microINR®

CHIPS

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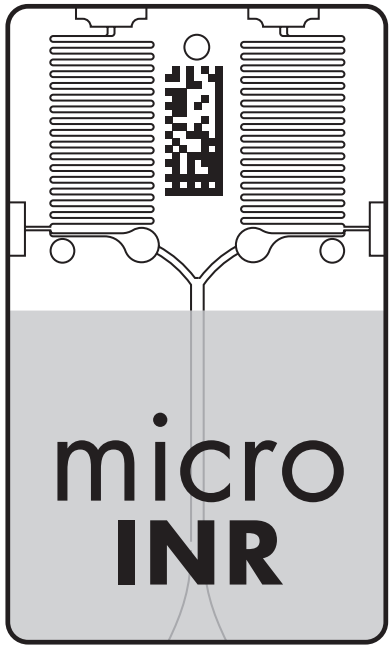

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microINR®

CHIPS

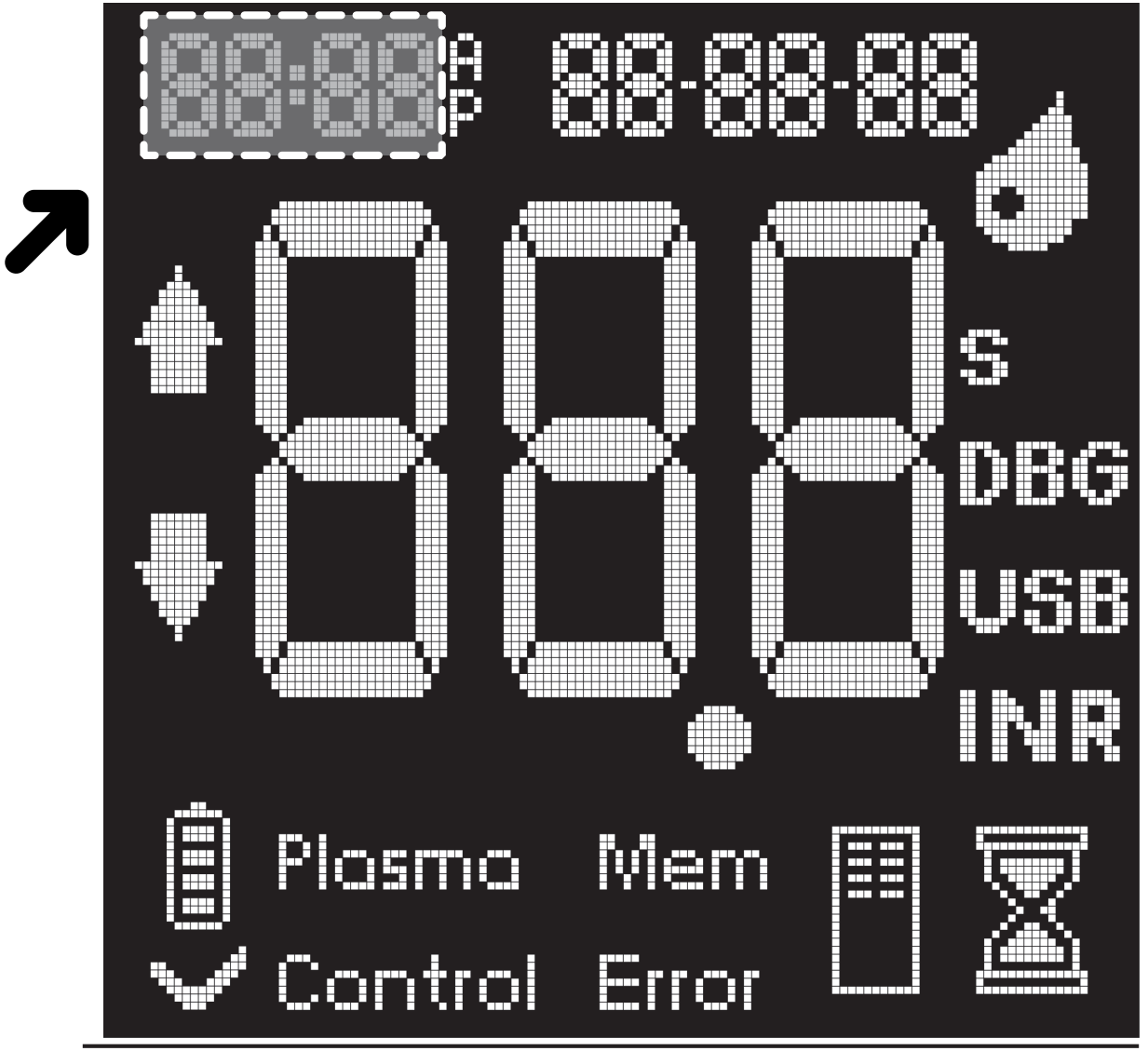
en

Before starting to use the microINR system, make sure that the Chip reference is compatible with the software version of your Meter.

