iLine® microsystems

friendly technology

microINR®

Instructions for use

The information contained in these instructions for use was correct at the time of printing. However, iLine Microsystems reserves the right to introduce changes to the specifications, equipment and maintenance procedures of the system at any time, without prior notification. Any substantial changes will be added to the next revision of these instructions for use. In case of conflict between the information of the instructions for use of the microINR Meter and the microINR Chip, the information contained in the instructions for use of the microINR Chip will have priority.

microINR®

microINR Meter

For monitoring of oral anticoagulation treatment based on Vitamin K antagonist drugs.

CONTENTS

English

1. INTRODUCTION

1.1 INTENDED USE

The microINR system is intended to monitor oral anticoagulation therapy (OAT) with vitamin K antagonist drugs. The microINR system determines quantitative prothrombin time (PT) in INR (International Normalized Ratio) units with fresh capillary blood performed by fingersticking.
The microINR system is a medical device for in-vitro diagnostics intended for professional and self-testing use.

1.2 BEFORE STARTING TO USE THE microINR® SYSTEM

The microINR Meter is intended to be used exclusively with the microINR Chips manufactured by iLine Microsystems.
Before starting to use the microINR system, read these instructions for use completely, as well as the instructions for use of the microINR Chip. Also, do not forget to read the instructions for use of the lancing device and lancets used to obtain the capillary blood sample.

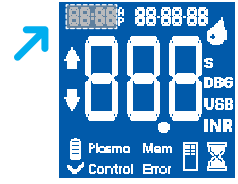
Keep these instructions for use near the microINR system and refer to them if you have any questions about proper operation of the system.

Users of the microINR system (patients and healthcare professionals) must receive proper training before starting to use the system.

Before starting to use the microINR system, verify the compatibility between the software version of your Meter and the reference of the Chips you are going to use.

REF	SOFTWARE VERSION*
CHA0025AA	All software versions
CHB0025AA	>07:03

*The software version appears at the top of the display, immediately after turning the Meter on. If you cannot read the version, repeat the attempt by turning the Meter off and on again.



Safety 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 danger which could result in death, injury or damage of the patient or user 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 or the integrity of the device is displayed over a blue background.

Infection Risk Control on Multi-Patient Tests

- Healthcare professionals must wear gloves during the entire process of the test.
- A separate lancet or lancing device should be used for each individual.
- Used Chips, lancets and gloves might be source of infection. Dispose them in accordance with local regulations to prevent infections.
- Also, comply with your centre's internal hygiene and safety regulations.

There is a potential risk of infection. The healthcare professionals using the microINR system on several patients must take into account that all objects that come into contact with human blood are a possible source of infection. (See: National Committee for Clinical Laboratory Standards: Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue. Approved Guideline, NCCLS document M29-A, 1997).

Electromagnetic Compatibility and Electrical Safety

The microINR system complies with electromagnetic compatibility requirements according to IEC 61326-1 and 61326-2-6 standards.

Do not use the microINR system near sources of intense electromagnetic radiation, as this could interfere with its correct operation.

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

Do not connect the Meter to computers that do not comply with standard IEC 60950.

The Meter must be disposed of as indicated in the WEEE Directive (Waste Electrical and Electronic Equipment 2012/19/UE).

1.3 ORAL ANTICOAGULANT THERAPY

Oral anticoagulant therapy is given to patients to prevent thromboembolic events such as vein thrombosis, pulmonary embolism or those linked to atrial fibrillation or replacement of 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 cause for oral anticoagulant therapy a therapeutic range is defined for each patient meaning the value of the test should lie within that range.

INR and Prothrombin Time

The activity of oral anticoagulants is monitored by measuring the prothrombin time (PT) in seconds, which is the time it

takes for a fibrin clot to form. Thromboplastin is used as a reagent to calculate the prothrombin time (PT). Depending on the nature of this reagent and the equipment used variations on the PT results are to be expected.

