EN

Professional User Guide

INRatio®2 Prothrombin Time (PT) Monitoring System

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Professional User Guide

Welcome

Congratulations on your purchase of the INRatio2® PT Monitoring System. This guide will provide you with useful information on how to perform PT testing with the INRatio2.

Table of Contents

1. Introduction

Before You Begin

Before using this system to test Prothrombin Time (PT), read this entire User Guide and the inserts that came with the INRatio® Test Strips and the Lancet device.

Take special note of CAUTIONS ⚠ throughout this User Guide. You must complete proper training on the INRatio2 PT Monitoring system before you begin using the system.

Intended Use

The INRatio®2 PT Monitoring system is used for the quantitative measurement of Prothrombin Time (PT) in fresh, capillary whole blood. The INRatio2 PT Monitoring system is intended for use outside the body (*in vitro* diagnostic use) by people taking warfarin and other oral anticoagulant (blood thinning) therapy who need to monitor the clotting time of their blood. The INRatio2 PT Monitoring System is not intended to be used for screening purposes.

Test Principle

A drop of blood is applied to the test strip, where it is drawn into the test area. The blood mixes with reagents that start the clotting reaction. As the blood clots, there is a change in the impedance in the sample. The monitor detects the change and then calculates the PT for the sample and reports the result on the screen.

The reagents used in performing PT tests can vary substantially between testing methods. This may cause differences in test results depending on the method used. For this reason, the International Normalized Ratio (INR) unit was developed. The INR is a mathematical correction of the PT result that adjusts for sensitivity differences in reagents. The INRatio2 PT Monitoring system provides both a PT and INR result with every test.

2. Getting your System ready for Testing

Your INRatio®2 PT Monitoring system comes with:

- INRatio2 PT Monitor
- Professional User Guide
- CD-ROM of User Guides in other languages
- Quick Reference Guide
- Lancets
- Power Supply
- Training Video
- Capillary Tubes
- Carrying Case

NOTES:

- **DO NOT use any other Power Supply with the INRatio2 PT Monitor or you may damage the system.**
- **The INRatio2 PT monitor can also be powered using standard AA alkaline batteries.**

You will also need:

- INRatio Test Strips (INRatio Test Strips are compatible with the INRatio2 PT Monitor)
- Alcohol pads
- Gauze pads
- Puncture resistant (Sharps) container

Additional INRatio Test Strips and Lancets may be ordered through an authorized INRatio2 distributor.

3. Contacting Technical Support

Contact Technical Support if you have questions about using your system correctly or if you are having problems with the monitor or strips.

Technical Support

+1-877-441-7440 (toll free) or +1-321-441-7200

To re-order supplies, contact the distributor who provided you with the INRatio®2 system kit.

Product	Part Number	Description
INRatio Test Strips (Box of 12)	0100071	12 single-use test strips for use with the INRatio2 PT Monitor
INRatio2 Test Strips (Box of 48)	0100139	48 single-use test strips for use with the INRatio2 PT Monitor
INRatio2 PT Monitor Power Supply USA	0100011	USA Power Supply for use with the INRatio2 PT Monitor
INRatio2 PT Monitor Power Supply with Worldwide Plugset	0100260	Worldwide Power supply for use with the INRatio2 PT Monitor
MicroSafe Capillary Tubes	0200235	Bag of 50 disposable capillary sampling tubes
Unistik 21g Single Use Lancets (Box of 50)	0902009	Disposable single use lancets

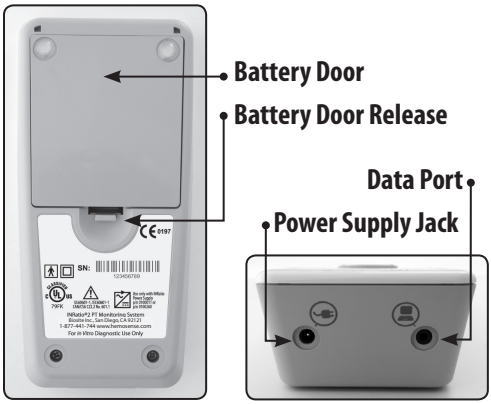
4. System Description

The INRatio®2 PT Monitor

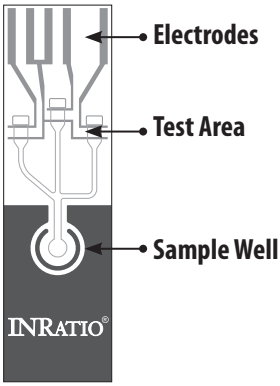
Top View

The INRatio®2 PT Monitor

Top End and Bottom Views



The Test Strip



5. Precautions and Limitations

Certain conditions limit the effectiveness of the INRatio®2 PT Monitoring system to work properly and provide accurate results. Take note of these limitations and precautions.

Care of your INRatio2 PT monitor

- **DO NOT** allow any liquid to spill on the monitor. If this should occur, unplug the monitor (if it is plugged in) and call Technical Support immediately.
- The monitor is a delicate instrument, and should be handled with care. Dropping or other mishandling may cause it to malfunction.
- The monitor should be transported in a carrying case or another secure container.
- **DO NOT** store the monitor below -4°F/-20°C or above 158°F/70°C.

Testing environment

- Room temperature for testing should be between 50°F and 95°F (between 10°C and 35°C).
- The monitor and test strip must also be at room temperature before use.
- Relative humidity should be between 15% and 95%, without condensation.
- Atmospheric pressure should be between 700 hPa and 1060 hPa.

Patient health status

⚠ Current patient health status may affect test results and cause inaccurate results or results that are not what you expect. It's important to take certain health factors into consideration when interpreting test results and deciding on a course of action for your patients. Failure to do so may lead to an incorrect interpretation of the PT monitor result. See the *Performing a Test* (Section 8) of this Professional User Guide for more information about unexpected results.

