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# Smart monitoring of warfarin therapy



# microINR





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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.

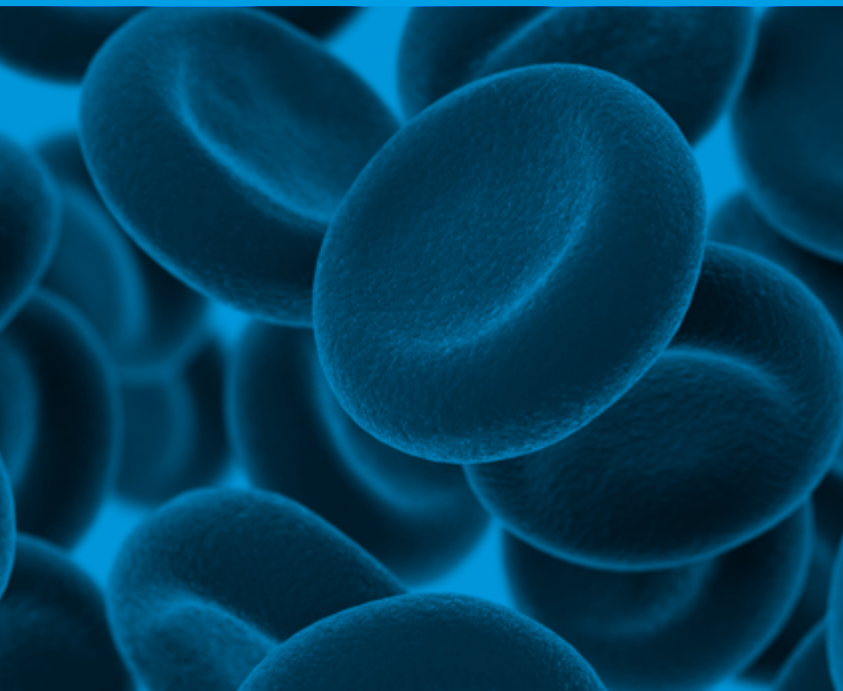






# Microfluidic & Modular platform design

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



**iLine's Core 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 warfarin.

The microINR System refers to the reader (microINR 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 it is intended for patient self-testing use, as well as for healthcare professionals at

Point of Care settings.

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



### Meter 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-to-use design.

#### Meter dimensions

119 x 65 x 35 mm

#### Screen dimensions

45 x 45 mm

#### 2 Buttons

For time/date settings and turning on/off

#### View data history

Up to 199 tests and error messages

#### Power supply:

Rechargeable battery (approx. 70 Test per battery cycle)

