microINR expert

INSTRUCTIONS FOR USE

iLine® microsystems friendly technology

expert

microINR® Expert meter

For monitoring Oral Anticoagulation Therapy with warfarin.

CONTENTS

English

1. INTRODUCTION

1.1 INTENDED USE

The microINR System measures prothrombin time (PT) expressed in International Normalized Ratio (INR), for monitoring oral anticoagulant therapy with warfarin.

The microINR System consists of a meter and chips (test strips) and uses fresh capillary whole blood from a fingerstick.

The microINR System is intended for patient self-testing use as well as for healthcare professionals at point-of-care settings.

The microINR System is intended for use in patients 18 years old or older. Patients must be stable on warfarin medication for at least 6 weeks before starting to use the microINR System.

For self-testing use: The System is intended for properly trained users under specific prescription of a physician.

Caution: The microINR System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy. The microINR System is not intended to be used for screening purposes.

1.2 BEFORE USING THE microINR® SYSTEM

These instructions for use will guide you on the handling and use of the microINR Expert meter. Please, read them together with the instructions for use of the microINR Chip completely.

Additionally, read the instructions for use of the disposable lancets and/or lancing device used to obtain the capillary blood sample.

Federal law restricts the device to sale by or on the order of a physician.

Users must receive proper training before using the microINR System.

Keep these instructions for use near the microINR Expert meter and refer to them if you have any questions about proper operation of the system.

Throughout these instructions the names of the on-screen options are shown as bold text.

The microINR Expert meter can communicate with a Data Management System (DMS) through wireless technology (Wi-Fi or Bluetooth) or hard-wired Ethernet through the Ethernet adapter (available separately). The microINR Expert meter can communicate and transfer results to electronic devices, such as smartphone, tablets or computers, through a wireless Bluetooth connection. The data handling function may vary depending on the particular Data Management System (DMS). Please contact your local distributor for further information on the DMS compatible with the meter and configuration required for connection.

Users should be careful to use apps from reliable sources only and only connect the meter through USB cable to a secure, trusted computer. This may reduce the risk of transferring malware to the meter.

A terminology index is provided in Section 10 at the end of these Instructions for Use.

Important Information

General Safety Warnings

Throughout these instructions for use you will find safety warnings and information on the correct use of the microINR System:

This warning symbol indicates a possibility of patient health damage due to an incorrect INR result leading to a mistreatment or danger which could result in death, injury or harm to the patient or user or environmental damage due to secondary events if the procedures and instructions for use are not strictly followed.

This precaution symbol indicates the possibility of deteriorating or damaging the equipment and losing data, if the procedures and instructions for use are not strictly followed.

Important information regarding the correct use of the system that does not affect the safety of the patient, the user or the integrity of the device is displayed over a blue background.

Dispose of the meter

The meter must be disposed of as indicated by applicable local and federal laws. Bear in mind that:

- Used meters may have been in contact with blood, so may be a source of infection.
- The meter contains lithium batteries.

Touchscreen

The touchscreen is designed to be used with your finger even when wearing latex or nitrile gloves. Using other objects could damage the screen.

Physical access control

To prevent unauthorized access or tampering with the meter's data, be sure to keep the microINR Expert meter safe from unauthorized physical access and theft. Do not leave the meter in publicly accessible areas.

Important information for Healthcare professionals

The microINR System can be used at physicians' offices and anticoagulation clinics, as well as in home settings, whereas it cannot be used in nursing homes, emergency rooms and intensive care units.

Infection Risk Control on Multi-Patient Test System

- Healthcare professionals must wear gloves during the entire process of the test.
- Healthcare professionals must use a new pair of clean gloves before testing each patient.
- A separate lancet must be used for each patient.
- Used chips, lancets, and gloves may be a source of infection. Dispose of them in accordance with local regulations to prevent infections.
- Also, comply with your center's internal hygiene and safety regulations.

All parts of the microINR System should be considered potentially infectious and are capable of transmitting blood-borne pathogens.

The meter should be disinfected after use on each patient. Please, follow the directions in these instructions for use for cleaning and disinfection (Section 5).

When using the meter in a multi-patient setting, use only auto-disabling single use lancets.

Electromagnetic Compatibility and Safety Requirements

The microINR System complies with electromagnetic compatibility (EMC) requirements according to IEC 60601-1-2. See EMC/Safety Requirements Compliance Information in Annex I.

CLIA categorization

These instructions for use are for self-testing patients and for healthcare professionals at point-of-care settings. This is a CLIA Waived test system. Facilities performing testing must have a CLIA Certificate of Waiver (or higher). Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing a test. All applicable state and local laws must be met.

1.3 ORAL ANTICOAGULANT THERAPY

Oral Anticoagulant Therapy (OAT) is given to patients to prevent thromboembolic events such as venous thrombosis and pulmonary embolism or those linked to atrial fibrillation or artificial heart valves.

The treatment entails the need to monitor and adjust the doses periodically for each patient based on a blood test.

Depending on the pathology, a therapeutic range is defined for each patient, meaning the value of the test should lie within that range.

If you are a self-testing patient, you need to discuss with your physician about the best monitoring model for you. Always refer to your healthcare provider's instructions as you may need to communicate your results for dose adjustment.

Prothrombin Time and INR

The activity of oral anticoagulants is monitored by measuring the Prothrombin Time (PT) in seconds. Depending on the nature of the reagent and the equipment used, variations of the PT results are to be expected.

For standardization purposes, the World Health Organization (WHO) recommended a system in 1977.

Prothrombin Time values are converted into INR values, International Normalized Ratio, by using a specific equation.

1.4 MEASURING PRINCIPLE

The technology used by the microINR System is based on the microfluidics of the microINR Chip.
The chips contain human recombinant thromboplastin as reagent.
The blood sample is applied to the chip through the entry channel and mixed with the reagents contained in the micro-reactors. The coagulation cascade is triggered instantly. When the blood coagulates, a change in blood flow behavior occurs.
The meter captures the position of the sample by means of a Machine Vision System (MVS) and determines the INR result.

Calibration

Each lot of microINR Chips is calibrated against a reference lot of human recombinant thromboplastin traced to the International Reference Thromboplastin Preparation of the World Health Organization.
The calibration parameters needed for the INR equation are encoded in each microINR Chip along with information related to the expiration date. Therefore, every test is automatically and individually calibrated, reducing any risk of error.

2. microINR Expert METER

2.1 DESCRIPTION OF THE microINR Expert KIT

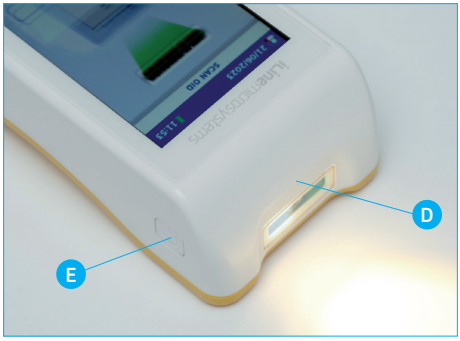
The microINR Expert kit includes:

- Case
- microINR Expert meter
- Charger
- Plug adapter
- USB-C/USB-A cable
- Instructions for use of the microINR Expert meter
- Easy guide for self-testing patients
- Error guide
- Questionnaire

microINR Chips are sold separately.

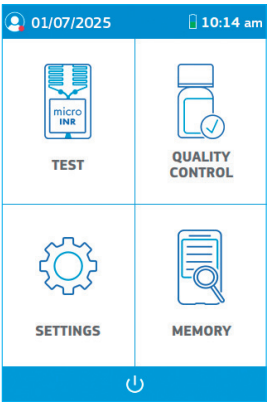
It is recommended to store and carry the meter inside its case.

2.2 PARTS OF THE microINR Expert METER



A: Touchscreen **B:** Chip insert slot **C:** USB-C port **D:** Barcode scanner **E:** ON button

2.3 microINR EXPERT ON / OFF



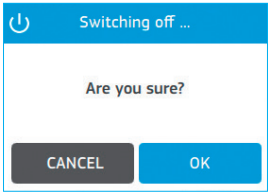
The microINR Expert meter can be turned on by pressing the ON button located on the upper right side of the meter or by inserting a microINR Chip.

The meter can also be switched on by connecting it to the power source, Ethernet adapter or a computer through the USB-C/USB-A cable.

The loading screen appears temporarily when the meter is turned on and the main menu is displayed a few seconds later.

Tap the **OFF bar** located at the bottom of the main menu to turn the meter off after use. A message will be shown to confirm or cancel shutdown.

If the meter does not respond to user action when tapping the touchscreen, press the ON button for a longer- than-usual time (10-15 seconds) to turn the meter off. Then press the ON button again as usual to turn the meter on.



2.4 MENU ICONS OVERVIEW

User logged off	OFF button	pm — Time between noon and midnight (in 12-hour time format)
User logged on	Data synchronization	am — Time between midnight and noon (in 12-hour time format)
Wi-Fi	Data synchronization failed	INR — Results are displayed in INR units
No Wi-Fi signal	Return to main menu	s — Results are displayed in seconds
Bluetooth	Section blocked	Delete; for custom comments
Ethernet	Option enabled	Search; for Memory menu
USB	Option disabled	Calendar icon; for Setting menu
Battery	The meter is connected to the power supply	Clock icon; for Setting menu
Chip expiration date		

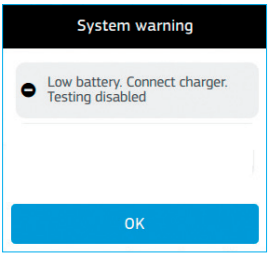
2.5 CHARGING THE microINR Expert METER

The meter uses a lithium-ion battery and is recharged through the USB-C connection on the left side of the unit with the power source provided in the kit.

Charge the battery completely before using the meter for the first time. The recommended charging time is approximately 3.5 hours.

The battery level is displayed in the battery icon on the status bar located at the top of the screen. This icon has four segments, each representing approximately 1/4 of the total battery capacity.

The following message will appear on the display when the battery is depleted.



The battery charging icon is displayed in the status bar while charging.

Disconnect the meter from the charger and the charger from the socket once the battery is fully charged.

It is not recommended to charge the meter by connecting it to a computer.

Do not open or manipulate the meter. The manufacturer will not warrant meters that have been opened.

Do not pierce or burn the battery.

Do not change the battery.

Do not store microINR Expert meter near a heat source since it could result in battery swelling, leak or malfunction.

For battery replacement or meter repairs, the equipment must be sent to the manufacturer. Battery manipulation could result in a hazard.

Use only the supplied charger, plug adapter and cable provided by the manufacturer or you may damage the meter. Other accessories may negatively affect the meter and even can lead to an injury.

Do not use loose power sockets or damaged power source units or cables.

2.6 STATUS BAR AND DROPDOWN MENU

Status bar

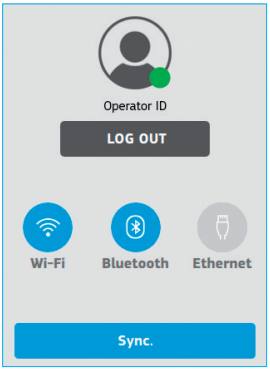
The status bar is located at the top of most screens and displays the following information:

- Operator or administrator logged on (green) or logged-off (red)
- Date
- Wi-Fi, Ethernet, Bluetooth, USB and/or Synchronization
- Battery icon
- Time

Dropdown menu

The dropdown menu can only be displayed by tapping the status bar on the main menu. The dropdown menu displays the operator/administrator identification, if a user is logged on and enables the operator/administrator log-on or log-off.

The available configured communications are also displayed with the associated icon in blue (or grey if they are not configured).
Tap the status bar again to return to the main menu.



2.7 SETTING THE TIME AND DATE

Before using the microINR System, check that the time and date displayed in the Status bar are correct, as it is necessary for the chips' expiration date determination.

If you need to modify the date and/or the time, please follow the indications provided in Section 7.4.

2.8 microINR Expert DEFAULT CONFIGURATION

The following tables show the default configuration options set up in the meter.

Menu	Submenu	Setting	Default Values
Meter settings	Screen & Sound	Brightness	5
		Beeper	ON
	Results	Result unit	INR
	Language		English
	Date / Time	Time	0:00
		Time format	12 h
		Date	00/00/0000
		Date format	MM/DD/YYYY
	Auto-Off		5 min

Menu	Submenu	Default Values
ID Set Up	OID Request	Optional
	PID Request	Optional
EasyControl Settings	EasyControl Lockout	OFF
Connectivity	Ethernet	OFF
	Wi-Fi	OFF
	Bluetooth	OFF

2.9 QUALITY CONTROL

The microINR System provides Quality Controls on every test.

