return to the previous screen.
- After step 2 and 3 are finished, tap [Next].

➡ The screen changes to the Vital logger Setting screen.

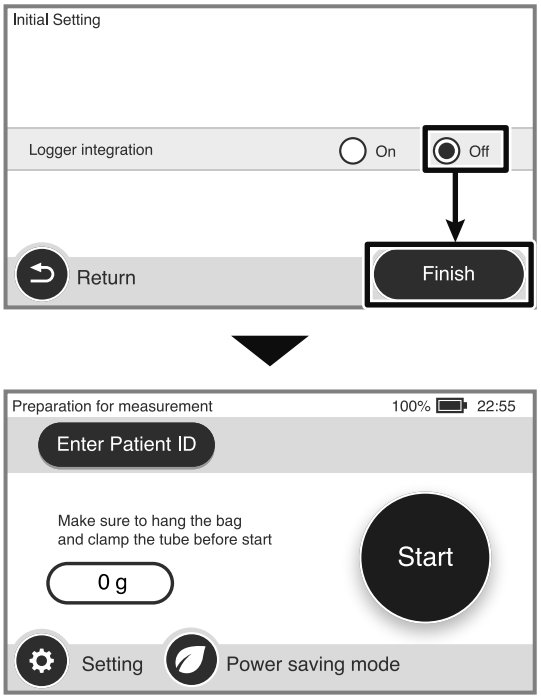




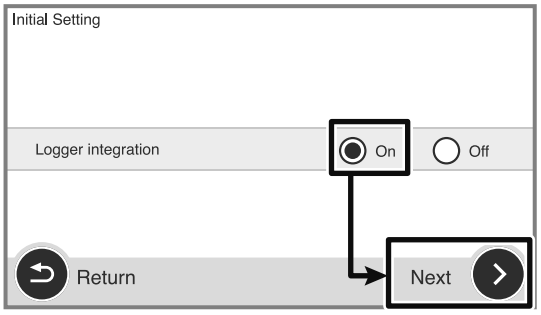
4. Enable or disable the integration with Vital Logger.

- Select [On] or [Off].

➡ When [Off] is selected: Tap [Finish]. This is the end of initial setting. The screen changes to the Preparation for measurement screen.



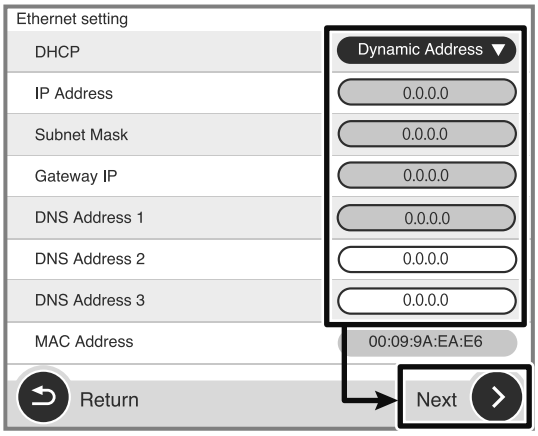
➡ When [On] is selected: Tap [Next]. The screen changes to the network settings for Vital Logger. Proceed to the next step.



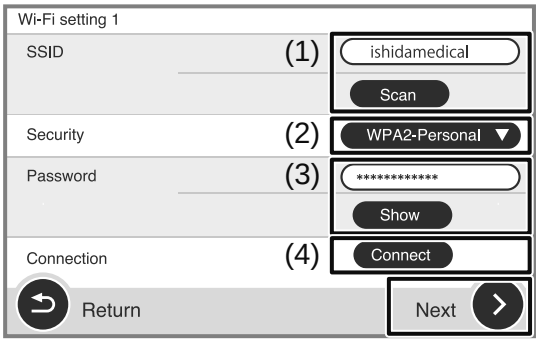
5. Configure the wired LAN connection settings.

- Set the DHCP, IP address, subnet mask, gateway IP, and DNS address. When the input area is tapped, a keyboard is displayed. Check with the network administrator (medical information representative) for the values to be set.
- When you finished entering the information, tap [Next].

➡ The screen changes to the Wi-Fi security settings for Vital Logger.



6. Configure the Wi-Fi security settings and connection.



(1) SSID
Enter the name of a desired network.

(2) Security
Select [Open], [WPA2-Personal], or [WPA2-Enterprise].

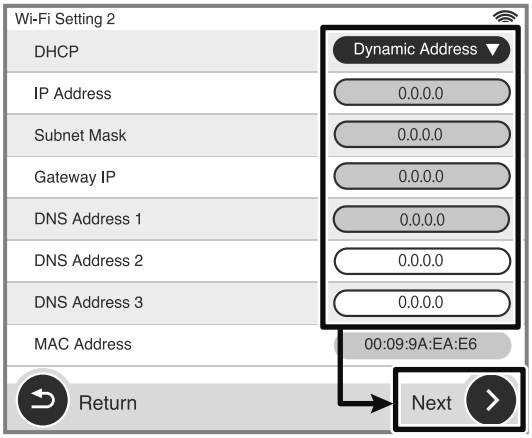
(3) Password
Input the password if necessary.

(4) Connection
Tap [Connect] to check the connection to the access point.

- Check with the network administrator (medical information representative) for the values to be set.
- After all information above is entered, tap [Next].

➡ The screen changes to the Wi-Fi settings.

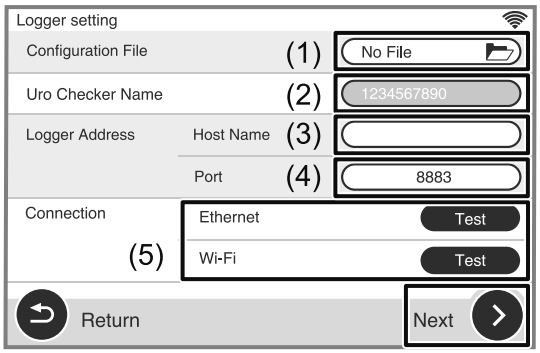
7. Configure the Wi-Fi settings.



- Set the DHCP, IP address, subnet mask, gateway IP, and DNS address. When the input area is tapped, a keyboard is displayed. Check with the network administrator (medical information representative) for the values to be set.
- When you finished entering the information, tap [Next].

➡ The screen changes to the connection settings for Vital Logger.

8. Configure the connection settings for Vital Logger.



(1) Configuration File
Issue the certification from Vital Logger and install into the product via USB flash drive.

(2) Uro Checker Name
The name registered in the Vital logger's authentication settings is displayed.

(3) Logger Address Host Name
Enter the IP address of Vital Logger.

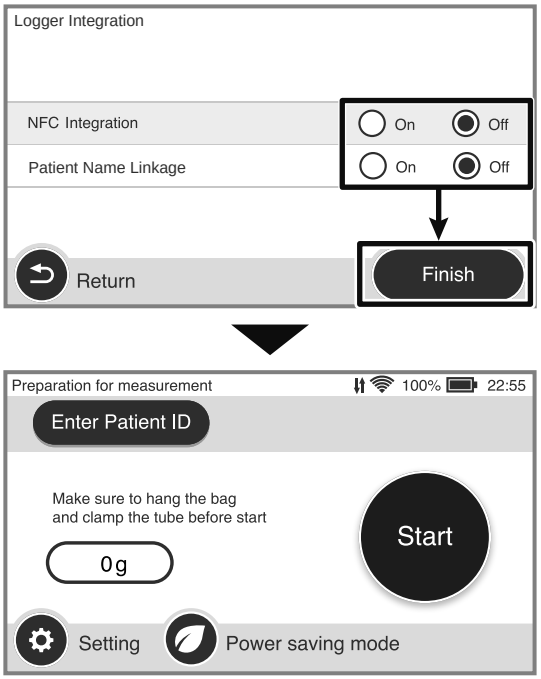
(4) Logger Address Port
Enter the port number of Vital Logger.

(5) Connection
Tap [Test] to confirm the connection with Vital Logger.

- Check with the network administrator (medical information representative) for the values to be set.
- After all information above is entered, tap [Next].

➡ The screen changes to the NFC integration setting for Vital Logger.

9. Configure the NFC integration setting with Vital Logger.

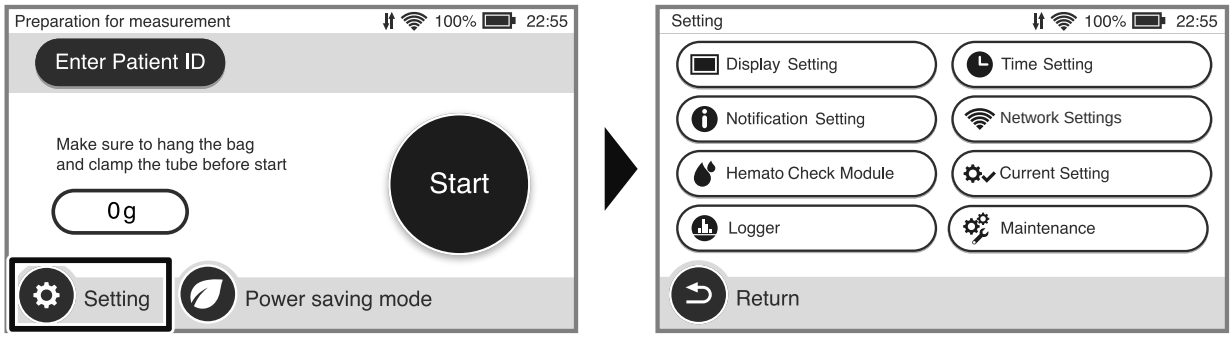


- Select [On] or [Off] to determine whether to establish NFC communication. After that, tap [Finish].

➡ This is the end of initial setting. The screen changes to the Preparation for measurement screen.

Various Settings

In addition to the initial settings, various settings mainly related to measurement are available. Before starting measurement, tap [Setting] at the bottom left of the Preparation for measurement screen to check or change the settings.



■ List of various settings

Many of the settings can be changed during measurement, whereas some of the setting items cannot be changed during measurement (module connection, current time, etc.). Before starting measurements with Uro Checker, be sure to check all the setting items and change them if necessary.

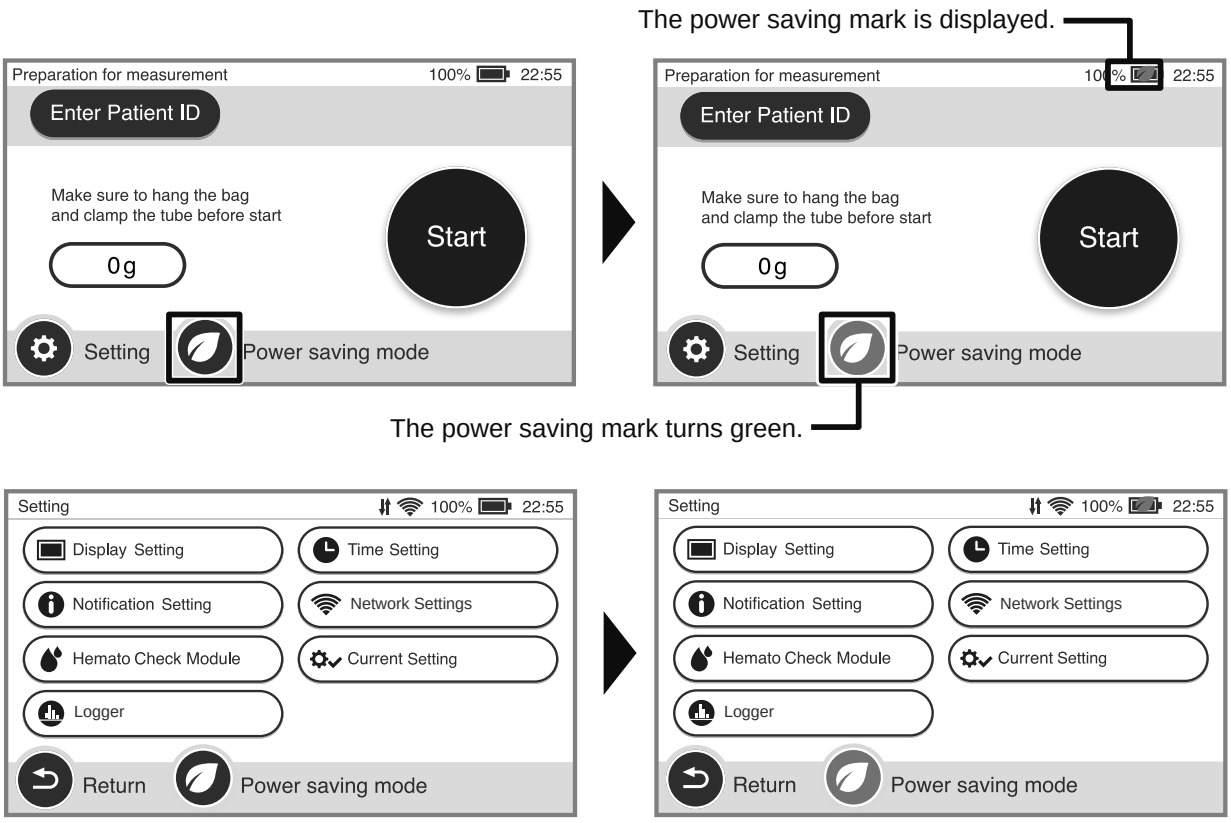
Setting item	Description
Display Setting	Set the method of displaying the measurement screen.
Time Setting	Set the current time and the measurement time.
Notification Setting	Set the settings for the detection when the measured urine output exceeds the threshold.
Network Settings	Switch on/off the Wi-Fi and Ethernet. This button is displayed only when the integration with Vital Logger is set to [On] in the initial setting.
Hemato Check Module	Configure various settings for measurement of urine hemoglobin concentration. This setting is required only when the hemato check module is connected.
Maintenance	Set the items related to maintenance of the product.
Logger	Switch on/off the integration with Vital Logger. This button is displayed only when the integration with Vital Logger is set to [On] in the initial setting.
Current Setting	The current setting status is displayed as a list.

