

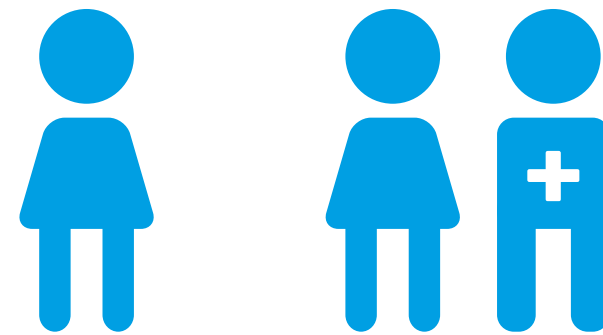


friendly
technology

microINR

THE NEXT GENERATION POINT-OF-CARE AND
SELF TESTING SYSTEM FOR OAT MONITORING





microINR is intended for use in Oral Anticoagulation Therapy (OAT) Point-of-care monitoring. This device has been developed to fulfill the needs of the existing models in decentralized OAT monitoring, and has been CE mark certified for both patient self-testing and for use by healthcare providers making it suitable for both uses.

microINR system tackles these demands through its compact easy-to-use design, low-volume sample requirement and multilevel integrated and independent quality controls.

microINR employs patent granted technology and provides accurate and reproducible results as proven in extensive performance evaluations.