First, microINR Expert meter performance is automatically checked for electronic components, correct power battery level and environmental temperature conditions.

Then, on-board controls provide a quality control check for each individual microINR Chip used with the microINR Expert meter. microINR System has been designed to detect errors prior to and during the test in order to prevent inaccurate INR results through a multi-level strategy.

These quality controls are performed automatically, so it is not necessary to run extra quality controls.

Additionally, optional liquid controls can be analyzed in the meter. These liquid controls are provided to help meet the regulatory requirements if applicable to your facility. To know more about the microINR EasyControls, check Section 8.4.

3. CONDUCTING THE TEST

3.1 GETTING READY FOR THE TEST

Prepare all items needed for the testing:

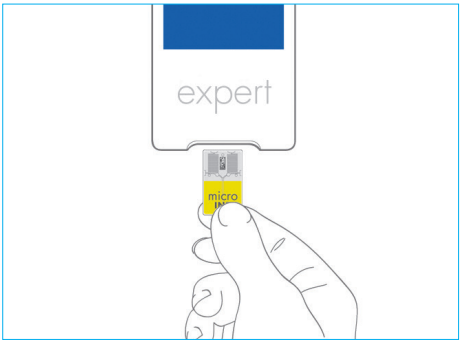
- microINR Expert meter.
- microINR Chips (not supplied).
- Disposable lancets and/or lancing device (not supplied).
- Means for skin cleaning (not supplied).

The fingerstick area must be clean, free of contaminants and completely dry. It is recommended to warm your hands. See Section 3.3 of these instructions for use.

3.2 MEASUREMENT PROCEDURE

Turning the Meter On

The meter can be turned on: - By inserting the chip: - By pressing the **ON button** located on the upper right side of the meter:



Do not manipulate the meter with wet or dirty hands/gloves.

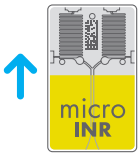
The meter displays information visually and emits acoustic signals (if the beeper is enabled) to guide the user throughout the testing process.

Inserting the Chip

Verify the expiration date and the storage conditions of the chip before conducting the test.

*Before inserting the Chip, tap the **Test** option on the main menu to conduct a test.*

- Open the chip pouch and remove the chip from the package.
- When the "Insert microINR Chip" message is displayed, insert the chip into the slot.



Hold the chip by the yellow part so that the "microINR" logo can be read correctly. Insert the chip into the slot and push it until it stops.

- Ensure the chip has reached the end.

In case a chip is already inserted, the meter will ask you to reinsert it.

- A "microINR Chip detected" message will be displayed when the chip is inserted.

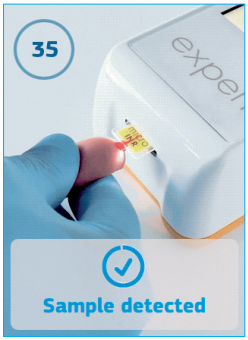
Do not use the chip if you detect that the chip is defective or its pouch is opened or damaged.
Do not manipulate the chip with wet or dirty hands/gloves.

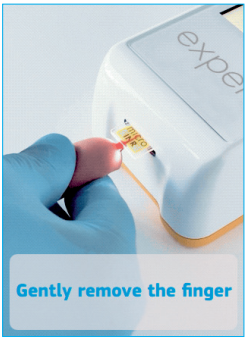
Conducting the Test

- The meter must be placed on a flat and steady surface.
- Once the chip is inserted, the meter performs a quality control to check the system's integrity prior to sample application.
- While waiting for the device to be ready, ensure your hand is warm and the fingertip clean (see Section 3.3 of these instructions for use).
- If the quality control fails, an error message will be displayed. In that case, check the "Error Guide" section of these meter instructions for use (see Section 6).
- If the quality control is correct, the chip begins to flash and warms up until it reaches the appropriate temperature. Once this temperature is reached:
  - The device emits an audible signal (beep tone) (if enabled).
  - A countdown (80s) and the "Apply sample" message are displayed.
  - The chip emits a steady light.

- Once the meter is ready, perform the fingerstick (see Section 3.3 of these instructions for use).
- Ensure to obtain a spherical and properly sized drop, equivalent to a teardrop.
- For self-testing patients: Rest the pricked finger on the other hand leaning on a flat surface to help you during the blood application.
- Apply the drop of blood on the chip immediately by putting it in contact with the chip's entry channel, without resting the finger on the chip.
- The meter will emit a beep tone (if enabled) and display a "Sample detected" message when it detects that the sample volume is enough, and the countdown disappears.
- After the beep tone, as displayed, gently remove the finger trying to leave a small amount of blood at the chip's entry channel.
- Wait until the INR result is displayed on the screen.

If you apply the sample and the "Sample detected" message is not displayed, this means that there is not enough sample volume.





Remove the chip and repeat the test with a new one. Ensure that the size of the drop is sufficient and do not block the entry channel during application.

Do not reapply sample or try to add more blood to the channel.

Never perform the fingerstick before the start of the countdown.

Do not touch the chip's entry channel with the finger while inserting the sample.

The meter must be placed on a flat and steady surface and do not move the meter or the chip until the test is over. Keep the meter away from direct sunlight and avoid light intensity changes during the test.

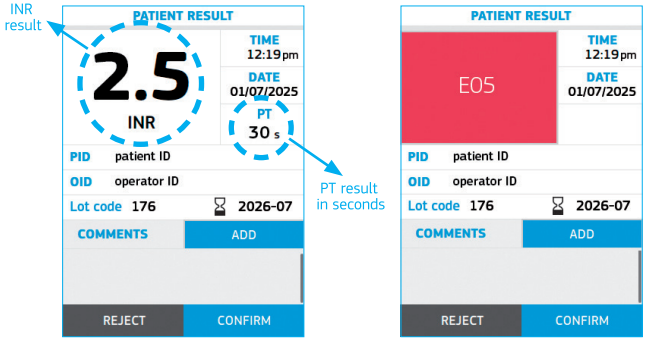
For healthcare professionals: *do not shake or drop the meter. If the meter is dropped or gets wet and the frequency of error messages increases, contact your local distributor.*

For self-testing patients: *do not shake or drop the meter. If the meter is dropped or gets wet and the frequency of error messages increases, contact your healthcare provider.*

Test Result

- The measurement is performed, and the meter displays the result in INR units or an error message.

See example below.



Note: if optionally configured by the administrator, the results can be also displayed in PT seconds.

Error messages are displayed as a letter "E" followed by a number.

If an error message is shown, follow the steps described in the Error guide section (see Section 6).

In addition, the test result displayed includes the time and date of the test, the chip Lot code and its expiration date. The Lot code consists of three digits, matching the initial three digits of the chip lot number utilized for the test.

Adding Comments (Optional)

Users may add comments to a test result as additional information. Up to 5 custom comments with a maximum of 30 characters in length can be entered.

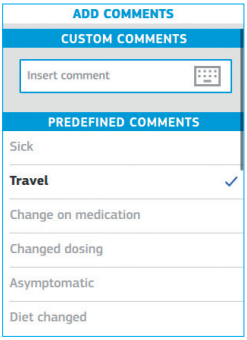
There are also 11 selectable predefined comments.

To add comments:

- Tap the **Add** option on the Patient Result screen.
- Tap the **Insert Comment** text entry box to type a custom comment. Use the keypad to enter the comment. An inserted comment can be deleted by sliding the delete comment icon to the left.

When entering a custom comment to a result, do not include patient or operator sensitive information (name, age, etc.) as it will be stored in the meter and can be viewed.

- Select the desired predefined comment(s) from the list.



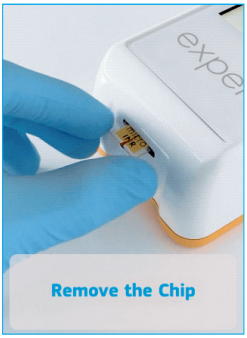
• Scroll down to **Confirm** the selection to return to the results screen once the desired comment(s) have been selected.

Finishing the Test

The operator may choose to confirm or reject the test result. Tap **Confirm** or **Reject** when the result is displayed.

All results will be stored including rejections. In the latter case a "Test rejected" comment will be added automatically.

The meter will request removal of the chip once the test result has been confirmed or rejected. Remove the chip by holding it from both sides and dispose of it appropriately.



For healthcare professionals: *Used chips, lancets, and gloves may be a source of infection. Dispose of the materials according to your institution´s infection control policy and the appropriate local regulations.*

For self-testing patients: *Dispose of the used chip with your regular waste. Dispose of used lancets carefully.*

Use a sharps container to prevent injury to yourself or to others with the needle. Contact your healthcare provider to help you get a sharps container.

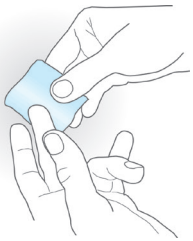
The test result will be sent to the DMS automatically once it has been confirmed or rejected provided the meter has a connectivity channel enabled.

The meter will automatically return to the main menu.

3.3 COLLECTION AND TESTING THE BLOOD SAMPLE

The steps to obtain and apply a capillary blood sample correctly are detailed below:

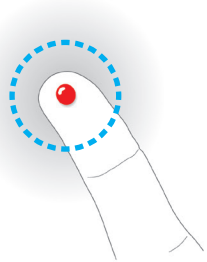
• Read the instructions for use of the fingerstick device or lancet.



The fingerstick site must be clean, completely dry and free of contaminants. Washing hands with warm soapy water is recommended. You may also use alcohol to clean the fingerstick area. Always dry the area thoroughly to remove any traces of substances that may interfere with the result. Always use a new, clean and dry gauze.

Any alcohol (disinfectants, shaving creams, etc.), lotions or sweat on the fingerstick area or the blood sample may cause incorrect results.

Before lancing the finger, it is recommended to warm hands. There are several techniques that can be used for that purpose such as keeping hands below the waist and massaging the fingertip softly.



• You can use any finger for the fingerstick. The recommended site is the one shown on the following image.

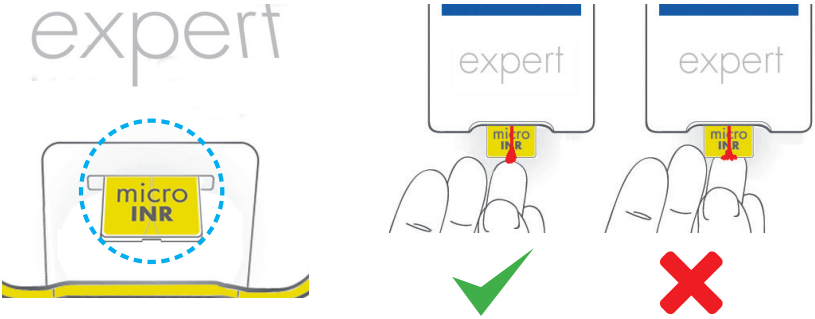
• Once the meter is ready for testing and the 80-second countdown appears on the screen, place the lancet firmly against the fingertip and activate it. Massage the finger to bring blood to the fingertip and gently press to help form a drop of blood. Do not press the fingerstick site or let the drop of blood spread on the finger.

• Before placing the sample on the chip, ensure to obtain a spherical and properly sized drop (equivalent to a teardrop), large enough to leave a small amount of blood (remnant) at the entry channel.

Sampling technique can affect the result of the test. Do not squeeze or "milk" the fingerstick area as this can alter the coagulation process. Do not let the drop of blood spread on the finger.

When using the meter in a multi-patient site, use only auto-disabling single use lancets.

- For self-testing patients: Rest the pricked finger on the other hand leaning on a flat surface to help you during the blood application.
- Apply the drop to the chip immediately, in contact with the entry channel.



Samples must be applied immediately after collection, since blood clotting naturally occurs upon fingerstick.

Avoid contact between the chip and the finger in order not to obstruct the entry channel and to allow for uninterrupted blood absorption. Only the drop of blood must make contact with the chip.

Apply the sample on a single attempt. Never add more blood to the chip.

- Once the sample has been detected, the meter emits a beep (if enabled), displays a "Sample detected" message, and the countdown disappears.
- After the beep tone, if enabled, gently remove the finger, leaving a small amount of blood (remnant) at the entry channel as shown in the picture.
- If you need to repeat the test, you must perform the fingerstick in a different finger with a new lancet and a new chip.

3.4 INTERPRETING THE RESULTS

The results are shown as International Normalized Ratio (INR) units. The microINR Expert system's results range between 0.8 and 8.0.

If you obtain a result out of the measuring range, the display shows < 0.8 (below 0.8) or > 8.0 (above 8.0).