Performing a test

⚠ Running a test with an incorrect strip code may cause inaccurate results. Confirm the strip code each time a test strip is inserted.

⚠ Test with the monitor on a level surface that is free of vibrations. Testing on an uneven surface or shaking may cause inaccurate results. **DO NOT** hold the monitor in your hand while running a test.

⚠ Blood sample must be applied to the test strip immediately after collection or the blood will begin clotting. This may cause inaccurate results.

⚠ Test strips are for single use only. **DO NOT** reuse them or re-apply blood to them. This may cause inaccurate results or a testing error.

⚠ **DO NOT** move or touch the monitor while it is running a test.

Collecting a fingerstick blood sample

⚠ Use only fresh capillary blood for testing.

⚠ Squeezing the fingerstick site excessively (milking) may release interstitial fluid into the blood sample. This may cause inaccurate results.

⚠ The fingerstick site must be completely dry. If any alcohol remains on the finger, it may cause hemolysis. This may cause inaccurate results.

6. Turning the Monitor ON and OFF

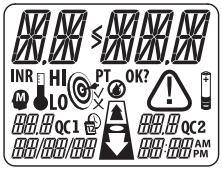
Follow these steps to turn the monitor ON or OFF.

NOTE: The INRatio®2 PT Monitor comes with a Power Supply but you must plug it into the INRatio2 and a wall jack before the monitor will turn ON.

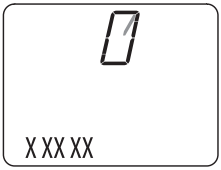
Turning the monitor ON

You have 2 options for turning the monitor ON:

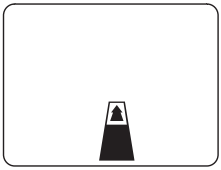
1. Press and hold the (OK) button until the monitor turns on.
2. Insert a fresh test strip if you are ready to perform a test.



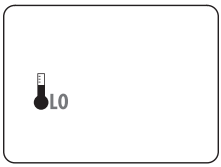
In both cases the monitor will automatically perform a self test where all segments will appear on the display.

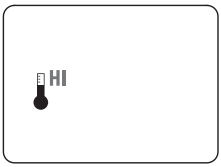


The monitor will prepare for testing for a few seconds.



The monitor will then prompt you to insert a test strip, or to confirm the strip code if you inserted a test strip to turn on the monitor.



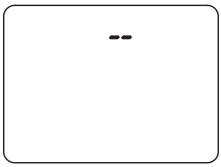


NOTE: The Low Temperature symbol (LO) or High Temperature symbol (HI) will appear on the display if the ambient temperature is outside the operating range of the monitor. If you get a "LO" or "HI" message, move the monitor to a location that is within the operating range and begin again. You will not be able to perform a test until the ambient temperature is within the monitor's operating range.

With the monitor ON you can:

- perform a test, or
- enter Setup mode where you can change the monitor settings, or
- enter Memory mode where you can review past results.

See the appropriate sections of this User Guide for complete information for all of these options.

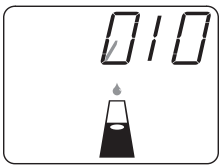


NOTE: If your monitor is connected to a computer or other external device, 2 dashes "- -" will appear on the display. This means the monitor is turned OFF but is communicating with the external device.

Turning the monitor OFF

You can turn the monitor OFF whenever it is idle (not in the process of performing a test) by pressing and holding the (OK) button for about two seconds.

If you are using the external power supply, the monitor will stay on indefinitely.



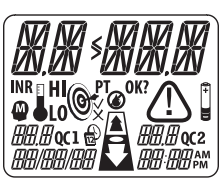
(Example timeout when being prompted to apply blood)

NOTE: Turning the monitor OFF manually when it is not being used will help conserve battery power. If you are using battery power, and the monitor is left idle for about 10 minutes, the monitor will count down for about 10 seconds and then turn OFF. Press any button to keep the monitor turned ON and return to the previous monitor display.

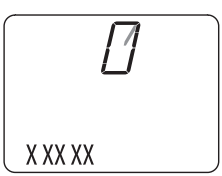
7. Changing the Monitor Settings

Follow these steps to change the date, time, units (how you want your test results displayed), and whether you want to set a target range for your results.

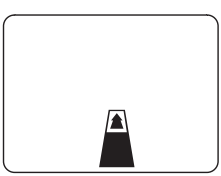
1. Press and hold the (OK) button to turn the monitor ON



The monitor will automatically perform a self test where all segments will appear on the display.



The monitor will begin preparing for a test for a few seconds.



The monitor will then prompt you to insert a test strip.

NOTE: You may access Setup mode whenever your monitor is turned on, or after performing a test.

2. Enter Setup mode

Press the Setup button to enter Setup mode.

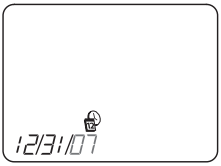
The Setup symbol ( ) will appear on the display along with the year that's currently set in the monitor.

NOTE: When you turn on the monitor for the first time, the date will be set to 01/01/2004 and the time will be set to 12:00.

(Example MM/DD/YY format)

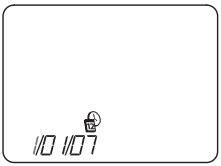
3. Select the desired format for displaying the date

Choose between MM/DD/YY or DD/MM/YY formats. The first 2 sets of digits (DD/MM or MM/DD) will be flashing on the display. Use the ▲ and ▼ buttons to switch between date formats. Press the (OK) button when you have the correct date format on the display.



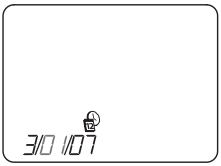
4. Set the year

The last 2 digits of the year will begin to flash on the display. Use the ▲ and ▼ buttons to change the year. Press the (OK) button when you have the correct year on the display.