Therefore, the WHO recommended a system standardisation 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 corresponding to the thromboplastin. The values of the MNPT and ISI parameters come from clinical calibration studies.

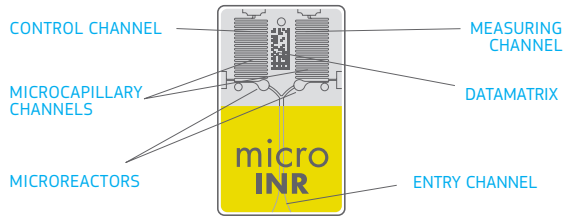
The pharmacological activity of vitamin K-antagonist oral anticoagulants can be modified by other drugs; therefore, you should only take the medicines prescribed by your physician.

Certain liver diseases, thyroid disorders and other diseases or conditions, as well as nutritional supplements, medicinal herbs or changes in diets can affect the therapeutic activity of oral anticoagulants and INR results.

1.4 MEASURING PRINCIPLE

The technology used by the microINR system is based on the microfluidics of the microINR Chip, which allows storing, dosing, moving and/or mixing small volumes of liquids to perform a chemical reaction.

The microINR Chips contain two channels, one for measurement and the other for control. An image of the Chip is shown below:



Each channel consists of a micro-reactor that contains the reagent and a microcapillary where the INR 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 on the Chip through the entry channel, separated into two channels and mixed with the reagents contained in each micro-reactor. The coagulation cascade is triggered instantly. When blood coagulates, its viscosity

increases, which results into a change in blood flow behaviour. The Meter captures the position of the sample by means of a Machine vision system and the position is transformed mathematically into speed and acceleration curves, from which an INR value is 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 eliminating any risk of human error.

2. microINR® SYSTEM

2.1 DESCRIPTION OF THE microINR® KIT

The microINR kit includes:

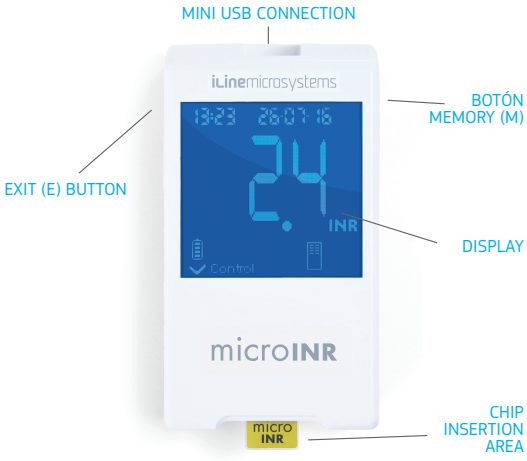
- Case
- microINR Meter
- Charger
- Power adapter
- Mini USB cable
- microINR Data Extraction Software CD
- Instructions for use of the microINR Meter
- Quick guide
- Error guide
- Lancing device (exclusive for Reference Kit KTA0001XX)
- Lancets (exclusive for Reference Kit KTA0001XX)

microINR Chips are sold separately.

Always carry the Meter inside its case.

(1). Expert committee of the WHO on biological normalization. Report forty-eight. Geneva, World Health Organization, 1999 (WHO technical report series No. 889)

2.2 PARTS OF THE microINR® METER



2.3 CHARGING THE microINR® METER

The Meter uses a lithium battery that can be recharged through the mini USB connection on the top of the Meter. Do not place the device in a way that handling the disconnection element is made difficult.

The recommended charging time is approximately 3 hours.

Charge the battery completely before using the Meter for the first time.

Do not open or manipulate the Meter.
Do not pierce or burn the battery.
Do not change the battery. The manufacturer will not warranty Meters that have been opened.
If opening the Meter is necessary, the equipment must be sent to the manufacturer.

Use only the supplied USB cable and wall power adapter provided by the manufacturer or you may damage the Meter.