If an error message is displayed, see the Error guide section (Section 6) and follow the instructions.

Some liver diseases, thyroid dysfunction and other diseases or conditions as well as nutritional supplements or changes in dietary habits, can affect the activity of warfarin and the INR results.

For healthcare professionals: If an unexpected result is obtained, repeat the test ensuring that the directions in these instructions for use are strictly followed. If an unexpected result is obtained again, the result must be checked using another method.

Results are unexpected when they do not match the patient´s symptoms (i.e., hemorrhages, bruises, etc.).

For self-testing patients: If an INR result is obtained outside the specific therapeutic range defined by your physician, contact your healthcare provider and follow their instructions.

If optionally configured by the Administrator (depending on the meter settings), the prothrombin time (PT) in seconds can be also displayed. The reported value is derived from the INR result and its equation. The calculation is performed with an ISI of 1.0 and a typical Mean Normal Plasma Prothrombin Time of 12.0 seconds.

3.5 OPERATOR AND PATIENT IDENTIFICATION (Optional)

The operator who performs the test may log on their identification (OID) and the patient identification (PID) may also be introduced in the patient tests. Refer to Section 8 (8.2 and 8.3, respectively) to perform these actions.

3.6 LIMITATIONS OF USE

For information regarding limitations of the microINR System refer to the instructions for use of the microINR Chips.

4. MEMORY

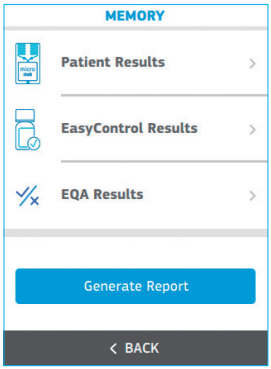
The microINR Expert meter can store up to 2,000 patient test results and 500 quality control test results together with their respective times and dates.

A maximum of 5,000 Operator and 4,000 Patient IDs are allowed.

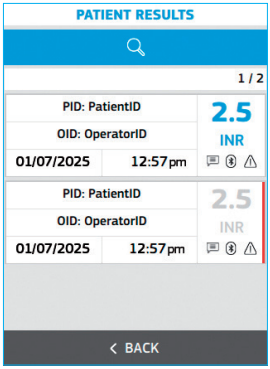
If there is no free storage space when conducting a test, the oldest result will be automatically deleted to store the new one. To avoid losing stored test results, the meter may generate a PC-removable PDF document or connect the meter to a DMS through one of the various communication channels available.

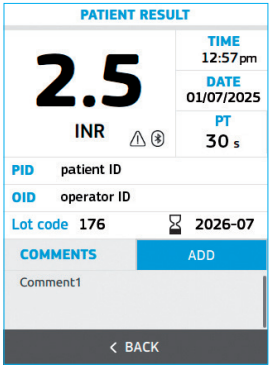
Tap the **Memory** option in the main menu to review the test results.

The Memory menu contains three distinct areas:

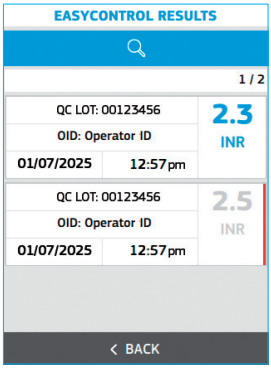


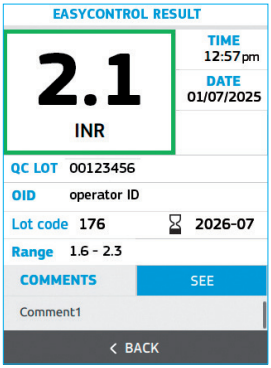
- **Patient Results:** it contains all patient test results performed through the Test option on the main menu. The patient results list is sorted by date and time. The most recent patient result is at the top of the list. The patient results are presented with the PID, the OID (if included), test result, date and time. A result with the INR value in grey and marked with a red line on the side indicates that the stored result was rejected. To browse the results simply scroll down with the finger.
  Tap a patient result from the list to see other information (Lot code, added comments...) on a specific result.





- **EasyControl Results:** this area contains all plasma tests performed using the Test EasyControl option in the Quality Control menu. The EasyControl result list is sorted by date and time. The most recent result is at the top of the list. The EasyControl results are presented with the EasyControl Lot, the OID (if included), EasyControl result, date and time. A result with the INR value in grey and marked with a red line on the side indicates that the stored result was rejected. To browse the results simply scroll down with the finger.
  Tap an EasyControl result from the list to see other information (Lot code, added comments...) on a specific EasyControl result.





- **EQA Results:** this area contains all plasma tests performed using the Test EQA option in the Quality Control menu. The EQA results list is sorted by the date and time. The most recent result is at the top of the list. The EQA results are presented with the EQA Lot, the OID (if included), EQA result, date and time. A result with the INR value in grey and marked with a red line on the side indicates that the stored result was rejected. To browse the results simply scroll down with the finger.
  Tap an EQA result from the list to see other information (Lot code, added comments...) on a specific EQA result.

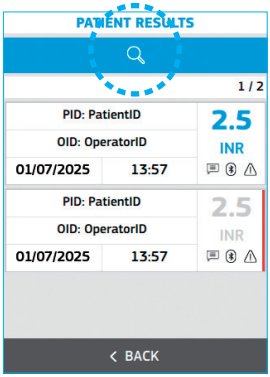
Together with a specific result, there may be icons providing additional information:

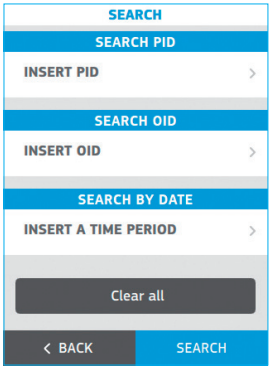
Comment(s) added to the result	Unprocessed or failed QC	Bluetooth: means that a result has been done with Bluetooth available

Search (Optional)

You can execute searches in each area of the Memory menu by applying one or more filters.

Tap on the **Search** icon button to enter the search filters. The following filters can be entered:





- **PID / LOT:** Enter a Patient ID (Patient result area) or a LOT number (EasyControl and EQA result area) using the barcode scanner or manually with the keypad.
- **OID:** Enter an Operator ID with the scanner or manually with the keypad.
- **Period:** Enter the date range of choice by moving the date wheels.

Tap on **Search** to get a result list with the defined filters applied.

Tap on **Clear all** to clear the defined filters.

Generate Report (Optional)

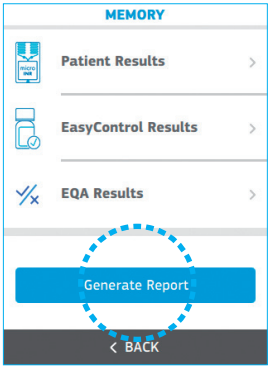
microINR Expert can generate a PDF file containing all the memory data stored in the meter.

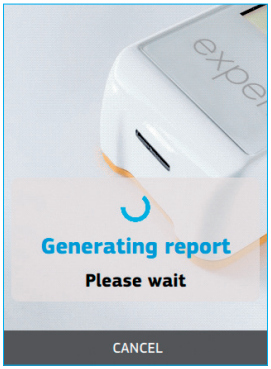
Tap on **Generate Report** in the Memory menu.

Depending on the number of stored results this process could take a few minutes. An alert will appear on the screen when the report is ready.

Connect the meter to a PC using the supplied USB cable to access the report. The meter appears as a removable disk on the PC screen. Copy the PDF file to the desired location on the PC.

Safely disconnect the meter from the PC when you have finished.





5. CLEANING AND DISINFECTING

Cleaning and disinfecting the meter is essential to prevent blood-borne transmission of pathogens.

Disinfection of the meter destroys most, but not all, pathogenic and other types of microorganisms.

For healthcare professionals: The FDA recommends that point-of-care testing devices used with multiple patients be properly cleaned and disinfected after every use.

Clean the meter to remove visible dirt before disinfecting.

For self-testing patients: Clean and disinfect the meter and/ or the lancing device when there is visible dirt or when there is blood on it. Also, clean and disinfect the meter and/or the lancing device before anyone else handles them.

Needed Equipment:

All these materials can easily be found and purchased on internet.

- Super Sani-Cloth® Germicidal Disposable Wipes (EPA reg. no. 9480-4)
- Lint-free cloth
- Lint-free microbrush 0.059 in (1.5mm) tip

Additional equipment for Healthcare Professionals:

- Gloves

For healthcare professionals:

Always use applicable Personal Protective Equipment.

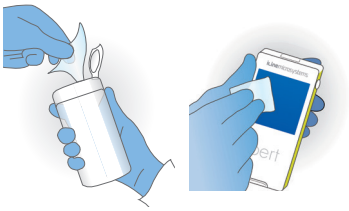
Always follow the infection control procedures of your institution when handling portable coagulation equipment.

Always wear a new pair of gloves while cleaning and disinfecting the meter.

What to Clean / Disinfect:

The following parts of the meter and system components may be cleaned and disinfected:

- The area around the chip insertion zone
- The meter screen
- The meter housing (entire meter surface)

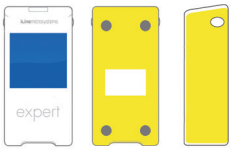


Cleaning process

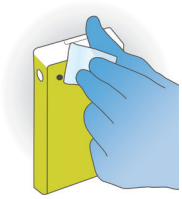
1. Turn the meter off and ensure the cable is unplugged.
2. Take a Super Sani-Cloth® wipe and clean the microINR Expert meter (all areas) for 10 seconds and dispose of the wipe.

Disinfection process

1. The disinfection routine must be performed for 2 minutes (contact time).
2. Take a new Super Sani-Cloth® wipe and start wiping the back and front surfaces and continue with the laterals.
3. Wipe the critical parts of the meter gently (USB port, microINR Chip insertion area, buttons, and display area) ensuring no liquid enters or accumulates near these critical areas.
4. Allow the microINR Expert meter to air dry thoroughly for 10 minutes before using it.



5. Wipe the meter using a drying lint-free cloth to remove any liquid that may remain on the meter.



6. Use a swab to remove any lint that may remain at the chip insertion area by introducing the swab in the entry and sliding it to both sides. Introduce the swab properly to avoid any meter internal component damage.

For healthcare professionals: Remove the used gloves.

For self-testing patients: If using a lancing device, always follow its instruction for use to clean and disinfection.

Warnings and precaution tips when cleaning-disinfecting

- Do not clean or disinfect the meter while conducting a test. Always use Super Sani-Cloth® Germicidal Disposable Wipes (EPA* reg. no. 9480-4) to clean and disinfect the meter.
- Do not use any other cleaning or disinfecting solution. Using solutions other than that mentioned above could result in damage to system components.
- Verify that the gauze or wipe is just moist, not soaked. Ensure that no liquid enters the meter or the chip insertion area or USB port.
- Do not let liquid accumulate near any opening.
- Do not spray fluids on the meter or submerge the meter.
- The chip insertion area must always be clean and dry before conducting a test as remains of liquid can contaminate the sample.
- Do not handle the chips with liquid-contaminated hands or gloves.
- Comply with all recommendations regarding cleaning and disinfection of the meter. Not doing so could cause incorrect results.
- If you notice any signs of deterioration of the meter after cleaning or disinfecting, stop using the system and contact your local distributor or healthcare provider.

6. ERROR GUIDE

The microINR Expert meter's performance is automatically checked when the system is turned on and during testing. The microINR on-board quality control checks for unforeseen conditions that may arise due to mishandling or technical issues (faulty components, consumables or external conditions).

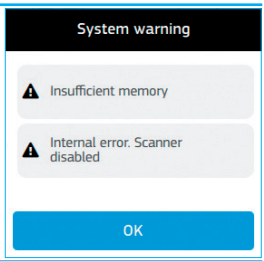
Error messages that may appear during testing are displayed with the letter "E" followed by a number.