Notes

- For the details of various settings, refer to “ "6 Details of Various Settings" ☞ (p 35).
- To measure the urine hemoglobin concentration using the hemato check module, refer to the instruction manual of the hemato check module and turn on the connection setting.
  ☞ 3. Preparing hemato check module" - "Setting of hemato check module"

Power Saving Mode

The product has the power saving mode to reduce battery consumption. Tapping [Power saving mode] on the Preparation for measurement screen or the Setting screen during measurement turns on this function.

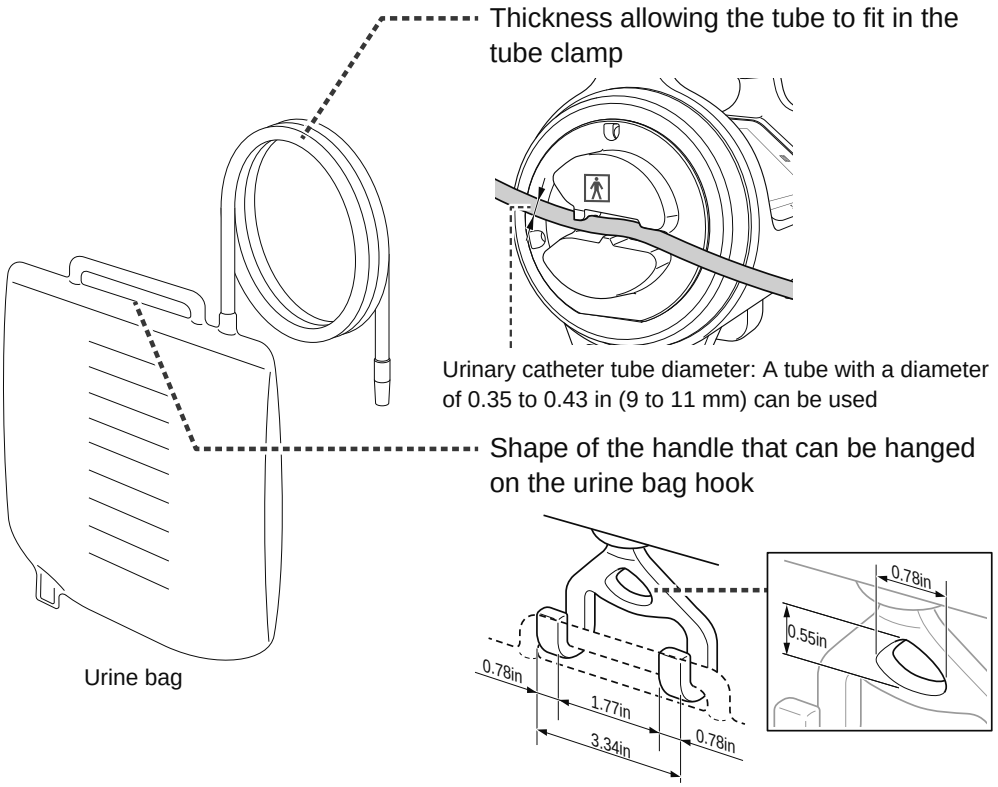


Notes In the power saving mode, the screen backlight will dim.

4 Installing Uro Checker

Compatible Urine Bags

Although the product is designed to fit for a wide variety of urine bags commercially available, the users should prepare a urine bag that satisfies the following conditions.



The opening and attachment hole of the handle must fit for the hook dimensions specified above.

Inspection before Use

Before using Uro Checker, perform the following inspections.

What to be inspected	Detail of inspection and actions to be taken
Uro Checker and its accessories	Are all necessary items provided? Check that the following items are included in the package. Uro Checker, AC power cable, battery, mounting bracket, and urine bag hook
	Are they clean? Clean them if you find dirt or chemicals on them. "Care after use (cleaning)" ☞ (p 45)
	Is there any damaged part? Contact ISHIDA MEDICAL or our distributor if you find any item too damaged to use.
Battery level	Is the battery level sufficient? Turn on Uro Checker with the battery installed in it and check the battery charge level. To supply power to the product only with the battery, use the battery fully charged. "Starting Uro Checker (when using for the first time)" ☞ (p 8).

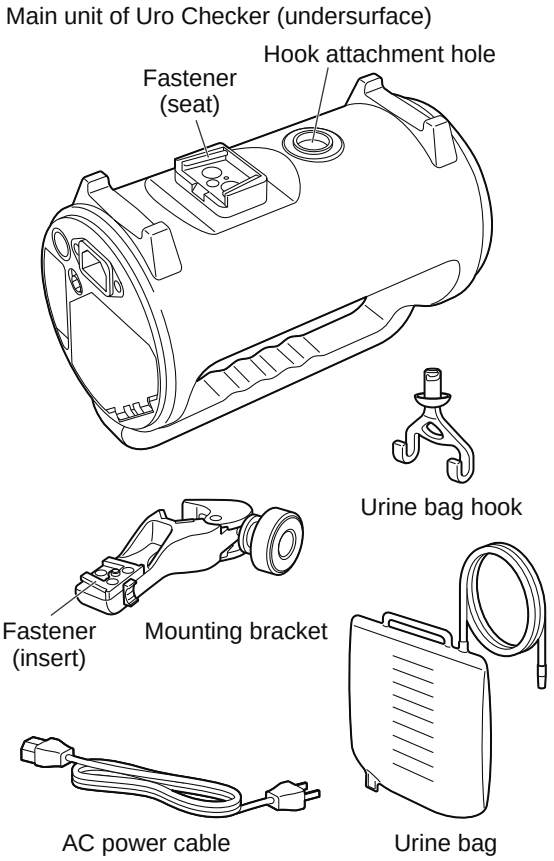
Installing to IV Stand

This section describes the installation of Uro Checker to an IV stand.

1 Prepare the main unit and accessories of Uro Checker and a urine bag.

! Notice Perform inspections before use to ensure that the product and its accessories are clean and free from damage beforehand.

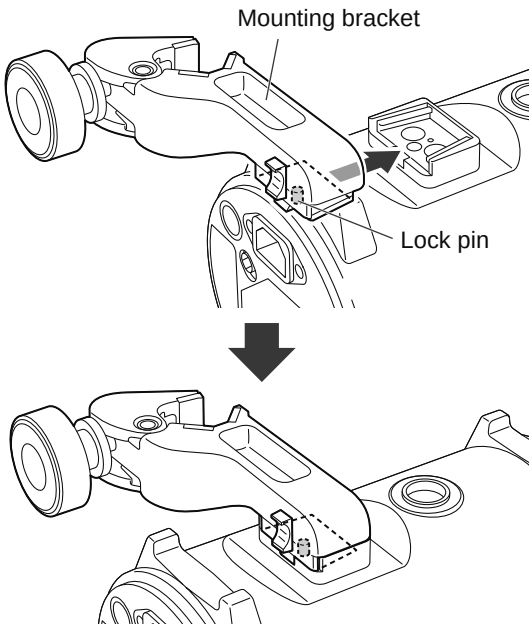
Notes Check that the battery is inserted ☞ (p 8).



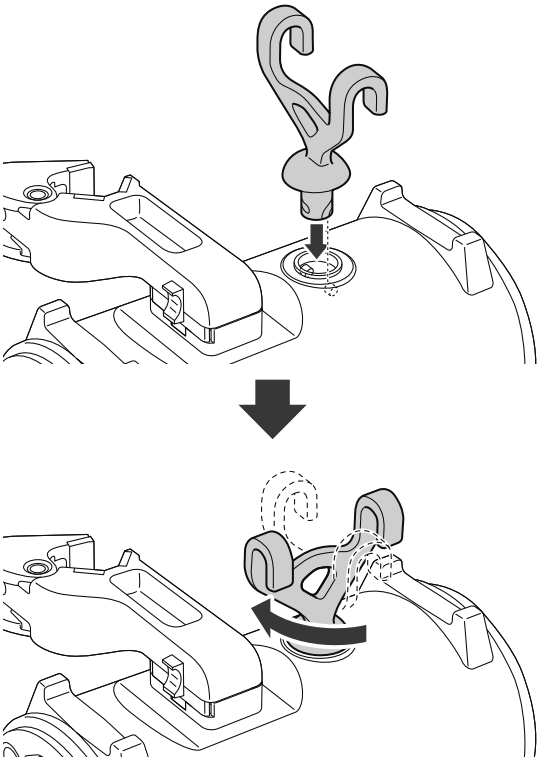
2. Slide and fit the fastener (insert) of the mounting bracket into the fastener (seat) on the underside of Uro Checker.

- Firmly fit the fastener (insert) all the way to the fastener (seat).

➡ When the mounting bracket and the lock pin engage, a click sound is heard.



3. **Insert the urine bag hook into the hook attachment hole on the underside of Uro Checker as far as it will go and turn it 90° clockwise to fix it.**

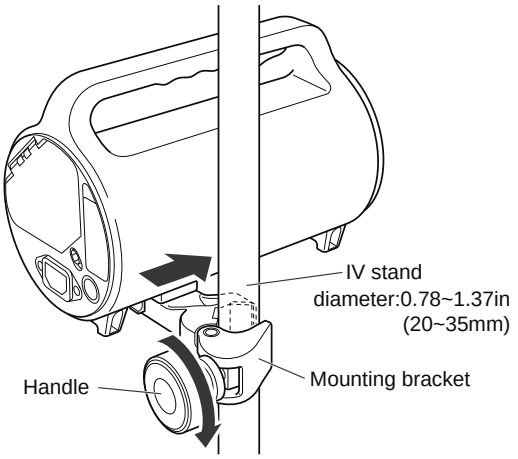


4. **Prepare an IV stand to which Uro Checker is installed.**

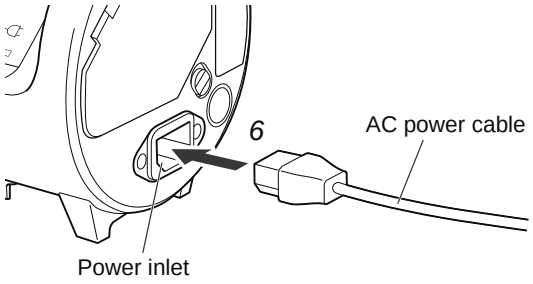
- Check that the IV stand does not wobble and is stable.

5. **Pinch the IV stand with the clamp of the mounting bracket and turn the handle to clamp the stand.**

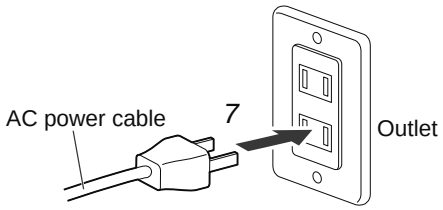
- Securely fix the mounting bracket to prevent it from wobbling.



6. Plug the AC power cable into the AC power inlet of Uro Checker.

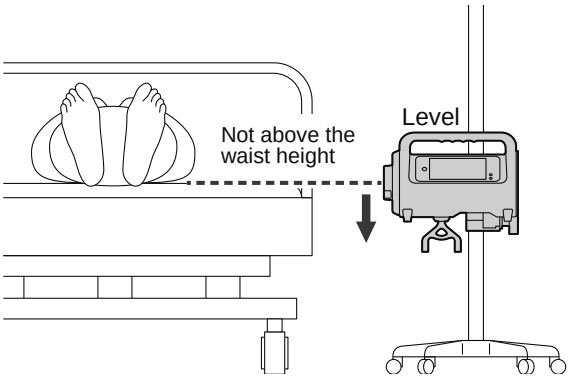


7. Connect the power plug to an outlet.



8. Check whether Uro Checker is installed properly.

- After installing Uro Checker, make sure that the tube clamp is lower than the waist position of the patient and that the urine bag does not touch the floor.
- Check that Uro Checker is level.
- Check that Uro Checker does not wobble and the device installed to the IV stand is stable.



