micro**INR**®
expert

INSTRUCTIONS FOR USE

iLine® microsystems — friendly technology

PUBLICATION INFORMATION

Revision	Changes
2022-09	New document

microINR expert ®

microINR® Expert Meter
For monitoring oral anticoagulation treatment based on Vitamin K antagonist drugs.

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English

1. INTRODUCTION

1.1 INTENDED USE

The microINR system (Expert), consisting of the microINR Expert meter and the microINR Chips, is intended to monitor oral anticoagulation therapy (OAT) with vitamin K antagonist drugs. The microINR system (Expert) determines quantitative prothrombin time (PT) – INR (International Normalized Ratio) units with fresh capillary blood obtained by fingersticking.

The microINR Expert meter is a medical device for *in-vitro* diagnostics intended for multiple-patient use by professional healthcare providers.

1.2 BEFORE USING THE microINR® SYSTEM

These Instructions for Use provide guidelines on handling and use of the microINR Expert meter. Please read them and the Instructions for Use of the microINR Chips carefully before using the device. There is a USB flash drive containing these instructions in various languages among the items provided with this meter.

Make sure you also read the instructions of the disposable lancets and/or lancing device used to obtain the capillary blood sample. These products are not provided with microINR Expert meter.

The term "microINR Expert meter" refers to the reader device.

The term "microINR Chips" refers to the test strips intended to be used exclusively with microINR meters (microINR, microINR Link and microINR Expert meters).

The microINR system (Expert) refers both to the microINR Expert meter and the test strips (microINR Chips) and it is intended to be used for near-patient testing and not for self-testing.

Keep these instructions in a convenient place near the microINR Expert meter and refer to them if you have any queries about proper operation of the system.

The microINR Expert meter is equipped with a touchscreen that displays information and icons about the meter usage and test results. Users can work with this touchscreen while wearing latex or nitrile gloves.

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 adaptor (available separately). 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.

You will find a terminology index at the end of these Instructions for Use.

Safety Instructions

This section describes the system safety-related messages and information and how they are presented in these Instructions for Use.

General Safety Warnings

You will find safety warnings and information on proper use of the microINR system (Expert) throughout this document.

This warning symbol indicates a potential hazard that could result in death, injury or harm to the patient or user if the procedures and instructions contained herein are not strictly followed.

This precaution symbol indicates a hazard that could damage the equipment and cause data loss if the procedures and instructions contained herein are not strictly followed.

Important information regarding proper use of the system that does not affect the safety of the patient or the integrity of the device is displayed on a blue background.

User qualification

⚠️ *Users of the microINR Expert meter must receive proper training before using the system.*

Infection Risk Control on Multi-Patient Test System

• Users must wear gloves during the entire testing process.

• A new lancet or lancing device must be used for each patient.

• Used chips, lancets and gloves could be source of infection. Dispose of them in accordance with local regulations to prevent infection.

• Also comply with your center's internal hygiene and safety regulations.

⚠️ *There is a potential risk of infection. Healthcare professionals using the microINR system (Expert) on multiple patients must bear in mind that all objects that come into contact with human blood are a possible source of infection.*

Electromagnetic Compatibility and Electrical Safety

The microINR Expert meter complies with electromagnetic compatibility (EMC) requirements according to the IEC 61326-1 and 61326-2-6 standards.

The microINR Expert meter complies with electrical safety requirements according to the IEC 61010-1 and IEC 61010-2-101 standards.

Any external device connected to the meter must meet the IEC61010, IEC62368 requirements or the appropriate component end-product standard.

The microINR Expert meter should not be used adjacent to or stacked with other equipment and if it must be stacked or used in this way the microINR Expert meter must then be examined to verify normal operation in the configuration in which it will be used.

Always use cables and accessories provided by the manufacturer. Other cables and accessories may negatively affect EMC performance.

Avoidance of electrical shock

⚠️ *Do not use cables, chargers and plug adapters different from those provided by the manufacturer. If you do not follow this requirement, you may damage the meter or yourself. Do not use loose power sockets or damaged power source units or cables.*

Lithium-ion battery

The microINR Expert meter contains an internal lithium-ion battery. Fully charge the battery before using the meter for the first time. The recommended charging time is approximately 3.5 hours.

⚠️ *Do not open or tamper with the meter.*

Do not pierce or burn the battery.

Do not change the battery. The manufacturer's warranty will not cover meters that have been opened.

The unit must be sent to the manufacturer for battery replacement or repairs to the meter.

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.*

Disposal of the meter

⚠️ *The meter must be disposed of as indicated in the applicable local and/or national regulations. Bear in mind that:*

• *Used meters may have been in contact with blood and therefore could be a source of infection.*

• *The meter contains lithium-ion batteries.*

The meter must be disposed of as indicated in the European WEEE Directive and/or local waste disposal requirements.

Operating conditions

Use the meter according to the following guidelines to ensure that it works properly:

- *Only use the meter at room temperature between 15ºC and 35ºC.*
- *Only use the meter at a relative humidity below 80% without condensation.*
- *Place the meter on a flat, stable surface during testing or hold it in your hand and avoid sudden movements.*
- *Keep the meter away from direct sunlight during the test.*
- *Do not shake or drop the meter. Contact your distributor if the frequency of error messages increases after the device has been dropped or has suffered an impact.*
- *Only use the meter at indoor settings with a pollution degree of 2.*

Quality controls

The microINR system (Expert) performs automatic quality controls on every test.

Electronic quality control

The microINR Expert meter carries out automatic checks on electronic components, battery power level and ambient temperature conditions when the system is turned on.

Integrated independent on-board quality controls

On-board controls provide quality control checks for each individual microINR Chip used with the microINR Expert meter throughout testing.

Level 1 – Pre-test

- Chip integrity check
- Proper insertion check
- Automatic system calibration and rejection of expired chips

Level 2 – Measuring channel

- Analytic verification of measurement for proper pre-analytical treatment of the sample and failures in processing the sample during the test.

Level 3 – Control channel

- The control channel provides highly-controlled clotting times. The system's reliability is guaranteed when the control clotting time is within a pre-defined range.

Liquid control

iLine Microsystems provides an optional liquid control (microINR EasyControl) for the microINR systems. This control is provided to help meet the regulatory requirements applicable to your facility. Contact your local distributor if you wish to acquire it.

1.3 ORAL ANTICOAGULANT THERAPY

Oral anticoagulant therapy is prescribed 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 periodically monitor and adjust the doses for each patient on the basis of a blood test.

A therapeutic range is defined for each patient depending on the condition requiring oral anticoagulant therapy. This means that the test result should lie within a certain range.

The therapeutic range (INR range) will be established by the patient's healthcare provider on the basis of the patient's clinical condition.

Prothrombin Time and INR

The activity of the vitamin K antagonist drugs is monitored by measuring the prothrombin time (PT) – the time it takes for a fibrin clot to form – in seconds. Thromboplastin is used as a reagent to calculate the prothrombin time (PT). Variations of the PT results are to be expected depending on the nature of this reagent and the equipment employed. Therefore, the World Health Organization (WHO) recommended a system standardization method in 1977. Prothrombin time values are converted into INR values (International Normalized Ratio) using the following equation:

$$INR = \left(\frac{PT}{MNPT} \right)^{ISI}$$

where PT is the prothrombin time obtained in the test, MNPT is the mean normal prothrombin time and ISI the international sensitivity index associated with the thromboplastin. The values of the MNPT and ISI parameters are taken from clinical calibration studies.

> The pharmacological activity of vitamin K-antagonist oral anticoagulants can be modified by other drugs. Consequently, patients should only take the medicines prescribed by a physician.
>
> Certain liver diseases, thyroid disorders and other diseases or conditions and nutritional supplements, medicinal herbs or diet changes can affect the therapeutic activity of oral anticoagulants and INR results.

