



**friendly
technology**



**Smart monitoring of
oral anticoagulation
therapy**



microINR



**friendly
technology**

iLine Microsystems is a biotech company researching, developing and manufacturing POCT IVD devices in the Hemostasis area since 2007. The company incorporates proprietary technology that provides innovative and highly reliable products for the current and future needs of the changing healthcare models.





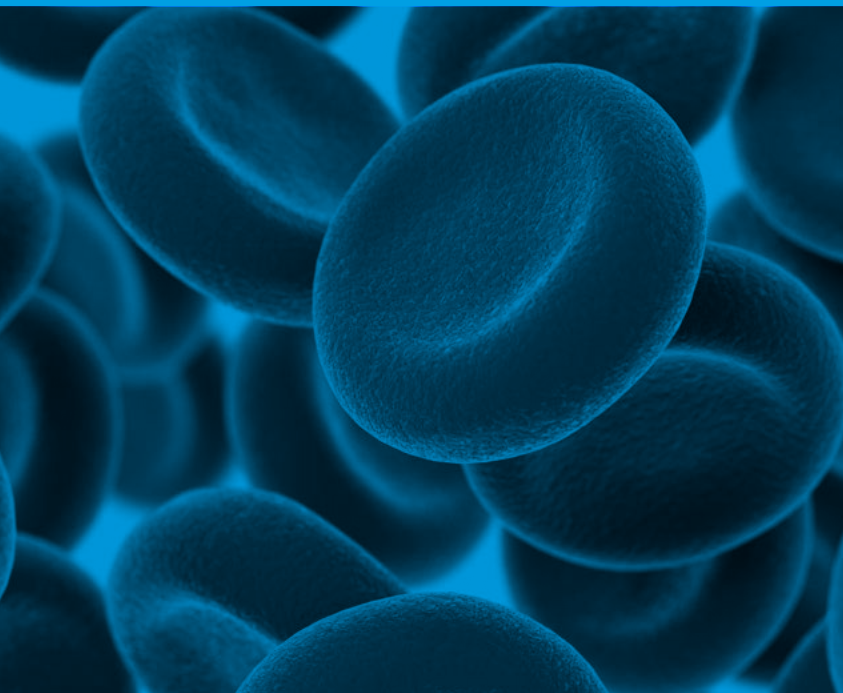
Microfluidic & Modular platform design

From a simple diagnostic solution to the modular platform concept to address coagulation diagnostic systems challenges.

iLine Microsystems

technology is based on microfluidic and Lab-on-a-Chip technology. This technology provides means to perform a biological test comprising sample application, reagent storage, mixing, detection and QC, all these embedded in a miniaturized chip using a minimum volume of blood sample. This innovative concept retains quality

equivalents to the classical laboratory processes, and it also provides the advantages of a user-friendly one-step assay. The Core Technology comprises means for Chip manufacturing, based in microengineering and microfabrication processes, which allows massive production that combines high quality at a significant cost efficiency.



microINR System

The microINR System is an in vitro diagnostics medical device, intended to monitor oral anticoagulation therapy (OAT) with vitamin K antagonist drugs.

The microINR System refers to the meter and the analytic test strips (microINR Chips). Our system provides quantitative

determination of prothrombin time (PT) in INR (International Normalized Ratio) units with fresh capillary blood performed by fingersticking.

The microINR System has been developed to fulfill the needs of all the existing OAT monitoring models and have been CE mark certified for

patient self-testing and for use by healthcare professionals.

The System employs patent granted technology, based on the iLine's Core Technology and provides accurate and reproducible results as proven in extensive and independent performance evaluations.



microINR

The microINR Meter is an in vitro diagnostics medical device, intended to monitor oral anticoagulation therapy (OAT) with vitamin K antagonist drugs.



microINR link

The microINR Link Meter combines all the advantages of the microINR Meter (fully automatic, minimum testing steps, low sample volume, multilevel QC strategy) with a built-in wireless Bluetooth® Low Energy 5.0 technology.



microINR expert

The microINR Expert Meter is a professional PT/INR coagulometer for near-patient testing. State-of-the-art technology with multiple connectivity options, traceability, and the highest safety standards.



microINR Chips

The microINR Chip is a disposable plastic test strip, that encloses two microcapillary channels, of extremely simple construction and fully passive (i.e. no built-in sensors, nor electrodes, nor external pumping).



microINR EasyControl

microINR EasyControl allows the performance of external quality controls at professional settings.