⚠ 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.

5 Performing the Measurement

Starting Measurement

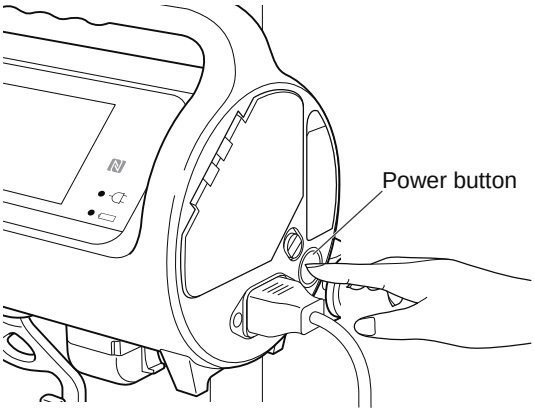
After completing the settings before measurement and the installation of Uro Checker, you can start measurements. This section describes how to start measurement.

1. Press and hold the power button on Uro Checker.

➡ The Preparation for Measurement screen appears.

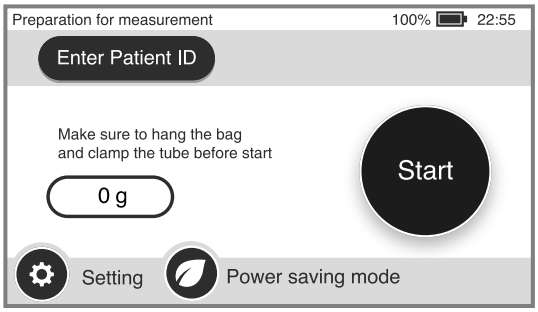
- Check that the battery is adequately charged.

Notes When the initial setting for Uro Checker is not yet completed, the Initial Setting screen appears. ☞ (p 9)



2. Check the operation of the weighing sensor.

- Check the measured value of the weighing sensor changes and returns.

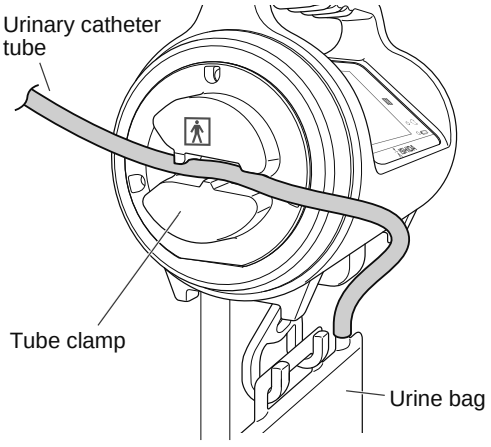


3. Hang a urine bag on the urine bag hook.

- Check that urine bag does not contact with the foot or pole of IV stand, the bed or floor.

4. Attach the urinary catheter tube through the tube clamp.

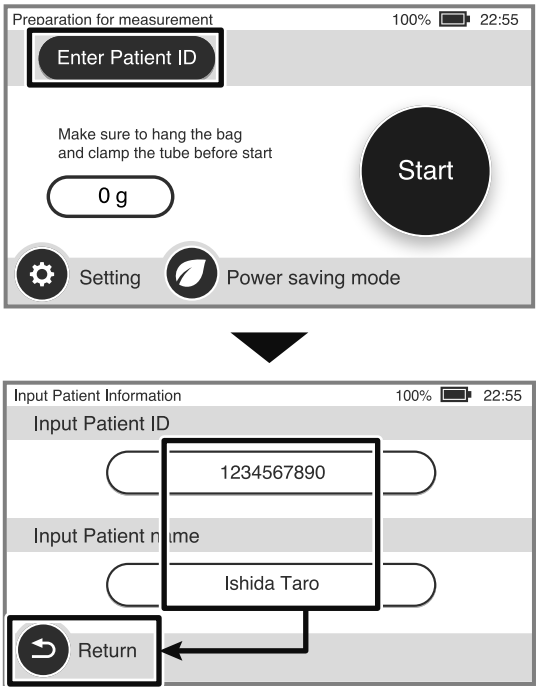
- Allow some slack so that the urinary catheter tube is not under tension.
- Make sure that the urinary catheter tube is not kinked.



5. Enter the patient information (patient ID/ name) as necessary.

- Tap [Enter Patient ID] and type the patient ID and name using the software keyboard on the display.
- After typing, tap [Return] to return to the Preparation for measurement screen.
- Measurement can be executed without entering the patient information.

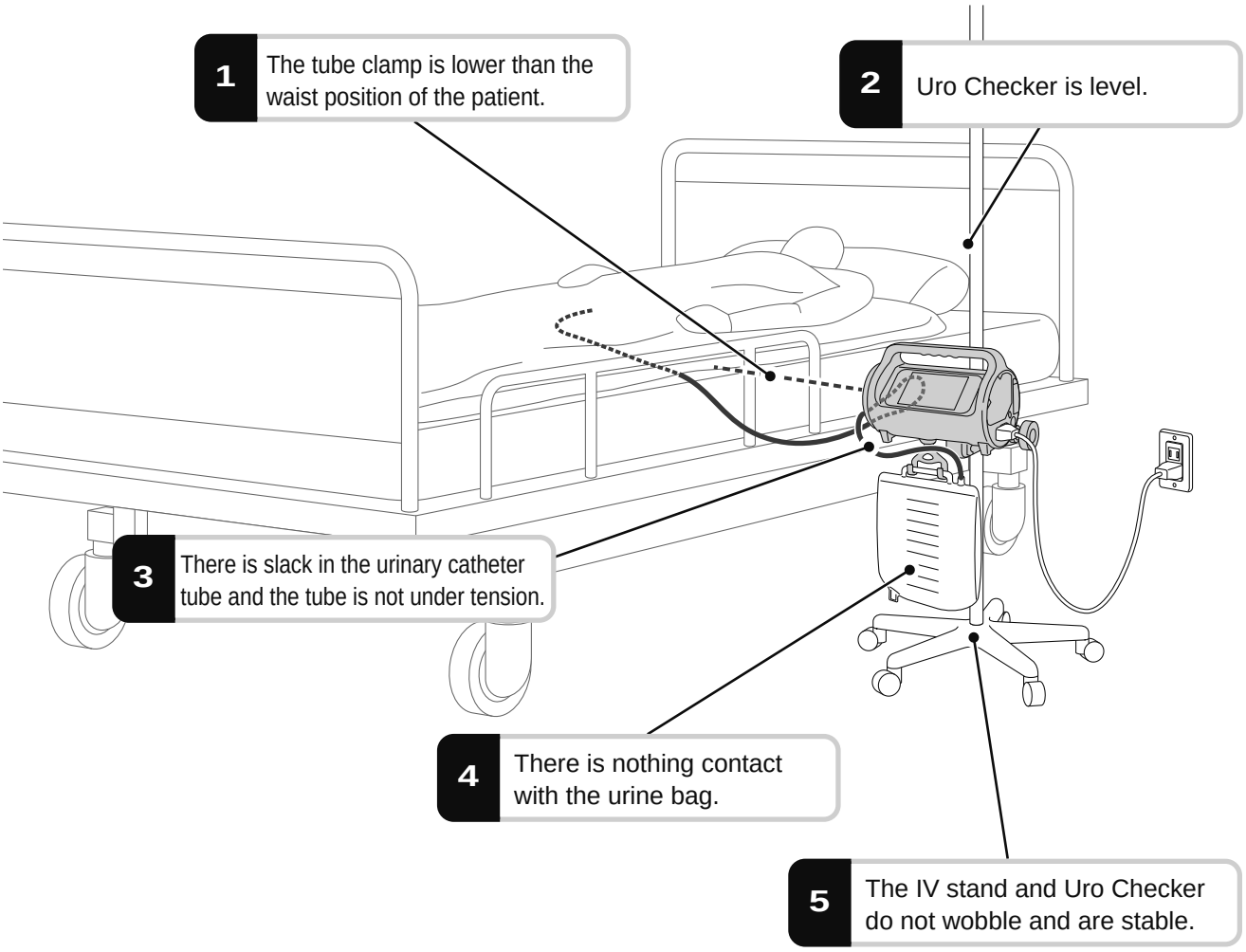
Notes The patient ID can be scanned from the barcode of patient when an optional barcode reader is attached.



6. Before starting measurements, check that the device is properly installed.

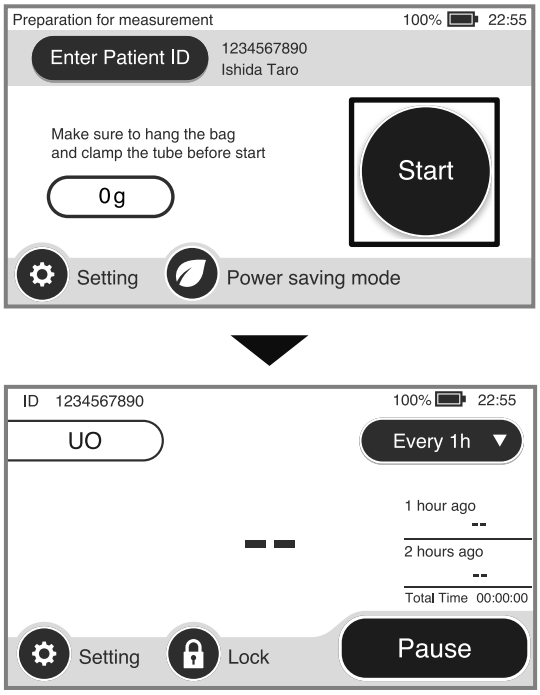
⚠ CAUTION

Be sure to perform the installation inspection to ensure that the device is properly installed before starting measurements.



7. Tap [Start].

➡ The screen changes to the measurement screen, and the measurement starts.



Notes

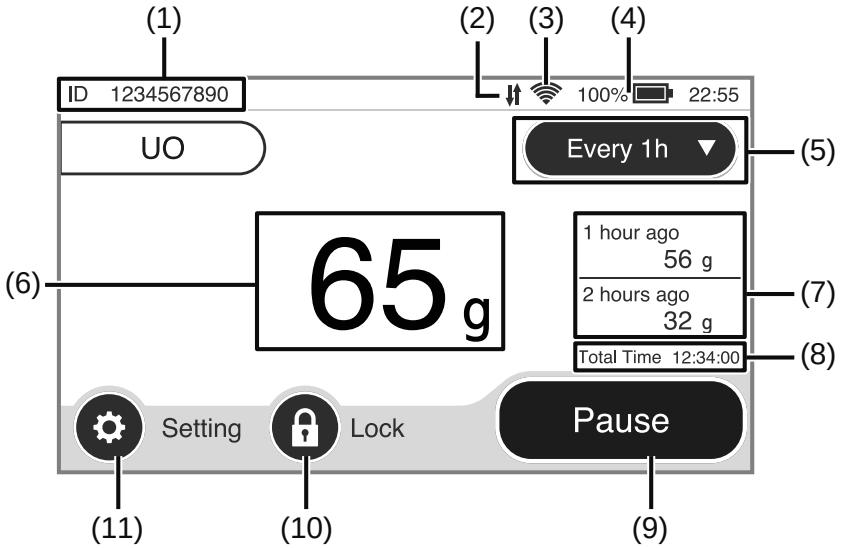
- It is tared automatically after the measurement starts.
- To operate the product only with the battery, check the battery level on the screen to ensure that the battery is fully charged. If the battery is not fully charged, connect the power cord to fully charge the battery before using the product.
- For how to operate the measurement screen or the contents displayed, refer to "How to Interpret Measurement Screen" ☞ (p 24).
- Some settings can be changed during measurement if necessary. For changeable setting items and options, refer to "Changing Settings during Measurement" ☞ (p 27).

How to Interpret Measurement Screen

The Measurement screen appears during measurement. This section describes the contents displayed on the Measurement screen and transition of screens.

Common display items

The following describes the common display items on the Measurement screen.



No.	Name of button/ display item	Description
(1)	Patient information (Patient ID/name)	The patient ID or name registered before the start of measurement is displayed. The information to be displayed can be selected on the display setting screen. ☞ (p 35)
(2)	Vital Logger connection display	When the Vital Logger integration setting is enabled, the status of Vital Logger communication is displayed with an icon.
(3)	Network connection display	When the Wi-Fi setting is enabled, the signal strength of wireless communication is displayed with an icon. If the communication is established via wired LAN, the LAN mark (🖧) is displayed.
(4)	Battery level indication	The battery level is displayed with a gauge and a numeric value (%). When the power saving mode is on, a power saving mode mark (🍃) is displayed above the battery icon. "Power Saving Mode" ☞ (p 14).
(5)	Screen switch button	Select from the pull-down menu to switch to the screen of the measurement result in a different measurement period. For the details of screen transition, refer to "Switching screens by measurement period" ☞ (p 25).
(6)	Measurement result (latest)	The latest measurement results are displayed. Tap the screen switch button (5) to display the measurement result in a different measurement period.
(7)	Measurement results (past two measurements)	The past 2 measurement results are displayed. Tap the screen switch button (5) to display the measurement result in a different measurement period.
(8)	Total time	It displays the elapsed time since the measurement starts.