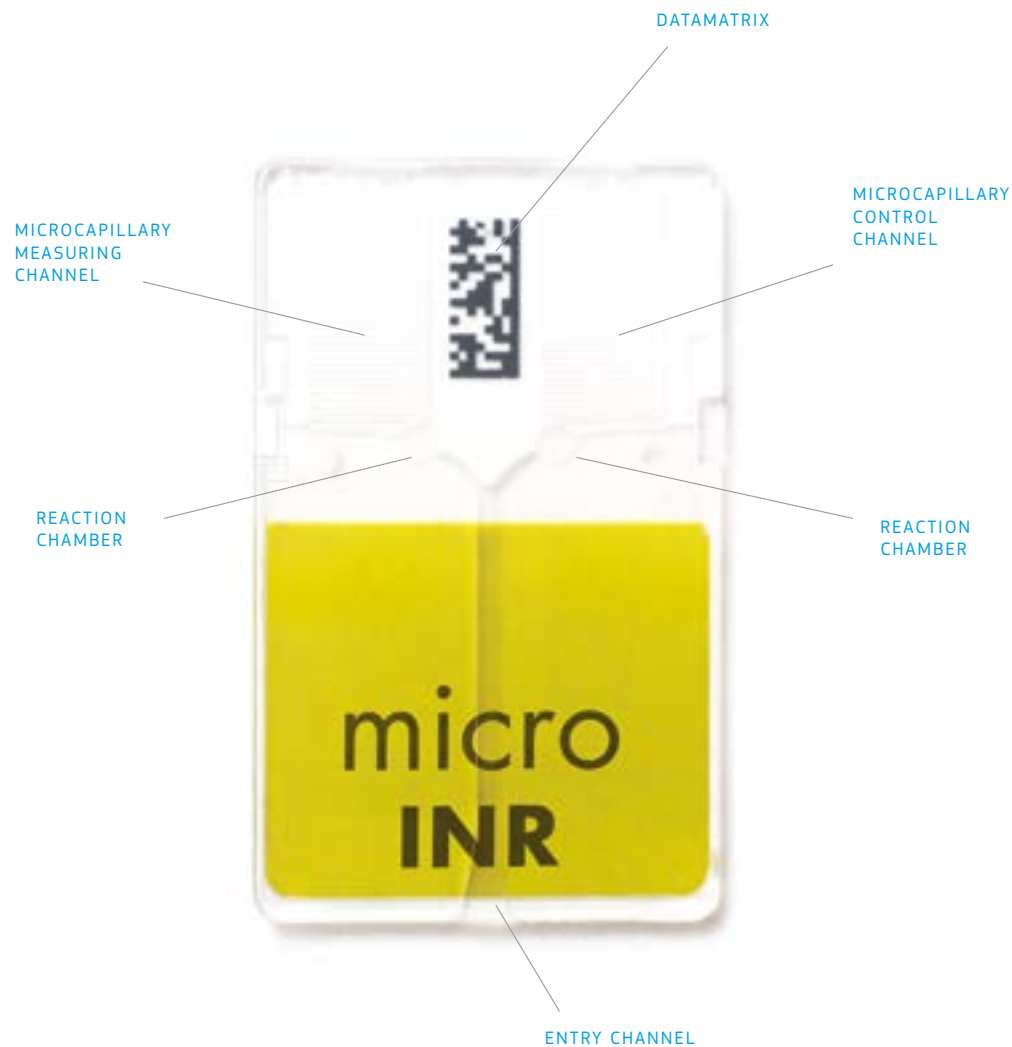
WORKING PRINCIPLE

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.



SYSTEM KEY SPECIFICATIONS

- VALID FOR FRESH CAPILLARY BLOOD
- SAMPLE VOLUME 3 μ L
- SYSTEM ISI FOR WHOLE BLOOD IS APPROXIMATELY 1
- INTEGRATED AND INDEPENDENT ON-BOARD QC
- EXTERNAL QC ASSESMENT USING CONTROL PLASMAS

CHIP SPECIFICATIONS

- HIGH SENSITIVITY HUMAN RECOMBINANT THROMBOPLASTIN
- ON-BOARD QC
- CODING INTEGRATED INTO CHIP
- PACKED INDIVIDUALLY
- STORAGE AT ROOM TEMPERATURE

METER DESCRIPTION

Consisting of an embedded artificial vision system that provides interfacing and detection means, the Meter also offers the best qualities for a portable coagulometer: no buttons to be pressed during testing, automatic strip identification, minimum sample volume and easy-to-use design.



METER SPECIFICATIONS

- DIMENSIONS: 119 X 65 X 35 MM
- SCREEN DIMENSIONS: 45 X 45 MM
- VIEW DATA HISTORY, UP TO 200 TESTS AND ERROR LOGS
- POWER SUPPLY: RECHARGEABLE BATTERY (MORE THAN 100 TESTS PER BATTERY CYCLE)
- 2 BUTTONS (FOR TIME AND DATA SETTING)
- USB INTERFACE FOR RESULTS TRANSFER
- USER-FRIENDLY PC PROGRAM FOR RESULT DOWNLOAD AND DISPLAY

QUALITY CONTROLS

INTEGRATED AND INDEPENDENT ON-BOARD QC

1st Level – Pretest

Chip integrity check.

Correct insertion check.

Automatic barcode reading: The Datamatrix printed on the Chip allows automatic calibration of the system and rejection of expired strips.

2nd Level – Measuring Channel

Analytic verification performed on measuring channel during ongoing test, allowing identification of errors on Meter or Chip, as well as proper pre-analytic handling of the sample.

3rd Level – Control Channel

Control channel provides highly controlled clotting times. System reliability is guaranteed when control clotting time lies within a defined narrow band.