1.4 MEASURING PRINCIPLE

The technology used by the microINR system (Expert) is based on the microfluidics of the microINR Chip, which enables storage, dosage, moving and/or mixing small volumes of fluids to obtain a chemical reaction.

The microINR Chips contain two channels, one for measurement and one for control. An image of the chip is shown below:
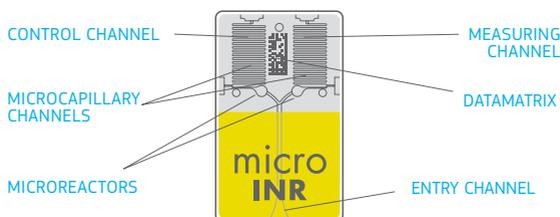
Each channel consists of a micro-reactor that contains the reagent and microcapillaries where the PT is determined. The reagent used in the measuring channel contains human recombinant thromboplastin and the reagent in the control channel contains recombinant thromboplastin and human coagulation factors to normalize the patient's blood.

The blood is applied to the chip through the entry channel which is divided into two channels and mixed with the reagents contained in each micro-reactor. The coagulation cascade is triggered instantly. When 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 the position is transformed mathematically into speed and acceleration curves from which PT-INR values are obtained.

Calibration

Each batch of microINR Chips has been calibrated against a reference batch of human recombinant thromboplastin traced to International Reference Thromboplastin of the World Health Organization[1].

These calibration values (ISI and MNPT) are encoded in the printed Datamatrix of each microINR Chip. Therefore, every test is automatically and individually calibrated, thus eliminating any risk of human error.

(1) WHO Expert Committee on Biological Normalization. Report forty-eight. Geneva, World Health Organization, 1999 (WHO technical report series No. 889)

2. microINR Expert METER

2.1 microINR Expert KIT DESCRIPTION

The microINR Expert kit includes:

• microINR Expert meter
• Charger
• Plug adapter
• USB-C cable
• Instructions for Use in English
• USB Flash driver (contains PDF files of the Instructions for Use in other languages)
• Transport Case

The Instructions for Use in English are also available in iLine Microsystems S.L. webpage:
https://www.ilinemicrosystems.com.

Printed copies of the Instructions for Use in other languages can be made available.
Please contact your local distributor for further assistance.

microINR Chips and the ethernet adaptor are sold separately.

(!) *Always carry or keep the meter inside its case.*

2.2 microINR Expert METER ELEMENTS

A: Touchscreen
B: Chip insert slot
C: USB-C port

D: Barcode scanner
E: On/Off 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 into the insertion slot.
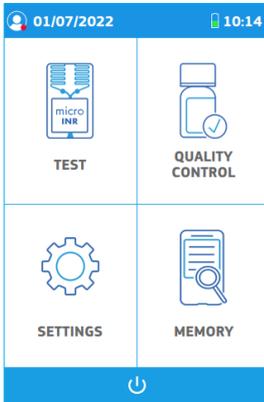
The meter can also be switched on by connecting it to the power source, ethernet adaptor or a computer through the USB-C cable.

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.

The meter will be turned off if the On/Off button is pressed for a longer-than-usual time (10-15 seconds).

2.4 CHARGING THE microINR Expert METER

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

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.

> *Do not use cables, chargers and plug adapters different from those provided by the manufacturer. If you do not follow this requirement, you may damage the meter or yourself. Do not use loose power sockets or damaged power source units or cables.*

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.

2.5   MENU ICONS OVERVIEW

User logged off		Off button	**pm**	Time between noon and midnight (in 12-hour time format)
User logged on		Data synchronization	**INR**	Results are displayed in INR units
Wi-Fi		Data synchronization failed	**s**	Results are displayed in seconds
Bluetooth		Return to main menu		Reports troubleshooting when an error message is triggered
Ethernet		Section blocked		Delete; for custom comments
USB		Option enabled		Search; for Memory menu
Battery		Option disabled		Calendar icon; for Setting menu
The meter is connected to the power supply	**am**	Time between midnight and noon (in 12-hour time format)		Clock icon; for Setting menu

2.6   STATUS BAR AND DROPDOWN

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 be only 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 again on the **status bar** to return to the main menu.
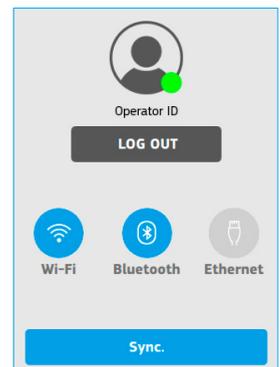
2.7 OPERATOR IDENTIFICATION

The user who performs the tests may log on either through the dropdown menu or when a patient or QC test is initiated, depending on the meter's configuration (see section 3.3).

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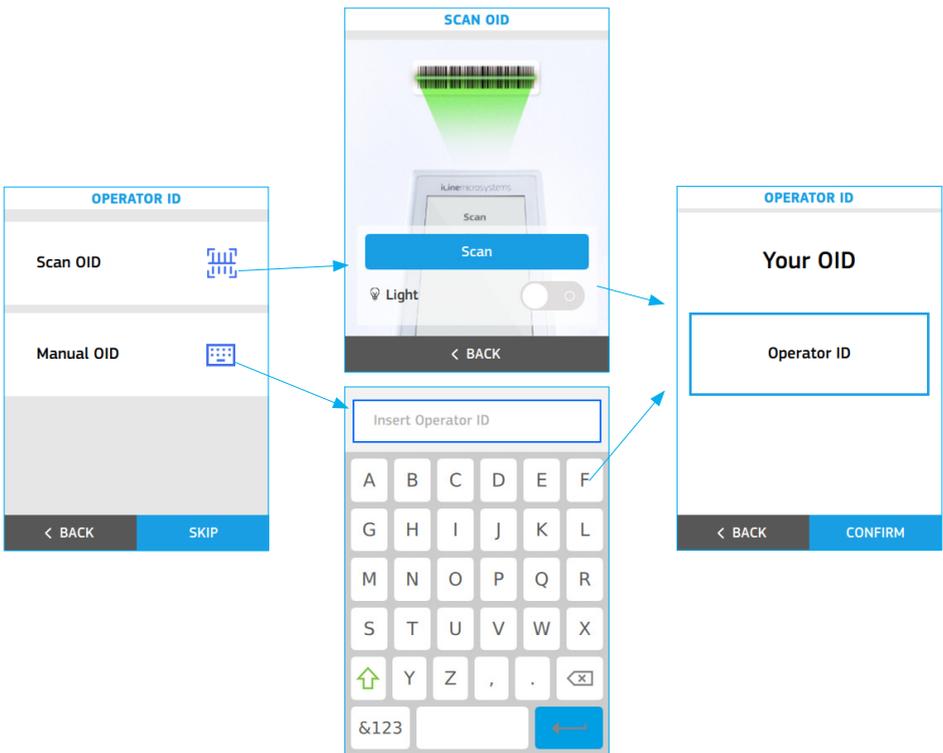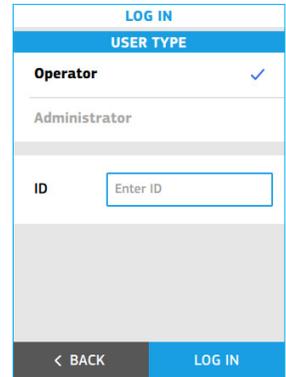
The User icon changes to green on the status bar once an operator has been identified. The operator's identification will be displayed on the dropdown menu.

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.