2.4 SETTING THE TIME AND DATE

- Date format: DD/MM/YY; Time format: 24 hours.
- Press and hold the left and right buttons (E and M) at the same time for 10 seconds until the time fields flash.
- Press the left button (E) to set the hour.
- After selecting the right time, press the right button (M) and set the minutes.
- After selecting the minutes, press the right button (M) again and the date fields will start flashing.
- Use the left button (E) to select the correct day.
- When you reach the correct day, press the right button (M) to set the month. Use the left button (E) to select the correct month.
- When you reach the correct month, press the right button (M) to

set the year. Use the left button (E) to select the correct year.

- After setting the month, time and date, press the right button (M) again to save your settings.

Conducting a test without setting the date correctly might cause a non-detection of expired Chips (E02).

2.5 PATIENT IDENTIFICATION (OPTIONAL)

To identify the patient (PID), take the following steps before conducting a test:

- Hold the right button while inserting a Chip and release it afterwards. Upon releasing the button, "PID" and a 24 alphanumeric field will be displayed, to fill in.
- To enter the characters corresponding to the PID:
  - The first field will flash when selected.
  - To enter the first character, press the left button until you reach the desired character.
  - Validate the character with the right button and go to the next field.
  - Repeat the previous steps until you reach the last field.
  - After accepting the last field, the first field is automatically selected in case you want to correct any characters.
  - To confirm the ID entered and go back, hold the right button for 3 seconds.

While you are entering the PID, if one minute elapses without pressing any buttons, an E01 message will be displayed.

When consulting the results on the Meter, the result of a test (INR or error message) is displayed along with its corresponding PID, date and time. When exporting the microINR results to a PC, the PID will be exported as one more piece of test information.

2.6 QUALITY CONTROL

Internal quality control

Meter performance is automatically checked when the system is turned on.

Integrated and independent on-board quality controls

Level 1 – Pre-test

- Chip integrity check
- Correct insertion check
- Automatic system calibration and rejection of expired Chips

Level 2 - Measuring channel

- Analytic verification performed on the measuring channel that identifies failures when processing the sample during the test, as well as proper pre-analytical treatment of the sample.

Level 3 - Control channel

- Control channel provides highly controlled clotting times. System reliability is assured when control clotting time lies within a pre-defined range.

PROFESSIONAL USE:
Liquid control:
The microINR system has a number of on-board quality control functions integrated into the Meter and the Chip and therefore there is no need to run quality control tests with liquid quality controls. However, iLine Microsystems has available an optional liquid quality control for the microINR system. This control is provided to help meet the regulatory requirements applicable to your facility. Contact your local distributor.

3. CONDUCTING THE TEST

3.1 PREPARING THE NECESSARY MATERIALS

- microINR Meter
- microINR Chips (not supplied)
- Fingersticking material
  - Professional use: disposable lancets (not supplied)
  - Self-testing: lancing device and lancets (exclusive Reference Kit KTA0001XX)
- Skin cleaning material (not supplied)

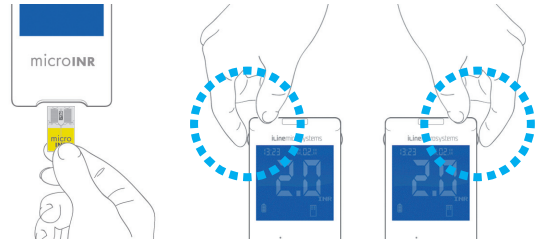
Always use CE marked lancing devices and lancets.

3.2 MEASUREMENT PROCEDURE

Turning the Meter On

The Meter can be turned on:

- By inserting the Chip:
- By pressing any button:

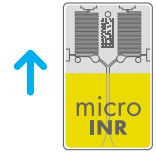


Inserting the Chip

Verify the expiry date and the stored conditions of the Chip before conducting the test.