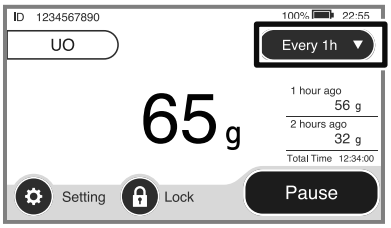
No.	Name of button/ display item	Description
(9)	[Pause] button	To pause or terminate measurement, tap this button. For the details of how to operate the button, refer to the following. "Pausing/Resuming Measurement" ☞ (p 28) "Terminating Measurement/Removing Uro Checker" ☞ (p 30)
(10)	[Lock] button	Press and hold down this button for at least 2 seconds to lock the displayed screen. When the screen is locked, no screen operation other than unlocking is accepted. Press and hold down the unlock button for at least 2 seconds to unlock the screen.
(11)	[Setting] button	Tap this button to display the menus that can be configured during measurement. For the menus that can be configured, refer to "Changing Settings during Measurement" ☞ (p 27).

Switching screens by measurement period

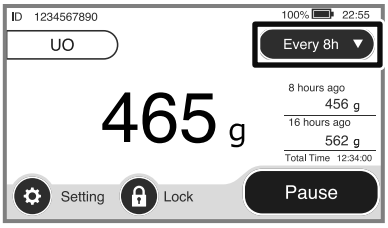
The user can switch the measurement screen by the preset measurement period. Press the screen switch button, and select the time interval from the pull-down menu to switch the display.

Notes The 2 types of measurement periods other than the 24-hour interval can be changed.
"Time Setting" ☞ (p 38).

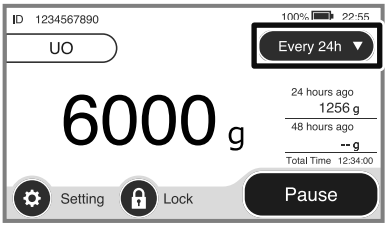
Every 1 hour (example)



Every 8 hours (example)



Every 24 hours



Notification and Error

If an error occurs during measurement or preparation for measurement, or if the notification setting is triggered, a pop-up message is displayed on the screen, and this is also notified with the status LED and the buzzer on the device.

Actions to be taken when a notification or error is issued

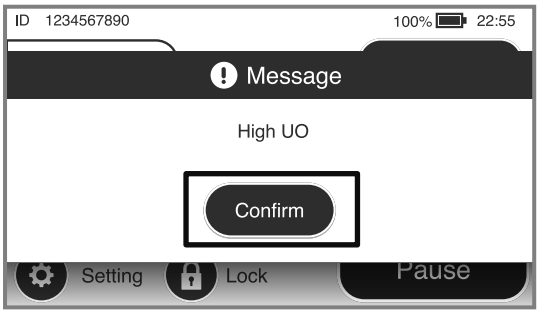
When a notification or error occurs, the buzzer sounds repeatedly, and the status LED blinks in green. Take the following actions.

1. Check the message and tap [Confirm] on the screen.

➡ The buzzer stops, and the screen returns to the previous screen.

➡ The message is displayed at the top of the screen.

➡ The status LED (green) stops blinking and changes to lighting.



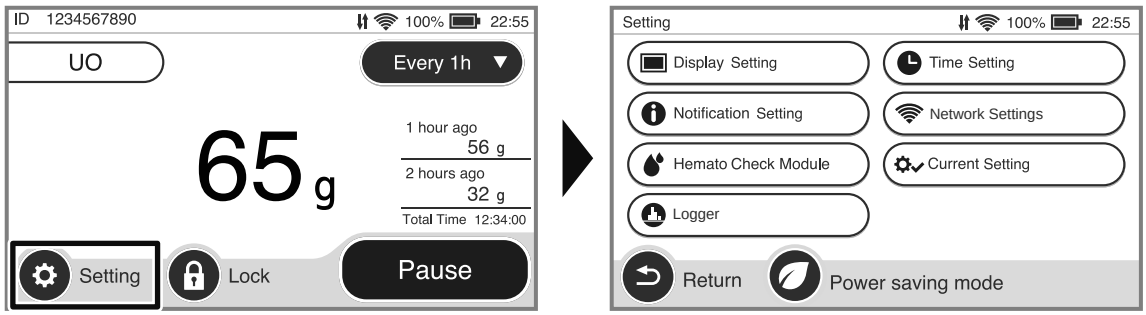
2. Deal with the cause according to the message displayed.

- For details of the message, conditions of issue, and actions to be taken, refer to "List of Messages" ☞ (p 51).

➡ When the cause is eliminated, the screen returns to the previous screen.

Changing Settings during Measurement

Some of the settings can be changed during measurement. Tap [Setting] at the bottom left of the Measurement screen to display the Setting screen and select the setting item you want to change.



■ List of various settings

Setting item	Description
Display Setting	Set the method of displaying the Measurement screen
Notification Setting	Set the notification for urine output exceeding the threshold (High UO or Low UO), urine bag full, and pause.
Network Settings	Switch on/off the Wi-Fi and Ethernet. This button is displayed only when the integration with Vital Logger is set to [On] in the initial setting.
Hemato check module	Configure various settings for measurement of urine hemoglobin concentration. This setting is required only when the hemato check module is connected.
Logger	Switch on/off the integration with Vital Logger. This button is displayed only when the integration with Vital Logger is set to [On] in the initial setting.
Current Setting	The current setting status is displayed as a list.

Notes

- Some of the display setting items cannot be changed during measurement.
- For the details of various settings, refer to "6 Details of Various Settings" ☞ (p 35)
- To measure the urine hemoglobin concentration using the hemato check module, refer to the instruction manual of the hemato check module and turn on the connection setting.
  ☞ "3. Preparing hemato check module" - "Setting of hemato check module"

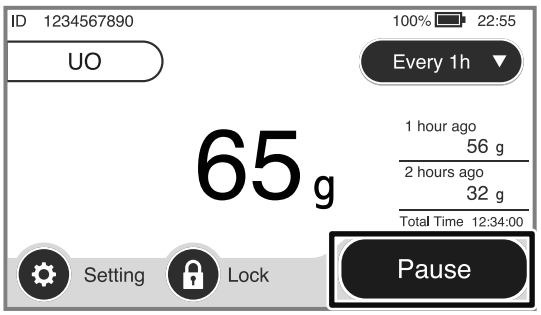
Pausing/Resuming Measurement

The measurement needs to be temporarily paused in some cases. (e.g., draining urine in the urine bag). Changes in bag weight during the pause will not be measured.

Pause

1 Tap [Pause].

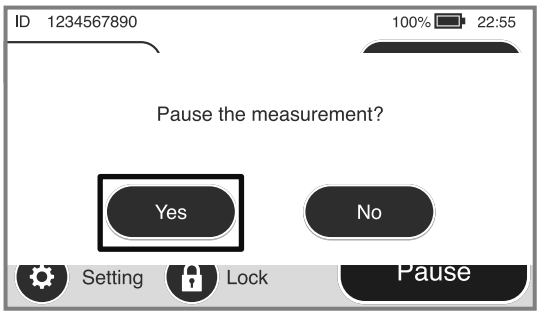
➡ A dialog box appears prompting the user to confirm the pause.

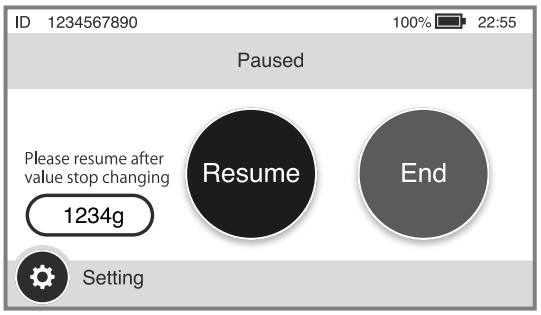


2. Tap [Yes].

➡ The screen changes to the Paused screen and the measurement is temporarily stopped.

- If you tap [No], the dialog box disappears and the operation to pause the measurement is cancelled.





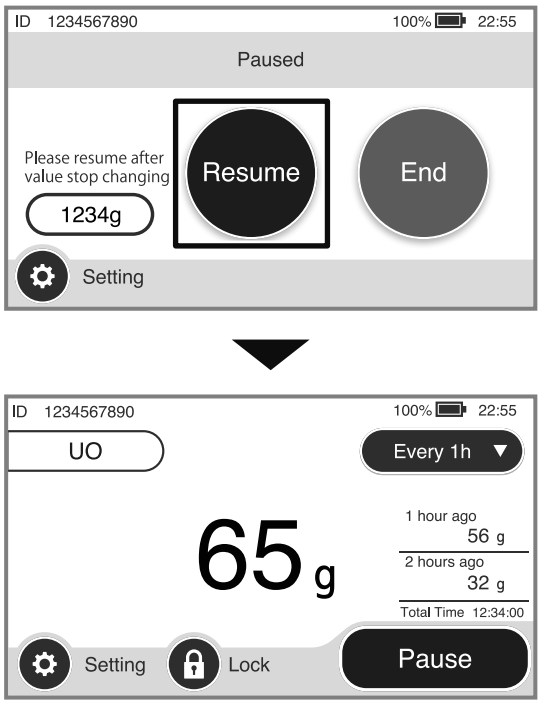
Notes When the pause status exceeds a certain time, the pause notice is given. For the details of how to configure the setting, refer to "Notification Setting" ☞ (p 40).

Resuming measurement

1 Tap [Resume] on the Paused screen.

➡ The screen returns to the measurement screen, and the measurement is resumed.

Notes Tap the Resume Button after values has stabilized.



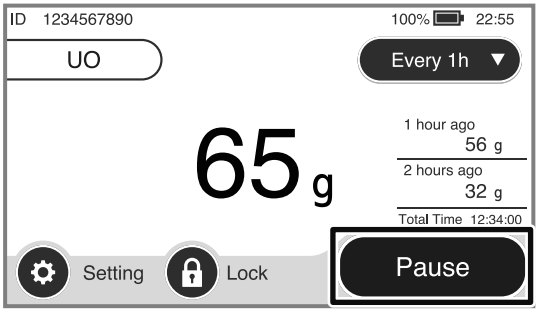
Terminating Measurement/Removing Uro Checker

This section describes how to terminate measurement and the removal of the urine bag or Uro Checker.

Terminating the measurement

1 **Tap [Pause].**

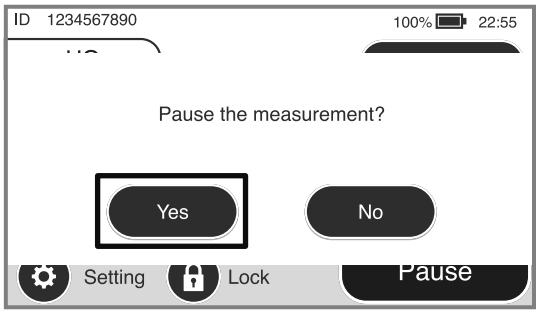
➡ A dialog box appears prompting the user to confirm the pause.



2. **Tap [Yes].**

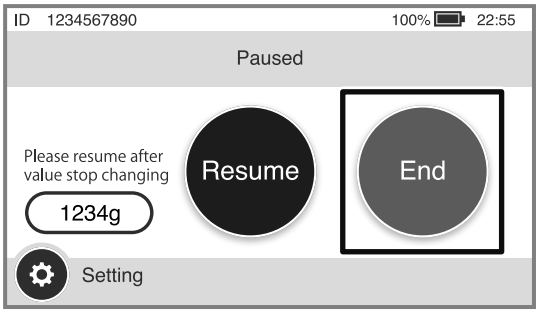
➡ The screen changes to the Paused screen and the measurement is temporarily stopped.

- If you tap [No], the operation to pause the measurement is cancelled and the screen returns to the previous one.



3. **Tap [End].**

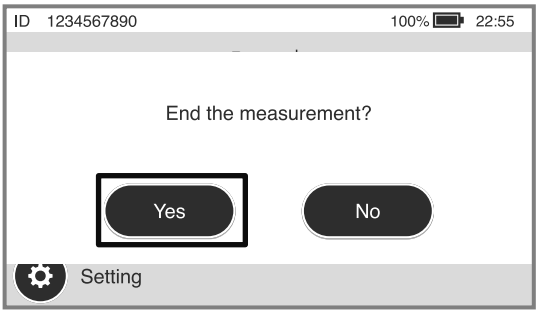
➡ A dialog box appears prompting the user to confirm termination of measurement.



