INRATIO®

The INRatio Prothrombin Time Monitor with On-Board Controls from HemoSense

Abstract

The HemoSense INRatio System is a new generation of Prothrombin Time monitoring instrument. The INRatio monitor and test strip have the unique ability to measure two levels of controls on each test. This technology can eliminate the need to run costly and difficult liquid control tests. The INRatio monitor provides the Prothrombin Time and corresponding INR value by measuring the electrical impedance of a blood sample.

Introduction

The INRatio System is an *in vitro* diagnostic system that provides quantitative prothrombin time (PT) and INR results using fresh capillary whole blood at the point of care.

It is intended for use by health care professionals or self-test patients for the purpose of monitoring the patient's prothrombin time during warfarin anticoagulation therapy. The system consists of a monitor and a disposable test strip with integrated, on-board controls.

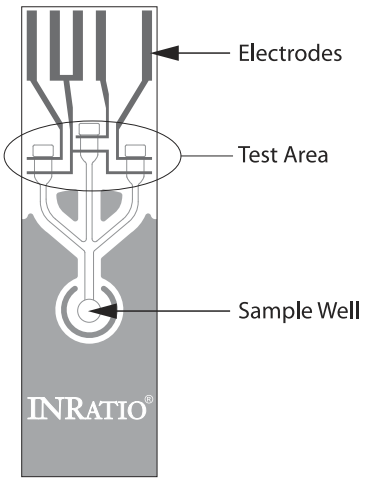
The INRatio System performs a modified version of the one-stage prothrombin time test. It uses a recombinant human thromboplastin reagent. The clot formed in the prothrombin time reaction is detected by a change in the electrical impedance of the blood sample that occurs when fibrinogen is converted to fibrin.

The INRatio Test Strip

The test strip consists of layers of transparent plastic, which are laminated to each other. The "electrode layer" is printed with electrodes. The top layer has a sample well for blood application, and forms the channels through which the blood sample flows to reach the electrode/reagent areas. The composition of the reagents is different for each channel. One channel contains the thromboplastin reagent where the PT test is performed. The other two channels contain additional reagents to produce a normal and therapeutic clotting time, regardless of the clotting time of the sample.

When assembled, the test strip consists of a sample well where the blood sample (~15µL) is applied, and three test channels. The test channels contain the electrodes and reagents for the PT test and the on-board controls.

Figure 1. INRatio Test Strip



On-Board Quality Controls

The INRatio System's on-board quality controls, in conjunction with electronic checks built into the INRatio monitor, have been developed to function in place of liquid quality controls. Traditionally, liquid controls are used to monitor common sources of error, and alert the user when reagent quality and/or system performance has deteriorated.

The common potential sources of error for the INRatio System are monitor malfunction, not following the proper test procedure, or degradation of the test strips due to improper storage. The on-board controls are designed primarily to detect test strip degradation. The two environmental factors that typically cause test strip degradation are elevated temperature or humidity. The test strip is packaged with a desiccant to protect it from humidity. The on-board controls serve as a safe-guard, to ensure that test results are only reported when the test strip has been stored properly.

The INRatio test strip contains three test zones, one for determining the patient PT result and two others for the normal and therapeutic controls. All three test zones of the test strip contain dry reagents, which are simultaneously activated upon application of a blood sample to the test strip when a PT test is performed.

The on-board controls on the INRatio test strip are formulated to clot at a normal (low) and a therapeutic (high) clotting range. The ranges for the two controls are determined and programmed into the INRatio monitor. If the "INR+PT+QC" feature is selected, the monitor will display the actual Quality Control results for each test, along with the PT and INR result.

Exposure of the INRatio test strip to harsh and/or adverse environmental conditions such as elevated temperature or humidity will cause one or both of the controls to degrade before the PT test, and as a result cause a QC (Quality Control) error message to be displayed. The INRatio monitor recognizes a control failure when a test strip yields control results out of the preset ranges. Use of a degraded test strip will be detected by the INRatio monitor's QC mechanism and will cause the monitor to display a QC ERROR message.