- Open the pouch. Hold the Chip by the yellow part and so the “microINR” inscription can be read correctly. Insert the Chip into the slot and push it until it stops. Make sure the Chip has reached the end.

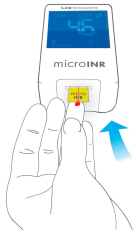
If the pouch of the Chip is open, damaged or the film of the Chip is removed, please, dispose of the Chip and use a new one.



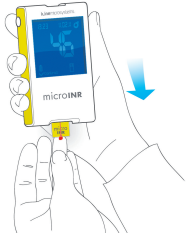
Modes of Use

The microINR system provides two application modes of the sample:

- Approaching the sample to the Meter.

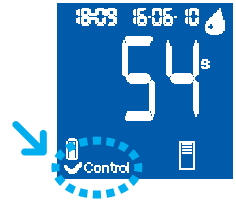


- Approaching the Meter to the sample.



iLine Microsystems only recommends the option of approaching the Meter to the sample for users who are experienced in conducting INR assays with the microINR system.

Conducting the Test



- Once the Chip is inserted, the Meter will perform the quality controls mentioned in section 2.6 of these instructions for use. After conducting the aforementioned quality controls prior to the test, the “control” symbol will light up. If the first level of quality control is not passed, an error message will be displayed on the screen of the Meter.

- The Chip begins to flash and heats up until it reaches the proper temperature. Once this temperature is reached:
  - The device emits an audible signal (beep).
  - The drop symbol begins to flash on the display.
  - A count down appears (80s).
  - The Chip emits a steady light.
- Perform the fingerstick (see section 3.3 of these instructions for use).
- Make sure to obtain a spherical, properly sized drop.
- Apply the drop of blood on the Chip immediately, in contact with the entry channel, without resting the finger on the Chip.
- The Meter will emit a beep when it detects the sample for the test and the drop symbol will stop flashing.

• After the beep, gently move the finger away and wait until the INR results are 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 Chip. Ensure that the size of the drop is enough and the entry channel is not blocked when placing it.

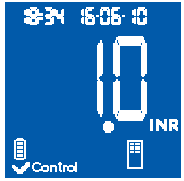
Never perform the fingerstick before the start of the countdown.
Do not touch the Chip's entry channel with the finger while inserting the sample.
Do not touch the Chip or add more blood during the test.

Keep the Meter away from direct sunlight during the test. Do not shake or drop the Meter. If the Meter is dropped or gets wet and the frequency of errors messages increases, contact your distributor.

Test Result and Assay End

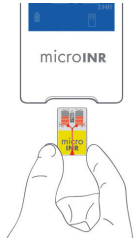
• The measurement is performed and the Meter displays the result in INR units or an error message.

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



If the message E08 appears, do not attempt a new test and proceed to charge the Meter.

• Remove the Chip, holding it from both sides.



The used Chips, lancets and gloves might be source of infection. For healthcare professionals: dispose the materials according to your institution´s infection control policy and the appropriate local regulations. For self-testing patients: you can dispose all the materials in your garbage bin. Discard the used lancets with care to prevent injuries.

Turning the Meter Off

There are two ways to turn the Meter off:

• The Meter turns off automatically after 5 minutes of inactivity.

• Press the left button (EXIT) to turn the Meter off, holding it for 3 or 4 seconds.

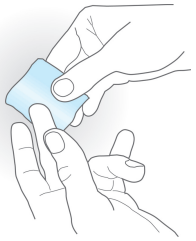
If you don't remove the Chip before turning the Meter off, the results will not be stored.

The Meter cannot be turned off while connected to the power supply or to a computer with the USB cable.

3.3 OBTAINING AND APPLYING THE CAPILLARY BLOOD SAMPLE

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

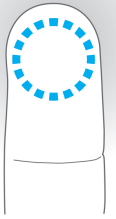
- Read the instructions of the fingersticking devices.
- Hands should be warmed before conducting the fingerstick. You can achieve this by different means: keeping hands below your waist, massaging your finger softly, washing your hands with hot water, etc.