MINI-USB CONNECTION

DISPLAY

BUTTONS

CHIP INSERTION SLOT

microINR

Consisting of a Machine Vision System (MVS) that provides automatic interfacing and detection means, the **microINR Meter** also offers the best qualities of a portable coagulometer:

no buttons to be pressed during the testing, automatic strip identification, minimum sample volume and easy-to-use design.

Meter dimensions

119 x 65 x 35 mm

Screen dimensions

45 x 45 mm

USB interface

For results transfer

View data history

Up to 199 tests and error messages

Power supply:

Rechargeable battery (approx. 70 Test per battery cycle)

2 Buttons

For time/date settings and turning on/off





microINR link

The microINR Link Meter combines all the advantages of the microINR Meter (fully automatic, minimum testing steps, low sample volume, multilevel QC strategy) with a built-in wireless Bluetooth® Low Energy 5.0 technology.

Bluetooth® connection with microINR is easy and convenient. By pairing microINR Link with a compatible device, the results will be automatically sent after its performance, keeping the testing steps set to the minimum.



Wireless Connectivity through Bluetooth Low Energy 5.0:

- Extremely low power consumption
- Faster data transfer
- Improved security
- Robust and reliable connections indoors and outdoors
- Prevention of interferences, which improves wireless coexistence
- More data capacity

User friendly

- Configurable settings
- Intuitive icons for an easy workflow



microINR expert

The state-of-the-art technology included in the microINR Expert meter provides health-care professionals with a superior tool to monitor their patients under oral anticoagulant therapy.

The advanced connectivity options, the traceability of patients and operators, the innovative and sophisticated software, and the configurable settings make the microINR Expert appropriate for a wide range of settings and markets.



User Experience

- High resolution capacitive touch screen
- Quick learning curve and intuitive handling
- Animations and acoustic signals supporting the testing process.
- Integrated troubleshooting messaging
- Rechargeable lithium battery

Safety

- Automatic Chip lot ID: No manual lot identification needed.
- Multilevel on-board QC: assessment of any potential source of error.
- Optional liquid control through dedicated QC menu.
- Optional QC lockout to meet potential regulatory requirements.

Traceability

- Operator ID and Patient ID
- Barcode scanner for 1D and 2D codes
- Test result in INR + PT units.
- Option to add comments
- Memory extraction in PDF file.

Connectivity

- Wi-Fi
- Bluetooth Low Energy 5.0
- Ethernet
- Superior components that allow a quick and reliable integration to DMS/LIS/HIS



microINR Meters



User-friendly

- No calibration chip needed
- Fully automatic
- Rapid test performance (less than 1 minute)
- Easy-to-use: testing steps set to the minimum
- Capacity touch screen

Small sample volume

- Painless fingersticking
- Gentle fingersticking reduces forced tissue factor activation
- Easy sample collection