Error code	Probable Cause	Possible Solution
E01	The Datamatrix could not be read or used chip detected.	Ensure the chip has not been previously used or is not damaged. Insert the same chip again, ensuring correct insertion. If the problem persists, repeat the test with a new chip. If, despite this, the problem is still not solved, the meter may be damaged.
E02	Expired chip.	Verify the date of the meter. If the date is not correct, enter the current date (see Section 7.4) and insert the same chip again. If the date is correct, repeat the test with a new lot of chips. Always verify the chip expiration date.
E03	The 80-second countdown for sample application has been exceeded. Sample has not been correctly detected.	If the sample has not been applied yet, repeat the test with the same chip. If the sample has been applied, repeat the test with a new chip. Make sure to apply enough sample volume.
E04	Chip inserted upside-down.	Rotate the chip and repeat the test. See picture at Section 3.2.
E05	Wrong application of the blood sample.	Repeat the test with a new chip. Make sure you do not block the chip's entry channel and you are applying a sufficient amount of blood. Gently remove the finger after the blood application. Go to Section 3.3 of the meter instructions. Verify proper chip storage conditions (see microINR Chip instructions).
E07	Temperature below the defined range.	Verify that the temperature is above 59ºF (15ºC). Repeat the test in a warmer location. If the problem persists, the device may be damaged.
E09	Inadequate coagulation of the sample during the test. Irregularities during the test.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see Section 3.2 and 3.3) and verify proper chip storage conditions (see microINR Chips instructions).
E10	Possible chip degradation (not correctly stored) or sample contamination.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see Section 3.2 and 3.3). Review the Storage and Stability, Limitations and Interference Sections at microINR Chips instructions.
E11	Incorrectly inserted chip. Chip used or damaged. Meter damaged.	Strictly follow instructions on inserting the chip into the meter (see Section 3.2). Insert the same chip again, ensuring its correct and complete insertion. If the problem persists, repeat the test with a new chip. If, despite this, the problem is still not solved, the meter may be damaged.
E12	Temperature above the defined range.	Verify that the temperature is below 104ºF (40ºC). Repeat the test in a cooler location. If the problem persists, the meter may be damaged.
E13	Wrong chip reference.	Make sure your chip reference begins with CHC.
E14 E15	Error while processing the sample during the test. Possible chip degradation (not correctly stored) or chip damaged. The device has been hit or moved abruptly during the test.	Repeat the test with a new chip. Verify proper chip storage conditions (see microINR Chips instructions). Do not hit/touch or move the chip or meter during the test.
E16	Inadequate coagulation of the sample during the test. Contaminated sample or sample with abnormally high INR values.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see Section 3.2 and 3.3). Review the Storage and Stability, Limitations and Interference Sections at microINR Chips instructions.
E17	Error while processing the sample during the test. The device has been hit or moved abruptly during the test. Chip damaged.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see Section 3.2 and 3.3). Do not hit/touch or move the chip or meter during the test. Verify proper chip storage conditions (see microINR Chips instructions).
E18	Wrong application of the blood sample or unusual/abnormal sample.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see Section 3.2 and 3.3). Make sure to apply enough sample volume in a single attempt. If error E18 is displayed again, contact your healthcare provider (your hematocrit value defined for the microINR system may be out of range).
E19	Sample type detection mismatch.	The sample type detected does not match the testing mode. Make sure to apply blood on the patient testing mode and plasma control on the QC testing mode.

Different warning messages may appear due to technical aspects of the meter. Perform the suggested actions or check the meter settings.

For healthcare professionals: If a problem persists after performing the actions stated in the Error Guide section or if you require additional information, you can contact your local distributor.

For self-testing patients: If a problem persists after performing the actions stated in the Error Guide section or if you require additional information, you can contact your healthcare provider.

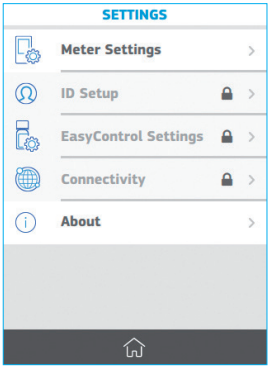


7. microINR Expert METER CONFIGURATION

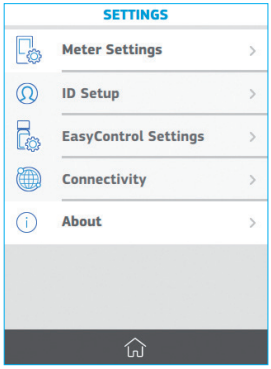
7.1 SETTINGS

The microINR Expert settings can be customized through the **Settings** option located in the main menu.

Some of the setting options can be only changed by the administrator. If the administrator is not logged on, these options will be clearly marked in grey with a padlock symbol.



Administrator logged-off



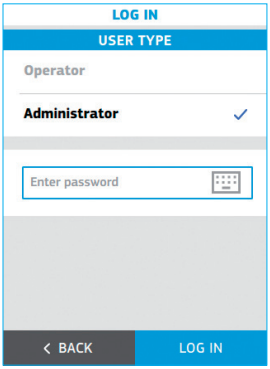
Administrator logged-on

7.2 ADMINISTRATOR IDENTIFICATION (Optional)

The administrator has special credentials to change certain settings and is the only person who can do so. The testing menus (Tests and Quality Control) are deactivated when the administrator is logged-on.

Tap on the **status bar** located at the top of the main menu and then tap on the **Log in** button to log on through the dropdown menu.

Select **Administrator** in the User Type section so that the option is highlighted (bold type with a check mark) and then tap the password in the **Enter password** text entry box.



Default password: iline

The administrator can change this password (see Section 7.5).

The predefined administrator password must be changed as a security measure.

Key in the proper password using the keypad and confirm the administrator identification by tapping the **Log in** button.

The user icon changes to green on the status bar once the administrator has been identified.

The administrator's identification will be displayed in the dropdown menu.

To log out as administrator, simply tap the **Log out** button in the dropdown menu.

If the meter is turned off, the administrator will be automatically logged out.

7.3 SETTINGS SUMMARY

The following tables show all the setting options that can be accessed on the meter.

Menu	Submenu	Setting	Values
Meter settings	Screen & Sound	Brightness	1-10 (5*)
		Beeper	ON* / OFF
	Result		INR*
			INR + PT
	Language		Español
			English*
	Date / Time	Time	0:00
		Time format	24 h
			12 h*
		Date	00/00/0000
		Date format	DD/MM/YYYY
			MM/DD/YYYY*
			YYYY/MM/DD
	Auto-Off		5*/15/30/45 or 60 min
Menu	**Submenu**	**Setting**	**Values**
ID Setup	Administrator		Change password
	OID Request		No
			Optional*
			Required
	PID Request		No
			Optional*
			Required
EasyControl Settings	EasyControl Lockout	ON / OFF*	
		Frequency	No
			Daily
			Weekly
			Monthly
			Annually
			Number of test
		Lockout Mode	Enable test with QC Warning
			Meter lockout

Menu	Submenu	Setting	Values
Connectivity	Ethernet	ON / OFF*	
	Wi-Fi	ON / OFF*	
		My Network	Network
			User
			Password
			Test connection
	Bluetooth	ON / OFF*	Pair:
			Free mode / Password mode
			Unpair
			Send data
	POCT1A	Server information	Address
			Port
		Data Sync	PID List / OID List

Menu	Section	Values
About the system	System updates	Information
	Software version	A7
		M4
		DSP
		BT
	More information	HW version
		SN
		Battery
	Clear memory	
	Default parameters	

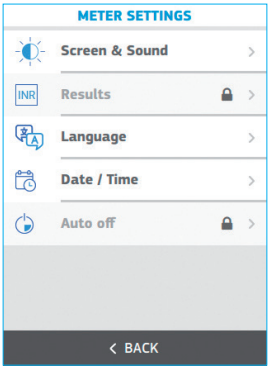
(*) Default values.

7.4 METER SETTINGS

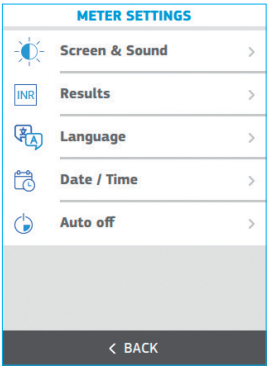
Tap on **Settings** on the main menu.

Then tap **Meter Settings** to access the meter configuration.

Some of the meter's setting options can be only changed by the administrator. If the administrator is not logged on, these options will be clearly marked in grey with a padlock symbol.



Administrator logged-off



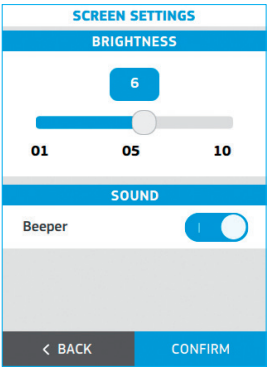
Administrator logged-on

SCREEN and SOUND

The **Screen & Sound** setup area contains the option for changing brightness and enables or disables the Beeper function.

Adjust screen brightness by moving the slider from 01 to 10. This parameter is set at 05 by default.

Enable or disable the Beeper function by sliding the **ON/OFF** button. This parameter is ON by default.



When the Beeper function is enabled the meter will emit a beep in the following cases:

- *Chip warm-up process is complete and sample application is required.*
- *Sample is detected.*
- *An error has occurred.*
- *A barcode has been scanned.*
- *Scanning error or scanner time-out.*

Keeping the Beeper enabled at all times is recommended.

Tap **Confirm** to save this setting or tap **Back** to return to the previous screen without saving the changes.

RESULTS

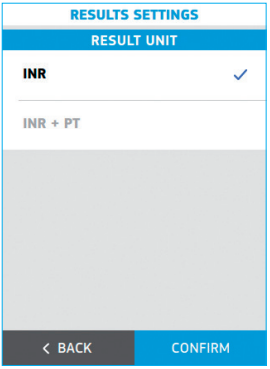
The **Results** setup area contains the options to select the unit(s) in which the patient's result is displayed. This setting must be configured by the meter administrator (the administrator must be logged on).

- **INR:** only the results in INR units will be displayed.
- **INR + PT:** the results in INR units as well as the PT values in seconds (s) will be displayed.

The selected unit of measure setting is highlighted in bold type with a check mark. The default setting is INR.

Tap any option to select the preferred unit(s) of measure.

Tap **Confirm** to save this setting or **Back** to return to the previous screen without saving the changes.



LANGUAGE

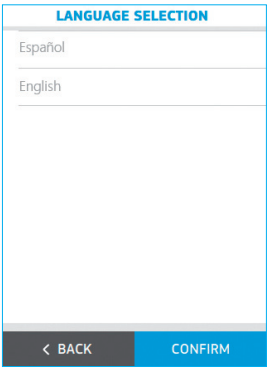
Use this setting to select the meter **Language**.

The selected language is highlighted in bold type with a check mark. The default setting is English.

Tap the selected language on the screen. Tap **Confirm** to save this setting or **Back** to return to the previous screen without saving the changes.

The following languages are available in the meter:

- Español
- English



DATE / TIME

Use this setting to adjust the **Date / Time**.

Date

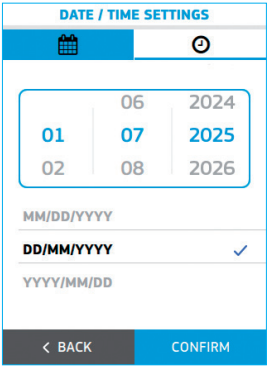
Tap the **Calendar icon** to manually set the date.

Select the date by moving the wheels to the current date.

The selected date format is highlighted with a check mark. This parameter is set as MM/DD/YYYY by default.

Tap the selected date format on the screen:

- MM/DD/YYYY: Month/Day/Year, e.g., 09/29/2025
- DD/MM/YYYY: Day/Month/Year, e.g., 29/09/2025
- YYYY/MM/DD: Year/Month/Day, e.g., 2025/09/29



Time

Tap the **Clock icon** to manually set the time.

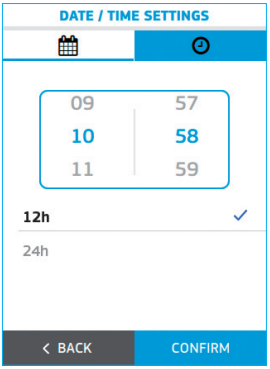
Select the time by moving the wheels to the desired time. The time display items depend on the selected time format.

The selected time format setting is highlighted with a check mark. This parameter is set as 12-hour by default.

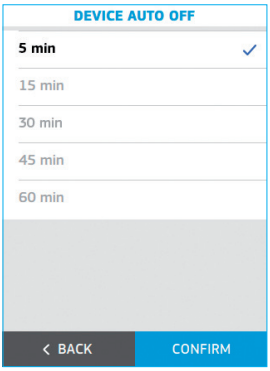
Tap the selected time format on the screen:

- 12 h: am/pm option is available with the hours and minutes.
  E.g., 02:30 pm
- 24 h: am/pm option is not available.
  E.g., 14:30

Tap **Confirm** to save these settings or tap **Back** to return to the previous screen without saving the changes.



AUTO OFF



The meter can be set to shut down automatically after a configurable period of inactivity, as long as no internal process is in progress. The auto off function is active even when the Meter is charging.