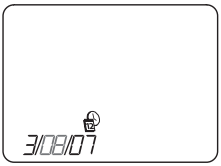
5. Change the month

The month will be flashing on the display. Use the ▲ and ▼ buttons to change the month. Press the (OK) button when you have the correct month on the display.

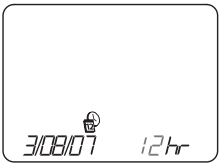


6. Change the day

The day will be flashing on the display. Use the ▲ and ▼ buttons to change the day.



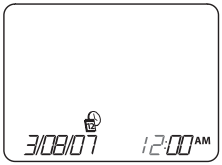
Press the (OK) button when you have the correct day on the display.



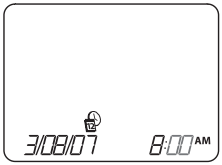
(Example 12-hour format)

7. Select the desired format for displaying the time of day

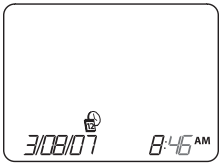
Choose between 12-hour (AM/PM) or 24-hour formats. The 2 digits next to "hr" will be flashing on the display. Use the ▲ and ▼ buttons to switch between 12-hour and 24-hour time formats. Press the (OK) button when you have the correct time format on the display.



8. Change the hour
The hour will be flashing on the display. Use the ▲ and ▼ buttons to change the hour. Press the OK button when you have the correct hour on the display.



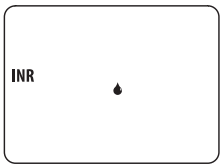
9. Change the minutes
The minutes will be flashing on the display. Use the ▲ and ▼ buttons to change the minutes.



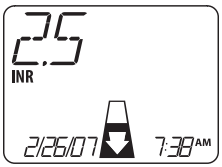
Press the OK button when you have the correct minutes on the display.

10. Select the test result display mode
Use the ▲ and ▼ buttons to choose 1 of 4 different unit display modes. This unit display mode controls how much information will appear along with your INR test result on the monitor display.

NOTE: The test result in INR units will appear on all of the 4 display modes.

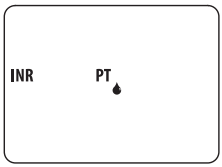


INR Mode

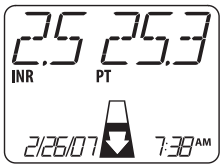


(Example INR Mode)

INR Mode
Test results are displayed in International Normalized Ratio (INR) units only. The INR is a mathematical correction of the Prothrombin Time (PT) result that adjusts for differences in the reagents that are used in calculating your test results.

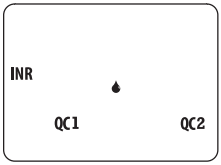


INR + PT Mode

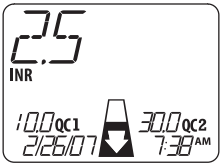


(Example INR + PT Mode)

INR + PT Mode
Test results are displayed in International Normalized Ratio (INR) units and Prothrombin Time (PT) seconds.

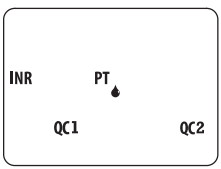


INR + QC Mode

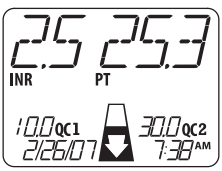


(Example INR + QC Mode)

INR + QC Mode
Test results are displayed in International Normalized Ratio (INR) units, along with the Quality Control (QC) results that are taken every time you perform a test.



INR + PT +QC Mode



(Example INR + PT + QC Mode)

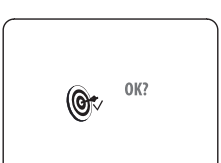
INR + PT + QC Mode
Test results are displayed in International Normalized Ratio (INR) units, Prothrombin Time (PT) seconds and the Quality Control (QC) results that are taken every time you perform a test.

Press the (OK) button when you have the correct display mode on the display.

11. Select the target range mode

An INR target range may be set in your monitor to alert you when test results fall outside the range.

⚠ CAUTION: If results fall outside the target range, or if results fall within the target range but are not consistent with the patient's current health status (e.g., they have symptoms such as bleeding or bruising), follow your usual procedures for taking corrective action.



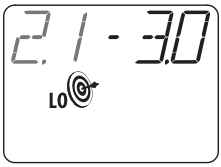
Use the the ▲ and ▼ buttons to switch between the Target ON and OFF modes.

If you want the target range mode ON, press the (OK) button when the Target Range ON symbol ((✓)) is on the display. **Go to step 12.** *(✓ = Target range mode ON)*

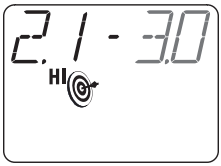
If you want the target range mode OFF, press the (OK) button when the Target Range OFF symbol ((✗)) is on the display. You will return to the monitor display that prompts you to insert a test strip. **Skip steps 12 and 13.** *(✗ = Target Range mode OFF)*

12. Set the lower limit of the target range

The lower limit of the target range will be flashing, and the Low Target symbol (LO) will appear on the display. The "LO" message will also appear on your test result display whenever your result falls below the lower limit. Use the ▲ and ▼ buttons to change the lower limit.



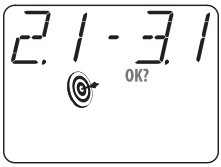
Press the OK button when you have the correct lower limit on the display.



13. Set the higher limit of the target range

The higher limit of the target range will be flashing, and the High Target symbol (HI) will appear on the display. The "HI" message will also appear on your test result display whenever your result falls above the higher limit. Use the ▲ and ▼ buttons to change the higher limit.

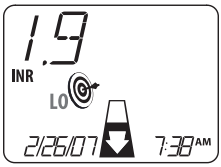
Press the OK button when you have the correct higher limit on the display.



