

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.

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Microfluidic & Modular platform design

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

iLine Microsystems 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 developed readers (microINR and microINR Link Meters) 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



Meters description

Consisting of a Machine Vision System (MVS) that provides 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-touse design.

Meter dimensions

119 x 65 x 35 mm

Screen dimensions

45 x 45 mm

USB interface

For results transfer

View data history

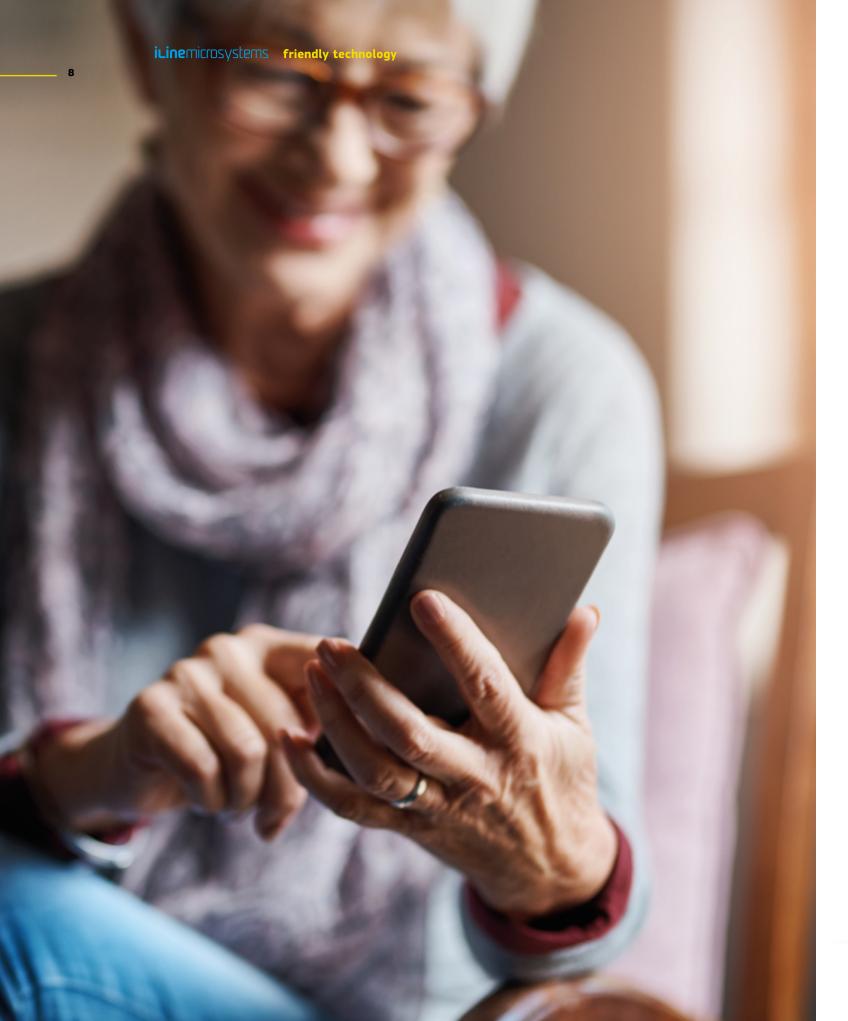
Up to 199 tests and error messages

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

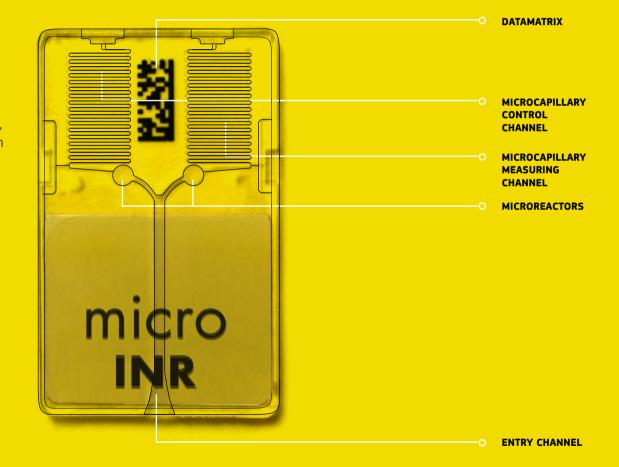
- Configurable settings
- Intuitive icons for an easy workflow

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).



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 Systems

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User-friendly

No calibration chip needed

Fully automatic

Rapid test performance (less than 1 minute)

Easy-to-use: testing steps set to the minimum

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Small sample volume

Painless fingersticking

Gentle fingersticking reduces forced tissue factor activation

Easy sample collection

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Reliability

Enhanced multilevel QC strategy assesses all possible sources of error

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Wireless connectivity

Bluetooth Low Energy 5.0

Automatic result transfer





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.

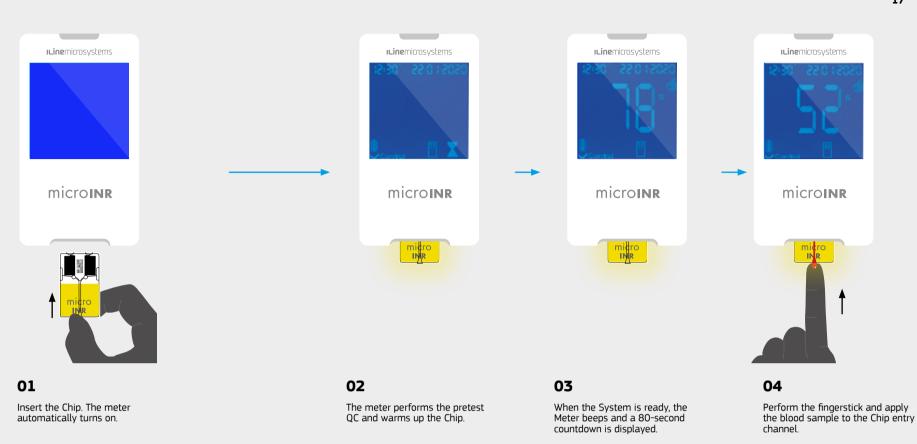


Step by step procedure

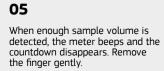
No buttons need to be pressed during this procedure. Test is fully completed in less than 1 minute. Acoustic signals and illumination of the Chip guide the user along key steps.

Watch the procedure









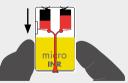


06The INR result is displayed in a few seconds.



The meter automatically sends the result through the Bluetooth connection (only on microINR Link Meter).





Used Chip can be discarded. Dispose of it properly.

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iLine range of products





CAT0001EN - Rev. 2021-05

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