This feature helps to save power and extend battery life. This setting must be configured by the administrator (the administrator must be logged on).

The auto-off function is enabled after a 5-minute inactivity period by default.

Tap **Auto off** to adjust this option.

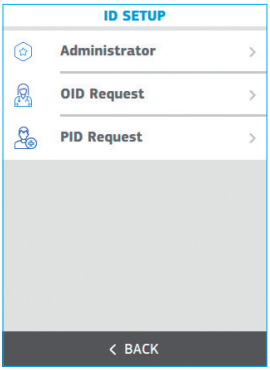
Select the inactivity period. It is highlighted in bold type with a check mark.

- 5 min
- 15 min
- 30 min
- 45 min
- 60 min

Tap **Confirm** to save this setting or tap **Back** to return to the previous screen without saving the change.

7.5 ID SETUP

The ID (identification) Setup menu is used to define settings for operator and patient management and for changing the administrator's password. These settings must be configured by the administrator (the administrator must be logged on).



There are three types of user profile used with the microINR Expert meter:

Administrator: The administrator has special credentials to specify configurable meter settings and is the only one who can change these settings. The testing menus (Tests and Quality Control) are deactivated when the administrator is logged-on.

Operator: Operator ID (OID) is assigned to healthcare professionals who use the meter to perform tests.

Patient: Patient ID (PID) is assigned to the person whose test results are being recorded.

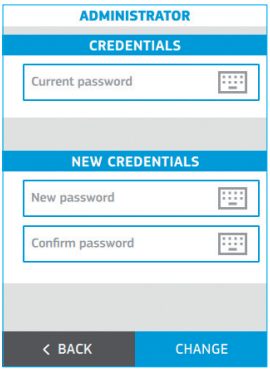
The meter can restrict its use to specific operators or a predefined group of users. In this case, an externally-created operator list must be transferred to the meter by a Data Management System (DMS). See Section 8.9 in these instructions for further details.

Patient lists can also be created externally and transferred to the meter by a DMS, thus restricting performance of the test to patients identified on said list. See Section 8.9 in these instructions for further details.

Tap **Settings** from the main menu to define the ID management settings.

Then tap **ID Setup** to open the three ID types:

Administrator:



The meter has a predefined password for the administrator by default. The system administrator can change this password.

Changing the predefined administrator password is recommended as a security measure.

Select main menu and tap the **status bar** to log on as administrator in the microINR Expert. Follow the steps indicated in Section 2.8.

Tap **Change** to save these settings or tap **Back** to return to the previous screen without saving the changes.

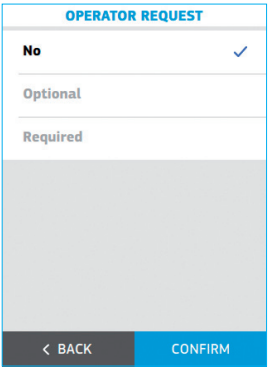
Operator ID (OID) configuration:

Tap the **Operator ID request** of choice on the screen:

- **No:** The meter does not request operator identification when a patient or QC test is initiated.
- **Optional:** The meter requests an operator identification when a patient or QC test is initiated and if the operator has not previously logged on, but this request may be skipped.
- **Required:** The meter forces operator identification when a patient or QC test is initiated and if the operator has not previously logged on.

The selected option is highlighted (bold type with a check mark).
This setting is set to "Optional" by default.

Tap **Confirm** to save this setting or tap **Back** to return to the previous screen without saving the changes.



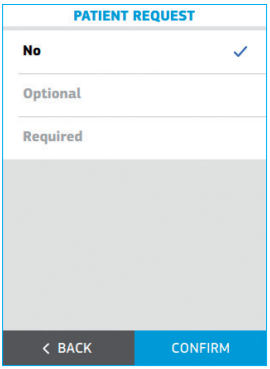
Patient ID (PID) configuration:

Tap the **Patient ID request** of choice on the screen:

- **No:** The meter does not request patient identification when a patient's test is initiated.
- **Optional:** The meter requests patient identification when a patient's test is initiated but this request may be skipped.
- **Required:** The meter forces patient identification when a patient's test is initiated.

The selected option is highlighted (bold type with a check mark).
This setting is set to "Optional" by default.

Tap **Confirm** to save this setting or tap **Back** to return to the previous screen without saving the changes.



7.6 EASYCONTROL SETTINGS

The EasyControl Settings menu contains options for its configuration.

These settings allow the optional liquid control tests to be run on a desired time basis.

This option is inactive by default.

These settings must be configured by the administrator (the administrator must be logged on).

Lockout, Frequency and Lock Mode

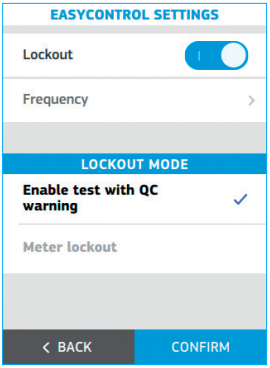
Tap **Settings** from the main menu to define the EasyControl Settings.

Then tap **EasyControl Settings**.

Slide the **ON/OFF** button to activate the EasyControl lockout.

Then set the **Frequency** for the microINR EasyControl scheme. Tap the selected frequency on the screen and a new window will open:

- No: the meter will only be locked in case an incorrect EasyControl result is obtained.
- Daily
- Weekly
- Monthly
- Annually
- Number of tests: from 1 to 2,000 tests.



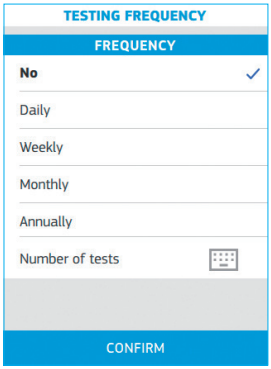
Various options can be configured according to the following description whenever the lockout option is active and the microINR EasyControl test is not conducted properly or the result is outside the acceptance range:

- **Enable test with QC warning:** operators may perform tests even if the QC test was not OK. However, said warning will be displayed together with the test result.
- **Meter lockout:** a microINR EasyControl test must be OK before a new test can be performed.

The selected option is highlighted in bold type and a check mark.

Tap **Confirm** to save these settings or tap **Back** to return to the previous screen without saving the changes.

A microINR EasyControl test must be run in order to initiate the selected testing frequency.

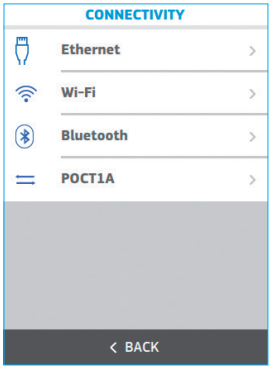


7.7 CONNECTIVITY

The data transfer options with external devices can be set in the Connectivity menu. The meter can be connected to a computer or host system (DMS) through various channels. The data handling function may vary depending on the particular Data Management System (DMS). Please contact your local distributor for further information on the DMS compatible with the meter and configuration required for connection.

These connectivity settings must be configured by the administrator (the administrator must be logged on). See Section 8.2 in these instructions for further information on the meter's data handling and connectivity features.

Tap **Settings** in the main menu and then tap **Connectivity** to define the system connectivity.

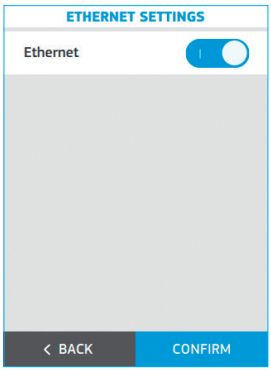


There are four options to choose from:

Ethernet: enable the Ethernet by sliding the **ON/OFF** button.

The meter must be connected to the Ethernet adapter (available separately) to communicate with a Data Management System (DMS) through the Ethernet Contact your local distributor to obtain the appropriate adaptor. Use only the adaptor supplied by the manufacturer to ensure the product performance and safety.

It is also necessary to configure the POCT1A settings to communicate with a DMS via Ethernet.



Wi-Fi: The microINR Expert meter can communicate and transfer results to a DMS by Wi-Fi to a specific Access Point (AP) Wireless Local Area Network (WLAN). The meter recognizes the existing AP WLAN protocol configuration (802.11b, 802.11g or 802.11n) and automatically transmits data using the POCT1-A2 communication protocol.

Enable the Wi-Fi by sliding the **ON/OFF** button to set the Wi-Fi Settings and connect to a specific WLAN.

Then fill in the network details:

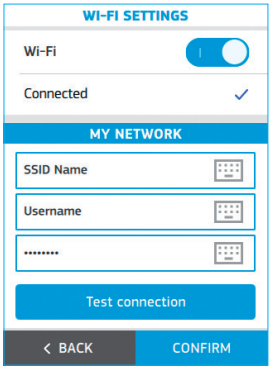
- **SSID:** tap the text entry box to type the network name using the keypad.
- **User:** tap the text entry box to type the username using the keypad.
- **Password:** tap the text entry box to type the network password using the keypad.

The username and password details may not be necessary. In this case leave the field blank.

A **Test connection** can be performed to check proper communication with the WLAN once all the network details have been filled in.

Tap **Confirm** to save these settings or tap **Back** to return to the previous screen without saving the changes.

It is also necessary to configure the POCT1A settings to be able to communicate via Wi-Fi with a DMS.



Bluetooth: The microINR Expert meter can communicate and transfer results to a DMS or other electronic devices (suitable smartphone/tablet Apps) through wireless Bluetooth connection.

Enable Bluetooth on the meter by sliding the **ON/OFF** button to set the Bluetooth Settings.

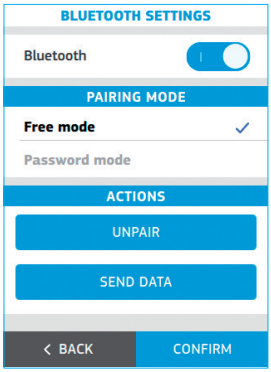
When Bluetooth is on the meter can be paired with a compatible device in two different configurable modes:

- **Free mode:** follow the instructions on the compatible software or smartphone/tablet app to pair the meter.
- **Password mode:** the microINR Expert meter shows a 6-digit password. Type the password on the compatible device and follow the software or app instructions.

The selected option is highlighted in bold type and a check mark.

Then, complete the connection process by tapping the **Pair** button to link the meter with a compatible device. The microINR Expert meter can only be paired with one device at a time.

The **Unpair** and **Send data** options will be available once the meter has been paired:



- **Unpair:** tap this option to unpair the meter from the connected device.
- **Send data:** tap this option to send all the results performed with the Bluetooth activated.

Tap **Confirm** to save these settings or **Back** to return to the previous screen without saving the changes.

Notice that the meter will only be able to transmit results via Bluetooth if they have been obtained with the Bluetooth setting activated. If results are obtained when the Bluetooth is deactivated, they cannot be subsequently sent via Bluetooth.

POCT1A: The microINR Expert meter supports data exchange via the POCT1A standard either through Wi-Fi or Ethernet.

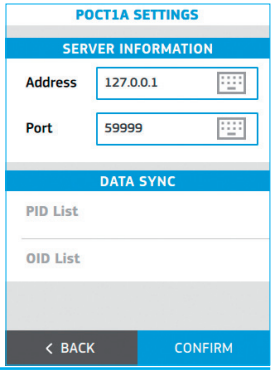
Fill in the Server information details to configure the POCT1A Settings:

- **Address:** tap the text entry box to type the server address using the keypad.
- **Port:** tap the text entry box to type the server port using the keypad.

The meter may also receive an operator and/or patient list from a DMS.

Select the **Operator list** and/or **Patient list** to enable these options. The selected option(s) is highlighted in bold type and a check mark. See Section 8.6. to learn more about this feature.

Tap **Confirm** to save these settings or tap **Back** to return to the previous screen without saving the changes.



7.8 ABOUT THIS SYSTEM

Information about the meter such as software and hardware data can be found in this section.

Tap **Settings** and then **About** to access this information.

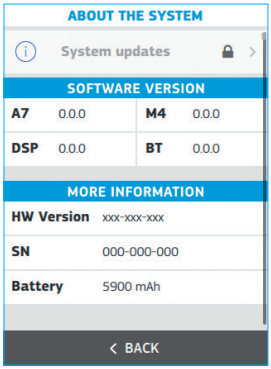
There are various sections on the About screen:

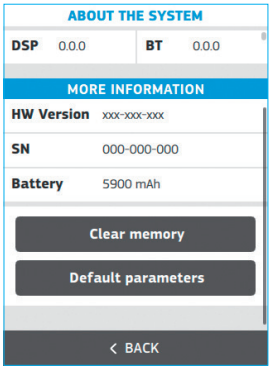
- **System updates:** tap this option to perform a meter software update. This option can only be performed by the administrator.
- **Software version:** information about the meter's electronic board software versions.
- **More information:** details of the hardware version, serial number (SN) and battery capacity.