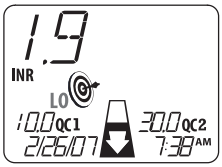
After setting the higher limit, "OK?" will begin flashing on the display. If the target range is correct, press the OK button to store the target range in the monitor. You will return to the monitor display that prompts you to insert a test strip.

Or, if you would like to re-enter a target range, press the ▲ and ▼ buttons to go back to the lower limit and repeat steps 12 and 13 until the correct target range is on the monitor display.

Example monitor displays when test results fall outside the target range

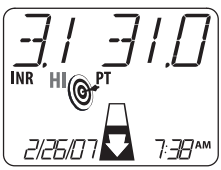


(Example test result below target range — INR mode)

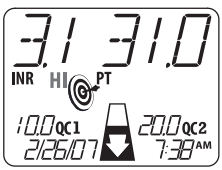


(Example test result below target range — INR + QC mode)

The Low Target symbol (LO) will appear with your test result on the display whenever your result falls below the lower limit of your target range.



(Example test result above target range — INR + PT mode)



(Example test result above target range — INR + PT + QC mode)

The High Target symbol (HI) will appear with your test result on the display whenever your result is above the upper limit of your target range.

NOTES:

- If you need to go back and correct any selections before you exit, you will need to repeat all Setup steps. Press the Setup button to return to the monitor display where you are prompted to insert a test strip. Press the Setup button again to re-enter Setup mode where you will begin by setting the date.

- After you complete all Setup steps, you will return to the monitor display where you first entered Setup mode.

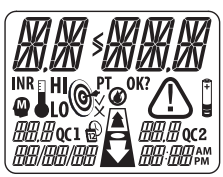
- Your date, time, display mode, and target range settings are stored in the monitor using battery power. If you are using a Power Supply and have removed the batteries (or the batteries have completely run down), you will lose your settings within about two hours if you unplug the Power Supply. To save your settings, install or replace the batteries as needed even when using a Power Supply.

8. Performing a Test

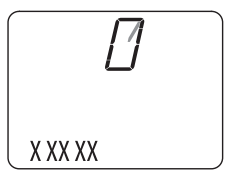
Follow these steps to perform a test.

⚠ CAUTION: Always place the monitor on a flat surface that is free of vibration while you perform a test. DO NOT hold the monitor in your hand. Failure to do so may cause inaccurate results.

1. Press and hold the (OK) button or insert a fresh test strip to turn the monitor ON



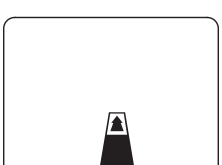
The monitor will automatically perform a self test where all segments on the display will appear.



The monitor will prepare for a test for a few seconds.

If you turned the monitor on by pressing the (OK) button, the monitor will prompt you to insert a test strip (go to step 2).

If you turned the monitor on by inserting a fresh test strip, the monitor will prompt you to confirm the strip's code (go to step 3).

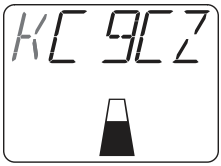


2. Insert a test strip into the test strip guide on the monitor

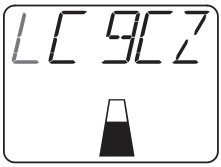
Remove a fresh test strip from its foil pouch. Insert it into the test strip guide so that the clear end with the vertical contact bars goes in first. On the blue end of the strip you should be able to read the word "INRatio®" appearing from left to right. Make sure the sample well in the strip lines up with the green light on the test strip guide.

3. Match the code on the monitor display with the strip code on the test strip pouch or strip container

If the codes match, simply press the (OK) button while "OK?" is flashing on the display and proceed to Step 4.

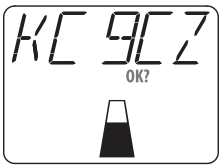


If the codes do not match, use the ▲ and ▼ buttons to change the first digit of the code which will then be flashing.



Press the (OK) button to accept the first digit and move to the next digit. Change each digit using the ▲ and ▼ buttons, then press the (OK) button to accept each digit and move to the next digit.

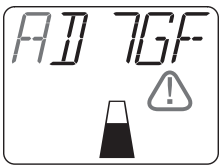
To scroll more quickly through letters and numbers while making changes, hold the ▲ and ▼ buttons down.



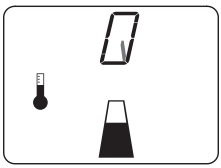
After setting the fifth digit, "OK?" will begin flashing on the display. If the code is correct, press the (OK) button to store the code in the monitor.

Or, if you need to correct the code, press the ▲ and ▼ buttons to go back to the first digit and repeat step 3 until the correct code is on the monitor display.

⚠ CAUTION: Always match the code on the monitor display with the strip code on the test strip pouch/container. Failure to do so may cause inaccurate results.

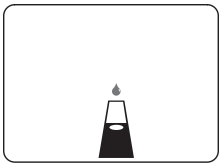


NOTE: If you entered an invalid strip code, the CAUTION symbol (⚠) will flash underneath the code. Re-enter the correct code beginning with the first digit, which is now flashing.



4. Wait for the monitor to warm up

The monitor will count down for a few seconds and display the Temperature symbol (🌡) as it warms up for the test.



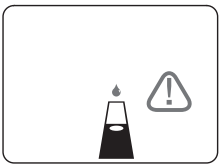
The monitor display will prompt you to apply a blood sample when it's ready to perform a test.

5. Get a fingerstick sample

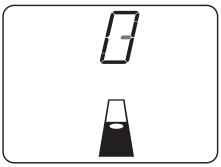
See Instructions for *Collecting a Fingerstick Sample* (Section 9) for getting the correct blood sample to perform a test.

6. Apply the blood sample to the sample well on the test strip

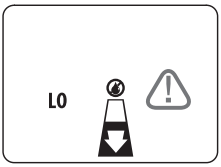
Make sure you apply the sample directly over the green light. **DO NOT** move the monitor or your finger as you apply the sample.