REF	SOFTWARE VERSION *
CHA0025AA	All software versions
CHB0025AA	>07:03

*The software version(1) appears at the top of the screen, immediately after switching on the Meter. If you cannot read the version, repeat the attempt by switching the Meter off and on again.

(1) SOFTWARE VERSION



INTENDED USE

The microINR system is designed to monitor oral anti-coagulation treatment (OAT) with vitamin K antagonists. The microINR system determines quantitative prothrombin time (PT) in INR (International Normalized Ratio) units with fresh capillary blood (performed by fingersticking).

The microINR system is a medical device for in-vitro diagnosis designed for professional and self-testing use.

BEFORE STARTING TO USE THE microINR® SYSTEM

The microINR Chips are designed to be used exclusively with the microINR Meter by iLine Microsystems.

Before starting to use the microINR system, read the instructions for use completely, as well as the instructions for use of the microINR Meter. Also, do not forget to read the instructions for

use of the lancing device used to obtain the capillary blood sample.

Bear in mind the precautions mentioned throughout these instructions for use and remember that you must receive appropriate training in the microINR system before starting to use it, whether as a professional or for your own use.

Keep these instructions for use near the microINR system and refer to them if you have any questions about the proper operation of the system.

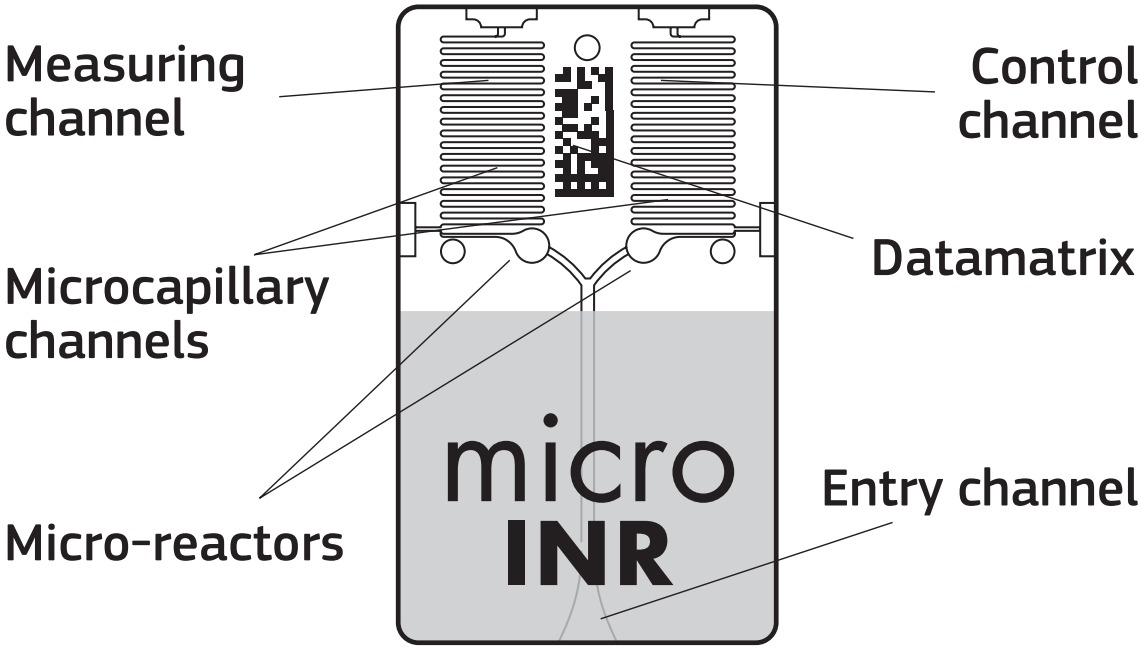
The meaning of the symbols used are shown at the end of these instructions for use.

ANALYSIS PRINCIPLE

The technology used by the microINR system is based on the microfluidics contained in the microINR Chip, which allows storing, dosing, moving and/or mixing small volumes of liquids to perform a chemical reaction.

The disposable Chips for the microINR Meter

contain two channels, one for measurement and the other for control. An image of the Chip is shown below:



Each channel consists of a micro-reactor that contains the reagent and a microcapillary where the INR is determined.

The reagent used in the measuring channel contains recombinant human thromboplastin and the reagent in the control channel contains recombinant human thromboplastin and human coagulation factors to stabilise the patient's blood.