2. Depending on the meter's configuration (see section 3.3), 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.
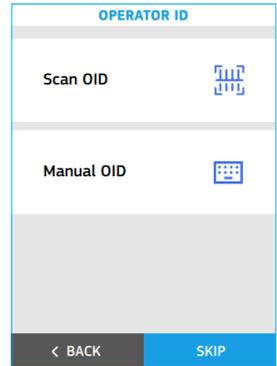
2.8   ADMINISTRATOR IDENTIFICATION

The administrator has special credentials to access the meter or 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 the **Log in** button in the dropdown menu to enter the administrator identification.

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 3.3). Changing the predefined administrator password is recommended as a security measure.
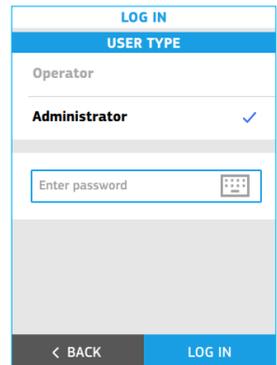
Key in the proper password using the keypad and confirm the administrator identification by tapping the **Log in** button.

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.

3.1 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 entered or changed by the administrator. If the administrator is not logged on, these options will be clearly marked in grey with a padlock symbol.

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

SETTINGS	
Meter Settings	>
ID Setup	🔒 >
EasyControl Settings	🔒 >
Connectivity	🔒 >
About	>
⌂	

Administrator logged-off

SETTINGS	
Meter Settings	>
ID Setup	>
EasyControl Settings	>
Connectivity	>
About	>
⌂	
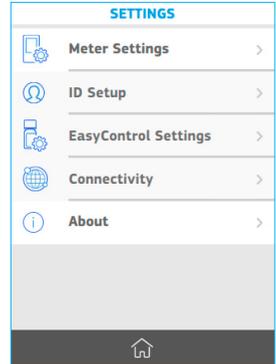
Administrator logged-on

Menu	Submenu	Setting	Values
Meter settings	Screen & Sound	Brightness	1-10 (5*)
		Beeper	ON* / OFF
	Result		INR*
			INR + PT
	Language		Español
			English*
			Deutsch
			Française
			Italiano
			Dansk
			Nederlands
			Norsk
			Português
			Suomi
			Svenska
	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	ON* / 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 / Number of tests
		Lockout Mode	Enable test with QC Warning
			Meter lockout
Connectivity	Ethernet	ON / OFF*	
	Wi-Fi	ON / OFF*	
		My Network	Network
			User
			Password
			Test connection
	Bluetooth	ON / OFF*	Pair:
			Free mode / Password mode
			Unpair
			Sent data
	POCT1A	ON / OFF*	
		Server information Data Sync	Address
			Port
			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.

3.2 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 entered or changed by the administrator. If the administrator is not logged on, these options will be clearly marked in grey with a padlock symbol
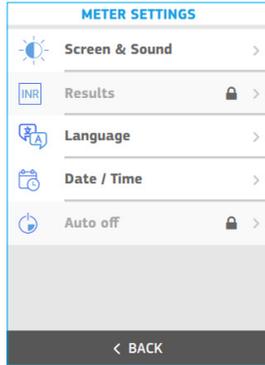
Administrator logged-off
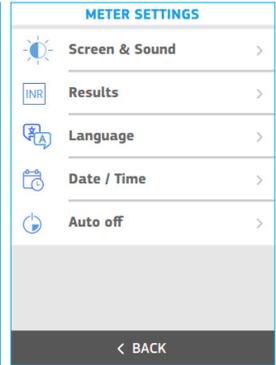
Administrator logged-on

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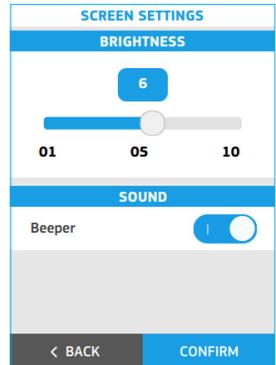
Tap **Confirm** to save this setting or tap **Back** to return to the previous screen without saving the changes.

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.
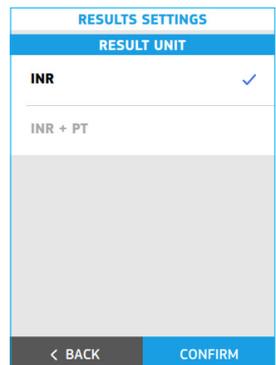
LANGUAGE

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
- Deutsch
- Français
- Italiano
- Dansk
- Nederlands
- Norsk
- Português
- Suomi
- Svenska

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 DD/MM/YYYY by default.

Tap the selected date format on the screen:

- MM/DD/YYYY: Month/Day/Year, e.g., 09/29/2022
- DD/MM/YYYY: Day/Month/Year, e.g., 29/09/2022
- YYYY/MM/DD: Year/Month/Day, e.g., 2022/09/29

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 24-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.
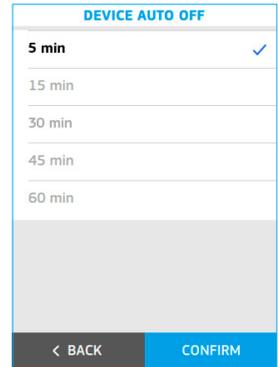
3.3 ID SETUP

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 enter and 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 8.6 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 8.6 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.
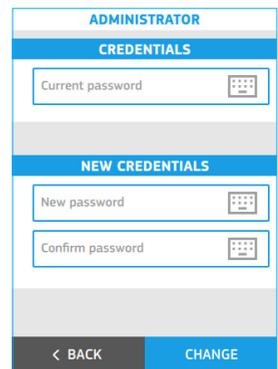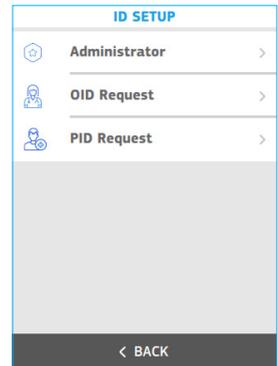
Operator ID (OID) configuration:

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 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 optional by default.

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

3.4   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
- 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.
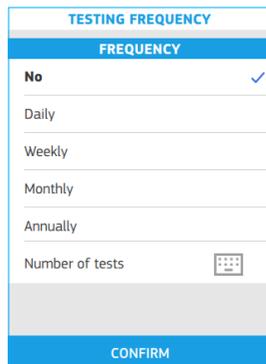
3.5 CONNECTIVITY

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 adaptor (available separately) to communicate with a Data Management System (DMS) through the Ethernet.

It is also necessary to configure the POCT1A settings to communicate with a DMS via Ethernet.
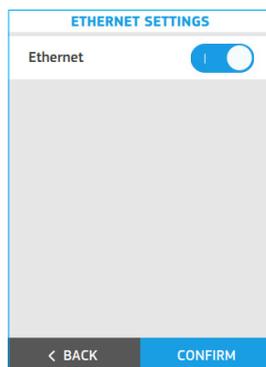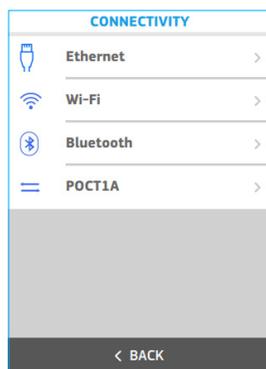
Wi-Fi: The microINR Expert meter can communicate and transfer results to a DMS by Wi-Fi to a specific Access Point (AP) Wireless Local Area Network (WLAN). The meter recognizes the existing AP WLAN protocol configuration (802.11b, 802.11g or 802.11n) and automatically transmits data using the POCT1-2A 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.
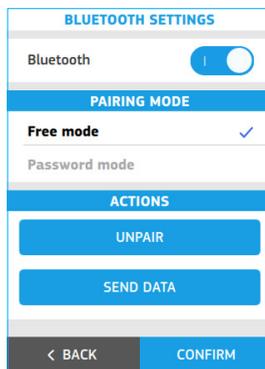
Notice that the meter will only be able to transmit results via Bluetooth if they have been obtained with the Bluetooth setting activated. If results are obtained when the Bluetooth is deactivated, they cannot be subsequently sent via Bluetooth.