The monitor also performs electronic self-checks that verify performance each time a test is performed. The monitor is designed to detect common test procedure errors, such as an inadequate blood sample, a previously used test strip, or use of the monitor outside its operating temperature range. If these conditions are detected, the monitor reports an error message and will not display PT test results.

The INRatio Monitor

The monitor is an impedance monitor with a heater, electronic components and a user interface. It has a prominent, easy to read Liquid Crystal Display (LCD) where instructions and results are displayed. There is an area for test strip insertion that consists of the test strip guide, the sample light and the cleaning door. The test strip is inserted into the test strip guide. The sample light is a bright green light that appears beneath the sample well on a properly inserted test strip, indicating where the sample should be applied. The cleaning door can be lifted for easy cleaning of the interior area of the monitor. The user interacts with the monitor using three buttons. The MENU button accesses the monitor menu and memory functions. The UP/DOWN button allows the user to change selections. The OK button allows the user to make selections.

When the monitor is turned on, it performs an electronic self-check. If any problems are detected, the monitor reports an error message. Otherwise, it displays an "INSERT TEST STRIP" message on the LCD. After the strip is inserted, the monitor displays a "STRIP CODE #?" message, asking the user to verify that the strip code is correct, and allowing the user to change it if required. The monitor then proceeds to warm the test strip to 37° C. When the strip reaches that temperature, the monitor beeps, displays an "APPLY SAMPLE" message and turns the green sample light on under the sample application well.

Figure 2. INRatio Monitor: Top View

After a drop of fresh capillary whole blood is applied to the sample well of the disposable test strip, it is drawn into the test area where it mixes with the reagents that cause coagulation to begin. Initially the electrode impedance is high, then it drops instantly to a low value when the blood sample fills the test area. This initial low impedance is detected and registered by the monitor. As the reaction progresses the impedance increases and then gradually drops as the clotting process is completed. The elapsed time, in seconds, until the endpoint is reached is the raw PT time. The raw PT time is then used to calculate the INR of the sample.

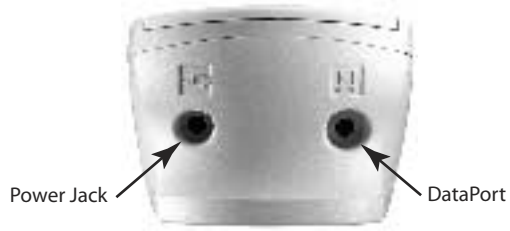
Before the patient's test results are displayed, the monitor determines whether the high and low controls are within the determined limits. If they are, (verifying strip integrity) the monitor then reports the result. If either or both of the control limits are not met, the monitor displays a QC ERROR message.

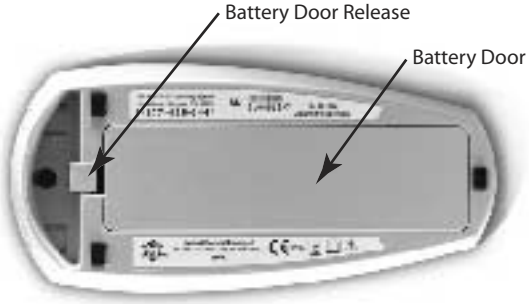
The test results can be reported as an INR result only, or PT seconds and INR, depending on the needs of the user. The results to be reported, as well as the time and date can be set by the user in a configuration menu.

Because of the simplicity of the system, calibration or maintenance is not required, only routine cleaning. No additional, external quality control checks are recommended. The monitor performs self-diagnostics to detect problems in the testing process, which are reported to the user as an error message.

The monitor uses four AA batteries or an AC adapter as a power source. The bottom has a removable door for battery replacement. It also contains an RS232 port to communicate with PCs or a printer.

Figure 3. INRatio Monitor: Back and Bottom Views





Specifications
Length: 6.2 inches (15.7 cm)
Width: 3 inches (7.6 cm)
Height: 2.25 inches (5.7 cm)
Weight: 11.6 oz. (330 g) with batteries
Power Source: 4 AA batteries or 120V

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