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iLine® microsystems

friendly technology

microINR®

Instructions for use

microINR®

microINR Meter

For monitoring of
Oral Anticoagulation Therapy
with warfarin.

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English

1. INTRODUCTION

1.1 INTENDED USE

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

The microINR System consists of a microINR meter and microINR Chip and uses fresh capillary whole blood from a fingerstick.

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

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

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

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

1.2 BEFORE USING THE microINR® SYSTEM

These instructions for use will guide you on the handling and use of the microINR meter, please, read them as well as the instructions for use of the microINR Chip completely.

Additionally, do not forget to read the instructions for use of the disposable lancets and/or lancing device used to obtain the capillary blood sample.

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

Users must receive proper training before starting to use the microINR System.

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

At the end of these instructions you will find a glossary of terms.

Important Information

General Safety Warnings

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

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

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

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

Dispose of the Meter

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

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

Important information for Healthcare professionals

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

Infection Risk Control on Multi-Patient Test System

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

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

The meter should be disinfected after use on each patient.

Please, follow the directions in these instructions for use for cleaning and disinfection (section 5).

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

Electromagnetic Compatibility and Safety Requirements

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

CLIA categorization

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

1.3 ORAL ANTICOAGULANT THERAPY

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

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

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

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

Prothrombin Time and INR

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

For standardization purposes, the World Health Organization (WHO) recommended a system in 1977. Prothrombin Time values are converted into INR values, International Normalized Ratio, by using a specific equation.

1.4 MEASURING PRINCIPLE

The technology used by the microINR System is based on the microfluidics of the microINR Chip.

The chips contain human recombinant thromboplastin as reagent.

The blood sample is applied to the chip through the entry channel and mixed with the reagents contained in the micro-reactors. The coagulation cascade is triggered instantly. When the blood coagulates, a change in blood flow behavior occurs.

The meter captures the position of the sample by means of a Machine Vision System (MVS) and determines the INR result.

Calibration

Each lot of microINR Chips is calibrated against a reference lot of human recombinant thromboplastin traced to the International Reference Thromboplastin Preparation of the World Health Organization.

The calibration parameters needed for the INR equation are encoded in each microINR Chip along with information related to the expiration date. Therefore, every test is automatically and individually calibrated reducing any risk of error.

2. microINR® SYSTEM

2.1 DESCRIPTION OF THE microINR® KIT

The microINR kit includes:

- Case
- microINR meter
- Charger
- Instructions for use of the microINR meter
- Easy guide for self-testing patients
- Error guide
- Questionnaire

microINR Chips are sold separately.

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

2.2 PARTS OF THE microINR® METER

2.3 CHARGING THE microINR® METER

The meter uses a lithium battery and is recharged through the mini USB connection on the top of the meter.

Charge the battery completely before using the meter for the first time. The recommended charging time is approximately 3 hours.

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

Do not pierce or burn the battery.

Do not change the battery.

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

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

Use only the supplied charger provided by the manufacturer or you may damage the meter.

Other cables and accessories may negatively affect the meter and even can lead to an injury.

2.4 SETTING THE TIME AND DATE

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

Time and date are set during the manufacturing process, so probably it is not necessary to change them.

Time format: 12 hours, where "A" represents AM and "P" stands for PM. Date format: MM-DD-YYYY.

Follow the steps described below to change the meter's time and date. Change only the digits needed to be set and confirm the rest digits:

- Press and hold the left and right buttons (E and M) at the same time for 10 seconds until the time field flashes.
- Press the button on the left (E) to set the hour.
- After selecting the correct hour, press the button on the right (M) and use the button on the left (E) to set the minutes.

- After selecting the minutes, press the button on the right (M) again and the date fields will start flashing.
- Use the button on the left (E) to select the correct month.
- When you reach the correct month, press the button on the right (M) to set the day. Use the button on the left (E) to select the correct day.
- When you reach the correct day, press the button on the right (M) to set the year. Use the button on the left (E) to select the correct year.
- After setting the time and date, press the button on the right (M) again to save your settings.

If the time and date setting is mistakenly initiated or a digit is unintentionally changed, the meter will automatically exit that setting without saving any change after 10 seconds of inactivity.

2.5 QUALITY CONTROL

The microINR System provides Quality Controls on every test.