The system administrator can clear the memory and restore the meter's default parameters.

Clear Memory: tap this option to delete all the meter results (patient and QC results).

Default parameters: tap this option to restore the meter's default parameters. All existing configurations will be deleted and the meter will recover its initial configuration (except for the administrator password if it was changed).





8. ADVANCED FUNCTIONALITIES (Optional)

8.1 BARCODE SCANNER (Optional)

The integrated barcode scanner is intended to scan operator, patient, and microINR EasyControl lot information and add this information to the result obtained.

Operator and patient IDs can consist of up to 20 alphanumeric and other special characters.

Alphanumeric characters are any combination of A - Z and 0 - 9. Some special characters may also be used.

After reading a barcode check the display to ensure proper barcode capture.

For reading barcodes printed on labels or documents, it is recommended to activate the light on the Scan screen. For reading barcodes from displays or refracting surfaces (e.g. glass) it is recommended to use the scanner with the light off.

The minimum barcode resolution requirements are 0.1 mm for 1D codes and 0.169 mm for 2D codes.

Supported barcodes:

1D Barcodes:

- Codabar
- Code 39
- Code 93
- Code 128
- Interleaved 2 of 5
- EAN 13

2D Barcodes:

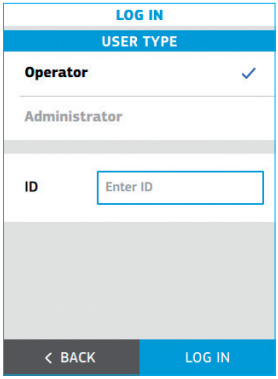
- Data Matrix
- QR Code
- PDF417
- Aztec Code

8.2 OPERATOR IDENTIFICATION (Optional)

The user performing the test may log on either through the dropdown menu or when a patient test is initiated depending on the meter's configuration (see Section 7.5). However, this step may be skipped if an operator has not been previously registered and Operator ID is configured as optional.

1. Tap on the **status bar** located at the top of the main menu and then tap on the **Log in** button to log on through the dropdown menu.

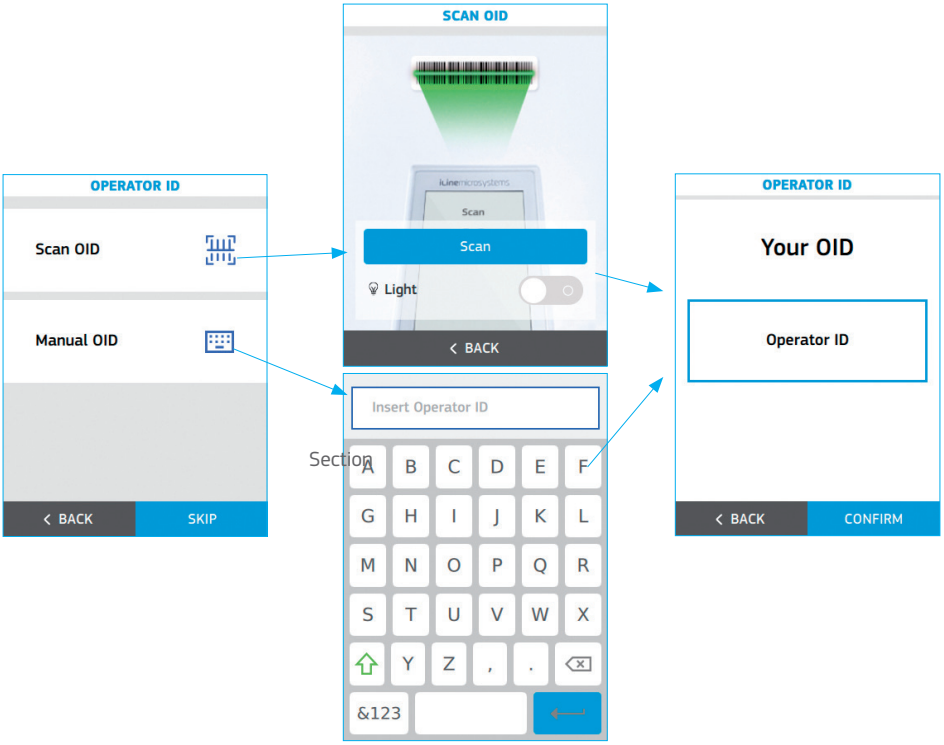
Select **Operator** in the User Type section so that the option is highlighted (bold type with a check mark) and then tap on the **Enter ID** text entry box.



Enter the identification by means of the barcode scanner by tapping the **Scan OID** button if a valid barcode is available. The identification can be also entered manually using the keypad by tapping the **Manual OID** button.

Place the barcode at a suitable distance depending on its size to enable scanning. The meter will emit a beep (provided the beeper is enabled) once the barcode has been successfully read. The barcode information appears in Your OID field. The scanner will turn off after 5 seconds if the barcode is not scanned (the meter beeps and a Scan error or time-out message is displayed).

Verify and **Confirm** the Operator ID or tap **Back** to restart the Operator identification process.

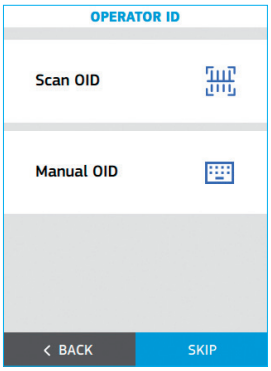


The User icon changes to green on the status bar once an operator has been identified. The operator's identification will be displayed on the dropdown menu.

Tap the **Log out** button in the dropdown menu and restart the operator identification process if another operator intends to use the meter.

Each time the meter is turned off, the identified operator will be automatically logged out.

When entering the OID to a result, do not include patient or operator sensitive information (name, age, etc.) as it will be stored in the meter and can be viewed.



2. Depending on the meter's configuration (see Section 7.5), when a patient or QC test is initiated the meter automatically displays the operator's log-on identification options through the barcode scanner and the manual option with the keypad.

Enter the identification through the barcode scanner if a valid barcode is available by tapping the **Scan OID** button. The identification can be also entered manually using the keypad by tapping the **Manual OID** button.

Verify and **Confirm** the Operator ID entered or tap **Back** to restart the Operator identification process.

The user icon changes to green on the status bar and the meter continues with the patient's identification (depending on the configuration described in Section 3.3) or with identification of the QC material once an operator has been identified.

Tap the **Log out** button in the dropdown menu and restart the operator identification process if another operator intends to use the meter.

Each time the meter is turned off, the identified operator will be automatically logged out.

8.3 PATIENT IDENTIFICATION (Optional)

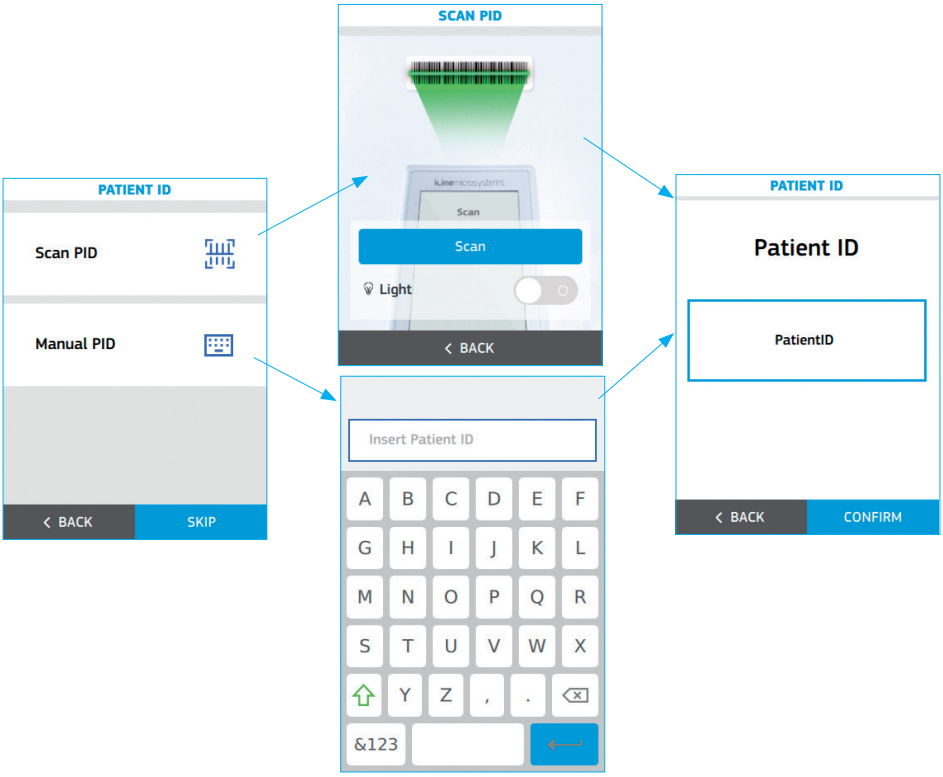
The meter may also request a Patient ID depending on the meter's configuration (see Section 7.5). but you may proceed to the next step if this option is configured as optional.

The Patient ID can be entered if necessary, by tapping the **Scan PID** button to use the barcode scanner. The identification can be also entered manually using the keypad by tapping the **Manual PID** button.

Place the barcode at a suitable distance to enable scanning. The meter will emit a beep (if enabled) once the barcode has been successfully read. The barcode information appears in the Patient ID field. The scanner will turn off after 5 seconds if the barcode is not scanned (the meter beeps and a Scan error or timeout message is displayed).

Verify and **Confirm** the Patient ID entered or tap **Back** to restart the Patient identification process.

When entering the PID to a result, do not include patient or operator sensitive information (name, age, etc.) as it will be stored in the meter and can be viewed.



8.4 QUALITY CONTROLS (Optional)

The microINR System provides Quality Controls on every test.

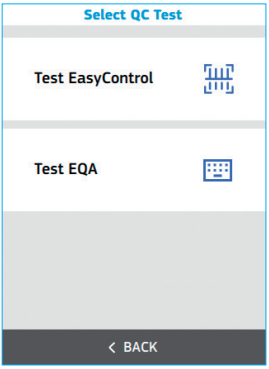
First, microINR Expert meter performance is automatically checked for electronic components, correct power battery level and environmental temperature conditions.

Then, on-board controls provide a quality control check for each individual microINR Chip used with the microINR Expert meter. microINR System has been designed to detect errors prior to and during the test in order to prevent inaccurate INR results through a multi-level strategy.

These quality controls are performed automatically, so it is not necessary to run extra quality controls.

Additionally, optional liquid controls can be analyzed in the meter. The microINR EasyControls can be provided to help meet the regulatory requirements if applicable to your facility. If your facility requires microINR EasyControls, please contact your local distributor.

8.4.1 PERFORMING microINR EasyControl TEST



Check the meter status information before performing a microINR EasyControl test:

- Check the battery level. See Section 2.5 of these instructions for battery-related information.
- Ensure the time and date are properly set. See Section 7.4 to change the time and date if necessary.
- Reconstitute the plasma control, following the microINR EasyControl Instructions for Use.

Tap the **Quality Control** option and then **Test EasyControl** to start performing a control test.

Operator ID & microINR EasyControl lot ID

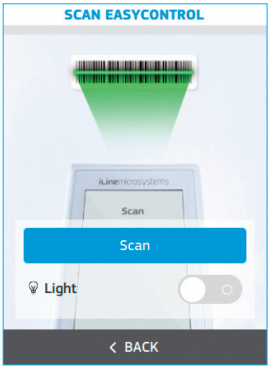
If an Operator ID is required by the administrator, follow the steps in Section 8.2 to enter the OID.

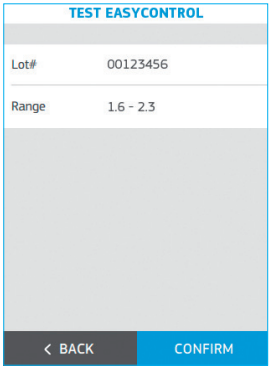
The meter will request the microINR EasyControl lot identification. Enter the identification by means of the barcode scanner by reading the 2D barcode located at the back of the microINR EasyControl Instructions for Use. The microINR EasyControl lot identification cannot be entered manually with the keypad.

Place the barcode at a suitable distance to enable scanning. The meter will emit a beep (if enabled) once the barcode has been successfully read.