4. **Tap [Yes].**

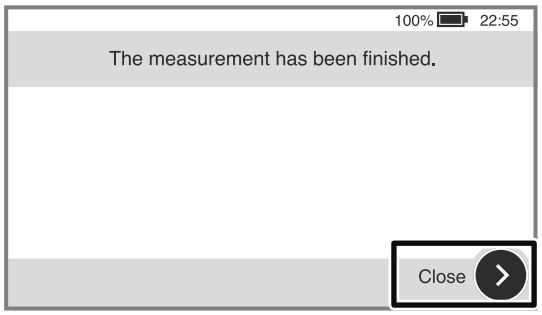
➡ The screen switches and the message "The measurement has been finished." appears.

- If you tap [No], the operation to end the measurement is cancelled and the screen returns to the previous one (Paused). To resume the measurement, tap [Resume].



5. Tap [Close].

➡ The screen changes to the Preparation for measurement screen.



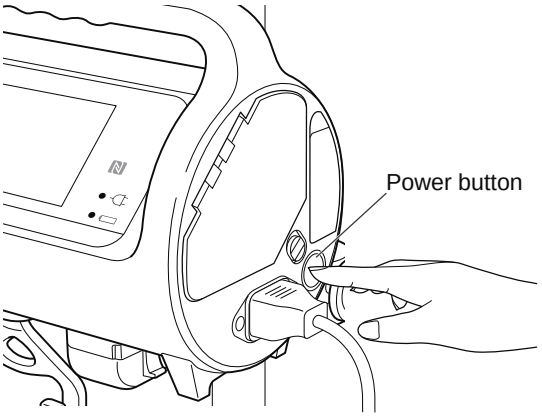
Removing urine bag

1. **Remove the urinary catheter tube from the tube clamp.**

2. **Detach the urine bag from the urine bag hook.**

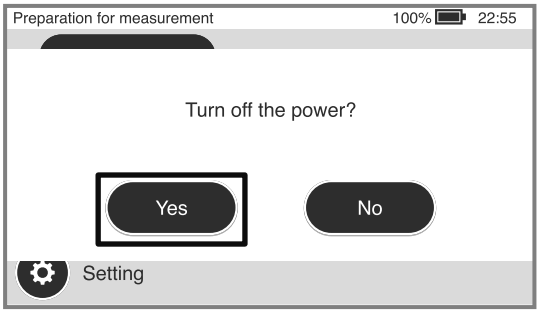
3. **Press and hold down the power button for at least 3 seconds.**

➡ A message "Turn off the power?" is displayed on the screen.



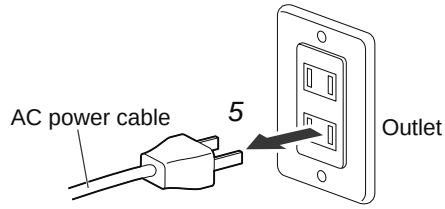
4. **Tap [Yes].**

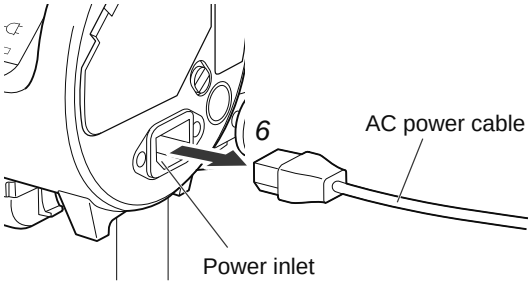
➡ The power is turned off.



5. **Unplug the AC power cable from an outlet.**

6. **Unplug the AC power cable from the AC power inlet.**



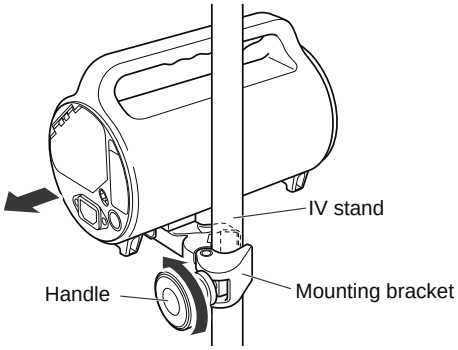


Removing Uro Checker

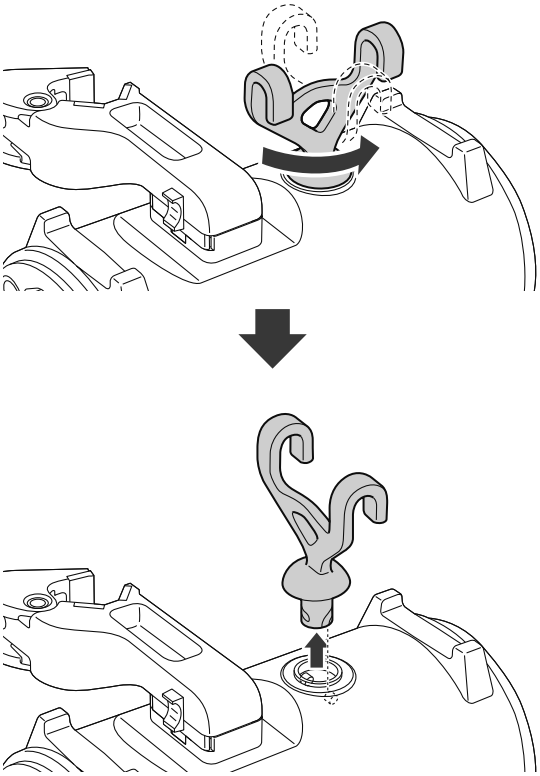
1. **Remove Uro Checker from the IV stand.**

- Turn the handle of the mounting bracket to loosen the clamp.

! Notice When loosening the clamp of the mounting bracket, turn the handle with care while holding the handle of Uro Checker to prevent from falling.

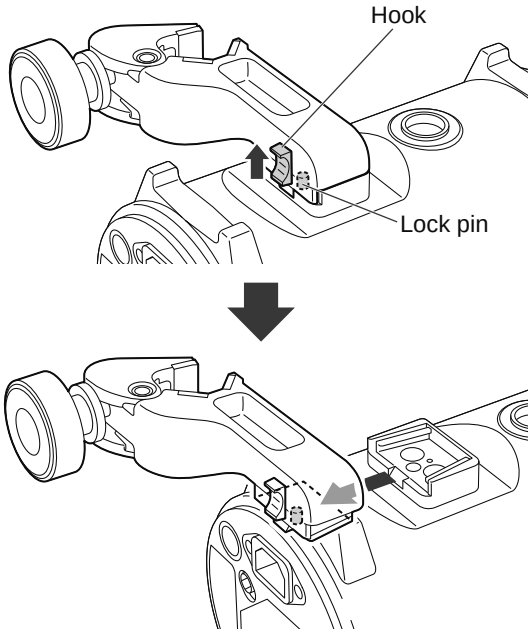


2. Turn the urine bag hook 90° counterclockwise and remove the urine bag hook from Uro Checker.



3. Slide the mounting bracket while pulling up the hook of the mounting bracket.

➡ The lock pin retracts and the mounting bracket comes off Uro Checker.



4. Clean Uro Checker.

Notes For cleaning Uro Checker, refer to "Care after use (cleaning)" ☞ (p 45).

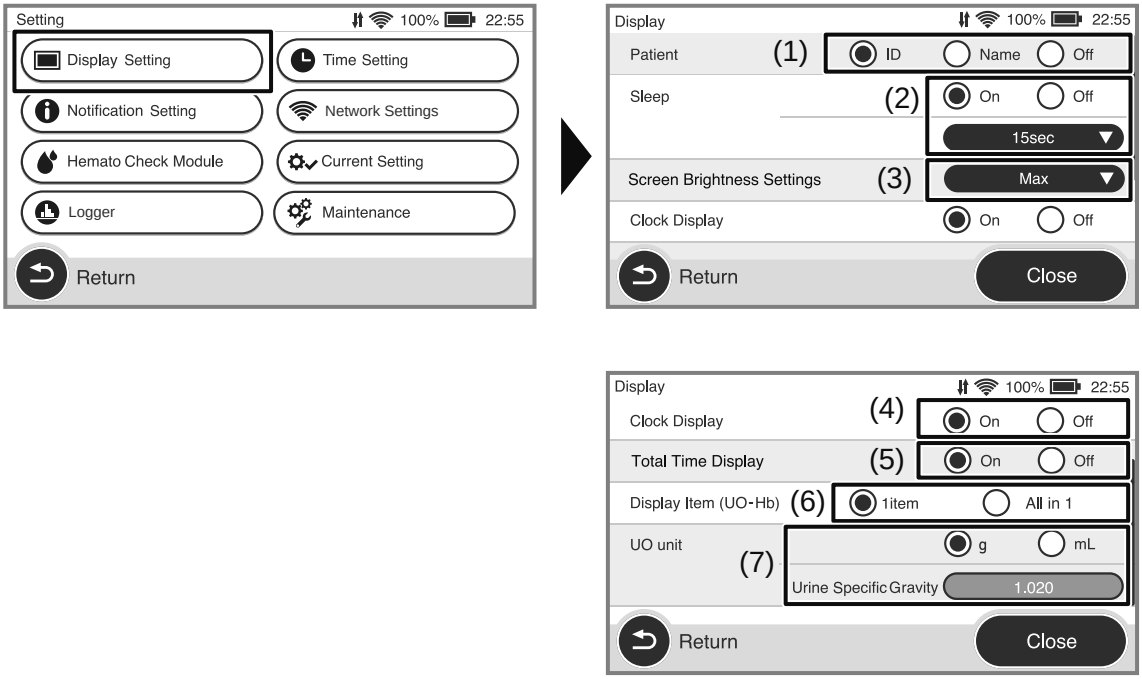
6 Details of Various Settings

Various settings of Uro Checker can be configured before and during measurement.
The configurable items are shown below. For details, refer to each referenced page.

Setting item	Description	Reference
Display Setting	Set the method of displaying the measurement screen.	☞p 35
Time Setting	Set the current time and the measurement time.	☞p 38
Notification Setting	Set the settings for the oliguria, polyuria, urine bag full, and pause notifications.	☞p 40
Network Settings	Switch on/off the Wi-Fi and Ethernet. This button is displayed only when the integration with Vital Logger is set to [On] in the initial setting.	☞p 41
Hemato Check Module	Configure various settings for measurement of urine hemoglobin concentration. This setting is required only when the hemato check module is connected.	☞p 42
Maintenance	Set the items related to maintenance of the product. The maintenance settings cannot be changed during measurement.	☞p 43
Logger	Switch on/off the integration with Vital Logger. This button is displayed only when the integration with Vital Logger is set to [On] in the initial setting.	☞p 44
Current Setting	The current setting status is displayed as a list.	☞p 44

Display Setting

Set the method of displaying the measurement screen. Tap [Display Setting] on the Setting screen.