The blood is inserted in the Chip through the entry channel, separated into two channels and mixed with the reagents contained in each micro-reactor. The coagulation cascade is activated instantly. When blood coagulates, its viscosity increases, which results into a change in blood flow behaviour.

The Meter captures the position of the sample by means of an artificial vision system and the position is transformed mathematically into speed and acceleration curves, from which the INR is obtained.

STORAGE AND STABILITY OF THE microINR® CHIP

Store the Chips in a cool and dry place between 2ºC and 25ºC. Protect from sunlight and heat.

Use the Chip during the 6 hours after the pouch is opened.

Do not use the Chips after the expiry date printed on the package.

PREPARING THE NECESSARY MATERIAL

- microINR Chips.
- microINR Meter (not supplied).
- Lancing device (not supplied).
  - Professional use: disposable lancets.
  - Self-testing: lancing device and lancets.
- Skin cleaning material (not supplied).

INTERNAL QUALITY CONTROL

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

INTEGRATED AND INDEPENDENT ON-BOARD QUALITY CONTROLS

1st Level – Pre-test

- Chip integrity check.
- Correct insertion check.
- Automatic system calibration and rejection of expired batches.

2nd Level – Measuring Channel

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

3rd Level –Control Channel

- Control channel provides highly controlled

clotting times. System reliability is assured when control clotting time lies within a pre-defined range.

PROFESSIONAL USE:

Liquid Control

The microINR system has a number of on-board quality control functions integrated into the Meter and the Chip and therefore there is no need to run quality control tests with liquid quality controls. However, iLine Microsystems has available an optional liquid quality control for the microINR system. This control is provided to help meet the regulatory requirements applicable to your facility. Contact your local distributor.

PROCEDURE FOR MEASURING AND OBTAINING THE CAPILLARY BLOOD SAMPLE

The steps to ***obtain and measure a capillary blood sample correctly*** are detailed below:

- Check the expiration date of the Chip before performing the test.
- Switch on the Meter by inserting the Chip or pressing the SET or OK button.
- Open the pouch and insert the Chip into the slot of the Meter, making sure that it reaches the end of the slot. Insert the Chip by holding it by the yellow part so the “microINR” inscription can be read correctly.
- Once the Chip is inserted, the Meter will perform the quality controls mentioned above in the instructions for use of the Meter.
- If the quality controls are OK, the “control” symbol will light up. Otherwise, the Meter will return an error message. Refer to the “Error

Guide" section of the Meter instructions for use to see the actions to be taken in the event of an error.

- The Chip begins to flash and heats up until it reaches the proper temperature. Once this temperature is reached:
  - The device emits an audible signal.
  - The drop icon begins to flash on the screen.
  - A time counter appears (80s).
  - The Chip emits a steady light.
- Perform the fingerstick when the countdown begins (see "capillary sample collection and application" of the Meter instructions for use).
- The fingerstick site must be clean, completely dry and free of contaminants.
- Place the lancing device firmly against the finger and press the button. Press the base of the finger gently until a drop of blood forms.
- Before placing the drop of blood on the Chip, make sure that it is sufficiently large and has a round shape. Do not press the fingerstick

site or let the drop of blood smear on the finger.

- Place the drop of blood on the Chip immediately, in contact with the entry channel, without resting the finger on the Chip.
- The Meter will emit a beep when it detects that the sample volume is sufficient and the drop symbol will stop flashing.
- After the beep, remove the finger gently, making sure to leave residual blood on the edge of the Chip.
- Do not touch the Chip or add more blood during the test. Do not shake the Meter or let it fall.
- Wait until the result appears on the screen. If an error occurs, refer to the “Error guide” of the Meter instructions for use.

To see the complete instructions, refer to the instructions for use included in the microINR Meter.

INTERPRETING THE RESULTS

The results are shown in the International Normalized Ratio format. Likewise, given that the desired ratios can vary according to clinical practice and analysis methods, an optimal therapeutic range should be established for this method and for each user.

Results are unexpected when they are outside the therapeutic range or do not match the patient's symptoms. In this event, repeat the test making sure to follow the guidelines included in the instruction and consult your doctor and/or distributor if a new unexpected result is obtained.

If a message error is displayed, refer to the "Error guide" section of the Meter instructions for use.

Do not make any decisions without contacting your physician first.

PROFESSIONAL USE:
If an unexpected result is obtained repeatedly, contact your distributor.

CALIBRATION

Each batch of Chips has been calibrated against a reference batch of human recombinant thromboplastin traced to International Reference Thromboplastin of the World Health Organization[1].