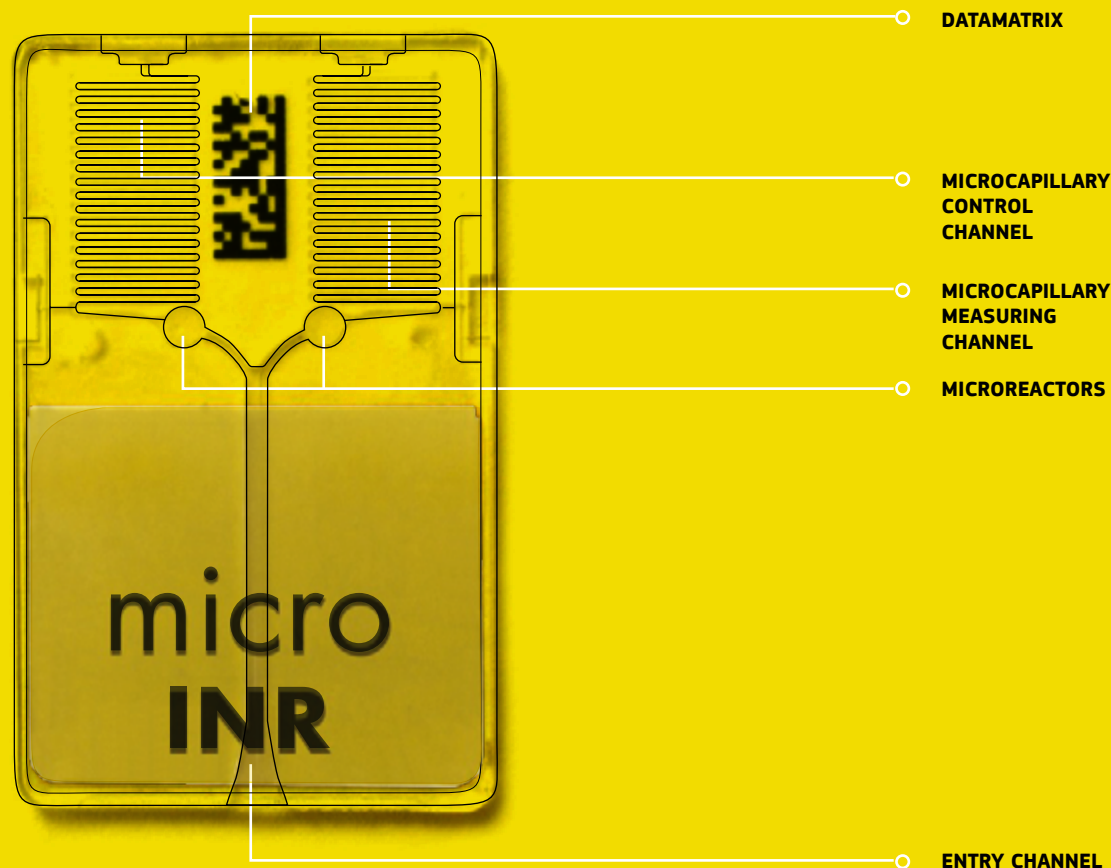
# microINR Chips

## 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 (36-77°F)

15 Months shelf life

## System specifications

3 µL sample volume required

Measurement range: 0.8 - 4.5 INR

System ISI: Approx. 1

Multilevel on-board QC performed in each assay

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





## microINR

### User-friendly

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No calibration chip needed

Fully automatic

Rapid test performance (less than 1 minute)

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

### Small sample volume

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Painless fingersticking

Gentle fingersticking reduces forced tissue factor activation

Easy sample collection

### Reliability

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Enhanced multilevel QC strategy assesses all possible sources of error

### Safety

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Automatic lot ID: No calibration chip needed

Test results only reported in INR units

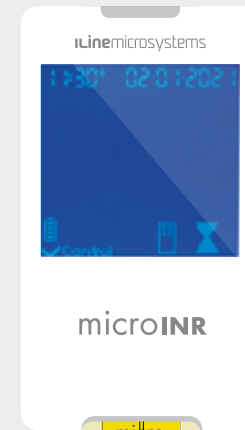
System protected for values above 4.5 INR

# Step by step procedure

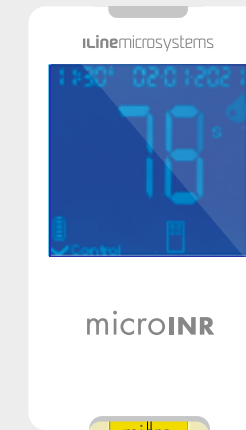
No buttons are needed to be pressed during this procedure. Test is fully completed in less than 1 minute. Acoustic signals and illumination of the Chip guide the user along key steps.



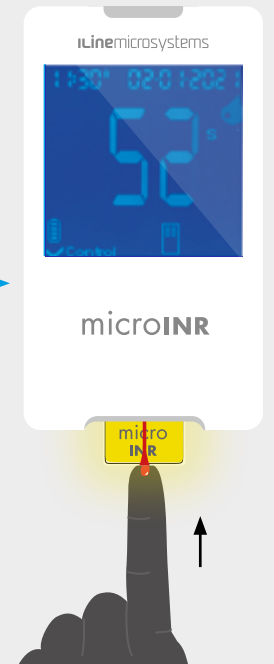
**01**  
Insert the Chip. The meter automatically turns on.



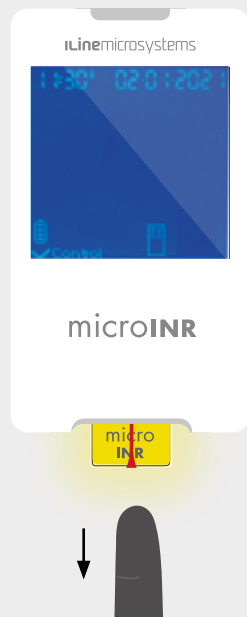
**02**  
The meter performs the pretest QC and warms up the Chip.



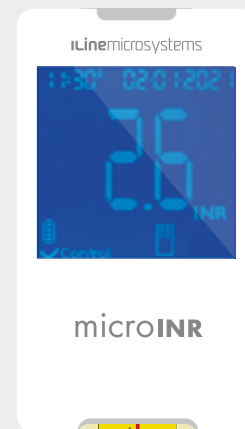
**03**  
When the System is ready, the Meter beeps and a 80-second countdown is displayed.



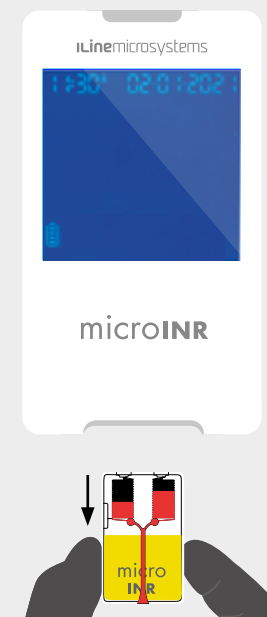
**04**  
Perform the fingerstick and apply the blood sample to the Chip entry channel.



**05**  
When enough sample volume is detected, the meter beeps and the countdown disappears. Remove the finger gently.



**06**  
The INR result is displayed in a few seconds.



**07**  
Used Chip can be discarded. Dispose of it properly.



# Our System







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#### **CLIA categorization**

This System is 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.

The information contained in this brochure is applicable to the product cleared by the FDA for the US market. Product registration and availability vary by country. For more information, please contact: [info@ilinemicrosystems.com](mailto:info@ilinemicrosystems.com)

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