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 lists** 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.
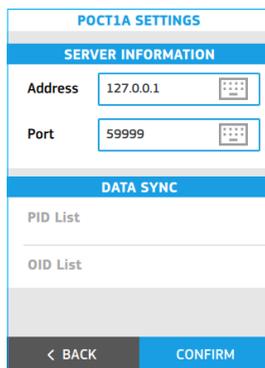
3.6 ABOUT THIS SYSTEM

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).

ABOUT THE SYSTEM		
ⓘ System updates	🔒	›
SOFTWARE VERSION		
A7 0.0.0	**M4**	0.0.0
DSP 0.0.0	**BT**	0.0.0
MORE INFORMATION		
HW Version xxx-xxx-xxx		
SN 000-000-000		
Battery 5900 mAh		
‹ BACK		

ABOUT THE SYSTEM		
DSP 0.0.0	**BT**	0.0.0
MORE INFORMATION		
HW Version xxx-xxx-xxx		
SN 000-000-000		
Battery 5900 mAh		
Clear memory		
Default parameters		
‹ BACK		
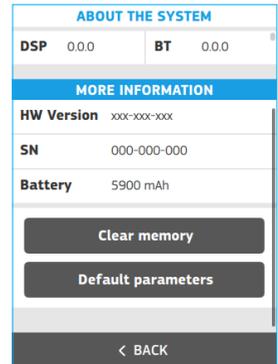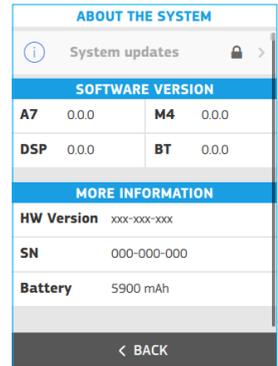
4. CONDUCTING A PATIENT TEST

4.1 PREPARING THE REQUIRED MATERIALS

• microINR Expert meter

• microINR Chips*

• Fingersticking material such as disposable lancets*

• Means for cleaning the skin*

* These products are not provided with microINR Expert meter.

⚠️ *Always use CE-marked lancing devices or lancets and follow the manufacturer's instructions.*

4.2 PRIOR STEPS BEFORE THE TEST

Check the system status information before performing a test with the microINR Expert:

• Check the battery level. See section 2.4 of these instructions for battery-related information.

• Make sure the time and date are set correctly. See section 3.2 to change the time and date if necessary.

Depending on the meter's configuration, additional steps may be required before performing a test:

• Meter lockouts: the Test option on the main menu may not be available if an EasyControl lockout is set. See section 3.4 of these instructions for the lockout configuration. A valid EasyControl test is required (refer to section 5 to perform a QC test) to make the testing option available again.

• Operator identification: the meter may require an Operator ID. See section 3.3 of these instructions for the required settings.

4.3 MEASUREMENT PROCEDURE

Tap the **Test** option on the main menu to conduct a test.

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

Operator ID & Patient ID

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 3.3). However, this step may be skipped if an operator has not been previously registered and Operator ID is configured as optional.

Follow the steps on the screen as set forth in section 2.7 to enter the operator ID.

The meter will also request a Patient ID 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.
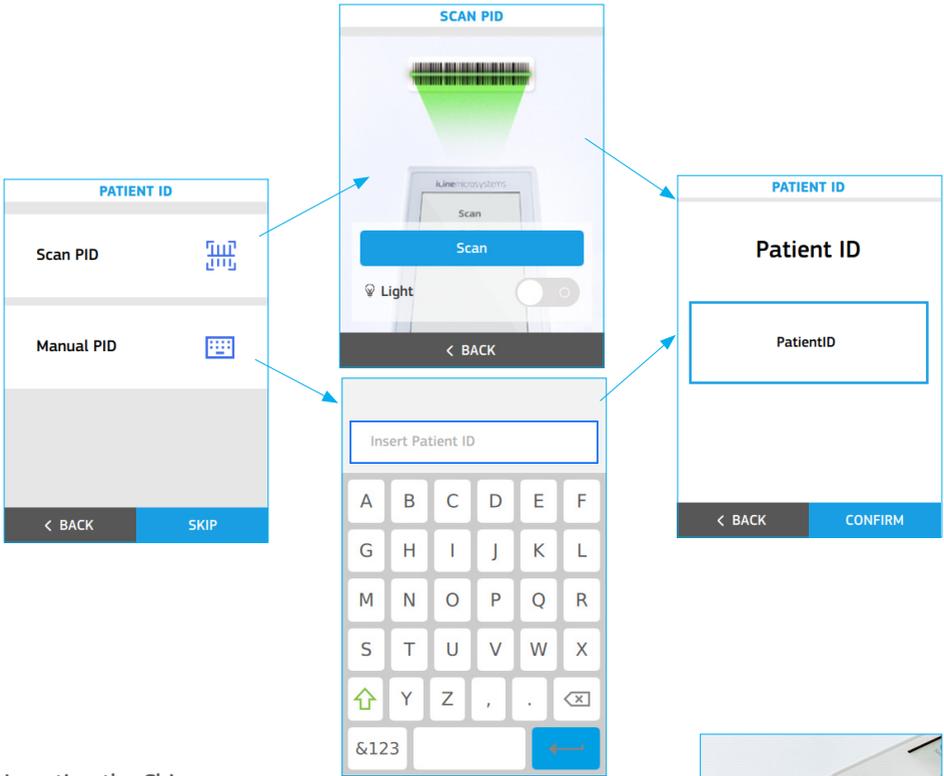
SCAN PID

Scan

Scan

💡 Light ⚪

< BACK

PATIENT ID

Scan PID ▥

Manual PID ⌨

< BACK   SKIP

PATIENT ID

Patient ID

PatientID

< BACK   CONFIRM

Insert Patient ID

A	B	C	D	E	F
G	H	I	J	K	L
M	N	O	P	Q	R
S	T	U	V	W	X
⇧	Y	Z	,	.	⌫
&123				↵

Inserting the Chip

⚠️ *Verify the expiry date and the storage conditions of the chip before conducting the test.*

Open the pouch and remove the chip from the package.

Hold the chip by the yellow part so that the "microINR" logo is facing up.

When the "Insert microINR Chip" message is displayed, insert the chip into the slot and push it all the way in.

ⓘ *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 it is defective or its pouch is open or damaged.*

Do not handle the chip with wet or dirty hands/gloves.

INSERT microINR CHIP

CANCEL

microINR CHIP detected

Conducting the Test

- Place the meter on a flat, stable surface during testing or hold it in your hand and avoid sudden movements.
  Once the chip is inserted, the meter will conduct a sequence of automatic steps to execute the on-board quality controls that lead to the chip warming-up. An error message will be displayed if the Level 1 onboard control has not been successful. Tap on the information symbol 🛈 for further details or follow the steps set forth in the Troubleshooting section (see section 6).

If the first level of the on-board control is successful:

- The chip begins to flash and warms up until it reaches the testing temperature. After this:

  - The device emits an audible signal (if enabled).

  - An 80-s countdown and the "Apply sample" message are displayed.

  - The chip emits a steady light.

- Perform the fingerstick only when the 80-s countdown has started (see section 4.4 of these instructions).

- Make sure you obtain a spherical drop of a suitable size (the equivalent of a teardrop).

- Apply the drop of blood to the chip within the 80-s time limit by allowing the blood to be absorbed at the entry channel.

- When the meter detects the sample it will display a "Sample detected" message, emit a beep (if enabled) and the countdown will disappear.

- It is then time to gently remove the finger and wait until the result is displayed on the screen.

  Do not reapply a 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.