These calibration values (ISI and MNPT) are encoded in the printed Datamatrix of each microINR Chip. Therefore, every test is automatically and individually calibrated eliminating manual entry errors.

(1). Expert committee of the WHO on biological normalization. Report forty-eight. Geneva, World Health Organization, 1999 (WHO technical report series No. 889).

SPECIFICATIONS

- Disposable Chips for single use only.
- Measurement interval: 0.8 –8.0 INR.
- Sample volume: minimum 3µL.
- Environmental operation conditions:
  - Temperature: 15ºC - 35ºC.
  - Maximum relative humidity: 80%.
- The device is only suitable for fresh capillary blood.

PRECAUTIONS OF USE

- Avoid direct sunlight on the Meter during test performance.
- Once the Chip is out of the original individual pouch, it must be used within the next 6 hours.
- If the pouch of the Chip is open, damaged or the film of the Chip is removed, please, dispose of the Chip and use a new one.

- Avoid touching the Chip entry with the finger during sample application.
- Do not touch the Chip during the test nor re-apply blood once the test has started.
- The pharmacological activity of oral anticoagulant drugs can be modified by other drugs, therefore, you must only take the drugs that have been prescribed to you by your physician.

LIMITATIONS OF USE

- Some liver diseases, thyroid dysfunction and other diseases or conditions as well as nutritional complements or changes in food habits, can affect the activity of OAT and the INR results.
- Not to be used to measure or Meter the anticoagulation status of patients under treatment with new oral anticoagulation treatments (non vitamin-k antagonists drugs).
- The performance of the microINR system has

not been demonstrated on blood samples with hematocrit values outside the range of 25% to 55%. Hematocrit out of this range may affect test results.

- The device is highly sensitive to vitamin K dependent coagulation factor deficiencies.

INTERFERENCES

The following drugs and pathologies can interfere with the microINR system and give rise to incorrect INR values. Follow the recommendations provided for each case:

- **Heparin:** the system does not show any significant interference with unfractionated heparin (UFH) up to 0.2 U/mL, and with low molecular weight heparin (LMWH) up to 0.4 U/mL. For higher heparin concentrations, the use of an alternative method is necessary.
- **Primary and secondary anti-phospholipid syndrome (systemic erythematous lupus)**:

The presence of anti-phospholipid antibodies (APAs) could be related with false elevated INR values. The use of an APA-insensitive laboratory method is recommended if the presence of APAs is known or suspected.

- **In vitro tests without significant effects**:
  - Bilirubin up to 55 mg/dL (940 µmol/L).
  - Triglycerides up to 3265 mg/dL (37 mmol/L).
  - Hemoglobin up to 600 mg/dL (93 mmol/L).

SPECIFIC TEST PERFORMANCE DATA

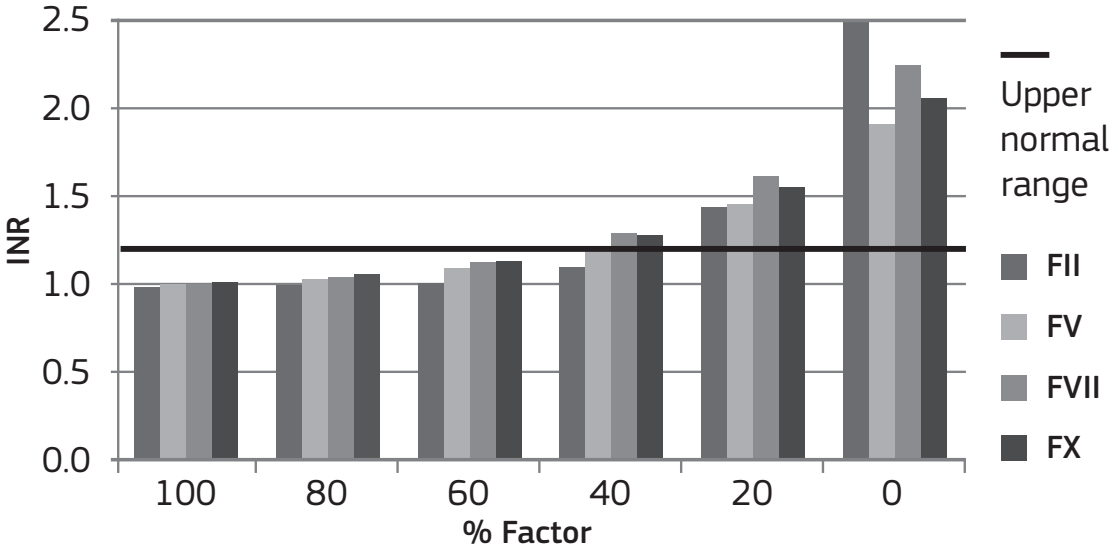
Sensitivity

Sensitivity to coagulation factors (II, V, VII and X) of the microINR system has been determined by in vitro tests.