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

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

These quality controls are performed automatically, so there is no need to run extra quality controls.

3. CONDUCTING THE TEST

3.1 GETTING READY FOR THE TEST

Prepare all items needed for the testing:

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

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

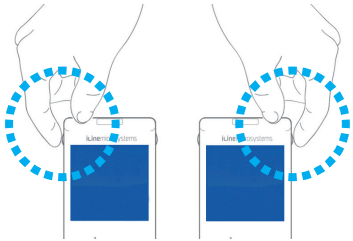
3.2 MEASUREMENT PROCEDURE

Turning the Meter On

The meter can be turned on:

- By inserting the chip:

- By pressing any button:



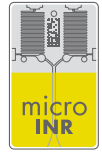
Do not manipulate the meter with wet or dirty hands/gloves.

Inserting the Chip

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

- Open the chip pouch and remove the chip from the package.

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



- Make sure the chip has reached the end.

Do not use the chip if you detect that the chip is defective or its pouch is opened or damaged.

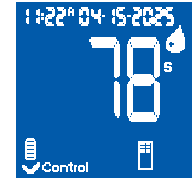
Do not manipulate the chip with wet or dirty hands/gloves.

If a "PID" message appears on the screen when starting a test, remove the chip to exit this mode. To initiate the test, reinsert the chip without pressing any buttons.

Conducting the Test

- The meter must be placed on a flat and steady surface.
- Once the chip is inserted, the meter automatically turns on. The chip and the hourglass symbols appear on the screen while the meter performs a quality control to check the system's integrity prior to sample application. A blinking chip symbol appears on the screen if no chip is inserted or it has not been inserted all the way until it comes to a full stop.

- While waiting for the device to be ready, make sure your hand is warm and the fingertip clean (see section 3.3 of these instructions for use).
- If the quality control is correct, the "Control" symbol will appear on the screen. If the quality control fails, an error message will be displayed. In that case, check the "Error Guide" section of these meter instructions for use.
- The chip begins to flash and warms up until it reaches the appropriate temperature. Once this temperature is reached:
  - The device emits an audible signal (beep tone).
  - The drop symbol begins to flash on the display.
  - A countdown appears (80s).
  - The chip emits a steady light.



- Once the meter is ready, perform the fingerstick (see section 3.3 of these instructions for use).
- Make sure to obtain a spherical and properly sized drop, equivalent to a teardrop.
- For self-testing patients: Rest the pricked finger on the other hand leaning on a flat surface to help you during the blood application.
- Apply the drop of blood on the chip immediately by putting it in contact with the chip's entry channel, without resting the

finger on the chip.

- The meter will emit a beep tone when it detects that the sample volume is enough, the drop symbol will stop flashing and the countdown disappears.
- After the beep tone, gently remove the finger trying to leave a small amount of blood at the chip's entry channel.
- Wait until the INR result is displayed on the screen.

If you apply the sample and no sound is emitted, this means that there is not enough sample volume. Remove the chip and repeat the test with a new one. Ensure that the size of the drop is sufficient and do not block the entry channel during application.

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

Never perform the fingerstick before the start of the countdown.

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

The meter must be placed on a flat and steady surface and do not move the meter or the chip until the test is over.

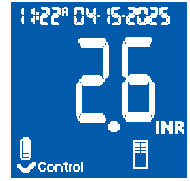
Keep the meter away from direct sunlight and avoid light intensity changes during the test.

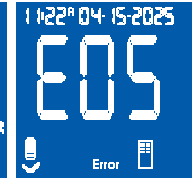
For healthcare professionals: *do not shake or drop the meter. If the meter is dropped or gets wet and the frequency of error messages increases, contact your local distributor.*

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

Test Result and Assay End

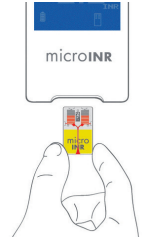
- The measurement is performed, and the meter displays the result in INR units or an error message.





Error messages are displayed as a letter "E" followed by a number. If an error message is shown, follow the steps described in the "Error Guide" section.

- Remove the chip, holding it from both sides.



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

For self-testing patients: *Dispose of the used chip with your regular waste. Dispose of used lancets carefully. Use a sharps container to prevent injury to yourself or to others with the needle. Contact your healthcare provider to help you get a sharps container.*

Turning the Meter Off

There are two ways to turn the meter off:

- The meter turns off automatically after 3 minutes of inactivity.
- Press the button on the left (EXIT) to turn the meter off, holding it for 3 or 4 seconds.