Pre-test QC

Do NOT apply sample yet

Warming up...

Do NOT apply sample yet

76

Apply sample

35

✓

Sample detected

Gently remove the finger

Test Result

The meter displays the test result in INR units and optionally in PT seconds. See example attached.

INR result

PT result in seconds
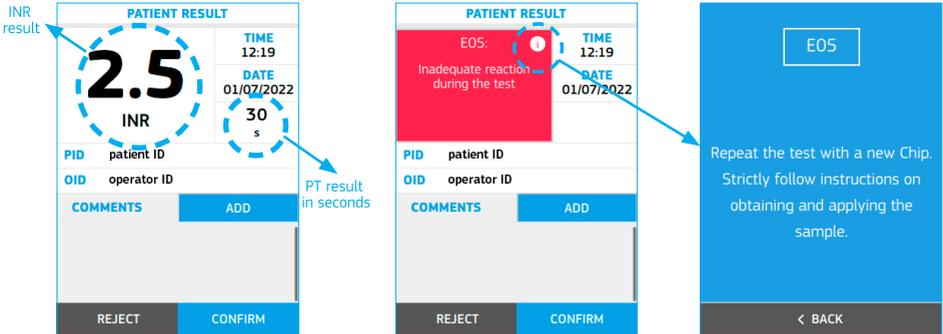
Error messages (EXX) may also be displayed. Errors detected include a number and a short description. If an error message is shown, tap on the information symbol 🛈 for further details or follow the steps described in the Troubleshooting section (see section 6).

Results outside the measuring range (0.8-8.0 INR and 9.6-96.0 s) are indicated by the symbols > (above) or < (below).

Adding Comments

Users may add comments to a test result as additional information. Custom comments up to 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.
- 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.
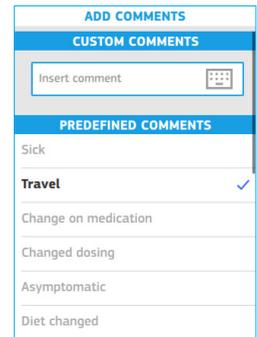
Finishing the Test

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 it by holding it from both sides and dispose of it appropriately.

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.

⚠️ *Used chips, lancets and gloves could be source of infection.*
Dispose of these materials according to your policy and the applicable local regulations.

Clean and disinfect the meter if necessary (see section 9.3).

Remove the Chip

4.4   OBTAINING AND APPLYING THE CAPILLARY BLOOD SAMPLE

The steps to **properly obtain and apply a capillary blood sample** are set forth below:

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

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

- It is advisable to warm the hands before lancing the finger. There are several techniques to do so such as washing hands with warm water, keeping them below the waist or gently massaging the fingertip.
- You can use any finger for the fingerstick. The site shown in the following image is recommended.
- Once the meter is ready for testing (an 80-s countdown and the "Apply sample" message are displayed), place the disposable lancet firmly against the finger and press the button. Press the base of the finger gently until a drop of blood forms. Do not press the fingerstick site or allow the drop of blood to spread on the finger.
- Make sure you obtain a spherical drop of a suitable size (the equivalent of a teardrop), large enough to leave a small amount of blood (remnant) on 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.*

- Apply the drop to the chip during the 80-s countdown.
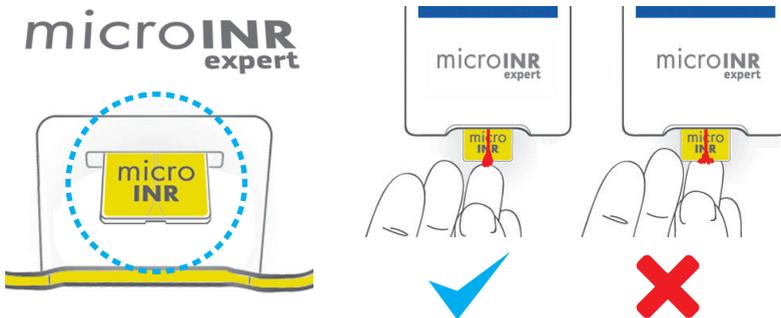
⚠️ *Samples must be applied immediately after collection since blood clotting occurs naturally on fingerstick.*

Avoid contact between the chip and the finger to avoid obstructing the entry channel and to allow for uninterrupted blood absorption. Only the drop of blood may make contact with the chip.

Apply the sample in a single attempt. Never add more blood to the chip.
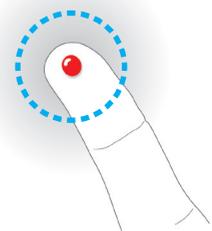
- The meter displays a "Sample detected" message, emits a beep (if enabled) and the countdown disappears once the sample has been detected.
- Gently remove the finger, leaving a small amount of blood (remnant) on the entry channel as shown in the picture.
- If you need to repeat the test you must perform the fingerstick in a different finger with a new lancet and a new chip.

4.5 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. INR results outside the measuring range will be shown as < 0.8 (below 0.8) or > 8.0 (above 8.0).

The prothrombin time (PT) in seconds can be also displayed depending on the meter settings. 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. PT results range between 9.6 and 96.0 seconds. PT outside the measuring range will be shown as < 9.6 s (below 9.6 s) or > 96.0 s (above 96.0 s).

If an error message is shown, tap on the information symbol ⓘ next to the error description for further details or follow the steps described in the Troubleshooting section (see section 6).

⚠️ *Repeat the test if an unexpected result is obtained, making sure that the instructions contained in this document are strictly followed. Contact your distributor if a second unexpected result is obtained.*

Results are unexpected when they lie outside the therapeutic range or do not match the patient´s symptoms: hemorrhages, bruises, etc.

4.6 LIMITATIONS OF USE

For information regarding limitations of the microINR system (Expert), please refer to the Instructions for Use of the microINR Chips.

As described at Quality Control section in 1.2, the microINR Expert meter's performance is automatically checked when the system is turned on and during testing.

Additionally, liquid controls can be analyzed in the meter. In order to perform an optional liquid quality control test using plasma control solutions, these elements are necessary:

• microINR Expert meter

• microINR Chips*

• Plasma control solution*: microINR EasyControl or an EQA material

* These products are not provided with microINR Expert meter.

The frequency of microINR EasyControl tests can be selected in the meter setup. (Refer to the section 3.4).

5.1 PERFORMING microINR EASYCONTROL TEST

Check the system status information before performing a microINR EasyControl test with the microINR Expert:

• Check the battery level. See section 2.4 of these instructions for battery-related information.

• Make sure the time and date are properly set. See section 3.2 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.

The meter displays information and emits acoustic signals (if the beeper is enabled), guiding the user throughout the testing process.
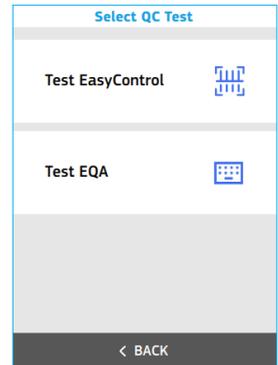
Operator ID & microINR EasyControl lot ID

The user performing the test may log on either through the dropdown menu or when a QC test is initiated depending on the meter's configuration (see section 3.3). However this step may be skipped if an operator has not been previously registered and Operator ID is configured as optional.

Follow the steps on the screen as set forth in section 2.7 to enter the operator ID.

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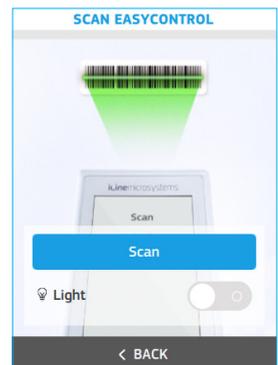
Place the barcode at a suitable distance to enable scanning. The meter will emit a beep (if enabled) once the barcode has been successfully read.

