

# microINR System Specifications

## SYSTEM DESCRIPTION

Point-of-care blood coagulation analyzer for INR testing.

#### **CALIBRATION**

Automatic test Chip identification.

## **SAMPLE TYPE & SIZE**

Fresh capillary whole blood: at least 3µL.

## **MEASURING RANGE**

0.8 - 4.5 INR.

### **RESULTS DISPLAYED**

INR

#### **MEMORY**

199 results / error messages with their date and time.

### **POWER SUPPLY**

Rechargeable lithium battery.

## **OPERATION CONDITIONS**

Temperature: 59 °F to 95 °F Maximum relative humidity: 80%.

#### STORAGE CONDITIONS

Meter: -4 °F to 122 °F Chip: 36 °F to 77 °F



**METER DIMENSIONS:** 4.68 x 2.55 x 1.37 in

**WEIGHT:** 7.51 ± 0.10 oz (Battery included)

**SCREEN:** LCD 1.77 x 1.77 in

## Core Technology



**Machine Meter Vision System: Artificial Vision** captures and processes high flow of pre-test and on-going test information.

**Microfluidic channels** perform PT/INR test comprising of sample application, reagent storage, mixing, detection and QC.

**Datamatrix** contains encoded lot calibration parameters. Automatic identification by the Meter.

This technology allows direct clot detection and the PT determination. Then PT is converted to INR by applying the calibration parameters printed in the Datamatrix.

## **Quality Controls**

The microINR System provides Quality Controls on every test.

First, microINR Meter performance is automatically checked for electronic components, correct power battery level and environmental temperature conditions.

Then, **On-Board Controls** provide a quality control check for each individual microINR Chip used with the microINR Meter:

#### Level 1 - Pre-test QC

This QC is based on Machine Vision System (MVS) analysis of the capture of the whole microINR Chip. Level 1 QC tasks check for defects in the Chip and Meter characteristics by several pattern recognition criteria prior to applying the sample. Specifically, system integrity, Chip insertion, Datamatrix reading, and luminosity are checked.

#### **Level 2 - Measuring Channel**

After sample detection, the captured images are analyzed and evaluated by the MVS. This process detects environmental Chip degradation and manufacturing defects, in addition to checking the Meter detection system, correct sample application and sample quality.

#### **Level 3 - Control Channel**

Parallel Control Channel provides INR results in a near normal INR range when the Chip is used under intended-use conditions. This process detects environmental Chip degradation, and contaminated or contraindicated sample type use.

microINR System has been designed to detect errors prior to and during the test in order to prevent inaccurate INR results through this multi-level strategy.

These quality controls are performed automatically, so there is no need to run extra quality controls.