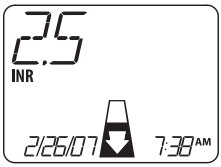
If you applied a blood sample before the monitor was ready, the CAUTION symbol (⚠) will flash on the display. Remove the test strip. **DO NOT** add more blood to the test strip. Go back to step 2 and re-test with a fresh test strip.



7. Wait for the monitor to beep and then count down for a few seconds as it performs the test



If the monitor does not beep and count down, it means not enough blood was applied. **DO NOT** add more blood to the test strip. Remove the test strip. Then go back to step 2 and re-test with a fresh test strip.



(Example INR mode result)

The test result will appear on the monitor display along with the date and time.

Test results are automatically stored in the monitor memory along with the date and time of the test. See *Reviewing Past Results in the Monitor Memory* (Section 10) for reviewing past results.

⚠ **CAUTION: Unexpected results:**

An unexpected result may include any result that falls outside the therapeutic target range, or a result that falls inside the target range, but is not consistent with the patient's current health status (e.g., they have symptoms such as bleeding or bruising).

What causes unexpected results:

1. A hematocrit (percentage of blood that is red blood cells) that is higher or lower than the validated operating range of the INRatio®2 system can cause an inaccurate result. Refer to the test strip package insert for more information. Verification of the patient's hematocrit will help ensure the reliability of results obtained with the PT monitor.
2. Lupus or antiphospholipid antibody syndrome (APS) may falsely prolong the INR value. Testing with an APS-insensitive laboratory method is recommended.
3. Certain prescription drugs (e.g., heparin–Refer to the test strip package insert for more information) and over-the-counter medications (e.g., antibiotics) can affect the action of oral anticoagulants and the INR value.
4. Liver diseases, congestive heart failure, thyroid dysfunction, and other diseases or conditions can affect the action of oral anticoagulants and the INR value.
5. Changes in diet, lifestyle, or taking nutritional supplements such as ginkgo biloba can affect the action of oral anticoagulants and the INR value.

Be aware of any of these conditions before you begin testing your patients, and ask them to alert you if there has been any change in their health status or medications once they begin testing.

What to do when you get an unexpected result:

Always follow your usual procedures for re-testing on the PT monitor, re-testing using an alternative method, adjusting the dose of anticoagulant medication, or any other corrective actions.

8. Turn the monitor OFF when you are finished testing

To turn the monitor off, press and hold the OK button for about two seconds. Remove the used test strip when prompted, and discard it in a Sharps or other puncture proof container.

If using batteries, the monitor will turn off automatically if you leave it unattended for a few minutes. If using the power supply, the monitor will stay on indefinitely. It is recommended that you turn the monitor OFF manually to conserve power.

Before turning the monitor OFF, you also have the option to:

1. Perform another test

Remove and discard the used test strip, then begin again at step 2 with a fresh test strip, using a different finger for the fingerstick sample.

2. Review past results in the monitor memory

Press the Memory button M to enter Memory mode (see *Reviewing Past Results in Monitor Memory* in Section 10 for reviewing past results).

3. Change the monitor settings

Press the Setup button to enter Setup mode (see *Changing the Monitor Settings* in Section 7 for changing your monitor settings).

9. Collecting a Fingerstick Sample

Follow these steps to obtain a drop of blood from a finger.

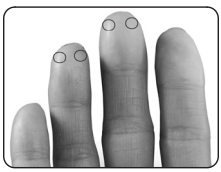
⚠ CAUTION: It is important that you use the correct technique and a 21 or 23 gauge lancet to obtain the right type and amount of blood sample. Failure to do so may cause inaccurate results. If you use another type of lancing device or lancet, make sure to follow the instructions that came with that device to get the correct blood sample.

1. Prepare sampling supplies

- Lancet
- Alcohol pad
- Gauze
- Sharps or other puncture resistant container

2. Increase blood flow to the fingers by:

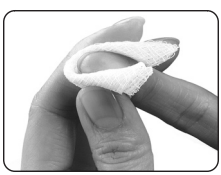
- Warming the hand (wash in warm water or use a heating pad/hand warmer)
- Gently massaging the finger
- Holding the hand below the heart



3. Identify a site on the fingertip to puncture

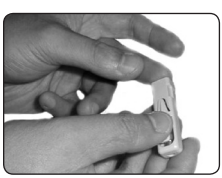
Choose:

- a middle finger on either hand
- an area near the top of the finger to either side of center
- an area away from any calluses or scars



4. Clean the puncture site

Clean the selected area with 70% isopropyl alcohol, or an alcohol solution. Dry thoroughly with gauze.



5. Puncture the fingertip

Follow the instructions that came with the Lancet device to puncture the fingertip.

6. Apply pressure to the fingertip

Apply gentle, continuous pressure until a large, hanging drop of blood (at least 15 µL) forms.

Apply the hanging drop of blood to the sample well on the test strip

See *Performing a Test* (Section 8) for complete instructions.

7. Clean and dry the puncture area after applying the sample

Hold gauze over the puncture site until the bleeding stops.

8. Dispose of all used materials into a sharps or other puncture proof container

NOTE: Used test strips, gauze, alcohol pads, lancing device and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

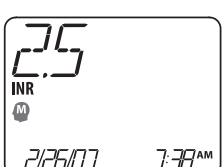
10. Reviewing Past Results in the Monitor Memory

Follow these steps to review past results that are stored in the monitor memory.

Whenever you successfully perform a test, the result is automatically stored in the monitor memory along with the date and time of the test. The monitor memory will store up to 120 results in the order in which the tests were taken, beginning with your most recent result. The latest 60 results are available for on-screen review.