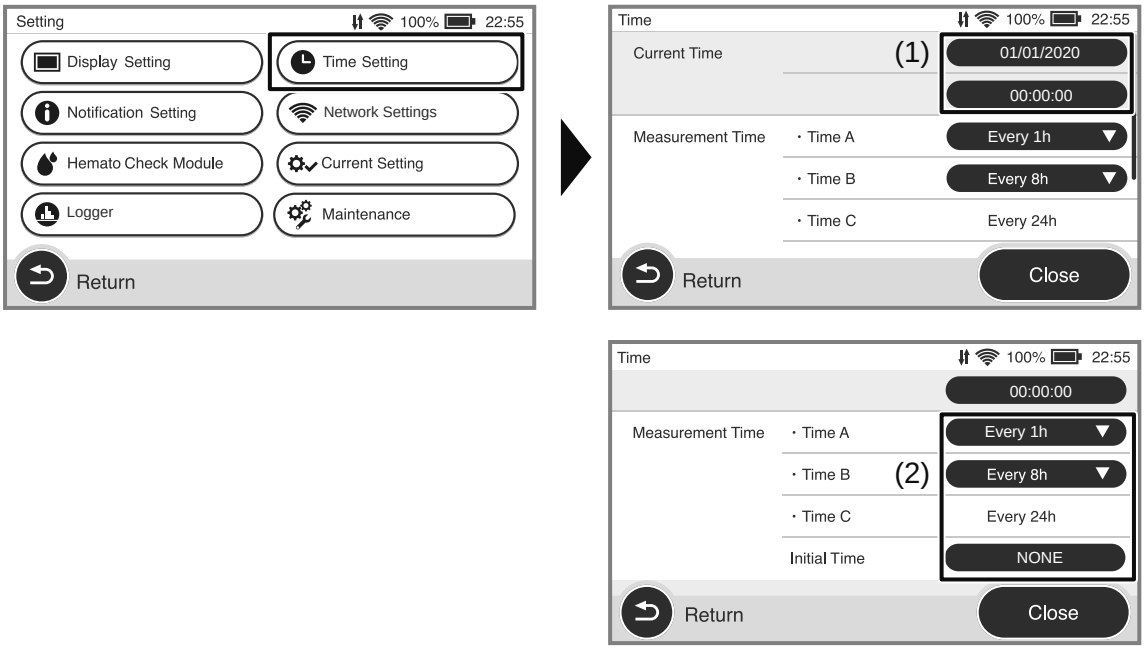


■ Details of setting items

No.	Setting item	Description	Initial value
(1)	Patient	Select how the patient information is displayed at the top of the Measurement screen. [ID] : The patient ID is displayed. [Name] : The patient's name is displayed. [Off] : No patient information is displayed. **Notes** If no ID has been registered, nothing is displayed.	ID
(2)	Sleep	Set On/Off of the screen sleep function and the wait time for screen sleep. [On] : The screen sleep function is enabled. [Off] : The screen sleep function is disabled. When [On] is selected, please set the wait time for screen sleep.	Off (15 sec)
(3)	Screen Brightness Settings	Set the brightness of the screen.	Max
(4)	Clock Display	Set whether the current time is displayed at the top of the measurement screen. [On] : The time is displayed. [Off] : The time is not displayed.	On
(5)	Total Time Display	Set whether the elapsed time since the start of measurement is displayed. [On] : The total time is displayed. [Off] : The total time is not displayed.	On
(6)	Display Item (UO-Hb)	Set how two types of measured values (urine output per time (UO) and urine hemoglobin concentration (Hb)) are displayed. [1 item] : Only the urine output per time or the urine hemoglobin concentration is displayed on one screen. [All in 1] : Both the urine output per time and the urine hemoglobin concentration are displayed on one screen.	1 item
(7)	UO Unit	Set the unit for display of urine output per time and urine specific gravity. [g] : The value is displayed as weight in grams. [mL] : The value is displayed as volume in milliliters. [Urine specific gravity] : Enter the value for urine specific gravity to convert the measured weight to a volume. **Notes** The value for urine specific gravity can be entered only when the unit is set as [mL]. The unit cannot be changed during measurement.	g 1.020

Time Setting

Set the current time and a measurement time period. Tap [Time Setting] on the Setting screen.



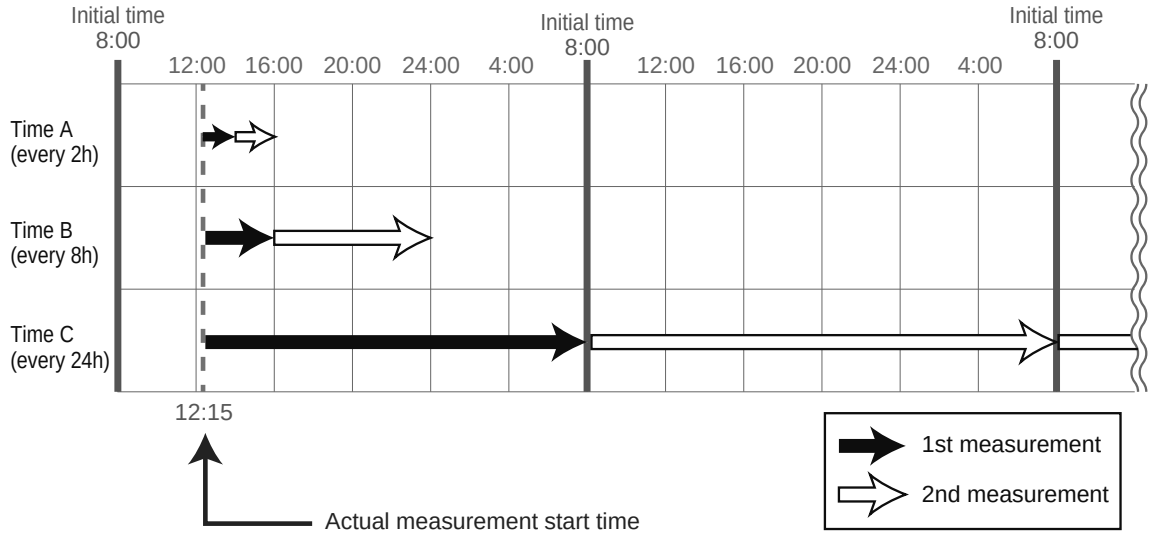
■ Details of setting items

No.	Setting item	Description	Initial value
(1)	Current Time	Set to change the current time. **Notes** This setting cannot be changed during measurement. This must be set before measurement. In addition, this setting cannot be changed even when time synchronization is set to [On] in the Initial setting.	–
(2)	Measurement Time	Set the time interval for measurement. Up to 3 time intervals of A, B, and C can be registered (C is fixed at 24-hour interval). [Time A] : Measurement period for the setting such as ICU where urine output needs to be measured at a short interval [Time B] : Measurement period for the setting such as general ward where urine output does not need to be measured frequently [Time C] : The urine output for 24 hours [Initial time] : Time to be specified as a common starting point for performing measurements on multiple Uro Checkers simultaneously **Notes** • This setting cannot be changed during measurement. It is necessary to set before starting the measurement. • For the details of the interval start time and the measurement period, refer to the next page.	Time A: Every 1 hour Time B: Every 8 hours Initial time: NONE

■ Interval start time and measurement period

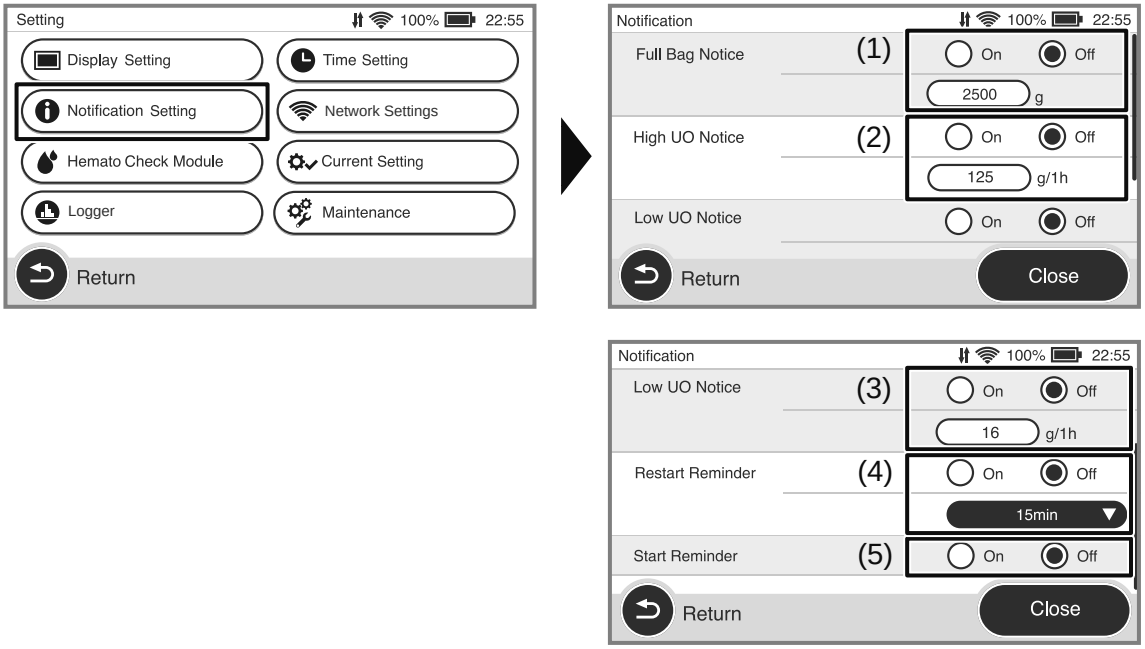
When the interval start time is set, the urine output is measured for 24 hours from the set interval start time, not from the actual start time. The following table and figure show the example with Time A of 2 hours, Time B of 8 hours, and the interval start time of “AM 8:00” (Measurement start time: 12:15).

Setting item	Setting (example)	Description	1st measurement time
Time A	2 hours	The measurement starts at the timing of the closest 2-hour interval from the interval start time.	2 hours from 14:00
Time B	8 hours	The measurement starts at the timing of the closest 8-hour interval from the interval start time.	8 hours from 16:00
Time C	24 hours (fixed)	24-hour measurement starts at the next interval start time.	24 hours from 8:00 on the next day



Notification Setting

Set thresholds (reference values) for issuing notification in case of High UO, Low UO, urine bag full, and pausing of measurement. Tap [Notification Setting] on the Setting screen.



■ Details of setting items

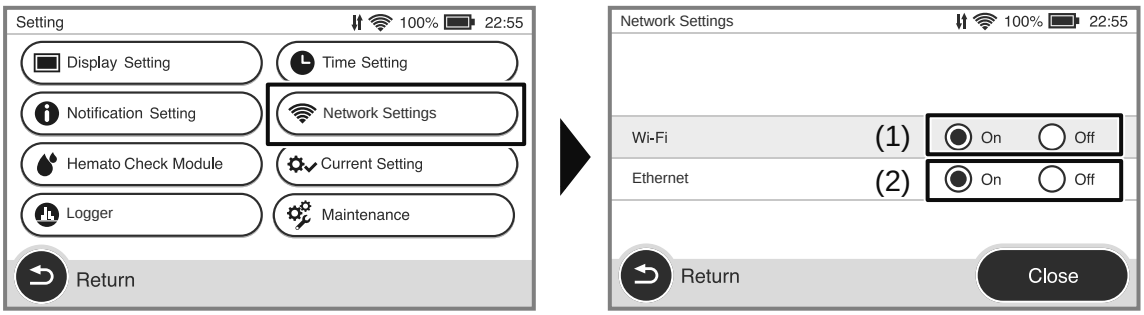
No.	Setting item	Description	Initial value
(1)	Full Bag Notice	A notification is issued when the urine bag is full. If [On] (issue the notification) is selected, enter the threshold. [On] : The full bag notice is issued. [Off] : The full bag notice is not issued.	On (2500 g)
(2)	High UO Notice	The High UO notice is a function to issue a notification that the urine output per time for Time A exceeds the specified threshold. If [On] (issue the notification) is selected, enter the threshold. [On] : The High UO notice is issued. [Off] : The High UO notice is not issued. **Notes** The unit of the threshold changes according to the measurement period set in [Time A].	Off (125 g/1h)
(3)	Low UO Notice	The Low UO notice is a function to issue a notification that the urine output per time for Time A is below the specified threshold. If [On] (issue the notification) is selected, enter the threshold. [On] : The Low UO notice is issued. [Off] : The Low UO notice is not issued. **Notes** The unit of the threshold changes according to the measurement period set in [Time A].	Off (16 g/1h)

No.	Setting item	Description	Initial value
(4)	Restart Reminder	With this option, a notification is issued when measurement is paused for more than the specified time. If [On] (issue the notification) is selected, specify the notification time. [On] : Pause status is notified. [Off] : Pause status is not notified.	On (15 min)
(5)	Start Reminder	This is a function to issue a notification that measurement have not been started for more than 10 minutes since the power was turned on.	Off

Network Settings

Switch On/Off of the Wi-Fi and Ethernet setting. Tap [Network Settings] on the Setting screen.

Notes This setting is required only for integration with Vital Logger.



■ Details of setting items

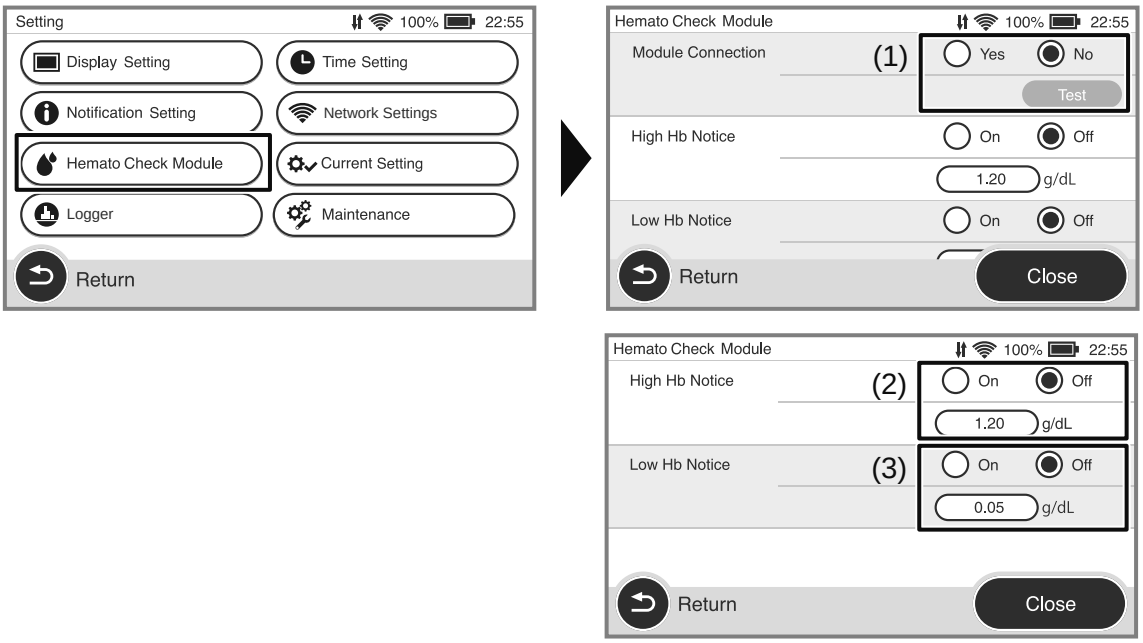
No.	Setting item	Description	Initial value
(1)	Wi-Fi	Select whether Wi-Fi is to be used for integration with Logger. [On] : Wi-Fi is used. [Off] : Wi-Fi is not used.	On
(2)	Ethernet	Select whether Ethernet is to be used for integration with Logger. [On] : Ethernet is used. [Off] : Ethernet is not used.	On

Notes To use Ethernet, it is necessary to configure the Ethernet settings for integration with Vital Logger during the initial setting.