Reliability and traceability

- Multilevel on-board QC strategy
- Patient ID
- Operator ID
- Barcode Reader

Connectivity

- Bluetooth Low Energy 5.0
- USB for data transfer
- Ethernet
- Wi-Fi

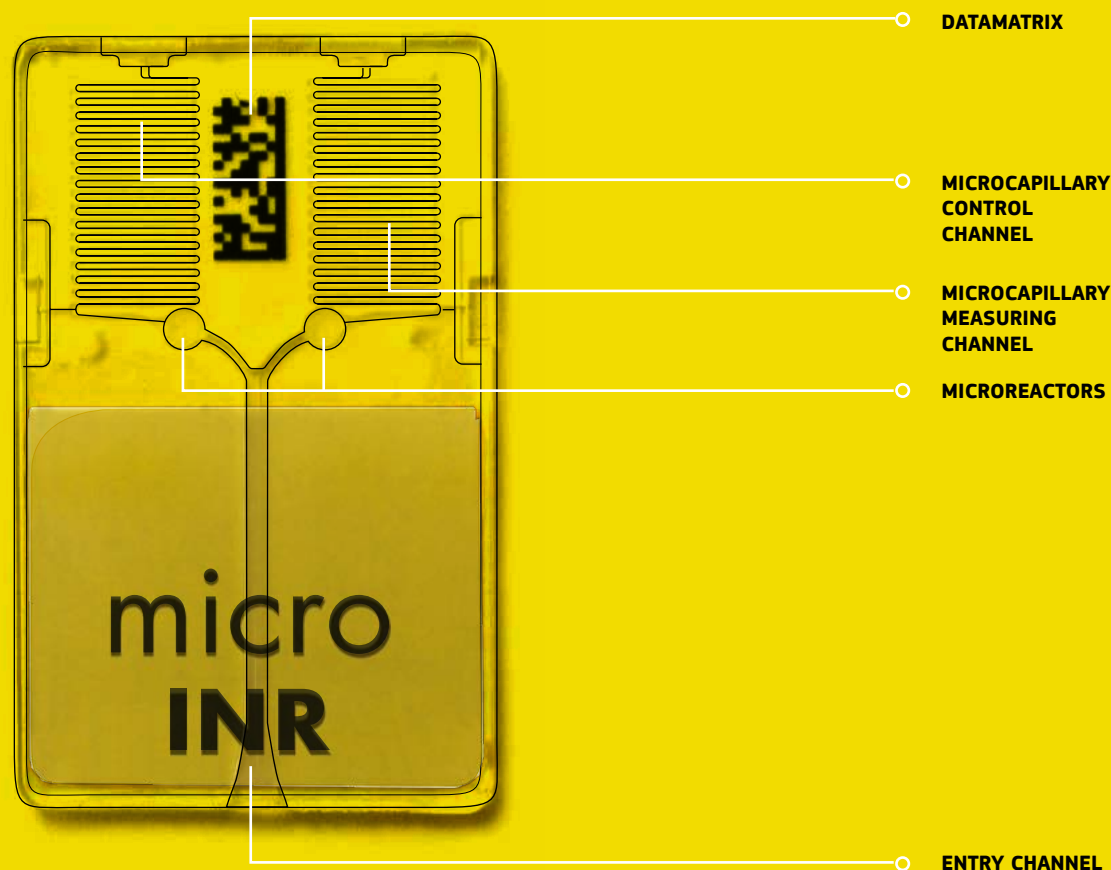
	microINR	microINR link	microINR expert
No calibration chip needed	●	●	●
Fully automatic	●	●	●
Rapid test performance (less than 1 minute)	●	●	●
Easy-to-use: testing steps set to the minimum	●	●	●
Capacity touch screen			●
Painless fingersticking	●	●	●
Gentle fingersticking reduces forced tissue factor activation	●	●	●
Easy sample collection	●	●	●
Multilevel on-board QC strategy	●	●	●
Patient ID	●	●	●
Operator ID			●
Barcode Reader			●
Bluetooth Low Energy 5.0		●	●
USB for data transfer	●	●	
Ethernet			●
Wi-Fi			●

Working principle

INR determination through sample flow monitoring along microcapillaries, following activation of the coagulation cascade. The current IVD test mimics the conditions of “in vivo” hemostasis, also referred as “ex vivo” (1).

Chip description

Disposable plastic test strip, that encloses two microcapillary channels, of extremely simple construction and fully passive (i.e. no built-in sensors, nor electrodes, nor external pumping).



(1) Armando Tripodi, The history of Phenotypic testing in Thrombosis and Hemostasis, Seminars in Thrombosis and Hemostasis, 2008, Volume 34, number 7

microINR Chips

Chip specifications

High sensitivity human recombinant thromboplastin

Chip expiry and calibration parameters coded and integrated into the Chip

Individually packed

Storage at room temperature (2-25°C / 36-77°F)

15 Months shelf life

System specifications

3 µL sample volume required

Measurement range: 0.8 – 8.0 INR

System ISI: Approx. 1

Multilevel on-board QC performed in each assay



microINR EasyControl

microINR EasyControl allows the performance of external quality controls at professional settings.

