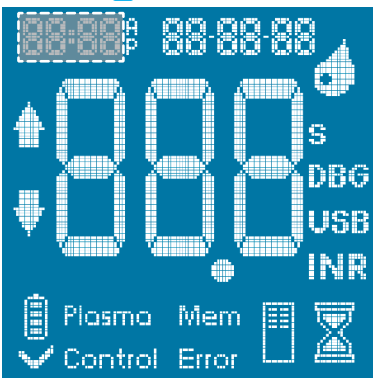
microINR® CHIPS

English

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 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.



INTENDED USE

The microINR system is intended to monitor oral anti-coagulation treatment (OAT) with vitamin K antagonist drugs. 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 diagnostics intended for professional and self-testing use.

BEFORE STARTING TO USE THE microINR® SYSTEM

The microINR Chips are intended to be used exclusively with the microINR Meter manufactured 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 and lancets 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.

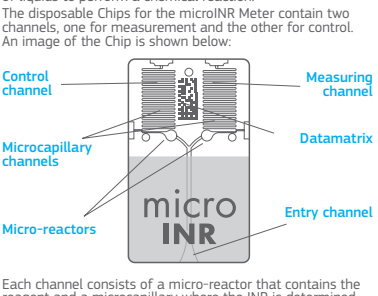
Keep these instructions for use near the microINR system and refer to them if you have any questions about the proper operation of the system.

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 a vision system and the sample 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 within 6 hours after opening the pouch.

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

Integrated and independent Quality Controls:

1st Level – Pre-test

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

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 control (plasma) for the microINR system. This control is provided to help meet the regulatory requirements applicable to your facility. To purchase, contact your local distributor.

PROCEDURE FOR OBTAINING AND TESTING THE CAPILLARY BLOOD SAMPLE

- Check the expiration date of the Chip before performing the test.
- Switch on the Meter by inserting the Chip or pressing the EXIT or MEMORY button.
- Open the pouch. Hold the chip by the yellow part so that the "microINR" inscription can be read correctly. Insert the chip into the slot and push it until it stops. Make sure the chip has reached the end.
- Once the Chip is inserted, the Meter will perform the quality controls mentioned above.
- 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 (beep).
  - The drop symbol begins to flash on the display.
  - A count down appears (80s).
  - The Chip emits a steady light.
- Perform the fingerstick when the countdown begins (see section 3.3 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 to obtain a spherical and properly sized drop (equivalent to a teardrop) and that it is large enough to leave a small amount of blood (remnant) at the entry channel. Do not press the fingerstick site or let the drop of blood smear on the finger.
- Apply 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, gently move the finger away and wait until the INR result is displayed on the screen.
- Do not touch the Chip or add more blood during the test. Do not shake the Meter or let it fall.

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 (INR) units.

The microINR system's results range between 0.8 and 8.0.

If you obtain a result out of the measuring range, the display will show an arrow.

If an error message is displayed, see the "Error guide" section of the meter instructions for use and follow the instructions.

If an unexpected result is obtained, repeat the test making sure that the indications described in these instructions for use are strictly followed.

If an unexpected result is obtained again, contact your doctor and/or distributor.

Results are unexpected when they lie outside the therapeutic range or do not match the patient´s symptoms: haemorrhages, bruises, etc.

CALIBRATION

Each batch of Chips has been calibrated against a reference batch of human recombinant thromboplastin traced to the 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 any risk of human error.

SPECIFICATIONS

- Disposable Chips are for single use only.
- Measurement range: 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.
- 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 vitamin K antagonist drugs and the INR results.
- Not to be used to measure or monitor the anticoagulation status of patients under treatment with new oral anticoagulation treatments (non vitamin-k antagonist 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, or 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 lupus erythematosus):** the presence of anti-phospholipid antibodies (APAs) could be related to falsely 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)

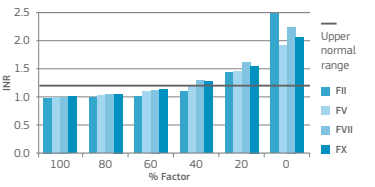
SPECIFIC TEST PERFORMANCE DATA

Sensitivity

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

Commercial plasmas deficient in specific individual factors were combined with normal donor blood samples to obtain a series of dilutions of each blood sample deficient in a given factor. These samples were analysed with 16 batches of Chips and 42 Meters. The results are shown in the following chart:

microINR Factor Sensitivity

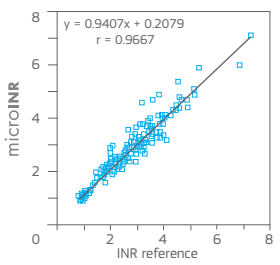


Accuracy

The accuracy of the microINR system has been evaluated against the ACL Elite PRO laboratory coagulation analyzer (Instrumentation Laboratory (IL)), 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:



If the system has been handled correctly by a trained user, at least 90% of the times the microINR system´s result will differ a maximum of ±30% from the laboratory test value.

Precision

The Coefficient of Variation (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

"Manufacturer"	"Keep away from Sunlight"
LOT "Batch code/ Lot number"	"Temperature Limit"
CE 0120 "CE Marking" 0120 Notified Body Identification number (only applies for the Selftesting Use certification)	"Do not re-use"
	"Use-by date"
"Consult instructions for use"	REF "Catalogue number"
"Do not use if package is damaged"	Σ n "Contains sufficient for "n" tests"
IVD "*In-vitro* diagnostic medical device"	"Precaution"

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

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