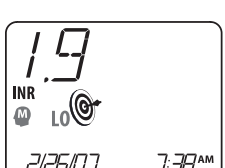
The monitor memory also stores PT computation errors, errors that occur when not enough blood has been applied to the test strip, and QC errors.

You may access the monitor memory after performing a test, or whenever your monitor is turned on. Simply press the Memory button (M). Once in Memory mode, the Memory symbol (M) will appear on the display as you review past results.



(Example test result in memory — INR mode)

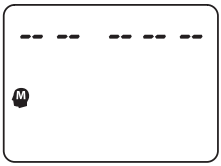
When you enter Memory mode, your most recent result will appear on the display. Use the ▼ button to scroll to your previous result.



(Example test result in memory — INR mode)

Use the ▲ and ▼ buttons to scroll forward and backward through your previous results.

To exit Memory mode, press the OK button. You will return to the monitor display where you are prompted to insert a fresh test strip.

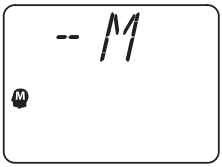


NOTE: If there are not yet any results stored in the monitor memory, such as when you first receive your monitor, a series of dashes will appear on the display.

Clearing memory

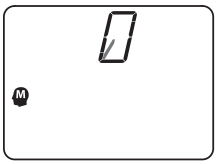
The monitor memory will store up to 120 results of which the latest 60 are available for on-screen review. You can clear the monitor memory of all previous test results to make room for newer results. Make sure to write down previous test results if you wish to keep them before you clear the monitor memory.

To clear the monitor memory, follow these steps:
1. Press the Memory button (M) to enter Memory mode.
2. Press and hold the Memory button (M) for two seconds.



You will see this screen to confirm that you want to clear the monitor memory.

3. Press and hold the Setup button (12) for two seconds to confirm that you want to clear the monitor memory.



It will take about 3 seconds for the monitor memory to be cleared.

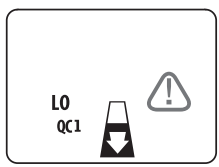
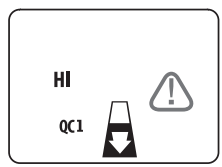
After the memory is successfully cleared, you will return to the monitor display where you first entered Memory mode.

11. Quality Control

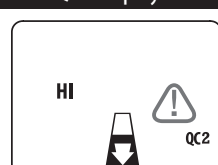
Quality Control (QC) is an important part of PT testing. QC ensures that you are performing the test correctly and that your PT monitor and test strips are working properly together as a system.

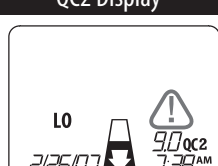
Each time a PT test is performed, a Low and High control test are performed automatically by the PT monitor. If either or both controls is/are out of range, you will be notified on the monitor with a flashing CAUTION symbol (⚠), and a "LO QC1", "LO QC2", "HI QC1", or "HI QC2" message. If your monitor is in either the INR + QC or INR + QC + PT display modes, you will also see the corresponding control result(s) and targets(s).

A "LO" or "HI" QC message appears when the test strips have expired, or have not been stored properly, and have deteriorated. If you get a "LO" or "HI" QC message, check to make sure your test strips have not expired, that the correct strip code was entered into the monitor, and confirm that the strips have been stored properly. Repeat the test if you believe the strips are okay. If you continue to get a "LO" or "HI" QC message, make note of the information on the monitor display and call Technical Support for assistance.

Monitor Display Mode	Example Low QC1 Display	Example High QC1 Display
INR or **INR + PT**		

Monitor Display Mode	Example Low QC1 Display	Example High QC1 Display
INR + QC or **INR + QC + PT**		

Monitor Display Mode	Example Low QC2 Display	Example High QC2 Display
INR or **INR + PT**		

Monitor Display Mode	Example Low QC2 Display	Example High QC2 Display
INR + QC or **INR + QC + PT**		

12. Care and Cleaning of your Monitor

Follow these steps to keep your monitor clean.

NOTE: No maintenance is required other than routine cleaning.

Clean the outside of the monitor with a clean damp cloth. If necessary, a mild detergent or disinfectant (such as a 5% bleach solution or 70% isopropyl alcohol) may be used.

Clean the area around the test strip guide with a swab or pad that has been dampened with alcohol or 5% bleach solution.

13. Installing/Replacing Monitor Batteries

Follow these steps to install/replace the monitor batteries.

The monitor batteries should be replaced whenever the Low Battery symbol ( ) appears with the flashing CAUTION symbol ( ) after turning the monitor ON. The batteries still have enough power to perform a test but should be replaced as soon as possible.

When both the Low Battery symbol ( ) and CAUTION symbol ( ) are flashing on any monitor display, it means the batteries must be replaced as soon as possible. The monitor will turn OFF after about 30 seconds.

1. Turn the monitor upside down so that the bottom is facing you

2. Remove the battery door by pressing down on the battery door release

3. Remove the old batteries and replace with 4 standard AA batteries.

Follow the direction for battery placement (+ and – ends) inside the battery compartment.

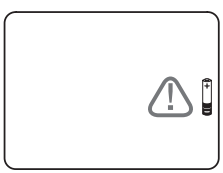
4. Replace the battery door

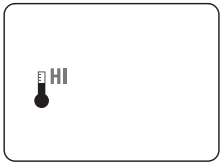
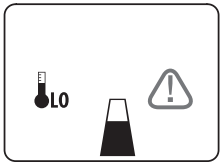
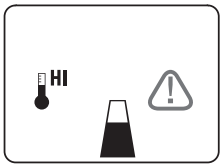
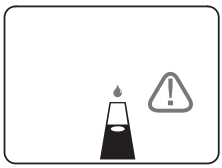
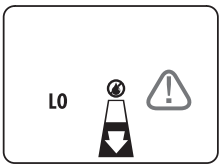
NOTE:

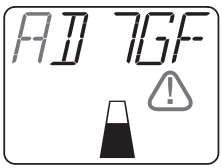
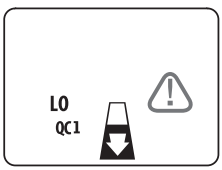
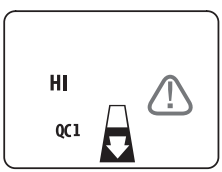
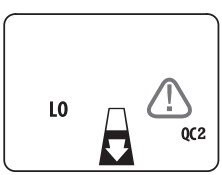
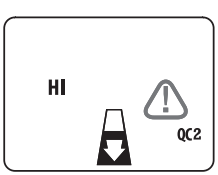
- Turning the monitor OFF manually when it is not being used will help conserve battery power.
- Your settings for date, time, display mode, and target range will be saved as long as you replace the batteries within about five hours of the Low Battery symbol first appearing on the display.