The meter displays the microINR EasyControl lot information with the lot number, the expiration date and the acceptance values range.

Verify and **Confirm** the microINR EasyControl lot information or tap **Back** to restart the microINR EasyControl identification process.





Conducting the test

To perform the test, follow the instructions provided in Section 3 above and always follow the microINR EasyControl instructions.

Comments can also be added to these tests as mentioned in Section 3: Custom comments up to 30 characters in length can be entered and there are also 4 selectable predefined comments.

Used chips, pipettes, and gloves may be a source of infection.
Dispose of these materials according to your policy and the appropriate local regulations.

8.4.2 PERFORMING EQA CONTROL / PROFICIENCY TESTING

External Quality Assessment (EQA) programs or Proficiency are sometimes required as part of the quality assurance programs of certain organizations.

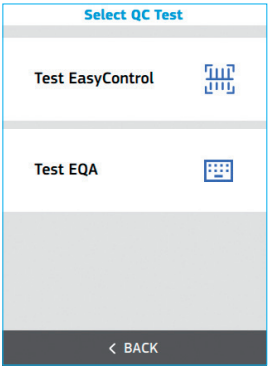
Always follow the applicable regulations and protocols of the competent agencies when performing EQA tests.

The compatible EQA control materials for the microINR System are the microINR EasyControl materials.

Check the following meter status information before performing an EQA test:

- Check the battery level. See Section 2.5 of these instructions for battery-related information.
- Ensure the time and date are properly set. See Section 7.4 to change the time and date if necessary.
- Prepare the EQA control material following its instructions.

Tap **Quality Control** and then **Test EQA** to start performing a control test.

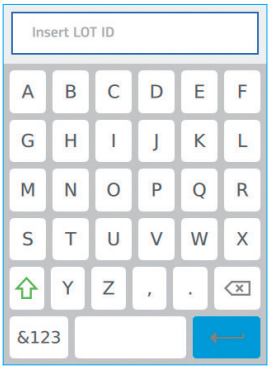


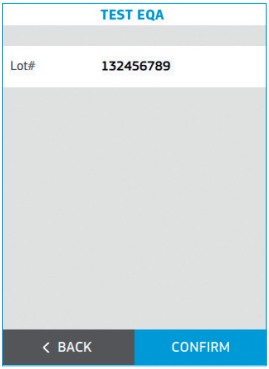
Operator ID & EQA Control lot ID

If an Operator ID is required by the administrator, follow the steps in Section 8.2 to enter the OID.

The meter will then request identification of the EQA control lot. Enter the identification manually through the keypad by tapping the LOT ID text entry box. EQA control lot identification cannot be entered by the barcode scanner.

The meter displays the microINR EQA control lot number. Verify and **Confirm** the EQA lot information or tap **Back** to restart the EQA lot identification process.





Conducting the test

To perform the test, follow the instructions provided in Section 3 above and always follow the microINR EasyControl instructions.

Comments can also be added to these tests as mentioned in Section 3: Custom comments up to 30 characters in length can be entered and there are also 4 selectable predefined comments.

Used chips, pipettes, and gloves may be a source of infection.
Dispose of these materials according to your policy and the appropriate local regulations.

8.5 DATA HANDLING (Optional)

The microINR Expert meter can be connected to a computer or host system (DMS) through various channels. The meter connectivity settings are available at the **Settings** option on the main menu (see Section 7.7). The administrator must be logged on to set or modify the connectivity settings.

The data handling function may vary depending on the Data Management System (DMS). Please contact your local distributor for further information on the DMS compatible with the meter and configuration required for connection.

The meter can connect to a DMS when at least one of the meter communication channels is available and set.

The following communication channels are available on the microINR Expert:

- Wi-Fi
- Bluetooth
- Ethernet

Wi-Fi and Ethernet connectivity cannot be enabled at the same time.

The connection between meter and DMS enables:

- Transfer of all stored results with their associated Patient ID, Operator ID, and comments from the meter to the DMS. This data transfer enables further assessment or proper storage.
- Transfer of patient and/or operator lists from the DMS to the meter.
- Transfer of the current date and time from the DMS.

8.6 Wi-Fi (Optional)

The microINR Expert can communicate wirelessly with a DMS through a specific Wireless Local Area Network (WLAN) or Wi-Fi.

WLANs use electromagnetic waves in the 2.4 GHz frequency range. The microINR Expert supports IEEE 802.11 b/g/n wireless connectivity. During wireless communication to an Access Point (AP), the meter recognizes this AP and automatically transmits data using the POCT1-A2 communication protocol.

The microINR Expert meter's bandwidth consumption is minimal since it is only activated during data transfer.

Poor WLAN connectivity will not impact the functionality of the meter but may delay the communication of results to the DMS. Users should keep in mind that real-time data communication cannot be guaranteed by the microINR Expert meter as it depends on various external factors such as the type and number of connected devices, the performance of the Access Point, the distance to the Access Point, the presence of electromagnetic disturbances and other potential interferences.

If the meter is using Wi-Fi connectivity, it will attempt to connect to the DMS one minute after the meter is turned on and every 10 minutes while the meter is on, whether or not there are test results to be sent.

In addition, the meter will attempt to establish a connection with the DMS immediately after confirming or rejecting a test result for transmission.

If the DMS is not available, the meter will store the result, and this will remain pending to be sent. The meter will try to send the pending results after performing a new test or one of the DMS connection attempts described above.

Alternatively, the user can manually initiate the connection to the DMS from the dropdown menu by tapping the **Sync.** button at any time.

In line with the POCT1-A2 industry communication standard, the DMS must acknowledge the meter's request for connection and actively request the result. Only upon receipt of this DMS query will the meter send the result. The following information may be sent by the meter via POCT1-A2:

- Correlation number: as unique Id for each test.
- Time and date at which the result was obtained.
- Meter ID.
- Test type: patient, microINR EasyControl or EQA.
- OID: max. 20 characters.
- PID or LOT: max. 20 characters.
- microINR EasyControl test: Lot ID, expiration date and the acceptance range.
- Patient result: INR + PT values or error message.
- microINR EasyControl and EQA results: INR value or error message.
- Comments added to the result.
- Confirmed or rejected result.
- Chip Lot code and its expiration date.

8.7 BLUETOOTH (Optional)

The meter can transfer results to electronic devices (smartphones, tablets, or computers) via Bluetooth.

microINR Expert enables data transfer to DMS or suitable smartphone/tablet apps.

Bluetooth is a form of radio frequency (RF) technology that operates in the unlicensed industrial, scientific, and medical band at 2.5 GHz. The meter uses a proprietary Bluetooth communication protocol based on the ISO/IEEE 11073.

The microINR Expert meter can only communicate with one compatible paired electronic device at a time; therefore, other devices with Bluetooth cannot access the information on the meter unless the paired meter is unpaired and paired to a new electronic device.

In the event of electromagnetic interference with another device it is recommended to increase the distance between the meter and said device. You could also shut the interfering device down.

The meter will only be able to transmit results via Bluetooth if they have been obtained with the Bluetooth setting activated. If results are obtained when Bluetooth is deactivated, they cannot be subsequently sent via Bluetooth.

The microINR Expert meter with Bluetooth connectivity active can be paired with a compatible device in two different configurable modes:

- Free mode: to pair the meter just follow the instructions on the compatible software or smartphone/ tablet app.
- Password mode: the microINR Expert meter shows a 6-digit password. Type the password on the compatible device and follow the software or app instructions.

The microINR Expert meter with Bluetooth-enabled connectivity will communicate results after every test.

The information sent by the meter via Bluetooth includes:

- Correlation number: as unique ID for each test.
- INR value or error message
- Time and date
- Meter ID
- Sample type: blood (for patient results) or plasma (for EasyControl or EQA results)
- PID: max. 16 characters. The meter will not send this information if the PID length exceeds 16 characters.

The meter will attempt to connect to the DMS or app immediately after the test has been confirmed or rejected.

If the paired device is not available, the meter will store the result, and this will remain pending to be sent. The meter will try to send the pending results after performing a new test or when the **Sync.** button in the dropdown menu is pressed.

In line with the ISO/IEEE 11073 industry communication standard, the DMS or app must acknowledge the meter's request for connection and actively seek the result.

The microINR Expert meter can also transfer all the test results stored by tapping the **Send Data** option in the Bluetooth Settings menu.

8.8 ETHERNET (Optional)

The microINR Expert can communicate through a wired Ethernet connection to a Local Area Network (LAN) when connected to the Ethernet adapter (available separately).

Ethernet is the technology for connecting devices in a wired local area network (LAN) or wide area network (WAN), enabling them to communicate with each other via a defined communication protocol.

The Ethernet adapter consists of a hardware unit with a RJ45 connector and an integrated USB-C cable to connect to the microINR Expert meter.

If the meter is using Ethernet connectivity, it will attempt to connect to the DMS one minute after the meter is turned on and every 10 minutes while the meter is on, whether or not there are test results to be sent.

In addition, the meter will attempt to establish a connection with the DMS immediately after confirming or rejecting a test result for transmission.

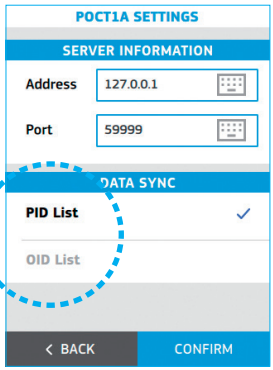
If the DMS is not available, the meter will store the result, and this will remain pending to be sent. The meter will try to send the pending results after performing a new test or one of the DMS connection attempts described above.

Alternatively, the user can manually initiate the connection to the DMS from the dropdown menu by tapping the **Sync.** button at any time..

In line with the POCT1-A2 industry communication standard, the DMS must acknowledge the meter's request for connection and actively request the result. Only upon receipt of this DMS query will the meter send the result. The following information may be sent by the meter via POCT1-A2 for each result:

- Correlation number: as unique Id for each test.
- Time and date at which the result was obtained.
- Meter ID.
- Test type: patient, microINR EasyControl or EQA.
- OID: max. 20 characters.
- PID or LOT: max. 20 characters.
- microINR EasyControl test: Lot ID, expiration date and the acceptance range.
- Patient result: INR + PT values or error message.
- microINR EasyControl and EQA results: INR value or error message.
- Comments added to the result.
- Confirmed or rejected result.
- Chip Lot code and its expiration date.

8.9 OPERATOR & PATIENT LISTS (Optional)



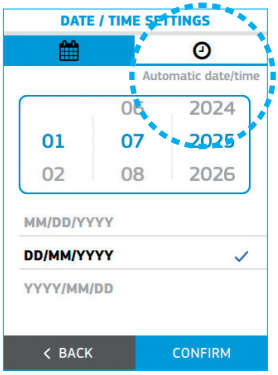
The meter has three different management modes for operator and patient identification. Depending on these configurations, the meter may require an operator and/or patient ID before performing a test (see Section 7.5).

The meter may also receive an operator and/or patient list from a DMS. When working with operator and/or patient lists the device can limit its use to those in the lists.

Select the **Operator list** and/or **Patient list** in the POCT1A settings in the Settings options (see Section 7.7) to enable these options.

In case of issues with PID or OID sent through the DMS, please contact your DMS provider.

8.10 AUTOMATIC DATE / TIME (Optional)



The meter may automatically receive the date and time from the DMS. Please contact your local distributor or your DMS provider to enable this option.

An "Automatic date/time" message is displayed in the Date and Time setting (Section 7.4) if the meter receives the date and time from the DMS.

9. ADDITIONAL INFORMATION

9.1 SPECIFICATIONS

- Dimensions of the meter: 6.46 x 2.76 x 1.69 in.
- Weight: 13.05 oz (battery included).
- Interface: High resolution capacitive color touchscreen (3.5 in) and barcode reader.
- Memory: 2,000 patient results / 500 plasma control results with their date and time.
- Power supply:
  - Battery: Lithium 5,900mAh; 3.7 V
  - Power supply: only use the power supply provided by the manufacturer.
  - Input: 100-240V, 50-60 Hz, 0.6 A
  - Output: 5V dc, 3A
- Battery life: *approximately 100 tests.
- Automatic power-off: programmable 5-15-30-45 or 60 min.
- Operation conditions:
  - Temperature: 59 ºF - 95 ºF.
  - Maximum relative humidity: 80% (with no condensation).
  - Maximum altitude: 10,000 ft.
  - Keep the meter away from direct sunlight during the test.
- Measurement range: 0.8 – 8.0 INR.
- Sample volume: at least 3 µL.
- Bluetooth: Low Energy 5.0 backwards compatible with 4.X versions. Data transfer via Bluetooth through proprietary communication protocol based on the standard ISO/IEEE 11073-10418.
- Wi-Fi: IEEE 802.11 b/g/n wireless connectivity. Data transfer via Wi-Fi through communication protocol standard POCT1-A2.
- Ethernet: data transfer through communication protocol standard POCT1-A2 and when connected to the Ethernet adapter (available separately).
- Memory data extraction via USB-C connection.