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

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

TEST EASYCONTROL	
Lot#	00123456
Range	1.6 - 2.3

< BACK   CONFIRM

Inserting the Chip

⚠️ *Verify the expiry date and the storage conditions of the chip before conducting the test.*

Open the pouch and remove the chip from the package.

Hold the chip by the yellow part so that the "microINR" logo is facing up.

When the "Insert microINR Chip" message is displayed, insert the chip into the slot and push it all the way in.

ⓘ *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 has been inserted.

INSERT microINR CHIP

CANCEL

✓ **microINR CHIP detected**

⚠️ *Do not use the chip if you detect that it is defective or its pouch is open or damaged.*
Do not handle the chip with wet or dirty hands/gloves.

Conducting the Test

• Place the meter on a flat, stable surface during testing or hold it in your hand and avoid sudden movements.
Once the chip is inserted, the meter will conduct a sequence of automatic steps to execute the on-board quality controls that lead to the chip warming-up. An error message will be displayed if the Level 1 onboard control has not been successful. Tap on the information symbol ⓘ for further details or follow the steps set forth in the Troubleshooting section (see section 6).

If level one of the on-board control is successful:

• The chip begins to flash and heats up until it reaches the testing temperature. After this:

  - The device emits an audible signal (if enabled).

  - An 80s countdown and the "Apply sample" message are displayed.

  - The chip emits a steady light.

↻ **Pre-test QC**
Do NOT apply sample yet

- Apply the control sample to the chip. Always follow the microINR EasyControl instructions.
- The meter displays a "Sample detected" message, emits a beep (if enabled) and the countdown disappears once the sample has been detected.
- It is then time to gently move the capillary dropper away and wait until the result is displayed on the screen.

Warming up...
Do NOT apply sample yet

76

Apply sample

35

Sample detected

Gently remove the pipette
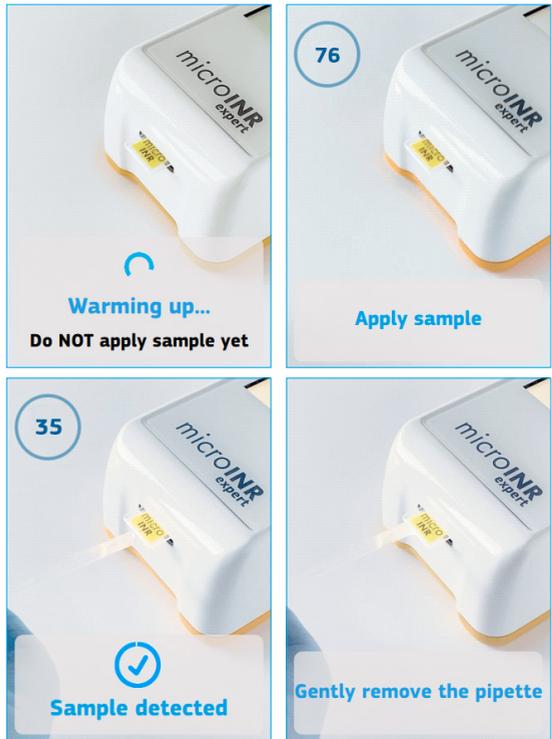
microINR EasyControl Test Result

The meter displays the control test result in INR units or an error message (EXX) once the measurement has been performed.

The INR control result appears inside a green frame if it is within the acceptance range.

If the INR control result is outside the acceptance range it will appear inside an orange frame.

Error messages are displayed as a letter "E" followed by a number and a short description. Tap on the information symbol ⓘ for further details or follow the steps indicated in the Troubleshooting section (see section 6) if an error message is shown.

EASYCONTROL RESULT

2.1
INR

TIME 12:19
DATE 01/07/2022

LOT 00123456
OID operator ID
Range 1.6 - 2.3

COMMENTS ADD

REJECT CONFIRM

EASYCONTROL RESULT

1.5
INR

TIME 12:19
DATE 01/07/2022

LOT 00123456
OID operator ID
Range 1.6 - 2.3

COMMENTS ADD

REJECT CONFIRM

EASYCONTROL RESULT

E09 : ⓘ
Inadequate reaction during the test

TIME 12:19
DATE 01/07/2022

LOT 00123456
OID operator ID
Range 1.6 - 2.3

COMMENTS ADD

REJECT CONFIRM

Adding Comments

Users may add comments to a test result as additional information. Custom comments up to 30 characters in length can be entered. There are also 4 selectable predefined comments.

To add comments:

- Tap the **Add** option on the EasyControl Result screen.

- Tap the **Insert Comment** text entry box to type the custom comment. Use the keypad to enter the comment. An inserted comment can be deleted by sliding the delete comment icon to the left.

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

- Scroll down to **Confirm** the selection to return to the result screen once the desired comment(s) have been selected.
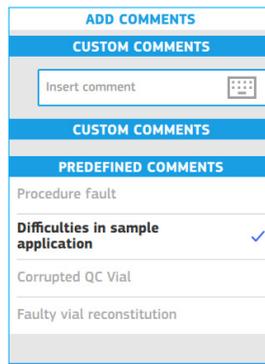
Finishing the Test

The operator may choose to confirm or reject the microINR EasyControl 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 microINR EasyControl result has been confirmed or rejected. Remove it by holding it on both sides and dispose of it appropriately.

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

The meter will automatically return to the main menu.

⚠️ *The used chips, capillary droppers and gloves could be source of infection.*

Dispose of these materials according to your policy and the appropriate local regulations.

Clean and disinfect the meter if necessary (see section 9.3).

5.2 PERFORMING EQA CONTROL

External Quality Assessment (EQA) programs provide optional means for the microINR system (Expert) performance. Some organizations require these EQA programs to be implemented as part of their quality assurance programs.

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

The control material provided by EQA programs are from unknown sources independent of the manufacturer. iLine Microsystems expressly declines all liability for results obtained using control materials that have not been validated by the manufacturer.

Check the following system status information before performing an EQA test with the microINR Expert:

- Check the battery level. See section 2.4 of these instructions for battery-related information.

- Make sure the time and date are properly set. See section 3.2 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.
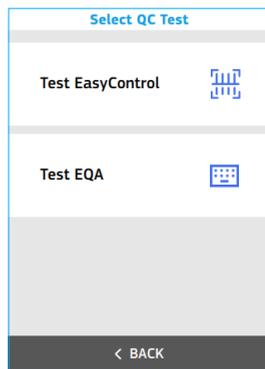
The meter displays information and emits acoustic signals (if the beeper is enabled) to guide the user throughout the testing process.

Operator ID & EQA Control lot ID

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 3.3). However this step may be skipped if an operator has not been previously registered and Operator ID is configured as optional.

Follow the steps on the screen as set forth in section 2.7 to enter the operator ID.

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.
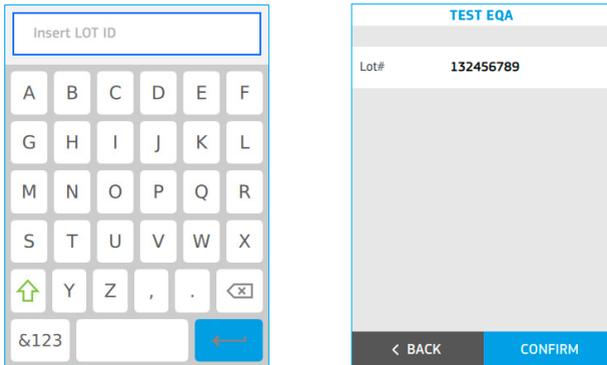
Inserting the Chip

⚠️ *Verify the expiry date and the storage conditions of the chip before conducting the test.*

Open the pouch and remove the chip from the package.

Hold the chip by the yellow part so that the "microINR" logo is facing up.