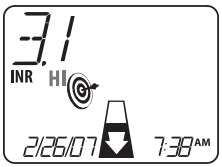
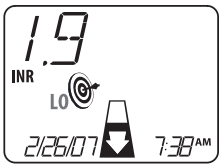
14. Troubleshooting Error Messages

Follow these steps to resolve most problems that you might encounter.

Display Screen	What it Means	Action to Take
	Battery power is low. However, there is still enough power to perform a test.	Replace batteries as soon as possible.
	Battery power is very low. There is not enough power to perform a test, and the monitor will turn off after about 30 seconds.	Replace batteries immediately.
	Ambient temperature is too cold (below the operating range) for the monitor to work properly.	Move the monitor to a warmer location and try again in a few minutes.

Display Screen	What it Means	Action to Take
	Ambient temperature is too hot (above the operating range) for the monitor to work properly.	Move the monitor to a cooler location and try again in a few minutes.
	The monitor, strips and/or ambient temperature is too cold (below the operating range) to continue with the test.	Make sure the monitor and strips are within the operating range of the monitor. Move the monitor and strips to a warmer location, then repeat the test in a few minutes with a fresh strip.
	The monitor, strips and/or ambient temperature is too hot (above the operating range) to continue with the test.	Make sure the monitor and strips are within the operating range of the monitor. Move the monitor and strips to a cooler location, then repeat the test in a few minutes with a fresh strip.
	You applied a blood sample to the test strip before the monitor warm-up was complete, or you inserted a used test strip.	Repeat the test with a fresh test strip. Make sure to wait until you are prompted to apply a blood sample.
	You did not apply enough blood to fill the sample well area.	Repeat the test with a fresh test strip. **DO NOT** add more blood to the test strip.

Display Screen	What it Means	Action to Take
	The strip code is invalid.	Re-enter the correct code beginning with the first digit.
	The QC1 test result is below the control range of the monitor.	Repeat the test with a fresh test strip. If this message continues, call Technical Support for assistance.
	The QC1 test result is above the control range of the monitor.	Repeat the test with a fresh test strip. If this message continues, call Technical Support for assistance.
	The QC2 test result is below the control range of the monitor.	Repeat the test with a fresh test strip. If this message continues, call Technical Support for assistance.
	The QC2 test result is above the control range of the monitor.	Repeat the test with a fresh test strip. If this message continues, call Technical Support for assistance.
	There is an error in calculating Prothrombin Time (PT) for this test. There may be a problem with the monitor and strips.	Repeat the test with a fresh test strip. If this message continues, call Technical Support for assistance.

Display Screen	What it Means	Action to Take
 *(Example shown is in INR display mode)*	Test result is above the high target you set in the monitor.	Repeat tet. If result is still above the high target, follow your standard procedure for treating patients with a high INR.
 *(Example shown is in INR display mode)*	Test result is below the low target you set in the monitor.	Repeat test. If result is still below the low target, follow your standard procedure for treating patients with a low INR.

15. Hazards and Symbols

⚠ The monitor generates radio frequency (RF) energy. If your monitor is not set up and used according to this User Guide, the RF energy may interfere with other devices in the area. Call Technical Support if you have any questions on RF interference.

⚠ Any devices connected to the data port must be certified according to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the data port that configures a medical system is responsible that the system complies with the requirements of IEC 60601-1-1. Please contact Technical Support if you have any questions about connecting devices to the data port.

⚠ Use only the INRatio Power Supply (Part #0100011 or 0100260) or you may damage the monitor.

⚠ IEC 60601-1:1988 + A1:1991 + A2:1995

Amendment 2, Sub-clause 6.8.2 a (EMC):
This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

– Reorient or relocate the receiving device.
– Increase the separation between the equipment.
– Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
– Consult the manufacturer or field service technician for help.

 Class II Equipment: The monitor is double insulated.

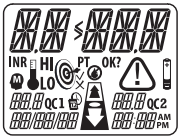
 Type BF Applied Part: The monitor has conductive contact with the patient.

 Biological Risks: Disposable items pose biological risks.

The monitor is classified as ordinary equipment.

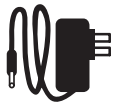
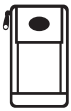
UL Classification
Medical Electrical Equipment
With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1
Class II/ Internally Powered Equipment
Type BF Applied Part
Continuous Operation

LCD Display Icons



 Insert Strip	 Apply Sample	 Not enough blood, **DO NOT** add more blood	 Remove Strip	 Setup Mode
 Temperature	 Caution	 Memory	 Batteries are low	 Replace Batteries
QC1 Quality Control 1	**QC2** Quality Control 2	 Target Range	 Target Range Feature "On"	 Target Range Feature "Off"

Symbols

 INRatio®2 Monitor	 Power Supply	 User's Guide	 Capillary Tubes	 User's Guide CD-Rom
 Quick Reference Guide	 Lancets	 Carrying Case	 Training Video	