Deficient commercial plasmas were combined in each factor with normal donor blood samples to obtain a series of dilutions of each blood sample deficient in a factor. These samples were

analysed with 16 batches of Chips and 42 Meters. The results are shown in the following chart:

microINR Factor Sensitivity

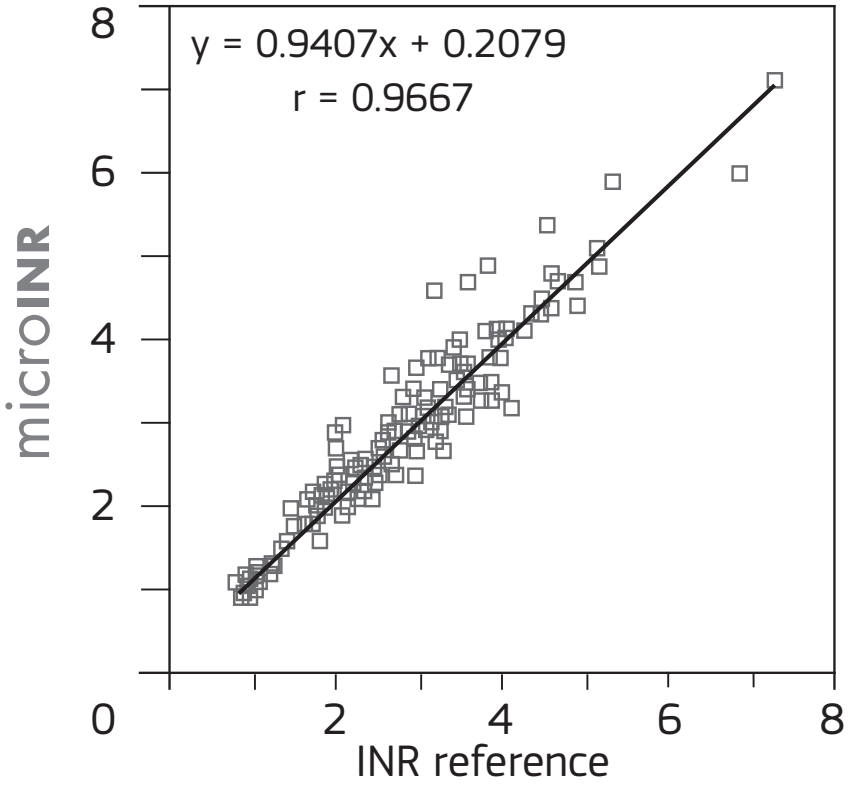


Accuracy

The accuracy of the microINR system has been evaluated against the ACL Elite PRO laboratory coagulation analyzer (Instrumentation Laboratory), using the Recombiplastin 2G reagent.

A sample of venous blood was extracted from 227 patients at 3 different sites for the laboratory method and a sample by fingersticking was obtained for the evaluation using the microINR system.

Shown below are the INR results obtained with the microINR system versus those obtained on the ACL Elite PRO reference system:



Our studies have shown that experienced users of the microINR system can expect to obtain, at least 90% of the times, test results within 30% of a laboratory test value, provided a correct handling of both systems is assured.

Precision

The Coefficient of Variance (CV) was calculated based on duplicate runs performed on 227 subjects (179 patients on oral anticoagulant therapy, 48 normal subjects) at three sites. The average CV across all subjects was 4.9 %.

CLEANING AND DISINFECTION

Cleaning and disinfection of the microINR Meter is essential to ensure proper microINR system maintenance and operation and to prevent blood-borne transmission of pathogens in multi-patient tests. Refer to the instructions of use of the microINR Meter for a detailed description of the cleaning and disinfection protocol.

Clean and disinfect the microINR Meter between one patient and the next.

SYMBOLS

	“Legal Manufacturer”		“Temperature Limitation”
	“Lot number”		“Single use”
	“CE Mark” 0120 Number of notified body		“Expiry date”
	“Read user instructions”		“Catalogue Reference”
	“Do not use if the packaging is damaged”		“Determination number” n = number of analysis
	“Medical device for *in-vitro* diagnostic”		“Precaution”
	“Keep away from Sunlight”		

iLine Microsystems S.L.

Paseo Mikeletegi, 69
20009 Donostia - Gipuzkoa (SPAIN)

www.ilinemicrosystems.com

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