



**friendly
technology**

microINR® SYSTEM: PRAXIS STEPS AND KEY OBSERVATIONS

The microINR system is intended to monitor oral anticoagulation therapy (OAT) with vitamin K antagonists. The microINR system determines quantitative prothrombin time (PT) in INR (International Normalized Ratio) units with fresh capillary blood performed by fingersticking. Please read the instructions for use before using the microINR system. 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.

The microINR System provides two sample application modes: approaching the sample to the Meter or approaching the Meter to the sample.

For new users, approaching the sample to the Meter is the recommended option. Once the user gains confidence in the system, approaching the Meter to the sample can be also applied.

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



6 KEY STEPS ON SAMPLE HANDLING

1. Getting ready for the test: cleaning the skin & warming hands

Prepare all items needed for the testing, the microINR Meter, a microINR Chip, a lancet and means for skin cleaning.

The fingerstick site must be clean, free of contaminants and completely dry. Washing hands with warm soapy water is recommended.

Dry the area thoroughly using a new clean and dry gauze to remove any trace of substances that might interfere with the result.

Any alcohol, disinfectants, shaving creams, lotions or sweat on the fingerstick area or the blood sample may cause an incorrect result.

It is convenient to warm hands by keeping them below the waist, massaging hand and finger softly...

2. Insert the chip correctly

Remove a Chip from its pouch and hold it 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.

The Meter will turn on automatically and a flashing hourglass appears on the screen. Wait for the Meter to be ready for testing, while preparing hands for the fingerstick. Make sure the hand is warm and fingertip clean.



3. Never fingerprick before the countdown has started

Do not perform the puncture until you hear a "beep" tone and both, the 80-second countdown and the drop symbol are displayed on the screen.



4. The drop must have the right size and a spherical shape

After fingersticking and 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 (point 6 of this document).

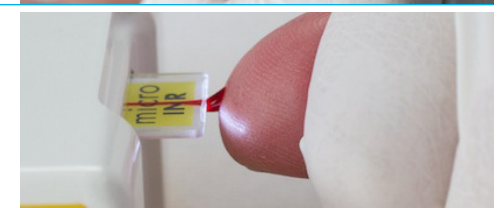
Do not press the fingerstick site or let the drop of blood spread on the finger.



5. Do not block the entrance of the Chip with the finger

Avoid contact between the Chip and the finger in order not to obstruct the entry channel and thus allow for uninterrupted blood absorption.

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



6. Remove the finger gently

After hearing the "beep" gently remove the finger, making sure that a remnant stays at the entry channel of the Chip.

Tip: gently remove the finger upwards.

Do not bump or shake the Meter after sample application.



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.

UNEXPECTED RESULTS

Results are unexpected when they do not match the patient's symptoms (i.e., haemorrhages, bruises, etc.), or when they lie outside the therapeutic range.

If an unexpected result is obtained, repeat the test on a different finger, using a new Chip and lancet, and making sure that the indications described in the instructions for use are followed, especially these 6 key steps on sample handling.

If after repeating the test, you obtain another unexpected result, conduct the necessary diagnostic tests in order to determine its cause.

What causes unexpected results:

- Any **contamination** of the sample **by alcohol** (disinfecting solutions, shaving lotions, etc.), lotions or sweat on the fingerstick area or in the extracted drop may cause incorrect results. This is the reason why the fingerstick area must be clean and dry.
- A **hematocrit** that is higher or lower than the validated **range** of the microINR system (25-55%) can cause an incorrect result. Verification of the patient's hematocrit will help ensure the reliability of results obtained with the meter..
- **Antiphospholipid syndrome (APS)** may falsely prolong the INR value. Testing with an APS insensitive laboratory method is recommended if APS is known or suspected.
- Certain **prescription drugs** (e.g., heparin) and over-the-counter medications can affect the action of oral anticoagulants and the INR value.
- Liver **diseases**, congestive heart failure, thyroid dysfunction, and other diseases or conditions can affect the action of oral anticoagulants and the INR value.
- **Changes in diet**, lifestyle, or taking nutritional supplements can affect the action of oral anticoagulants and the INR value.

iLine Microsystems S.L.
Paseo Mikeletegi 69
20009 DONOSTIA-SAN SEBASTIÁN
Gipuzkoa – Spain

www.ilinemicrosystems.com
info@ilinemicrosystems.com
Tel.: +34 943 005 651

PXA0001EN Rev 2020-12