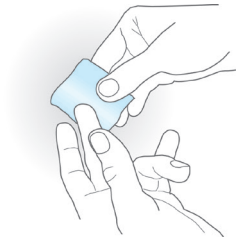
The meter cannot be turned off while connected to the power supply.

3.3 COLLECTION AND TESTING THE BLOOD SAMPLE

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

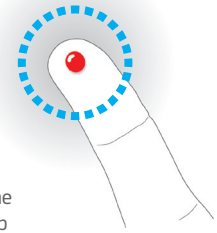
- Read the instructions for use of the fingerstick device or lancet.

The fingerstick site must be clean, completely dry and free of contaminants. Washing 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 any traces of substances that might interfere with the result. Always use a new, clean and dry gauze. Any alcohol (disinfectants, shaving creams, etc.), lotions or sweat on the fingerstick area or the blood sample may cause incorrect results.



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

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

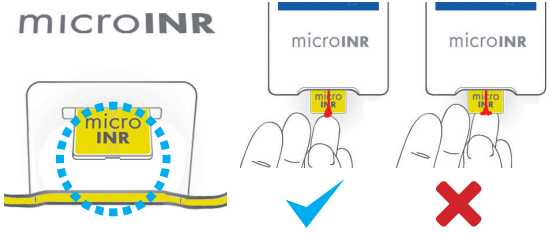


- Once the meter is ready for testing and the 80-second countdown appears on the screen, place the lancet firmly against the fingertip and activate it. Massage the finger to bring blood to the finger tip and gently press to help form a drop of blood. Do not press the fingerstick site or let the drop of blood spread on the finger.
- Before placing the sample on the chip, make sure to obtain a spherical and properly sized drop (equivalent to a teardrop), large enough to leave a small amount of blood (remnant) at the entry channel.

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

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

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



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

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

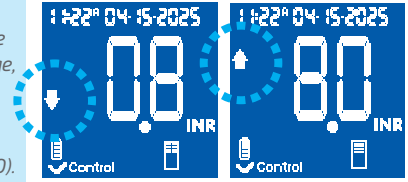
Apply the sample on a single attempt. Never add more blood to the chip.

- After the beep tone, gently remove the finger, leaving a small amount of blood (remnant) at the entry channel as shown in the picture.
- If you need to repeat the test, you must perform the fingerstick in a different finger with a new lancet and a new chip.

3.4 INTERPRETING THE RESULTS

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

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



If an error message is displayed, see the "Error guide" section and follow the instructions.

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

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

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

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

3.5 LIMITATIONS OF USE

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

4. MEMORY

The microINR meter can store up to 199 results. Each result is stored with the date and time of the test. When conducting a test, if there is no free storage space, the oldest result will be automatically deleted to store the new one.
To check the results:

- Press the button on the right (M). The result of the last test conducted will be displayed with its date and time.
- Press again to display the next result, corresponding to the second-to-last test and so on.
- Press the button on the left (E) to return to the initial screen. If you insert a chip while you are checking the memory, a new test will begin normally.

5. CLEANING AND DISINFECTING

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

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

For healthcare professionals: The FDA recommends that Point-Of-Care testing devices used with multiple patients be properly cleaned and disinfected after every use.
Clean the meter to remove visible dirt before disinfecting.

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

Needed Equipment:

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

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

Additional equipment for Healthcare Professionals:

- Gloves

For healthcare professionals:
Always use applicable Personal Protective Equipment.

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

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

What to Clean / Disinfect:

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

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

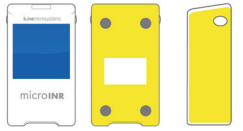
Cleaning process

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

Disinfection process

1. The disinfection routine must be performed for 2 minutes (contact time).

2. Take a new Super Sani-Cloth® wipe and start wiping the back and front surfaces and continue with the laterals.
3. Wipe the critical parts of the meter gently (USB port, microINR Chip insertion area, buttons, and display area) making sure no liquid enters or accumulates near these critical areas.
4. Allow the microINR meter to air dry thoroughly for 10 minutes before using it.
5. Wipe the meter using a drying lint-free cloth to remove any liquid that might remain on the meter.
6. Use a swab to remove any lint that might remain at the chip insertion area by introducing the swab in the entry and sliding it to both sides. Introduce the swap properly to avoid any meter internal component damage.



