

# Smart devices for OAT monitoring

## microinr





### iLine<sup>®</sup> friendly microsystems

As a result of years of biomedical and biotechnological research on IVD solutions, iLine Microsystems was founded in 2007 by enthusiastic professionals devoted to design, integrate and manufacture medical devices to meet the needs of present and future healthcare models, improving the effectiveness of healthcare professionals and patient's quality of life.



## Microfluidic & Modular platform design.

From a simple diagnostic solution to the modular platform concept to address coagulation diagnostic system's challenges.

#### iLine Microsystems

delivers a complete diagnostic solution based on a single-use microfluidic Chip and a Meter, intended for coagulation-oriented diagnostic. Our manufacturing line represents the company's core technology. It is focused on the Lab-on-a-Chip concept, integrating advanced biochemical processes into a miniaturized plastic platform. This innovative concept retains the efficiency and quality equivalents to the classical laboratory processes but, at the same time, provides the advantages of combined speed of analysis and competitive cost. Moreover, iLine's Core Technology allows the manufacturing of a wide range of microfluidic chip designs.



## **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

microINR

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.

Our device 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.



#### 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.

View data history
Up to 199 test and error messages
Power supply:
Rechargeable battery (approx. 70 Test per battery cycle)
2 Buttons
For time/date settings and switch on/off

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## micro**INR**

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<sup>®</sup> Low Energy 5.0 technology. Bluetooth<sup>®</sup> 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.

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#### 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 Chips

### Working principle

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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).



micro**INR** micro**INR** 

### Chip specifications

High sensitivity human recombinant thromboplastin

Chip expiry and calibration parameters coded and integrated into the Chip

Real control assay at parallel channel

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 (whole blood): Approx. 1

Integrated and independent on-board QC

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

### microINR Systems

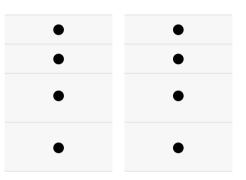
### micro**INR** micro**INR**

#### User-friendly

minute)

No calibration chip needed
Fully automatic
Rapid test performance (less than 1

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



#### Small sample volume

Painless fingersticking	•
Gentle fingersticking reduces forced tissue factor activation	٠

Less prone to insufficient sample volume errors



#### Reliability

Enhanced multilevel QC strategy assesses all possible sources of error



#### 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's Datamatrix.



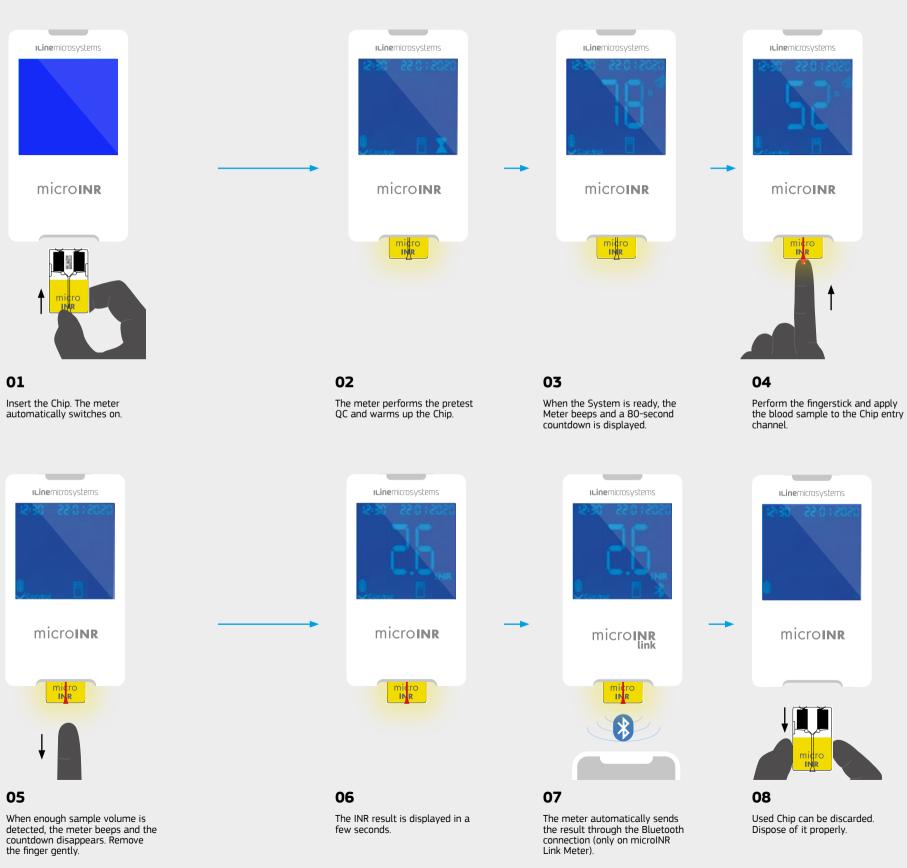
### Step by step procedure

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

Watch the procedure









#### improving clinical outcomes

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Prospect Diagnostics Ltd is the distribution partner in the British Isles and Ireland for iLine® Microsystems S.L.

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The information contained on 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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