16. Performance Characteristics and Product Specifications

Operating Conditions: Temperature: 50-95°F (10-35°C)
Humidity: 15 - 95% (without condensation)
Atmospheric Pressure: 700 hPa – 1060 hPa

Memory: 120 tests (60 available for on-screen review)

Data Port: RS232

Power: Battery: 4 x AA alkaline batteries
Supply: Input: 240 VAC, Output: 7.5 VDC
(Use only INRatio Part # 0100011 (USA) or 0100260 (outside USA) Power Supply or you may damage the monitor)

Size: 5.9" H x 2.9"W x 1.8" D (15.1 x 7.4 x 4.6 cm)

Weight: 9.3 oz. (263 g) with batteries

17. Warranty

Limited Two Year Warranty

Use of the INRatio®2 PT Monitoring system
The INRatio2 PT monitoring system (the "Monitor") is designed for use in monitoring patients on oral anticoagulant therapy. Proper adherence to the instructions in the User Guide and package insert are critical to proper operation. **WARNING: Failure to comply with the User Guide could lead to inaccurate results and resultant incorrect medication dosing which could result in injury or death.**

Limited Warranty
HemoSense guarantees to the original purchaser of the Monitor that the Monitor is free from material defects in material and workmanship for two years from the date of purchase. This warranty does not guarantee the uninterrupted operation of the monitor. HemoSense's only liability and Purchaser's only remedy under this warranty is that during the warranty period HemoSense shall replace or repair, at no charge, any Monitor component with defects in material or workmanship. HEMOSENSE MAKES NO OTHER WARRANTIES AND EXPRESSLY EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR USE.

The only user serviceable parts of the Monitor are the battery and the battery door. Tampering with any other portion of the Monitor, abusing the Monitor or using the Monitor in a manner inconsistent with its user manual will void this warranty. This warranty does not apply to any component that is damaged by improper storage or accident or that is subject to alteration, misuse, tampering or abuse. Before returning any defective components, you must obtain a "Return Material Authorization" number and return instructions from Technical Support by calling +1-877-441-7440.

HEMOSENSE'S ENTIRE LIABILITY IN CONNECTION WITH THE MONITOR, REGARDLESS OF THE LEGAL OR EQUITABLE BASIS OF ANY CLAIM, IS LIMITED TO THE PURCHASE PRICE OF THE MONITOR. IN NO EVENT WILL HEMOSENSE BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, CONSEQUENTIAL, OR PUNITIVE LOSS OR DAMAGES IN ANY WAY RELATED TO THE MONITOR, OR ANY THIRD PARTY CLAIMS, EVEN IF HEMOSENSE OR ITS DISTRIBUTORS ARE AWARE OF THE POSSIBILITY OF SUCH CLAIM OR DAMAGES AND NOTWITHSTANDING THE ESSENTIAL PURPOSE OF ANY REMEDY.

18. Glossary of Terms (listed alphabetically)

Capillary Blood: Blood from the smallest blood vessels of the body - usually obtained from a fingerstick.

Data Port: The port located on the top left side of the monitor for connecting to a computer.

Electrodes: The part of the test strip that generates an electrical current that is impeded by the blood sample once it mixes with coagulation reagents.

Fingerstick: A small puncture to the finger.

Hanging Drop: A drop of blood that forms after a fingerstick that is large enough to hang from the fingertip. Collecting a hanging drop helps to ensure that an adequate sample (at least 15µL) is being applied.

Hematocrit: The percentage of your blood that is red blood cells.

Heparin: A medication taken by injection that is used to prevent the formation of blood clots by inactivating thrombin.

Hemoglobin: The oxygen-carrying pigment and main protein in red blood cells.

Hemolysis: The destruction of red blood cells leading to the release of hemoglobin from within the red blood cells into blood plasma. Leaving alcohol on the fingertip puncture site prior to a fingerstick may lead to hemolysis. Hemolysis should be avoided because it may interfere with the results of the Prothrombin Time (PT) test.

Impedance: Resistance of the blood sample as it coagulates to the electrical current produced by the electrodes. The INRatio®2 PT monitor measures the change in impedance in the blood sample to calculate Prothrombin Time (PT).

International Normalized Ratio (INR): Standardized system of reporting Prothrombin Time (PT) that takes into account the different sensitivity of thromboplastins (reagents) used in various methods. INR results are comparable across PT measurement systems.

***In Vitro* Diagnostic:** A diagnostic test done outside the body.

Interstitial fluid: Fluid between cells in the body.

Lancet: A pointed device used to make a small incision or fingerstick to collect the small drop of blood used in performing a Prothrombin Time (PT) test.

Oral Anticoagulant: Any oral medication (e.g., Coumadin®) used to prevent the formation of blood clots.

Plasma: The liquid part of blood.

Power Jack: The power port located on the top right hand side of the monitor for use with the INRatio2 power supply.

Prothrombin Time (PT): Any test that measures the clotting time of plasma. The INRatio2 PT monitor measures PT time using a capillary blood sample.

Quality Control (QC): The testing done to show that the monitor is working properly and giving dependable results.

Reagent: A substance in the test strip that mixes with the blood sample

Sample Light: The green light on the monitor test strip guide that is directly under the sample well of an inserted test strip. This light helps users identify where to place the blood sample on a test strip.

Sample Well: The round hole (target) on the single-use test strip where the blood sample is applied.

Strip Code: Code entered and used by the INRatio2 PT monitor that corresponds to the code identified on the test strip pouch/container. This strip code must match each new lot of test strips for your results to be accurate.

Test Strip: A single-use test strip used to perform the Prothrombin Time (PT) test with the PT Monitor.

Thromboplastins: A substance used by blood platelets and combined with calcium that converts prothrombin (protein) into thrombin (enzyme) as part of the clotting cascade.

Warfarin: An oral medication used to prevent the formation of blood clots.

19. Index (listed alphabetically)

Technical Support
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Web: www.hemosense.com

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