For healthcare professionals: Remove the used gloves.

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

Warnings and precaution tips when cleaning-disinfecting

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

6. ERROR GUIDE

Error code	Probable Cause	Possible Solution
E01	The Datamatrix could not be read or used chip detected.	Ensure the chip has not been previously used or is not damaged. Insert the same chip again, ensuring correct insertion. If the problem persists, repeat the test with a new chip. If, despite this, the problem is still not solved, the meter may be damaged.
E02	Expired chip.	Verify the date of the meter. If the date is not correct, enter the current date (see section 2.4) and insert the same chip again. If the date is correct, repeat the test with a new lot of chips. Always verify the chip expiry date.
E03	The 80-second countdown for sample application has been exceeded. Sample has not been correctly detected.	If the sample has not been applied yet, repeat the test with the same chip. If the sample has been applied, repeat the test with a new chip. Make sure to apply enough sample volume.
E04	Chip inserted upside-down.	Rotate the chip and repeat the test. See picture at section 3.2.
E05	Wrong application of the blood sample.	Repeat the test with a new chip. Make sure you do not block the chip's entry channel and you are applying a sufficient amount of blood. Gently remove the finger after the blood application. Go to section 3.3 of the microINR meter instructions. Verify proper chip storage conditions (see microINR Chip instructions).
E06	Failure while checking the electronic components of the meter.	Turn the meter off and switch it on again. If the problem persists, the device may be damaged.
E07	Temperature below the defined range.	Verify that the temperature is above 59 ºF (15 ºC). Repeat the test in a warmer location. If the problem persists, the device may be damaged.
E08	Low battery.	Charge the device with the charger supplied by the manufacturer.
E09	Inadequate coagulation of the sample during the test. Irregularities during the test.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see section 3.2 and 3.3) and verify proper chip storage conditions (see microINR Chips instructions).
E10	Possible chip degradation (not correctly stored) or sample contamination.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see section 3.2 and 3.3). Review the Storage and Stability, Limitations and Interference Sections at microINR Chips instructions.
E11	Incorrectly inserted chip. Chip used or damaged. meter damaged.	Strictly follow instructions on inserting the chip into the meter (see section 3.2). Insert the same chip again, ensuring its correct and complete insertion. If the problem persists, repeat the test with a new chip. If, despite this, the problem is still not solved, the meter may be damaged.
E12	Temperature above the defined range.	Verify that the temperature is below 104 ºF (40 ºC). Repeat the test in a cooler location. If the problem persists, the meter may be damaged.
E13	Wrong chip reference.	Make sure your chip reference begins with CHC.
E14/15	Error while processing the sample during the test. Possible chip degradation (not correctly stored) or chip damaged. The device has been hit or moved abrutly during the test.	Repeat the test with a new chip. Verify proper chip storage conditions (see microINR Chips instructions). Do not hit/touch or move the chip or meter during the test.

Error code	Probable Cause	Possible Solution
E16	Inadequate coagulation of the sample during the test. Contaminated sample or sample with abnormally high INR values.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see section 3.2 and 3.3). Review the Storage and Stability, Limitations and Interference Sections at microINR Chips instructions.
E17	Error while processing the sample during the test. The device has been hit or moved abruptly during the test. Chip damaged.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see section 3.2 and 3.3). Do not hit/touch or move the chip or meter during the test. Verify proper chip storage conditions (see microINR Chips instructions).
E18	Wrong application of the blood sample or unusual/abnormal sample.	Repeat the test with a new chip. Strictly follow instructions on obtaining and applying the sample (see section 3.2 and 3.3). Make sure to apply enough sample volume in a single attempt. If error E18 is displayed again, contact your healthcare provider (your hematocrit value defined for the microINR System may be out of range).