When the "Insert microINR Chip" message is displayed, insert the chip into the slot and push it all the way in.

🛈 *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 has been inserted.

⚠️ *Do not use the chip if you detect that it is defective or its pouch is open or damaged.*

Do not handle the chip with wet or dirty hands/gloves.

Conducting the Test

- Place the meter on a flat, stable surface during testing or hold it in your hand and avoid sudden movements.

  Once the chip is inserted, the meter will conduct a sequence of automatic steps to execute the on-board quality controls that lead to the chip warming-up. An error message will be displayed if the Level 1 onboard control has not been successful. Tap on the information symbol 🛈 for further details or follow the steps set forth in the Troubleshooting section (see section 6).

Pre-test QC

Do NOT apply sample yet

Warming up...

Do NOT apply sample yet

If level one of the on-board control is successful:

- The chip will begin to flash and heat up until it reaches the testing temperature. After this:
  - The device emits an audible signal (if enabled).
  - An 80-s countdown and the "Apply sample" message are displayed.
  - The chip emits a steady light.
- Apply the control sample to the chip. Always follow EQA instructions.
- The meter displays a "Sample detected" message, emits a beep (if enabled) and the countdown disappears once the sample has been detected.
- It is then time to gently remove the capillary dropper and wait until the result is displayed on the screen.

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Apply sample

If the sample is applied but the "Sample detected" message is not displayed and no sound is emitted, it means that the control sample volume is insufficient. Remove the chip and repeat the test with a new one. Ensure that the drop is of a suitable size and that the entry channel is not blocked when placing the drop.

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Sample detected

Gently remove the pipette

EQA Test Result

The meter displays the control test result in INR units or an error message.

Error messages are displayed as a letter "E" followed by a number and a short description. If an error message is shown, tap on the information symbol 🛈 for further details or follow the steps described in the Troubleshooting section (see section 6).

EQA RESULT		
1.5 INR	**TIME** 12:19	
	DATE 01/07/2022	
LOT 132456789		
OID operator ID		
COMMENTS	**ADD**	
REJECT	**CONFIRM**	

EQA RESULT		
E05: 🛈 Inadequate reaction during the test	**TIME** 12:19	
	DATE 01/07/2022	
LOT 132456789		
OID operator ID		
COMMENTS	**ADD**	
REJECT	**CONFIRM**	

Adding Comments

Users may add comments to a test result as additional information about the test conditions or the control material. Custom comments up to 30 characters in length can be entered. There are also 4 selectable predefined comments.

To add comments:

- Tap the **Add** option in the EasyControl Result screen.
- Tap the **Insert Comment** text entry box to type the custom comment. Use the keypad to enter the comment. An inserted comment can be deleted by sliding the delete comment icon to the left.
- Select the desired predefined comment(s) from the list.
- Scroll down to **Confirm** the selection to return to the result screen once the desired comment(s) have been selected.

ADD COMMENTS
CUSTOM COMMENTS
Insert comment
CUSTOM COMMENTS
PREDEFINED COMMENTS
Procedure fault
Difficulties in sample application ✓
Corrupted QC Vial
Faulty vial reconstitution

Finishing the Test

The operator may choose to confirm or reject the EQA control 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 that the chip be removed after confirming or rejecting the EQA control result. Remove it by holding it from both sides and dispose of it appropriately.

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

The meter will automatically return to the main menu.

⚠️ *The used chips, capillary droppers and gloves could be source of infection.*
Dispose of these materials according to your policy and the appropriate local regulations.

Clean and disinfect the meter if necessary (see section 9.3).

Remove the Chip

6. TROUBLESHOOTING

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 and a short description. Tap on the information symbol 🛈 for further details if an error message is shown.

Error	Probable Cause	Possible Solution
Messages when preparing to test		
E01	Faulty or incorrectly inserted chip. Chip used or damaged.	Insert the same chip again, ensuring correct insertion. If the problem persists, repeat the test with a new chip.
E02	Expired chip.	Verify the date of the meter. Enter the current date and insert the same chip again if the date was incorrect. Repeat the test with a new batch of chips after verifying their expiry date if the date was correct.
E03	The time frame for applying the sample has exceeded.	If the sample has not yet been applied, repeat the test with the same chip.
E04	Chip inserted upside down.	Rotate the chip and repeat the test.
E11	Faulty or incorrectly inserted chip. Chip used or damaged.	Insert the same chip again, ensuring correct insertion. If the problem persists, repeat the test with a new chip.
Messages related to the test		
E05/ E09	Inadequate reaction during the test.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample.
E10	The INR value of the control channel is outside the defined range.	Repeat the test with a new chip. If the problem persists, repeat the test with a new box or batch of chips.
E14/E15/ E17	Error while processing the sample during the test.	Repeat the test with a new chip. Strictly follow instructions for conducting the test.
E16	Inadequate coagulation of the sample during the test. ATTENTION: Possible sample with abnormally high clotting times.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample. Use a different measurement method if error E16 is displayed again. This error occurs mainly in patients with high clotting times.
E18	Inadequate sample handling or hematocrit outside the defined range.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample. If error E18 is displayed again, use a different measurement method.
E19	Sample type detection mismatch.	The sample type detected does not match with the testing mode. Make sure to apply blood on the patient testing mode and plasma control on the QC testing mode.
Other messages		
E06	Failure while checking the electronic components of the meter.	If the problem persists, contact your local distributor.
E07	Temperature below the defined range.	Repeat the test in a location between 15-35 ºC.
E12	Temperature above the defined range.	Repeat the test in a location between 15-35 ºC.

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

Contact your local distributor if a problem persists after taking the measures described in this section or if you require additional information.

System warning

⚠ Insufficient memory

⚠ Internal error. Scanner disabled

OK

7. 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:

MEMORY	
Patient Results	>
EasyControl Results	>
EQA Results	>
Generate Report	
< BACK	

- **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. To browse the results simply scroll down with the finger.

  Tap a patient result from the list to see other information (added comments...) on a specific result.

PATIENT RESULTS	
🔍	1 / 2
PID: PatientID / OID: OperatorID / 11/04/2022 13:57	2.5 INR 💬 🚫 ⚠️
PID: PatientID / OID: OperatorID / 11/04/2022 13:57	2.5 INR 💬 🚫 ⚠️
< BACK	

PATIENT RESULT	
2.5 INR ⚠️🚫	TIME 13:57 / DATE 11/04/2022 / 30 s
PID PatientID	
OID OperatorID	
COMMENTS	SEE
Comment1	
< BACK	

- **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. To see more results simply scroll down with the finger.

  Tap an EasyControl result from the list to see other information (added comments...) on a specific EasyControl result.

EASYCONTROL RESULTS	
🔍	1 / 2
LOT: 00123456 / OID: Operator ID / 11/04/2022 13:57	2.3 INR
LOT: 00123456 / OID: Operator ID / 11/04/2022 13:57	2.5 INR
< BACK	

EASYCONTROL RESULT	
2.1 INR	TIME 13:57 / DATE 11/04/2022
LOT 00123456	
OID operator ID	
Range 1.6 - 2.3	
COMMENTS	SEE
Comment1	
< BACK	

- **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. To see more results, just scroll down with the finger.