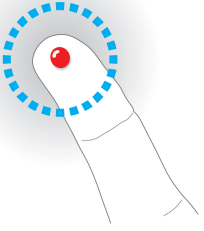
- The fingerstick site must be clean, completely dry and free of contaminants. Washing your hands with warm water and soap is recommended. If disinfecting with alcohol or some other disinfecting solution, you must thoroughly dry the area to remove any traces of substances that might interfere with the result. Dry with a clean and dry gauze and never use the same one you used to apply the disinfectant.

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

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

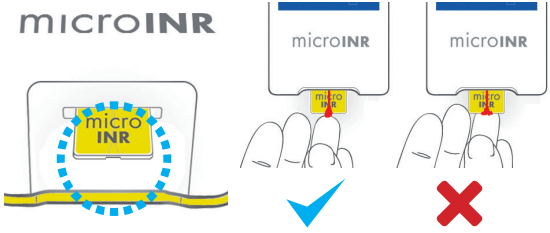


- Place the lancing device firmly against the finger and press the button. Press the base of the finger gently until a drop of blood forms. Do not press the fingerstick site excessively or let the drop of blood smear on the finger. Before placing the drop of blood on the Chip, make sure that it has the right size and a spherical shape. Right size means that it will provide a remnant.



Pressing the fingerstick site may accelerate the process of coagulation or release of interstitial fluid into the sample which may cause incorrect results.

- Apply the drop on the Chip immediately, in contact with the entry channel.



The sample must be applied immediately after obtaining it, otherwise coagulation would start naturally and an error message or an incorrect result might appear.

Avoid contact between the Chip and the finger in order not to obstruct the entry channel and thus 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, gently remove the finger, leaving a remnant in the entry channel as shown in the picture.
- If the test must be repeated, perform the fingerstick in a different site.

Using a correct technique to obtain and apply the sample is essential. Make sure to follow the instructions. Otherwise, the results might be incorrect.

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

If an unexpected result is obtained, repeat the test making sure that the indications described in these instructions for use are strictly followed. If an unexpected result is obtained again, contact your doctor and/or distributor.

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

3.5 LIMITATIONS OF USE

- Once the Chip is taken out of its original pouch, it should be used within the following 6 hours.
- Do not use to measure or monitor the anticoagulation status of patients under treatment with direct oral anticoagulation

treatments (non vitamin-k antagonist drugs).

- The performance of the microINR system has not been demonstrated on blood samples with hematocrit values outside the range of 25% to 55%. Hematocrit out of this range may affect test results.
- The device is highly sensitive to vitamin K dependent coagulation factor deficiencies.

For more information on interferences of the microINR system with other drugs and diseases, refer to the instructions for use of the microINR Chip.

4. MEMORY AND DATA EXTRACTION TO A COMPUTER

The microINR Meter can store up to 199 results of patients and liquid quality controls. 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 right button (M). The result of the last test conducted will be displayed with its date and time and the ID of the corresponding patient (if it was entered).
- Press again to display the next result, corresponding to the second-to-last test and so on.
- Press the left button (E) to return to the initial screen. If you enter a Chip while you are checking the memory, a new test will begin normally.

To prevent losing stored data, download the data to your computer with the Data Extraction Software on the CD that you will find inside the Meter's case along with its instructions.

The downloaded information will be displayed in the following order:

1. Meter ID (MID)
2. Number of test
3. Date
4. Time
5. Patient ID (PID)
6. INR
7. INR of the control channel
8. Datamatrix code
9. Acceptance range of the control channel
10. Type of sample (blood or plasma)

5. CLEANING AND DISINFECTING THE microINR® METER

Cleaning and disinfection of the microINR Meter is essential to ensure proper microINR system operation and to prevent blood-borne transmission of pathogens in multi-patient tests.

