**THE microINR® SYSTEM**

The microINR system is intended to monitor oral anticoagulant therapy. To use the microINR system, see these instructions for use. The microINR system has a proven accuracy and reliability over a wide range of INR levels and is validated by the World Health Organization (WHO). It has been shown that the INR results obtained with the microINR system have a high correlation with those obtained by fingersticking in patients undergoing oral anticoagulation therapy. The accuracy of the microINR system has been evaluated against the ACL Elite PRO laboratory coagulation analyzer marketed by Instrumentation Laboratory (IL, MA). The results show that the microINR system's results range between 0.8 and 8.0 (INR) units. Do not use the Chips after the expiry date printed on the packaging. The microINR system is intended to monitor oral anticoagulant therapy, 48 normal subjects) at three INR levels. The average CV across all subjects was 4.9%. The Coefficient of Variation (CV) was calculated based on the INR results obtained with the microINR system. These calibration values (ISI and MNPT) are encoded in the microINR system. The microINR system's results range between 0.8 and 8.0 (INR) units. Do not use if the Chip emits a steady light. A count down appears (80s). The drop symbol begins to flash on the display. If the quality controls are OK, the "control" symbol will be identify, as well as proper pre-analytic sample application. If the quality controls are OK, the "control" symbol will be displayed.

**PROCEDURE FOR OBTAINING AND TESTING THE CAPILLARY BLOOD SAMPLE**

- Place the lancing device firmly against the finger and press firmly for 2 seconds.
- The fingerstick site must be clean, completely dry and free of any skin lesions or trauma.
- Clean and disinfect the microINR Meter between one patient and the next.
- The microINR system is intended to monitor oral anticoagulant therapy.
- Place the lancing device firmly against the finger and press firmly for 2 seconds.
- Clean and disinfect the microINR Meter between one patient and the next.
- The microINR system's results range between 0.8 and 8.0 (INR) units. Do not use if the Chip emits a steady light. A count down appears (80s). The drop symbol begins to flash on the display. If the quality controls are OK, the "control" symbol will be displayed.

**SPECIFICATIONS**

- The microINR system has a proven accuracy and reliability over a wide range of INR levels and is validated by the World Health Organization (WHO). It has been shown that the INR results obtained with the microINR system have a high correlation with those obtained by fingersticking in patients undergoing oral anticoagulation therapy.
- The accuracy of the microINR system has been evaluated against the ACL Elite PRO laboratory coagulation analyzer marketed by Instrumentation Laboratory (IL, MA).
- The results show that the microINR system's results range between 0.8 and 8.0 (INR) units.

**INTERFERENCES**

Do not use the Chips after the expiry date printed on the packaging. The microINR system is intended to monitor oral anticoagulant therapy, 48 normal subjects) at three INR levels. The average CV across all subjects was 4.9%. The Coefficient of Variation (CV) was calculated based on the INR results obtained with the microINR system. These calibration values (ISI and MNPT) are encoded in the microINR system. The microINR system's results range between 0.8 and 8.0 (INR) units.

**CALIBRATION**

- The microINR system is intended to monitor oral anticoagulant therapy.
- Place the lancing device firmly against the finger and press firmly for 2 seconds.
- Clean and disinfect the microINR Meter between one patient and the next.
- The microINR system's results range between 0.8 and 8.0 (INR) units.

**INTERPRETING THE RESULTS**

- If the Chip emits a steady light, a count down appears (80s).
- The drop symbol begins to flash on the display.
- If the quality controls are OK, the "control" symbol will be displayed.