  Tap an EQA result from the list to see other information (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

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.
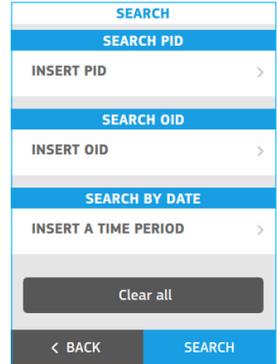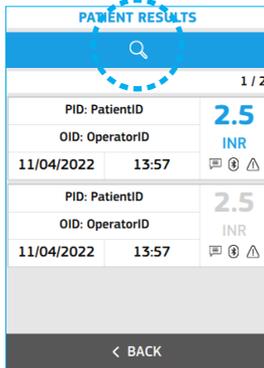
Generate Report

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.
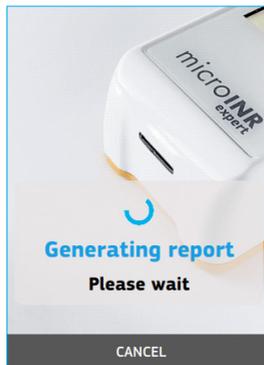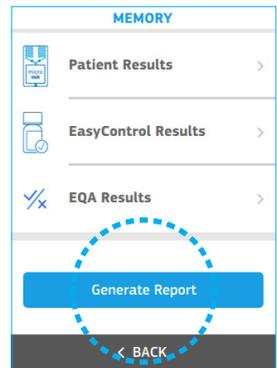
8.1 BARCODE SCANNER

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. Special characters may also be used.

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

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 49
- Code 93
- Code 128
- Interleaved 2 of 5
- EAN 13

2D Barcodes:
- Data Matrix
- QR Code
- PDF417
- Aztec Code

8.2 DATA HANDLING

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 3.5). 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.

8.3 Wi-Fi

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 POCT1-2A 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 send results after each test or when the Sync. button in the dropdown menu is pressed.

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

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 when the **Sync.** button in the dropdown menu is pressed.

In line with the POCT1-2A 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 POCT1-2A:

- 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 and expiry date.
- 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.

8.4 BLUETOOTH

The microINR Expert meter can communicate with and transfer results to a PC or other electronic devices (e.g., computers, tablets or smartphones) through a wireless Bluetooth connection.

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 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 ISO11073 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.

8.5   ETHERNET

The microINR Expert can communicate through a wired Ethernet connection to a Local Area Network (LAN) when connected to the ethernet adaptor (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 adaptor consists of a hardware unit with a RJ45 connector and an integrated USB-C cable to connect to the microINR Expert meter.

The meter will attempt to connect to the DMS immediately after the test has been confirmed or rejected. 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 when the **Sync.** button in the dropdown menu is pressed.

In line with the POCT1-2A 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 POCT1-2A 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 and expiry date.
- 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.

8.6 OPERATOR & PATIENT LISTS

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 3.3).

The meter may also receive an operator and/or patient list from a DMS. Select the **Operator lists** and/or **Patient list** in the POCT1A settings in the Settings options (see section 3.5) to enable these options.

The DMS may send these lists to the meter if the operator or patient lists are activated. Then the meter checks if these IDs are on the lists when an operator or a patient is identified.

When working with operator or patient lists, detection of these identities is limited to those included in the lists.

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

8.7 AUTOMATIC DATE / TIME

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 3.2) if the meter receives the date and time from the DMS.

9. microINR Expert METER CARE

9.1   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 –20 ºC and +50 ºC.
- The storage relative humidity is below 80% (with no condensation).

9.2   TRANSPORT CONDITIONS

- Always transport the meter inside its transport case.
- The meter may be transported within a temperature range between –20 ºC and +50 ºC.
- It should not be transported with relative humidity in excess of 80% (with no condensation).

9.3   CLEANING & DISINFECTION

Cleaning and disinfection of the microINR Expert meter is essential to ensure proper operation and to prevent blood-borne transmission of pathogens in multi-patient settings.

Clean and disinfect the meter before being used on another patient, when it is soiled and according to your center's internal hygiene and safety regulations.

Always clean the meter before disinfecting.
Use a new pair of gloves every time you clean and disinfect the meter.

Turn the device off and make sure the cables are unplugged before cleaning or disinfecting the meter.

To clean the meter:

- Clean the meter with a clean gauze or wipe moistened with isopropyl alcohol 70% until there is no visible dirt.
- Ensure there are no remaining fibers or lint on any part of the meter, especially on the chip insertion slot, the USB-C port and the scanner window.

To disinfect the meter:

- Disinfect the meter with a clean gauze or wipe moistened with isopropyl alcohol 70%.
- Wait one minute for the alcohol to act.
- Thoroughly dry the meter with a dry, clean, lint-free cloth or gauze.
- Wait at least 15 minutes for the meter to dry and ensure that it is completely dry before conducting a new test.
- Ensure there are no remaining fibers or lint on any part of the meter, especially on the chip insertion area, the USB-C port and the scanner window.
- Discard the used wipes and gloves.

> *Do not clean or disinfect the meter while conducting a test.*
>
> *Do not use aerosols or cleaning or disinfecting agents other than a clean gauze or wipe moistened with isopropyl alcohol 70%.*
>
> *Verify that the gauze or wipe is just moist, not soaked.*
>
> *Do not spray fluids on the meter or submerge it.*
>
> *Make sure that no fluids enter the meter or the chip insertion slot.*
>
> *The chip insertion slot must always be clean and dry before conducting a test. Remains of blood or alcohol can contaminate the sample when inserting a chip.*
>
> *Do not handle the chips with alcohol-contaminated gloves.*
>
> *Comply with all recommendations regarding cleaning and disinfecting the meter.*
>
> *Failure to follow these recommendations could cause anomalous results.*

10. ADDITIONAL INFORMATION

10.1 SPECIFICATIONS

- Dimensions of the meter: 164 x 70 x 43 mm.
- Weight: 370 g (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 6,000 mAh; 3.7 V
  - Power supply: Model No. GTM96180-1507-2.0 by GlobTek Inc.
  - 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: 15 ºC - 35 ºC.
  - Maximum relative humidity: 80%.
  - Maximum altitude: 3.048 m.
  - Keep the meter away from direct sunlight during the test.
- Meter storage and transport temperature: -20 ºC to 50 ºC.
- Measurement range: 0.8 – 8.0 INR (9.6 – 96.0 s).
- 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 11073-10418.
- Wi-Fi: IEEE 802.11 b/g/n wireless connectivity. Data transfer via Wi-Fi through communication protocol standard POCT1-2A.
- Ethernet: data transfer through communication protocol standard POCT1-2A and when connected to the ethernet adaptor (available separately).
- Memory data extraction via USB-C connection.

*Test conducted at 22 ºC with a 10-minute period between tests.

10.2 WARRANTY

iLine Microsystems guarantees that the microINR Expert meter is free of material and manufacturing defects on the purchase date.

The statutory warranty provisions on consumer rights in relation to the purchase of goods in the country of purchase shall apply.

This warranty does not cover component damaged due to inadequate storage in ambient conditions outside the defined range, accidents or modifications, misuse or mishandling. The buyer must submit a written warranty complaint to the manufacturer within the respective warranty period to claim indemnity for material or manufacturing defects.

10.3 TECHNICAL SERVICE AND REPORTING

Please contact your local distributor if a problem persists after taking the measures set forth in the troubleshooting table or for further information.

Note: the microINR Expert meter may only be repaired or serviced by personnel authorized by iLine Microsystems.

In case of any serious incident that has occurred in relation to the system shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

10.4 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 "SWL0001EN") on request at the following iLine Microsystems information email address: (info@ilinemicrosystems.com).

Verbatim copies of this license document may be freely copied and disseminated but it may not be changed in any way.

10.5 SYMBOLS

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

REF	**"Catalogue number"**
	"Manufacturer"
CE	**CE "CE Marking"**
IVD	**"*in vitro* diagnostic medical device"**
	"Consult the instructions for use"
	"Direct current"
	"Electronic waste selective collection"
	"Biological hazard"
SN	**"Serial number"**
LOT	**"Batch code / Lot Number"**
GTIN	**"Global Trade Item Number"**
UDI	**"Unique Device Identifier"**
	"Temperature limit"
	"Warning"
	"Precaution"

11. INDEX

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

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CE

IVD