LIQUID CONTROL

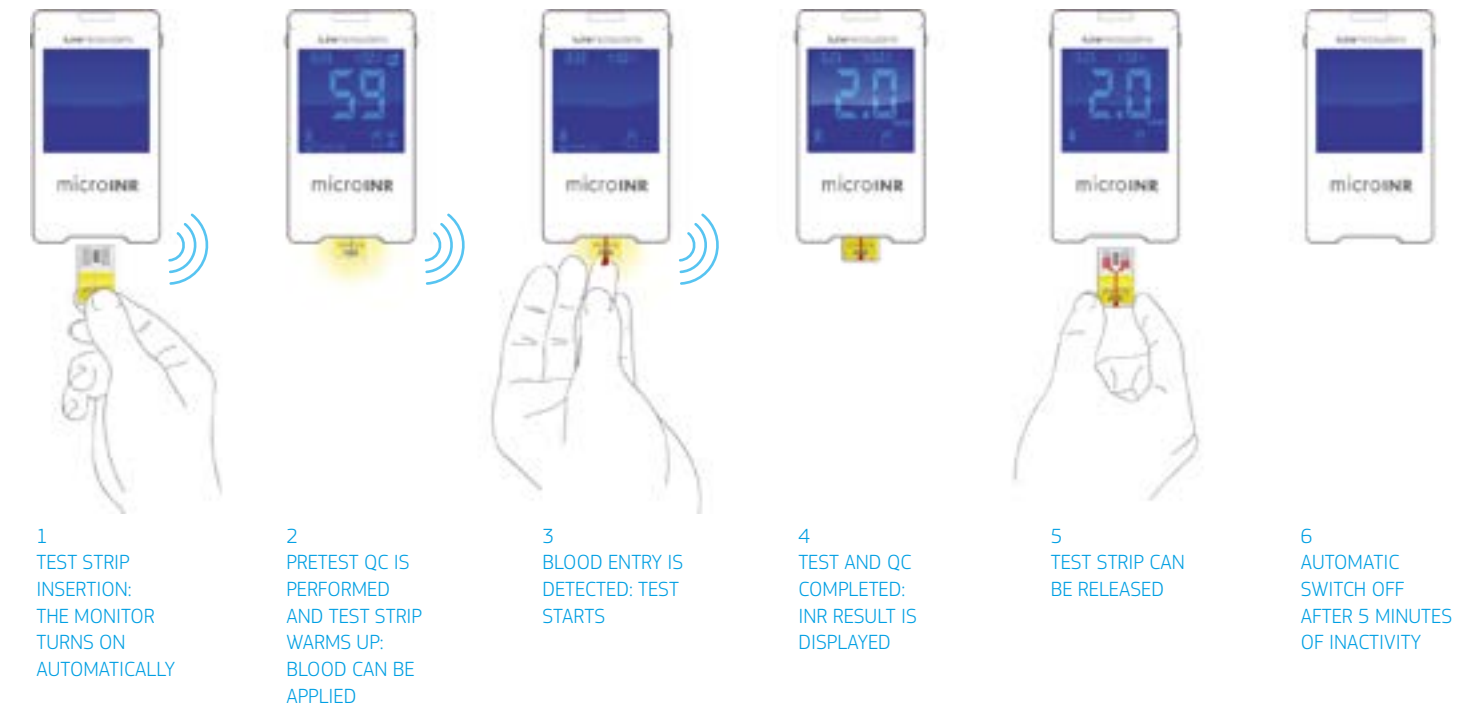
System is compatible with commercially available lyophilized control or certified plasmas, frequently used for instrument calibration and control. The system allows an External Quality Assessment (EQA) scheme as highly recommended by EU directive. Only for professional use.

INTERNAL QUALITY CONTROL

Monitor performance is automatically checked when the system is turned on.