Clean the Meter when it is visibly dirty and before disinfecting.

Use a new pair of gloves every time you clean and disinfect

the Meter.

Before cleaning or disinfecting the Meter, turn it off and make sure the cables are unplugged.

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 fibres or lint on any part of the Meter, especially on the Chip insertion area and the USB port.

To disinfect the Meter:

- Disinfect all the parts of 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 and clean lint-free cloth or gauze.
- Afterwards, wait 15 minutes for the Meter to dry and ensure it is completely dry before conducting a new test.
- Ensure there are no remaining fibres or lint on any part of the Meter, especially on the Chip insertion area and the USB port.
- Discard the used wipes and gloves.

Do not clean or disinfect the Meter while conducting a test.

Do not use aerosols or any 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 the Meter.

Make sure that no fluids enter the Meter or the Chip insertion area.

The Chip insertion area must always be clean and dry before conducting a test. When inserting a Chip, remains of blood or alcohol can contaminate the sample.

Do not handle the Chips with alcohol-contaminated gloves.

Comply with all recommendations regarding cleaning and disinfection of the Meter.
Not doing so could cause incorrect results.

6. ERROR GUIDE

Error	Probable Cause	Possible Solution
Messages when preparing to test		
E01	The Datamatrix could not be read.	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. If the date is not correct, enter the current date and insert the same Chip again. If the date is correct, repeat the test with a new batch of Chips after verifying their expiry date.
E03	The 80 second interval for applying the sample has been exceeded.	If the sample has not yet been applied, repeat the test with the same Chip.
E04	Chip inserted backwards.	Rotate the Chip and repeat the test.
E11	Faulty or incorrectly inserted Chip.	Insert the same Chip again, ensuring complete insertion. If the problem persists, repeat the test with a new Chip.
Messages related to the test		
E05/ E09	Inadequate coagulation of the sample during the test.	Repeat the test with a new Chip. Strictly follow instructions on obtaining and applying the sample. If the problem persists, repeat the test with a new box or batch of Chips.
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. If the problem persists, repeat the test with a new box or batch of Chips.
E16	Inadequate coagulation of the sample during the test. ATTENTION: Possible sample with abnormally high clotting times.	Repeat the test with a new Chip. If error E16 is displayed again, use a different measurement method. 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. This error occurs mainly in patients with a hematocrit outside the defined range for the microINR system (25%-55%).
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 warmer location.
E08	Low battery.	Charge the device with the charger supplied by the manufacturer.
E12	Temperature above the defined range.	Repeat the test in a cooler location.

7. ADDITIONAL INFORMATION

7.1 SPECIFICATIONS

- Dimensions of the Meter: 119 x 65 x 35 mm.
- Weight: 213±3 gr. (Battery included).
- Screen: LCD 45 x 45 mm.
- Memory: 199 results / error messages with their date and time.
- Power supply:
  - Battery: Lithium 2400mAh/2800mAh; 3.7 V. Consumption: 1 A.
  - Power supply: Only plug the charger to power supplies with the following characteristics (Input): 100-240 V, 50-60 Hz, Consumption: 0.2 A.
  - Power supply (Output): 5 V dc, 1000 mA via a mini USB connection.
- Battery life: *approximately 70 tests.
- Operation conditions:
  - Temperature: 15ºC-35ºC.
  - Maximum relative humidity: 80%.
- Meter storage temperature: -20ºC to 50ºC.
- Measurement range: 0.8 – 8.0 INR.
- Sample volume: at least 3µL.
- Data transfer via a mini USB connection.

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

7.2 CE DECLARATION OF CONFORMITY

This medical device complies with the standards and legal requirements of Directive 98/79/EC of the European Community for In vitro diagnostic medical devices, of 27 October 1998, and with Directive 2011/65/EU of the European Parliament and Council (RoHS) of 8 June 2011 on restrictions of use of certain hazardous substances on electrical and electronic equipment.