Designed to be exclusively used with the microINR System.

Easy to use material.

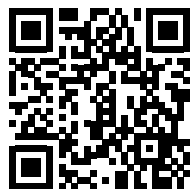
Automatic calibration for liquid control already coded on the microINR Chip Datamatrix.



Step by step procedure

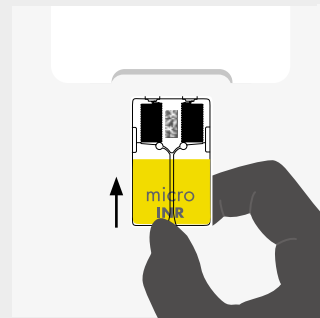
No buttons need to be pressed during this procedure. Test is fully completed in less than 1 minute. Acoustic signals and illumination of the Chip guide the user along key steps.

Watch the procedure



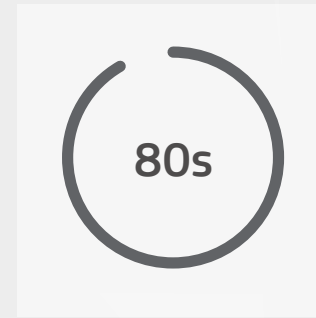
01

Insert the Chip. The meter automatically turns on. The meter performs the pretest QC and warms up the Chip.



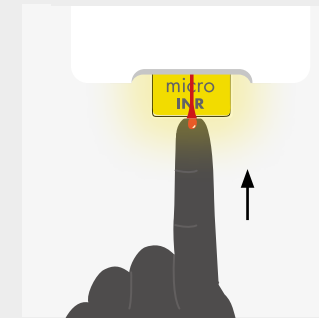
02

When the System is ready, the Meter beeps and a 80-second countdown is displayed.



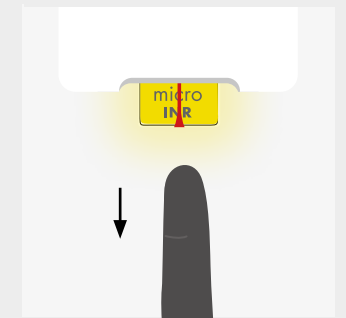
03

Perform the fingerstick and apply the blood sample to the Chip entry channel.



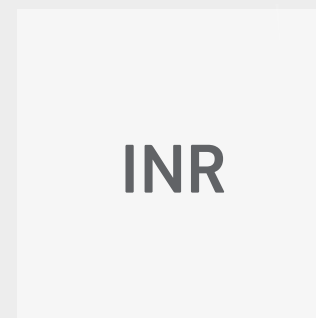
04

When enough sample volume is detected, the meter beeps and the countdown disappears. Remove the finger gently.



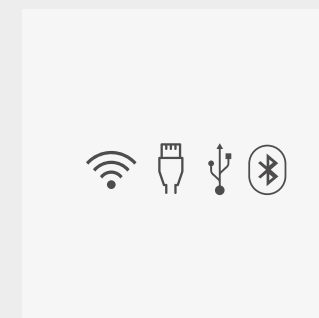
05

The INR result is displayed in a few seconds.



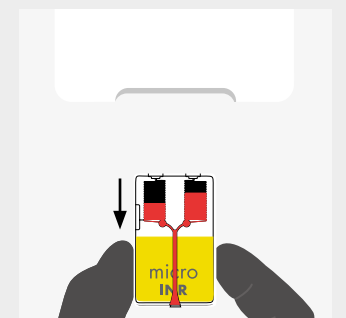
06

Result transfer through the different connectivity options offered by our meters (USB, Ethernet, Bluetooth, Wi-Fi)



07

Used Chip can be discarded. Dispose of it properly.



A growing family





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The information contained in this brochure is not applicable to all countries. Product registration and availability vary by country. For more information, please contact: info@ilinemicrosystems.com

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