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

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

7. ADDITIONAL INFORMATION

7.1 SPECIFICATIONS

- Dimensions of the meter: 4.68x2.55x1.37 in (119x65x35 mm).
- Weight: 7.51±0.10 oz or 213±3 g. (battery included).
- Screen: LCD 1.77x1.77 in (45x45 mm).
- Memory: 199 results / error messages with their date and time.
- Power supply:
  - Battery: Lithium 2400mAh/2800mAh; 3.7V. Consumption: 1 A
  - Power supply: Only use the charger provided with microINR meter. Model Number GTM96060-0606-1.0.
- Number of tests per charge cycle: *approximately 70 tests.
- Operation conditions:
  - Temperature: 59 ˚F to 95 ˚F (15 ºC to 35 ºC).
  - Maximum relative humidity: 80%.
- Meter storage temperature: -4 ˚F to 122 ˚F (-20 ºC to 50 ºC).
- Measurement range: 0.8 – 8.0 INR.
- Sample volume: minimum 3µL.

*Test conducted at 72 ˚F (22 ºC) with a 10-minute period between tests.

7.2 WARRANTY

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

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

7.3 SOFTWARE LICENSES

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”) under request at the iLine Microsystems information email: info@ilinemicrosystems.com

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

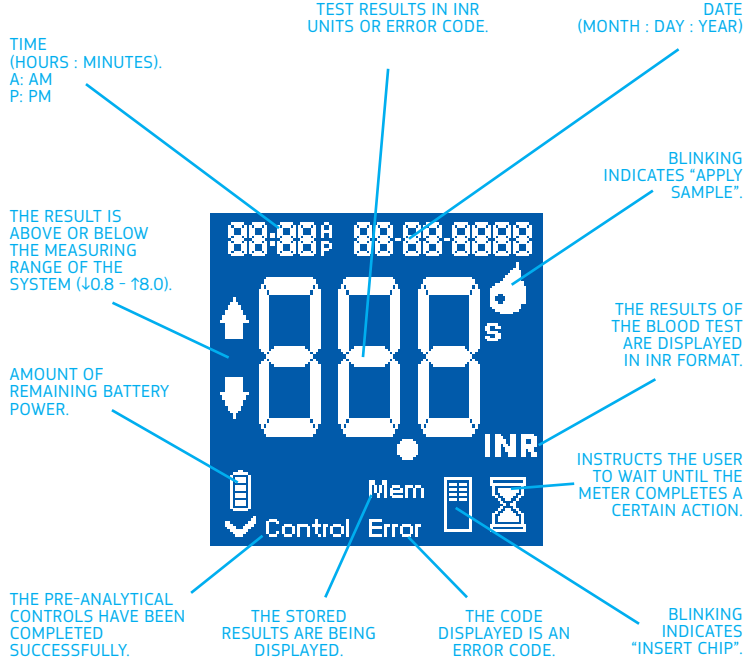
7.4 TECHNICAL SERVICE

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

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

7.5 SYMBOLS

	"Manufacturer"
SN	"Serial number"
REF	"Catalogue number"
	"Consult the instructions for use"
IVD	"*In-vitro* diagnostic medical device"
	"Direct current"
	"Temperature limit"
LOT	"Batch code / Lot Number"
	"Biological hazard"
	"Type BF Applied Part"
	"Class II Equipment"
IP22	"Degree of Ingress Protection Provided by Enclosure. Protected against solid foreign objects of 12.5 mm Ø and greater. Protection against vertically falling water drops when ENCLOSURE tilted up to 15''
	"Caution (consult accompanying documents). Refer to safety-related notes in the manual accompanying this instrument''.
CLASSIFIED C UL US E473708	"Medical - General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with "ANSI/ AAMI ES60601-1 (2005) + AMD 1 (2012)" and "CAN/CSA-C22.2 No. 60601-1:14" Control number E473708".
Rx only	"Prescription Use Only"
	"Caution"



7.6 GLOSSARY OF TERMS

Capillary blood: Blood obtained from capillary beds that consist of the smallest veins (venules) and arteries (arterioles) of the circulatory system. Capillary blood is usually obtained by puncturing a fingertip.

Capillary fingerstick: Small puncture on a finger to obtain capillary blood.

Chip: Disposable element insertable into the microINR meter, like a test strip. It serves to receive the capillary blood sample for the INR test.

Entry channel: Slot on the bottom of the microINR Chip that receives the blood.

International Normalized Ratio (INR): Standardized prothrombin time measurement that accounts for the different sensitivities of the thromboplastins used in different systems. The INR results from different prothrombin time measurement systems can be compared to each other but may not be identical.