7.3 WARRANTY

iLine Microsystems warranties to the original buyer that the microINR system is free of material and manufacture defects for two years after the purchase date.

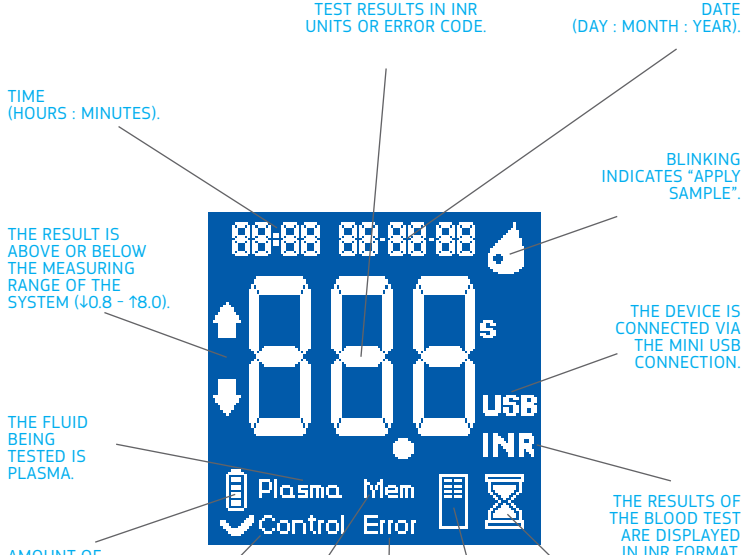
This warranty does not cover any component damaged due to inadequate storage in environmental conditions outside the defined range, accidents or modifications, incorrect use or handling and misuse. The buyer must deliver a written warranty complaint to the manufacturer within the corresponding warranty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

7.4 TECHNICAL SERVICE

If a problem persists after performing the actions stated in the table of errors or if you want additional information, you can contact your local distributor.

7.5 SYMBOLS

	“Legal Manufacturer”
SN	“Serial number”
REF	”Catalogue reference”
CE 0120	“CE Mark” 0120 Number of Notified Body
	“Electronic waste selective collection”
	“Read the instructions for use”
IVD	“Medical device for *in vitro* diagnostic”
	”Direct current”
	“Temperature limit”
LOT	“Lot number”
	“Biological hazard”
	“Warning”
	“Precaution”



7.6 GLOSSARY

Capillary blood: blood from the smallest blood vessels in the body, usually obtained by puncturing a fingertip.

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

Chip: disposable element inserted into the Meter. Serves to enter the sample for the INR test.

Control channel: channel used to measure the normalised coagulation time in order to detect degradation of the reagents.

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

International Normalized Ratio [INR]: standardised prothrombin time measurement system that accounts for the different sensitivity of the thromboplastins used in different methods. The INR results from different prothrombin time measurement systems can be compared to each other.

Lancet: piercing tool used to make a small cut or puncture to collect a small drop of blood, which will be used for the INR test.

Microcapillary: site on which the INR test takes place.

Microfluidics: technology for storing, dosing, transferring and/or mixing small volumes of fluid to cause a chemical reaction.

MicroINR Meter: electronic device that serves to conduct INR tests.

Microreactor: area of the Chip meant to store the reagents.

Mini-USB connector: connector on the top front of the microINR Meter.

Oral anticoagulant therapy: orally administered treatment that inhibits or interferes with the coagulation of the blood.

Plasma: liquid part of the blood.

Prothrombin time (PT): coagulation analysis performed to analyse the extrinsic coagulation pathway.

Quality control: tests to prove that a system performs correctly providing reliable results.

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

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

Therapeutic range: safe range of INR values. The physician determines a specific therapeutic range for each patient.

Thromboplastin: A substance used by blood platelets and combined with calcium that converts prothrombin (protein) into thrombin (enzyme) as part of the clotting cascade.

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

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