*Test conducted at 72 ºF with a 10-minute period between tests.

9.2 STORAGE CONDITIONS

- It is recommended to store the microINR Expert meter in the same environment in which it is used and keep it in its transport case when not use.
- Do not store the meter in direct sunlight or under extreme temperature conditions.
- The storage temperature range is between -4 ºF and 122 ºF.
- The storage relative humidity is below 80% (with no condensation).

9.3 TRANSPORT CONDITIONS

- Always transport the meter inside its transport case.
- The meter may be transported within a temperature range between -4 ºF and 122 ºF.
- It should not be transported in relative humidity in excess of 80% (with no condensation).

9.4 WARRANTY

iLine Microsystems warranties to the original buyer that the microINR System is free of material and manufacture defects for one year after the purchase date.

This warranty does not cover any component damaged due to inadequate storage in environmental conditions outside the defined range, accidents or modifications, incorrect use or handling and misuse. The buyer must deliver a written warranty complaint to the manufacturer within the corresponding warranty period.

9.5 SOFTWARE LICENSE

This product incorporates software modules developed under open source licenses.

The license conditions are available (in English only for legal reasons) as a text file (file name "SWL0002EN") under request at the iLine Microsystems information email: info@ilinemicrosystems.com

Everyone is permitted to copy and distribute verbatim copies of this license document, but changing it is not allowed.

9.6 TECHNICAL SERVICE

For healthcare professionals: If you need technical help, contact your local distributor.

For self-testing patients: if you have any questions, please contact your healthcare provider.

9.7 SYMBOLS

The following symbols may be found on the packaging materials and product labels:

	"Manufacturer"
SN	"Serial number"
REF	"Catalogue number"
	"Consult instructions for use"
IVD	"*In-vitro* diagnostic medical device"
	"Direct current"
	"Temperature limit"
LOT	"Batch code / Lot number"
	"Biological risks"
	"Class II Equipment"
	"Caution (consult accompanying documents). Refer to safety-related notes in the manual accompanying this instrument''.
℞ only	"Prescription Use Only"
GTIN	"Global Trade Item Number"
FCC ID	"Federal Communications Commission Identification"
IC	"Industry Canada"

10. INDEX

ANNEX I. ELECTROMAGNETIC COMPATIBILITY/SAFETY REQUIREMENTS/ RADIO COMPLIANCE INFORMATION

Electromagnetic emissions

The microINR System is intended for use in the electromagnetic environment specified below. microINR System's users should check that it is used in such an environment.

Emission's test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1 (confirm)	The microINR System's RF emissions are very low and are not likely to cause any interference in nearby electronic devices.
RF Emissions CISPR 11	Class B (confirm)	The microINR System is suitable for use in all establishments.

Electromagnetic immunity

The microINR System is intended for use in the electromagnetic environment specified below. microINR System's users should check that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV (contact) / ±15 kV (air)	±8 kV (contact) / ±15 kV (air)	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines / 1 kV for input/output lines	2 KV for power supply lines / 1 KV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±2 kV DM (line-to-earth) / ±1 kV CM (line-to-line)	±2 KV DM (line-to-earth) / ±1 KV CM (line-to-line)	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT during ½ cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT during 1 cycle and 70% UT during 25/30 cycles Single phase at 0° UT is the a.c. mains voltage prior to application of the test level	0% UT during ½ cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT during 1 cycle and 70% UT during 25/30 cycles Single phase at 0°UT is the a.c. mains voltage prior to application of the test level	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical domestic, commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V rms 150 kHz to 80 MHz in ISM an amateur radio band	3 V rms 6 V rms	Interference may occur in the vicinity of equipment marked with following symbol: 
Radiated RF IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	10 V/m	

The user of the microINR System can help prevent electromagnetic interference by maintaining a minimum distance between other portable/mobile RF communications equipment (transmitters) and the microINR System at least 30 cm (about 12 inches).

Immunity to proximity fields from RF wireless communications equipment:

The microINR Expert meter includes the following optional wireless communications:

- **Bluetooth:** Low Energy 5.0 backwards compatible with 4.X versions. Data transfer via Bluetooth through proprietary communication protocol based on the standard ISO/IEEE 11073-10418.

- **Wi-Fi:** IEEE 802.11 b/g/n wireless connectivity. Data transfer via Wi-Fi through communication protocol standard POCT1-A2.

Band (MHz)	Service	Immunity Test Level (V/m)
380-390	TETRA 400	27
430-470	GMRS 460, FRS 460	28
704-787	LTE Band 13, 17	9
800-960	GSM 800/900, TETRA 800, iDEM 820, CDMA 850, LTE Band 5	28
1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28
2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28
5100-5800	WLAN 802.11 a/n	9

FCC Part 15 User Information

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

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

Additional Recommendations:

The microINR Expert meter should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the microINR Expert meter should be observed to verify normal operation in the configuration in which it will be used. Use only the supplied charger, USB-C/USB-A cable and Ethernet adapter provided by the manufacturer or you may damage the meter. Other accessories may negatively affect EMC performance.

ANNEX II. CYBERSECURITY INFORMATION

The following cybersecurity measures and instructions are designed to ensure the secure operation of the microINR Expert meter and compliance with safety standards for in vitro diagnostic devices.

Authentication and Access Control

The microINR Expert meter employs a multi-tier authentication system to regulate access. Regular operators can use an Operator ID (OID) to perform routine tests, while Administrators have credentials that allow them to manage advanced configurations such as device configuration and software updates, minimizing the risk of unauthorized interference.

Upon first use, it is essential to change the default administrator password to one that is unique and robust, as this significantly enhances the device's security posture.

Only the manufacturer and authorized personnel can access critical functionalities of the meter. iLine's proprietary Communication Protocol (not public) is necessary to access the meter critical configuration parameters and to create a compatible application that enables the information download to a compatible device. Additionally, the meter must be set into a special mode (password protected) that is only known by the manufacturer and authorized personnel.

Communication Security

All communication initiated by the microINR Expert meter is protected by robust encryption protocols and Message Authentication Codes (MACs). These measures safeguard the integrity and confidentiality of data transmitted through Bluetooth Low Energy (BLE), Wi-Fi, and Ethernet connections. Each communication channel is designed to prevent replay attacks, ensuring that transmitted commands and data exchanges remain secure. For added protection, communications are only activated by explicit user configuration.

Network Ports and Interfaces

The device includes several interfaces for connectivity and data transfer.

- The USB port allows secure data transfers and software updates, with Administrator authentication required to enable these functions.
- The Bluetooth interface supports secure pairing using modes such as PassKey to enhance user validation.
- Wi-Fi and Ethernet connectivity require an Administrator to configure secure access to specific healthcare networks or endpoints.

These configurations ensure that only authorized users and systems can interact with the device.

Infrastructure Requirements

The device must operate within a secure network environment. Wi-Fi connectivity requires WPA2 or WPA3 encryption, while Ethernet connections must meet stringent validation protocols to protect medical data. Administrators are responsible for configuring device-specific security settings, including passwords and secure server connections for transmitting results or updates. The system's design prioritizes the integrity of healthcare networks by reducing potential vulnerabilities.

Software Bill of Materials (SBOM)

The microINR Expert meter´s Software Bill of Materials (SBOM) is available upon request to provide transparency regarding its internal software components.

Software and Firmware Updates

Firmware and software updates for the microINR Expert meter are performed exclusively through USB connections to ensure a secure update process. Before installation, updates undergo strict authentication checks and digital signature validation to confirm their authenticity. The meter applies several control mechanisms to identify irregularities in the software. In the event of communication interruption or update errors, the meter automatically maintains the previous version to prevent disruption of operation and clear error messages are displayed to alert the user about the update failure and prompt them to retry.

The device does not support over-the-air updates, which eliminates vulnerabilities associated with wireless updates and ensures a controlled update environment.

The users will be informed when a new software version and/or instructions for use are available. You can check iLine´s webpage for getting the most updated information (https://www.ilinemicrosystems.com/en-us/).

Handling Anomalous Conditions

The microINR Expert meter is equipped to detect and respond to anomalous conditions, such as unauthorized access attempts or abnormal configuration changes. When such events occur, the device generates real-time alerts and logs the incidents locally. This approach ensures transparency and allows users to address potential security risks proactively.

Critical Functionality Protections

To protect its critical functionalities, the device includes automated safeguards such as auto-off settings to prevent prolonged unauthorized access. Additionally, data generated during disruptions is securely stored within the device until it can be safely transmitted. These features ensure the continuity of operations and the integrity of the device's critical functions.

Backup and Restore Procedures

The device offers comprehensive backup and restore capabilities. Administrators can erase memory contents using authenticated procedures. Predefined configurations are retained within the system to simplify recovery processes (default configuration parameters), ensuring that the device can be quickly restored to a secure operational state if needed.

Configuration Retention and Recovery

The predefined configuration is retained within the system (default configuration parameters), ensuring that the device can be quickly restored to a secure operational state if needed.

Only the manufacturer and authorized personnel can access and modify critical configuration parameters, ensuring that stored information is protected against unauthorized tampering. Recovery tools and protocols are integrated into the system for secure restoration when necessary.

Secure Device Configuration

The microINR Expert meter is shipped with secure default settings. Communication interfaces such as Wi-Fi and Bluetooth are disabled by default and must be explicitly enabled by an Administrator. Diagnostic ports are locked, and users are advised not to store sensitive information in free-text fields. These measures prevent accidental exposure of data and maintain device integrity.

End-of-Support and End-of-Life Planning

iLine Microsystems follows a proactive approach to control the end-of-support of the device´s critical components tin order to minimize operational disruptions and maintain cybersecurity standards.

Secure Decommissioning

When the microINR Expert meter is retired from the market, secure decommissioning processes are followed. Although the meter does not store any sensitive information, the Administrator can erase all public memory and any specific configuration applied to the meter (such as Wi-Fi password, server information, etc).

It is recommended to inactivate any connectivity function before shipping the meter.

Important cybersecurity information

The microINR Expert meter can communicate with a Data Management System (DMS) through wireless technology (Wi-Fi or Bluetooth) or hard-wired Ethernet through the Ethernet adapter (available separately). The microINR Expert meter can communicate and transfer results to electronic devices, such as smartphone, tablets or computers, through a wireless Bluetooth connection. The data handling function may vary depending on the particular Data Management System (DMS). Please contact your local distributor for further information on the DMS compatible with the meter and configuration required for connection.

Cybersecurity warning information

If you are the Administrator of the device, you must change the default password as a security measure.

To prevent unauthorized access or the tampering of the meter's data, be sure to keep the microINR Expert meter safe from unauthorized physical access and theft. Do not leave the meter in publicly accessible areas.

Users should be careful to use apps from reliable sources only and only connect the meter through USB cable to a secure, trusted computer. Use only the USB-C/USB-A cable and Ethernet adapter provided by the manufacturer.

Ensure that any external storage devices (such as USB flash drives, network file systems) connected to the system are free of malicious software.

Ensure that attached networks are secure and monitored for security breaches. Users are responsible for the security of their local network, especially for protecting it from malicious software and cyberattacks.

When entering a custom comment, an OID and/or a PID to a result, do not include patient or operator sensitive information (name, age, etc.) as it will be stored in the meter and can be viewed.

Only use the barcode scanner for entering the OID, PID or microINR EasyControl lot information. Do not use it for reading other information.

It is recommended to inactivate any connectivity function before shipping the meter to the manufacturer or authorized personnel.

***For healthcare professionals:** If any abnormal behavior of the microINR Expert meter is identified, please disable the Wi-Fi, Bluetooth and/or Ethernet connectivity and if applicable, disconnect the meter from the computer. Please contact your local distributor for further information.*

***For self-testing patients:** If any abnormal behavior of the microINR Expert meter is identified, please disable the Wi-Fi, Bluetooth and/or Ethernet connectivity and if applicable, disconnect the meter from the computer. Please contact your healthcare provider for further information.*

iLine Microsystems is not responsible for data access restrictions, processing delays, or security risks arising from third-party apps or platforms used to receive or store device data. iLine Microsystems is not liable for unauthorized access, misuse of data or failure to comply with data protection obligations by third parties or distributors.

Charge completely the battery of the meter before its first use.

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