Lancet: Piercing tool used to make a small cut or puncture to collect a small drop of blood.

Machine Vision System (MVS): Set of Hardware and Software technology that enables a computing device to inspect, evaluate and identify still or moving images.
A machine vision system typically consists of digital cameras and back-end image processing hardware and software.

Microfluidics: Microfluidics is the science and technology of systems that process or manipulate small amounts of fluids, using channels measuring from tens to hundreds of micrometers.

Meter: Electronic device that serves to conduct INR measurements.

Micro-reactor: Area of the microINR Chip meant to store the reagents.

Mini-USB connector: Miniaturized version of the Universal serial bus (USB) interface for the charger connection.

Oral Anticoagulant Therapy (OAT): Orally administered treatment that inhibits or interferes with the coagulation of the blood to reduce the risk of thrombosis (clotting).

Prothrombin time (PT): Coagulation test in which coagulation is induced by exposing a blood sample to a thromboplastin reagent material.

Quality control: Procedures intended to assure that the device is performing within specifications, and therefore the results are suitable for their intended diagnostic use preventing inaccurate results.

Reagent: Substance used to cause a chemical reaction in order to measure a substance or process (such as the PT test).

Remnant: Small amount of excess blood that remains on the entry channel of the microINR Chip.

Therapeutic range: Range of drug level in the blood of a patient in which a drug has the desired effect upon the body.

Thromboplastin: Reagent used in the PT assay.

7.7 ANNEX I. EMC/SAFETY REQUIREMENTS COMPLIANCE INFORMATION

Electromagnetic emissions

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

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

Electromagnetic immunity

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

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

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

Immunity to proximity fields from RF wireless communications equipment:

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

Additional Recommendations:

The microINR should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the microINR should be observed to verify normal operation in the configuration in which it will be used.

The microINR meter should not be used inside an aircraft. The microINR meter should also not be exposed to unique medial emitters, such as electrocautery, MRI, electrosurgical units and diathermy devices.

Use only the supplied charger provided by the manufacturer or you may damage the meter. Other cables and accessories may negatively affect EMC performance.

7.8 ANNEX II. CYBERSECURITY INFORMATION

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

Authentication and Access Control

Only the manufacturer and authorized personnel can access critical functionalities of the meter. iLine's proprietary Communication Protocol (not public) is necessary to access the meter critical configuration parameters and to create a compatible application that enables the information download to a compatible device.

Communication Security

All communication initiated by the microINR meters are protected by robust encryption protocol. These measures safeguard the integrity and confidentiality of data transmitted through USB. This communication channel is designed to prevent replay attacks, ensuring that transmitted commands and data exchanges remain secure.

Network Ports and Interfaces

The meter includes a USB port for connectivity and data transfer. The USB port allows secure software updates, through iLine's proprietary Communication Protocol (not public).
This configuration ensures that only authorized users and systems can interact with the meter.

Infrastructure Requirements

The meter must operate within a secure network environment. Users are responsible for secure server connections for transmitting results or updates. The system's design prioritizes the integrity of healthcare networks by reducing potential vulnerabilities.

Software Bill of Materials (SBOM)

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

Software and Firmware Updates

Firmware and software updates are performed exclusively through USB connections to ensure a secure update process. Before installation, updates undergo strict authentication checks to confirm their authenticity. The meter applies several control mechanisms to identify irregularities in the software. In the event of communication interruption or update errors, the meter enters a fail-safe mode to prevent any malfunction.
The users will be informed when a new software version and/or instructions for use are available. You can check iLine´s webpage for getting the most updated information (https://www.ilinemicrosystems.com/en-us/).

Critical Functionality Protections

To protect its critical functionalities, the meter includes automated safeguards such as auto-off settings to prevent prolonged unauthorized access. This feature ensures the continuity of operations and the integrity of the meter's critical functions.

Secure Device Configuration

The microINR meters are shipped with secure default settings. The USB interface is enabled by default but must be explicitly connected to a compatible application by the user.

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

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

Secure Decommissioning

When the microINR meters are retired from the market, secure decommissioning processes are followed. The meter does not store any sensitive information.

Important cybersecurity information

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

Users should be careful to use apps from reliable sources only and only connect the meter through USB cable to a secure, trusted computer.

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