Hemato Check Module Setting

Configure various settings for measurement of urine hemoglobin concentration. Tap [Hemato check module] on the Setting screen.

Notes This setting is required only when the hemato check module is used.



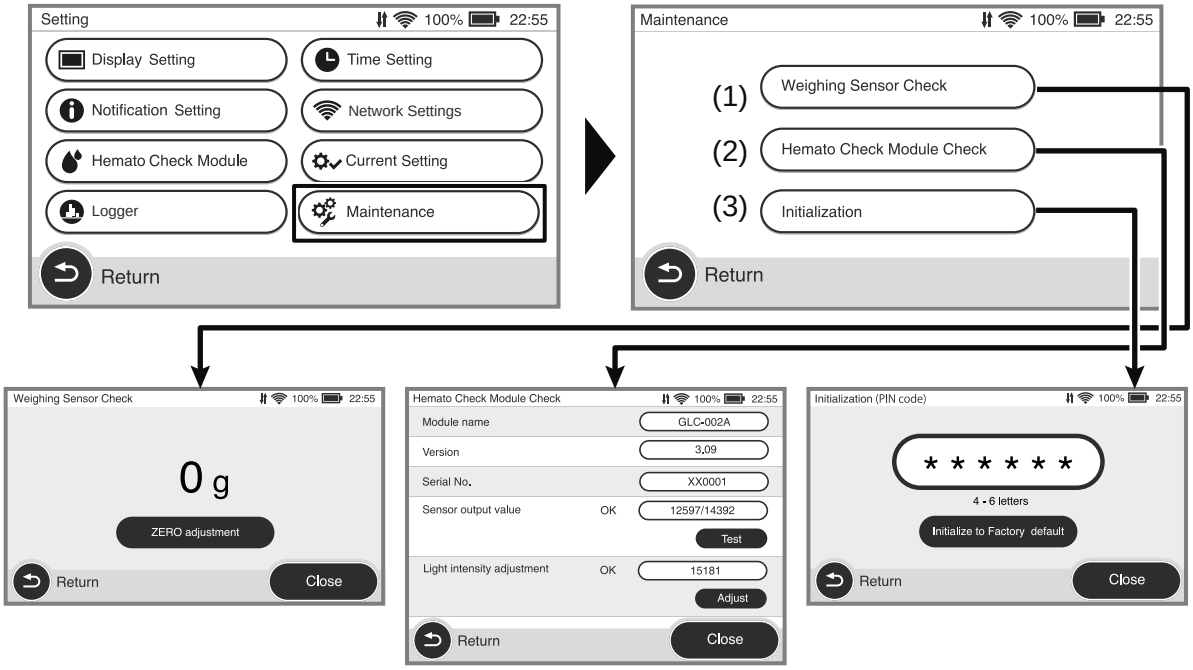
■ Details of setting items

No.	Setting item	Description	Initial value
(1)	Module Connection	Select whether the device is to be connected to the hemato check module. [Yes] : The module is to be connected. [No] : The module is not to be connected. • This setting cannot be changed during measurement. This must be set before start of measurement. • If [No] is selected, the measurement is not performed even if the hemato check module is actually connected.	No
(2)	High Hb Notice	The module can be configured to issue a notification when the urine hemoglobin concentration exceeds the specified value. If [On] is selected, enter the threshold. (Input range: 0.05 to 1.20) [On] : It is notified [Off] : It is not notified	Off (1.20 g/dL)
(2)	Low Hb Notice	The module can be configured to issue a notification when the urine hemoglobin concentration falls lower the specified value. If [On] is selected, enter the threshold. (Input range: 0.05 to 1.20) [On] : It is notified [Off] : It is not notified	Off (0.05 g/dL)

Maintenance

Set the items related to maintenance of the product. Tap [Maintenance] on the Setting screen.

Notes The maintenance settings cannot be changed during measurement. These settings must be set before start of measurement.



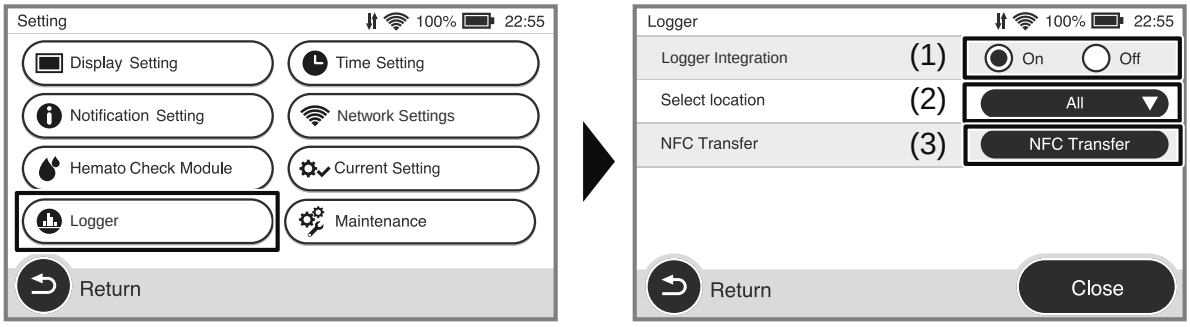
■ Details of setting items

No.	Setting item	Description
(1)	Weighing Sensor Check	Using the weight for maintenance, check that the weighing sensor is functioning properly. Perform the check as described below. 1. Attach the urine bag hook. 2.Tap [ZERO adjustment]. 3. Confirm that the indicated value is 0, and attach the weight to the urine bag hook. 4. Check that the indicated value is the same as the weight.
(2)	Hemato Check Module Check	Module name, version, serial number, and sensor output value of the hemato check module are displayed. Also, adjust the intensity of light. For details, refer to the instruction manual of the hemato check module. ☞ "3 Preparing Hemato Check Module" - "Settings of Hemato Check Module" **Notes** The "Hematо Check Module Check" can be checked only when the module connection is set to On in the "Hemato Check Module Setting" ☞ (p 42)
(3)	Initialization	This menu is used to initialize Uro Checker. To reset all settings and initialize the device, enter the PIN registered during the initial setting, and tap [Initialize to Factory default].

Logger Setting

Configure the settings for integration of Vital Logger. Tap [Logger] on the Setting screen.

Notes This setting is required only for integration with Vital Logger.

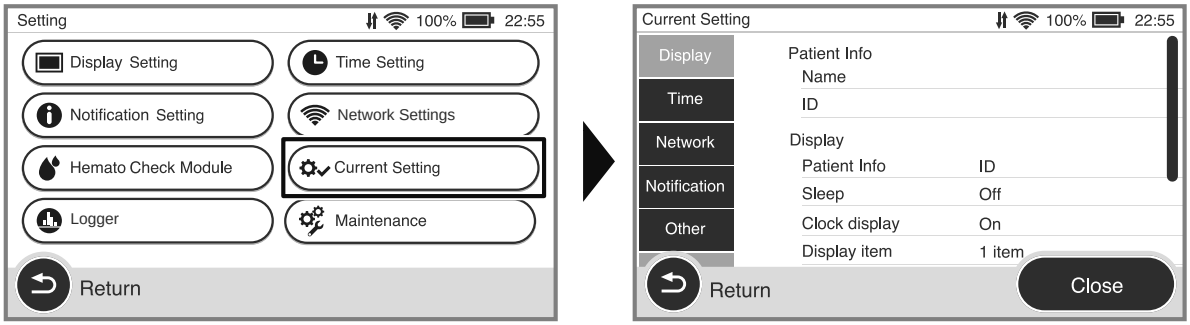


■ Details of setting items

No.	Setting item	Description	Initial value
(1)	Logger integration	Select whether Vital Logger is to be integrated. [On] : Vital Logger is to be integrated. [Off] : Vital Logger is not to be integrated.	On
(2)	Select location	By selecting the location of use, the list is filtered by Uro Logger and the list view is easier to see.	All
(3)	NFC Transfer	By holding the NFC reader over the Uro Checker and pressing a button, the measurement information is sent to the dedicated application.	–

Current Setting

The current status for various settings can be confirmed as a list. Tap [Current Setting] on the Setting screen.



Notes The setting status list can be scrolled.

7 Care and Inspection

This section describes periodic inspection, cleaning of the main unit and handling of consumables.

Care after use (cleaning)

Use of the contaminated product may result in improper operation or failure. To use the product safely, make sure to clean the main unit after use.

Notes

- If drug solution is attached, the device may not be function properly. If any drug solution, adheres to the device, promptly wipe it off.
- Periodically clean the AC power connector, the urine bag hook, and the tube clamp, mounting bracket. Use of the contaminated product may result in failure or malfunction.

⚠ WARNING

Make sure to turn off the main unit and unplug the AC power cable before cleaning. There is a risk of injury due to electric shock.

After cleaning of the AC power connector, dry it adequately before use. If the device is used without adequate dried, there is a risk of injury due to electric shock. In addition, the product failure such as short circuit may occur.

! Notice

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 water into the main unit of Uro Checker. The product may fail.

Do not use any disinfectant other than those compatible with the product. The product may be damaged or 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 81.4 vol%
Sodium hypochlorite solution for disinfection	Chlorine concentration: 0.02 to 0.1%
Chlorhexidine gluconate	Up to 5%
Cresol soap solution	-
Benzalkonium chloride	Up to 5%
Isopropyl alcohol	Up to 17%

Do not use disinfectants on the following parts. The product may be damaged or fail.

- Urine bag hook attachment hole
- USB connector and LAN connector
- Battery

■ 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.

Precautions for storage

Storage conditions	Supplementary information
Check the environmental specifications, and store at a location suitable for the conditions. "General Specifications" ☞ (p 53)	Charge the battery for the next use. In addition, remove the battery from the main unit when the device is not to be used and to be stored for a long time. • When the battery left for a long period of time after charging, its charge will be reduced by self-discharge. • If the battery is stored in the discharged state, the battery life may be reduced.

! Notice

Do not leave the device under sunlight or UV light. The exterior may be discolored, deformed, or degenerated.

Do not store the product in the following places. The product may malfunction or fail.

- A place where the product may be subjected to excessive vibration, dust, aerosol, corrosive gas, etc.
- A place where air pressure, temperature, humidity, ventilation, salts, and air containing sulfur, etc. may affect the product adversely.
- A place where chemical agents are stored or gas is generated.

Periodical inspection

To use the product safely and for a long time, inspect the product periodically. If any abnormality is observed during the inspection, stop using the product immediately and contact ISHIDA MEDICAL or our distributor. Even if no abnormality is observed in the appearance of the product, the product may be damaged internally, and the functions and performance of the product such as measurement accuracy and notification functions may not be obtained.

Timing of periodic inspection	Perform the periodic inspection approximately once every 6 months.

! Notice

Do not disassemble, modify or repair the product. The device may fail or be damaged, and the performance of the device may be reduced.

Inspection item	Details of inspection	Reference
Damage to or stain on each part	Check the following parts for damage and stain, and if there is any drug solution, etc. on the device, promptly wipe off. • Uro Checker • Mounting bracket • Urine bag hook • AC power cable • Battery	"Care after use (cleaning)" ☞ (p 45)
Battery life (timing of replacement)	Check to see if the estimated replacement period has expired since the battery was purchased. If it has expired, change to a new battery.	"Replacement parts" ☞ (p 49)
Urine bag hook and mounting bracket	Check that they are properly installed.	"Installing to IV Stand" ☞ (p 17)
Power On	Check that the power can be turned on normally.	"Starting Uro Checker (when using for the first time)" ☞ (p 8)
Weighing sensor (Maintenance screen)	Show the maintenance screen. Then, attach the weight, and check that the indicated value is the same as the weight. Precautions for weighing sensor check are below. • Uro Checker should be leveled. • When placing the weight, make sure that it is not contacting any surrounding objects. • Use only the specified weight.	"Maintenance" ☞ (p 43)
Communication status	Show the Setting screen and check that there is no issue with the Wi-Fi and NFC communications.	"6 Details of Various Settings" ☞ (p 35)
Power Off	Check that the power can be turned off normally.	"Terminating Measurement/Removing Uro Checker" ☞ (p 30)

Replacement parts

The fuse in the main unit of Uro Checker and the battery supplied with the product need to be replaced as deterioration over time. Ask ISHIDA MEDICAL or our distributor for the inquiries regarding replacement of each part.
The stock period of a parts for periodic replace and maintenance is after 6 years from discontinuation of manufacturing of Uro Checker. However, please note that if a long time has passed since the launch, it may not be possible to supply the parts even during the retention period due to the discontinuation of manufacture by the parts manufacturer.