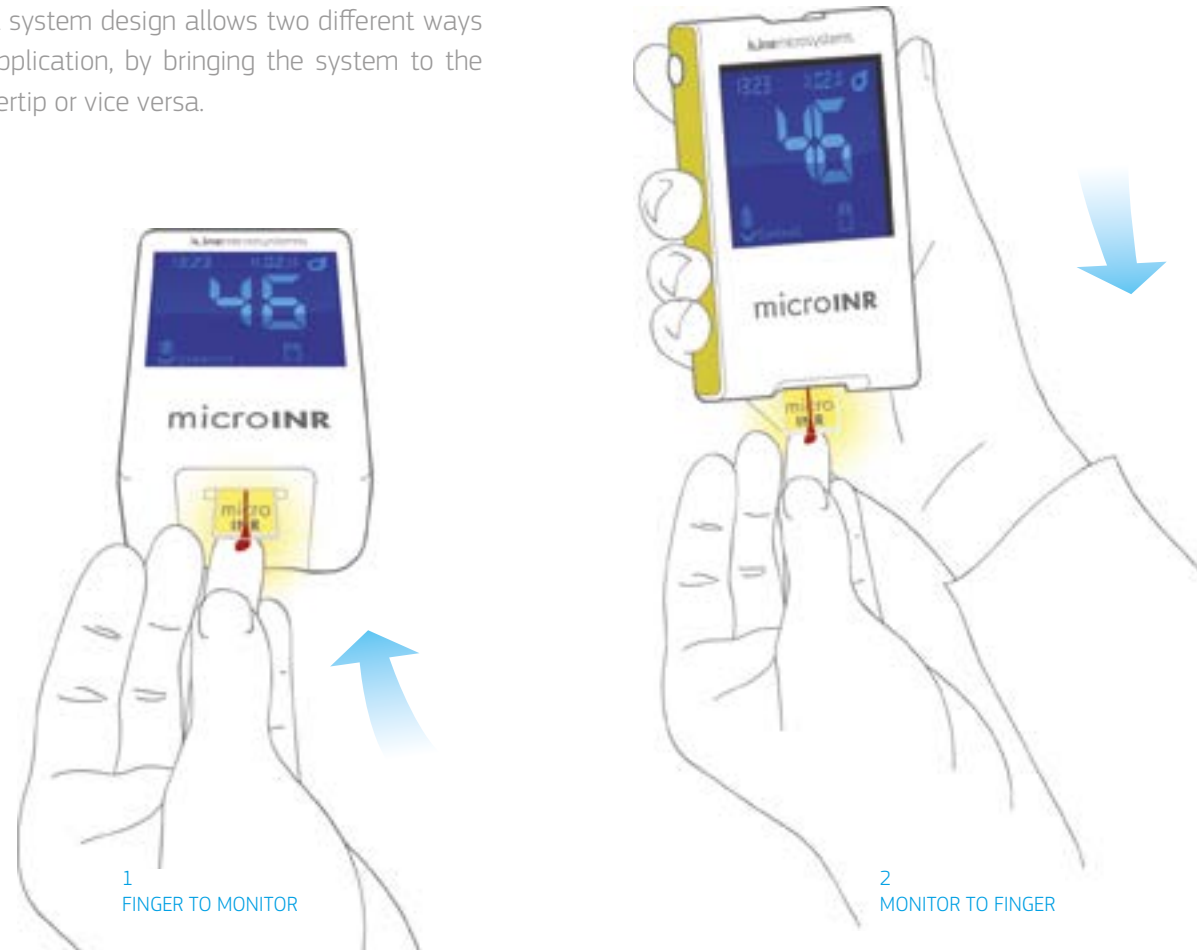
STEP BY STEP PROCEDURE

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.



DESIGN

The current system design allows two different ways of blood application, by bringing the system to the user's fingertip or vice versa.



KEY ADVANTAGES

USER-FRIENDLY:

- EASY-TO-USE SYSTEM
- NUMBER OF PROCEDURE STEPS SET TO A MINIMUM
- NO CALIBRATION CHIP NEEDED
- RAPID TEST PERFORMANCE (LESS THAN 1 MINUTE)

SMALL SAMPLE VOLUME:

- PAINLESS FINGER PRICKING
- GENTLE FINGER PRICKING REDUCES FORCED TISSUE FACTOR ACTIVATION
- LESS PRONE TO INSUFFICIENT SAMPLE VOLUME ERRORS

RELIABILITY:

- ENHANCED MULTILEVEL QC STRATEGY ASSESSES ALL POSSIBLE SOURCES OF ERROR



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