! Notice

Do not use replacement parts other than those specified by ISHIDA MEDICAL. Otherwise, the product may not function and perform properly.

■ Replacement of battery

As the number of charging cycles of the battery increases or as the battery ages, the duration that battery can operate the device for a single charge becomes shorter. If the battery depletes faster, it is near the end of the battery life. The battery needs to be replaced with a new one.

Timing of replacement	• The battery can be recharged and used 800 times. Please replace it every two years. • The battery should be replaced if the battery depletes in a short time even after charging.
Recycling of battery	The product uses a rechargeable lithium-ion battery. Do not dispose the used battery, and bring the used battery to a recycling service provider.  Li-ion

■ Disposal of parts

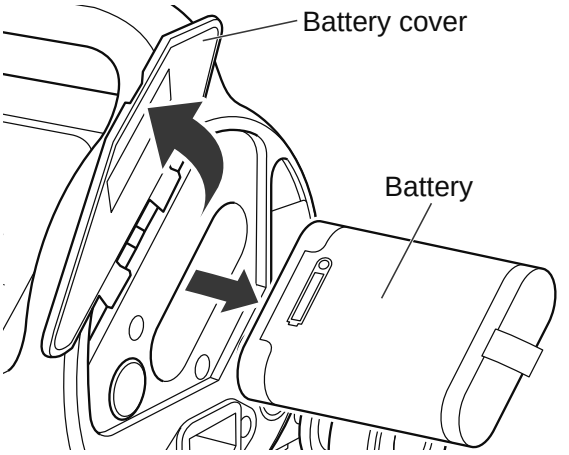
After replacement, dispose of the old parts properly according to your local waste disposal regulations.

■ Replacement of fuse

If Uro Checker does not start after turning on the power, the fuse may be blown. Replace the fuse with a new one as described below.

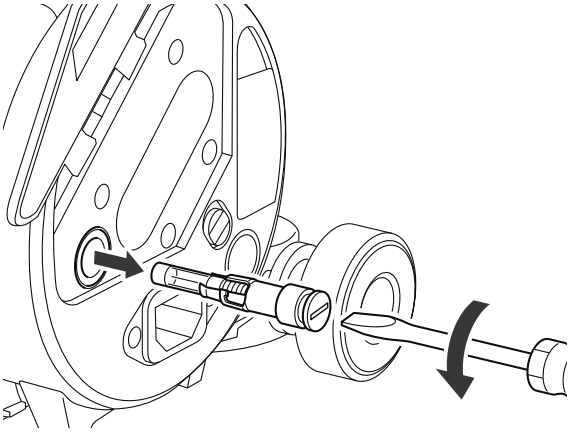
1. Disconnect the AC power cable, and remove the battery.

- Unplug the AC power cable from the outlet and the AC power inlet.
- Open the battery cover, and remove the battery.

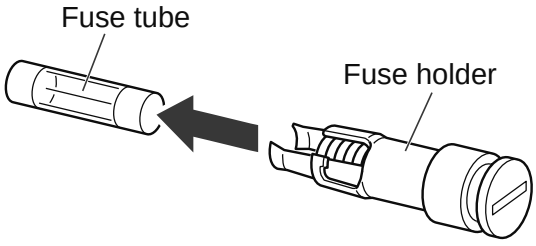


2. Remove the old fuse which is in a set with the fuse holder.

- Use a flathead screwdriver to turn it counterclockwise to remove it.



3. Remove the old fuse tube from the fuse holder and replace it with a new fuse.



4. Install the fuse holder.

- Use a flathead screwdriver to turn clockwise to secure it.
- After installing the fuse, return the battery, and close the battery cover.

5. Check that the power can be turned on.

- Plug the AC power cable to the AC power inlet on the main unit and to an outlet.
- Press the power button on the main unit to confirm that the power can be turned on.

8 Trouble Shooting

This section describes typical troubleshooting for the use of the product. If the trouble persists even if the instructions are followed or if the relevant symptoms are not listed, contact ISHIDA MEDICAL or our distributor.

List of Messages

Screen display	Conditions/actions to be taken
battery error	The battery may be damaged, resulting in a failure to fully charge the battery in a specified time, high internal temperature, etc. Inspect the battery. "Periodical inspection" ☞ (p 48)
Plug in the battery or power cable	No power is supplied, and the device is operating on the subbattery only.
Low battery	When the device is operated only on the battery power, if the remaining battery level becomes 10% or lower, the message is displayed. Connect the AC power cable to Uro Checker and supply the power from the outlet.
Weighing sensor error	The output value of the load cell is not normal. Perform the weighing sensor check again on the Setting screen for maintenance. "Maintenance" ☞ (p 43)
Hemato Check Module is not connected	Restart Uro Checker, and connect the module again from the Setting screen. For details, refer to the instruction manual of the hemato check module.
Urine bag is full	The urine volume in the urine bag is full, and no more urine can be collected. Pause the measurement and drain urine from the bag. "Pausing/Resuming Measurement" ☞ (p 28)
Uro Checker is tilted	Uro Checker is not level. Install the device properly so that it is not tilted. "4 Installing Uro Checker" ☞ (p 15)
Low UO	The urine output per time is below the threshold for the Low-UO notice specified in the "Notification Setting" ☞ (p 40).
High UO	The urine output per time is exceeding the threshold for the High-UO notice specified in the "Notification Setting" ☞ (p 40).
Wi-Fi Out of range	Wi-Fi is out of range while the Wi-Fi setting is on.
Measurement has not started	More than 10 minutes have passed on the Preparation for Measurement screen.
Paused	The pause notification specified in the "Notification Setting" ☞ (p 40).

If a Failure is Suspected

If the product does not operate normally, check as described below, and follow the instructions provided. If the product does not operate normally or the abnormality persists even after the actions are taken as instructed, the product may be failed. Stop using the product immediately and contact ISHIDA MEDICAL or our distributor.

Situation	Possible cause	Actions to be taken
The power cannot be turned on. The measurement screen is not displayed.	The AC power cable is disconnected from the outlet.	Check that it is connected to an outlet.
	The supplied AC power cable is not used.	Use the AC power cable supplied with the product.
	Low battery	Charge the battery.
	The fuse is blown.	Replace the fuse with a new one. "■ Replacement of fuse" ☞ (p 50)
The battery cannot be charged.	A battery other than one supplied with the product is used.	Use the battery supplied with the product.
The Wi-Fi connection cannot be established. (for integration with the Vital Logger)	The Wi-Fi setting is off.	Turn on Wi-Fi. "Network Setting" ☞ (p 41)
	The wireless LAN settings are incorrect.	Make sure that the settings are correct.
	It is outside the range of the wireless communication.	Move to a place where a good reception can be achieved.
Urine output is not measured. Measurement is not correct.	A non-compatible urine bag is used.	Check that the urine bag to be used meets the requirements. "Compatible Urine Bags" ☞ (p 15)
	The urine bag is not installed properly. The urine bag is contacting the floor.	Hang the urine bag on the urine bag hook and attach it so that the height of the top side of the urine bag is located below the waist level of the patient.
	The urinary catheter tube is not properly attached.	Allow some slack in the urinary catheter tube and pass through the tube clamp.
	Uro Checker is not properly installed to the IV stand. Uro Checker is tilted.	Uro Checker cannot perform measurement correctly if it is not secured horizontally and firmly. Check that it is properly installed on the IV stand. "Installing to IV Stand" ☞ (p 17)

9 Specifications

This section describes the detailed specifications and performance of the product.

General Specifications

Item	Description
Model	URC-001
External dimensions	W 10.03 × H 6.69 × D 5.11 in (W 255 × H 170 × D 130 mm) or smaller (excluding the urine bag hook and the mounting bracket)
Weight of main unit	3.4lb (1,550 g) or less (excluding the urine bag hook and the mounting bracket)
Battery	Type : RRC2040 (RRC Power Solutions) Capacity : 3,350mAh Maximum continuous measurement time : 36 hours (Depends on the operation mode) Time to full charge : More than 6 hours Compliant standard : IEC62133-2:2017 * The use environment and transportation/storage environment shall be the same as that of the Uro Checker.
Sub battery	Capacity : 660mAh Maximum Duration of protection : 30 minutes Compliant standard : IEC62133 ed.2
Fuse	Rated voltage : 250V Rated current : 3.15A Operation type : time lag Size : 0.19 × 0.78 in (5 × 20mm) Breaking capacity : Low
Ingress Protection	IP24
Rated power	Single-phase 120 VAC 60 Hz 0.3A
Use environment	Temperature during use : 41°F to 95°F (+ 5°C to + 35°C) Humidity during use : 10 to 85% RH (No condensation)
Transportation/storage environment	Temperature during transportation/storage : 32°F to 140°F (0°C to + 60°C) Humidity during transportation/storage : 10 to 85% RH (No condensation)
Measurement range	0 to 3,000 g
Measurement accuracy of urine output	± 2 g or less (machine accuracy) * The measurement accuracy depends on the states of installation of the urine bag.
Urine output measurement display scale	1 g

Item	Description
Interfaces	USB port LAN port : RJ-45 LAN port (≥ 10 Mbps) NFC : Compliant with ISO/IEC 18092 (NFC IP-1) Frequency 13.56 MHz Modulation type (ASK) Effective radiated power < 3 dBm Wi-Fi (FCC compliant) : IEEE802.11b/g/n/a (2.4 GHz / 5 GHz) Security authentication method: WPA2-Personal / WPA2-Enterprise Modulation type (DSSS, OFDM) Effective radiated power < 20 dBm Frequency range: 2.4 GHz 11b (2412MHz~2472MHz) 2.4 GHz 11g/n 20MHz (2412MHz~2472MHz) 5 GHz 11a/n 20MHz (5180MHz~5825MHz) 5 GHz 11n 40MHz (5190MHz~5795MHz) Hemato Check Module connection port : DC5V 0.05A UART Communication
Classification by type of protection against electric shock	When AC power is connected : Class II device When AC power is not connected : Internally powered equipment
Classification of applied part by degree of protection against electric shock	Type BF applied part
Service life	6 years (based on self-certification) * With standard use, specified maintenance/inspection, and replacement of consumables

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 Uro Checker URC-001, 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.
Harmonic Emissions IEC61000-3-2	Class A	

■ 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%.
Electrical fast transient/ burst IEC61000-4-4	±2 kV power supply lines ±1 kV input/output lines Repetition frequency 100 kHz	±2 kV power supply lines ±1 kV input/output lines Repetition frequency 100 kHz	The quality of the power supply should be the same as a typical commercial or hospital environment.
Surge IEC61000-4-5	±0.5 kV, ±1 kV line to line	±0.5 kV, ±1 kV line to line	The quality of the power supply should be the same as a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage changes on power supply input line IEC61000-4-11	0%Ut dip For 0.5 cycles 0%Ut dip For 1 cycle 70%Ut dip For 30 cycles 0%Ut Interruption for 300 cycles	0%Ut dip For 0.5 cycles 0%Ut dip For 1 cycle 70%Ut dip For 30 cycles 0%Ut Interruption for 300 cycles	The quality of the power supply should be the same as a typical commercial or hospital environment. If the user of the product requires continuous operation during power failure, it is recommended that the product be powered from an uninterruptible power supply or battery.
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.

Note: Ut is the AC mains voltage before application of the test level.

■ 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
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.7GHz Near-field transmission from wireless communication device a)	3Vrms 150kHz to 80MHz 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						

Test frequency [MHz]	Band [MHz]	Equipment	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]
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						
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.

Category/Generic Name of Medical Device

Title21CFR 876.1800 Urine flow or volume measuring system
Medical device classification: Class II 510(K) Exempt

Labeling on Main Unit

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 JIS C 0920.
	This mark indicates that the device must be operated in accordance with the instruction manual (this document).
	The power supply is a class II device.
SN	Serial number
	Manufacturer
	Turns the urochecker on / off from the standby state.
	Powered by AC power.
	Powered by battery power.
	Keep away from sunlight.
	Keep away from rain.
	Fragile.
	This way up.
	Stacking limit by number.
	Temperature limits.
	Handle with care.
	Cutter knife attention.

ISHIDA MEDICAL CO., LTD.

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

Distributor: