



Aleré INRatio<sup>®</sup>2  
PT/INR Professional Monitoring System  
User Guide



**Alere INRatio®2 PT/INR Professional  
Monitor Serial Number:**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**The distributor to call for  
Alere INRatio®2 supplies is:**

Name:

Phone:

**To re-order supplies, contact your Alere™ distributor.**

Product	Alere Part Number	Description
Alere INRatio®2 PT/INR Professional Test Strips (Box of 48)	99008G2, 99008	48 single-use test strips for use with the Alere INRatio®2 PT/INR Professional Monitor
Single Use Lancets 21or 23 Gauge	NA	Preloaded, auto-disabling, disposable single-use sterile blood lancing systems.
Alere Universal Printer Kit	14-716INR	Printer to print results from the Alere INRatio®2 PT/INR Professional Monitor. Includes printer, serial data cable, power cord and printer labels.
Alere Universal Printer Labels	11-785	Labels for Alere Universal Printer
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach, Individually Wrapped (69101)*	18117	Box of 50 pre-packaged towels, pre-moistened with disinfectant
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach, Individually Wrapped (69260)*	18141	Box of 60 pre-packaged towels, pre-moistened with disinfectant
Alere INRatio®2 Power Supply Set (USA)	0100011	USA Power supply for use with the Alere INRatio®2 PT/INR Professional Monitor

\*Clorox Dispatch® Hospital Cleaner Disinfectant Towels may have a different catalog number based on the distributor's system.



# Alere INRatio®2 Professional Monitoring System User Guide

## Welcome

Congratulations on your decision to test with the Alere INRatio®2 PT/INR Professional Monitoring System. This guide will provide you with useful information on how to perform International Normalized Ratio (INR) testing with this System.

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## Before You Begin

**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.**

**WARNING:** Upon receipt, if your monitor, power supply, or any accessories are damaged, do not use and contact Alere™ Technical Services immediately.

Frequent INR testing is important to maintain the proper dose of warfarin. Several important sources of information are available to help get you started and to refer to as needed to ensure accurate test results.

Before using this system, read this entire User Guide and the package insert that comes with the Alere INRatio®2 PT/INR Professional Test Strips and the lancet device. Take special note of CAUTIONS (⚠) throughout this User Guide.

Self-testing patients undergoing stable oral anticoagulant therapy, who have been selected for self-testing based on demonstrated motivation, capability and compliance to their treatment regimen, must complete proper training on the Alere INRatio®2 PT/INR Home Monitoring System and practice the test with a health care professional before using the system at home. It is recommended that health care professionals follow the validated Alere INRatio®2 **Training Program for Patients to Self-Test at Home**, (Reference number 99009), available from Alere.

### Important Safety Instructions

- ⚠ **WARNING:** Follow proper infection control guidelines for handling all blood samples and anything that comes in contact with blood.
- ⚠ **WARNING:** The single use lancets are preloaded, auto-disabling, single use sterile blood lancing systems. The lancet devices are for single patient use. Do not use on multiple patients!
- ⚠ **WARNING:** All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- ⚠ **WARNING:** Users should adhere to standard precautions when handling or using this device. All parts of the Alere INRatio®2 PT/INR Professional Monitoring System should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to the Center for Disease Control Document, “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007.”

- ⚠ **WARNING:** The Alere INRatio®2 PT/INR Professional Monitor should be disinfected after use on each patient. This Alere INRatio®2 PT/INR Professional Monitoring System may only be used for testing multiple patients when standard precautions and the manufacturer's disinfection procedures are followed.
- ⚠ Turn monitor off prior to disconnecting the power supply from the wall or the monitor.
- ⚠ No modifications to this device or any of its accessories are permitted.
- ⚠ Only auto-disabling, single use lancet devices may be used with this device.

## 1. How to Use this Guide

This User Guide is divided into 22 sections, in a logical sequence useful for both first-time and experienced users.

- Sections 2 – 7 provide information about oral anticoagulant therapy and the Alere INRatio®2 PT/INR Professional Monitoring System.
- Sections 8 – 15 provide step-by-step instructions that will help you use the Alere INRatio®2 PT/INR Professional Monitoring System quickly, easily and safely.

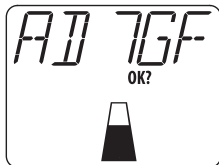
**When you see the image on the left, perform the action on the right:**

Example:

**When you see this:**

**Any display or image.**

Example:



**Do this:**

**Action to take.**

For example:

1. Match the 5-digit Strip Code on the display with the **Strip Code** printed on the test strip pouch.

## 2. Key Information Sources

### **Alere INRatio®2 PT/INR Professional Monitoring System User Guide**

This User Guide is designed to help you learn to use the Alere INRatio®2 PT/INR Professional Monitoring System. It is also your primary reference when you have questions. Make sure you read this guide thoroughly and refer to it often. Sections 8–15 help guide you, step-by-step, and are set up as *“When you see this... Do this”*.

### **Alere INRatio®2 PT/INR Professional Test Strip Package Insert**

A package insert is provided with every box of test strips. It provides detailed technical and performance information about the test strip and offers important updates. Review it often and keep a current copy with your monitor and test strips.

### **Alere INRatio®2 Quick Reference Guide(s)**

The Quick Reference Guide provides quick reminders to help you use the Alere INRatio®2 PT/INR Professional Monitoring System after you have been thoroughly trained.

### **Lancet Device Instructions for Use**

Be sure to read the instructions for use that come with your lancet device to learn how to do a fingerstick, and for important updates. Keep the insert from your current lancet with your Alere INRatio®2 System for future reference. Always use 21 or 23 gauge lancets.

The single-use lancet provided in this kit may be used for testing, or an equivalent auto-disabling, single-use 21 or 23 gauge lancet may be used.

**WARNING: Lancet devices are for single patient use. DO NOT use on multiple patients!**

△ Only auto-disabling, single use lancet devices may be used with this device.

**Note: The Alere INRatio®2 PT/INR Home Monitoring System is also available under prescription for patients to use to self-test at home.**

- There is an Alere INRatio®2 Training Program (99009) for Patients. It is recommended that health care professionals follow this validated Training Program, available from Alere, when training selected users to perform the test at home.

### 3. About Oral Anticoagulant Therapy with Warfarin

Warfarin is prescribed to prevent harmful blood clots from forming. Too much warfarin can cause bleeding, while too little can cause unwanted clots. Warfarin is affected by many things: diet, illness, and other medications. The response to a standard dose varies widely among patients and within a patient over time.

Patients taking warfarin must have their level of anticoagulation tested often using the Prothrombin Time (PT) blood test. PT measures the time it takes blood to clot, expressed as an International Normalized Ratio (INR) when monitoring warfarin. The warfarin dose is adjusted based on the INR result compared to recommended therapeutic ranges.<sup>2</sup>

The reagents used to measure PT vary substantially between test methods. This may cause differences when comparing test results from different systems. The INR is a mathematical correction of the PT result that adjusts for sensitivity differences in reagents, and reduces, but does not eliminate differences.

$$\text{INR} = (\text{Patient PT} / \text{Mean Normal PT of Population})^{\text{ISI}}$$

Many medical studies published over the past 10 years have demonstrated the effectiveness of weekly testing, once the patient is stable in the target range.<sup>1,2</sup> This regular testing helps ensure that the patient remains within their target INR range or, if they fall outside it, that their warfarin dosage is adjusted accordingly.







## Intended Use

*Alere INRatio®2 Professional Monitoring System:* The Alere INRatio®2 PT/INR Professional Monitoring System, consisting of the Alere INRatio®2 PT/INR Monitor and Alere INRatio®2 PT/INR Test Strip, is used for quantitative determination of International Normalized Ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time by health care professionals. The Alere INRatio®2 PT/INR Professional Monitoring System is intended for use outside of the body (*in vitro* diagnostic use). The Alere INRatio®2 PT/INR Professional Monitoring System is not intended to be used for screening purposes.

Limitations: The Alere INRatio®2 PT/INR Professional Monitoring System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

## Test Principle

A blood drop is applied to the test strip, where it is drawn into the test area. The blood mixes with reagents that start the clotting process. As the blood clots, the monitor detects a change in an electrical current passing through the blood sample. The monitor records the time it takes to form a blood clot (PT) and uses information provided by the STRIP CODE (entered into the monitor prior to application of the blood sample) to calculate the PT and INR. The PT/INR result is reported on the monitor display.

# About the Alere INRatio®2 PT/INR Professional Monitor

## 4. Materials Needed For Testing

Your Alere INRatio®2 PT/INR Professional Monitoring System comes with:	Professional
	REF 55128A
	REF 55128
Alere INRatio®2 PT/INR Professional Monitor ( REF 55111, REF 55130)	✓
User Guide	✓
Quick Reference Guide (fingerstick)	✓
Multilingual User Guide CD-ROM	✓
Lancets (21 or 23 gauge)	✓
Carrying Case	✓
Power Supply Plug Set*	✓

\*Power from a standard wall outlet can be used to power the monitor instead of using battery power.  
Do not use rechargeable batteries.

**⚠ CAUTION: DO NOT use any other power supply or you may damage the Alere INRatio®2 PT/INR Professional Monitor.**

### Accessories not provided with this system kit:

Alere INRatio®2 PT/INR Professional Test Strips, Clorox Dispatch® Disinfectant Towels, puncture proof (sharps) containers and a training video (DVD format) may all be ordered through an authorized Alere INRatio®2 distributor.

### Transporting the monitor:

The Alere INRatio®2 PT/INR Professional Monitor comes with a carrying case to protect your monitor during transportation. This case can hold your lancets, test strips and the Quick Reference Guide, as well as the package insert for the test strip.



## 5. System Description

### The Alere INRatio®2 PT/INR Professional Monitor

Top View



#### Test Strip Guide:

Insert test strip here to turn monitor ON for testing.

- 1 Monitor Display:** Symbols to guide testing, and test results, are displayed here.
- 2 OK Button:** Accepts and stores display entries; and turns monitor ON and OFF.
- 3 ▲ (UP) and ▼ (DOWN) Buttons:** Changes information on display and scrolls between results in the memory.
- 4 M Memory Button:** Puts monitor in Memory Mode to review past results.
- 5 Wrench and Screwdriver Setup Button:** To set up the monitor with correct date, time, results format and target range.
- 6 Printer Button**
- 7 Sample Light:** Turns green to indicate test strip is ready for sample application.

Bottom View



- 1 Battery Door**
- 2 Door Release**

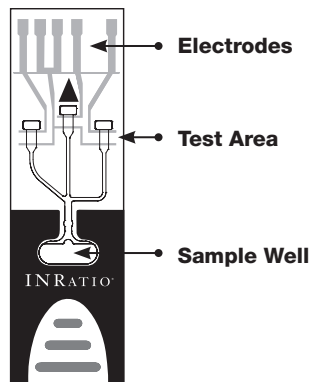


- 1 Power Supply**  
Connect only the external power supply provided with your monitor.
- 2 Data Port**

### The Alere INRatio®2 PT/INR Test Strip

The test strip contains everything needed to perform the PT test.

- **Sample well:** Apply the blood drop here.
- **Test Area:** Blood then flows into the 3 channels to reach the reagent test areas.
- **Electrodes:** Communicate with the Alere INRatio®2 Monitor.



**Test Areas:** From the Sample Well, three (3) channels lead to three (3) Test Areas. Each performs a PT test with different reagents: One channel contains the thrombo-plastin reagent where the actual PT test is measured. The other two channels contain “on-board” quality control tests. Please see the following **Quality Control** section of this User Guide, and the test strip package insert for more information about the QC.

## 6. Quality Control (QC)

QC is a very important part of PT testing. QC ensures that you are performing the test correctly and that your monitor and test strips are working properly together as a system. Each Alere INRatio®2 PT/INR Test Strip contains two levels of integrated “on-board” QC. The QC reports one result in the normal range and one result in the therapeutic range. The **Strip Code** contains important information about the QC, and therefore must be entered and confirmed every time you insert a test strip to perform a test. No external liquid controls are needed.

Each time a PT test is measured, the control tests are measured automatically by the Alere INRatio®2 PT/INR Professional Monitor. Only when both controls are within range is the PT/INR result displayed.

- As an important safety feature, the Alere INRatio®2 PT/INR Professional Monitor will NOT display the test result if either of the QC has failed (out of range compared to the QC ranges for each specific strip lot, as specified in the Strip Code). This prevents a potentially believable, but possibly inaccurate, result from being reported.
- If QC is out of range, the monitor display will show a flashing CAUTION symbol, ⚠, and a “**LO QC1**”, “**LO QC2**”, “**HI QC1**”, or “**HI QC2**”. If your monitor is in a display mode that shows QC ([INR + QC] or [INR + QC + PT]), you will also see the corresponding control results reported in “seconds”.
- **What causes a “LO” or “HI” QC message?**  
Test strips that have expired, or have not been stored properly (and have deteriorated) can cause QC error messages. See the **Troubleshooting and Error Message** section for example displays and what to do if you see a “**LO**” or “**HI**” QC message.

## 7. Important Safety Instructions, Precautions and Limitations

Certain conditions limit the effectiveness of the Alere INRatio®2 Professional Monitoring System to work properly and provide accurate results. Take note of these limitations, precautions, and IMPORTANT SAFETY INSTRUCTIONS.

**WARNING: The single use lancets are preloaded, auto-disabling, single-use sterile blood lancing systems. Lancet devices are for single patient use. DO NOT use on multiple patients!**

**WARNING: All parts of the kit are considered biohazardous after contact with human blood, and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.**

### Multiple Patient Use

The Alere INRatio®2 PT/INR Professional Monitoring System may be used in the testing of single or multiple patients. Follow instructions on proper disinfection in Section 14, **Cleaning and Disinfecting the Monitor**, within this User Guide.

### Care of the Alere INRatio®2 PT/INR Professional 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 Alere™ Technical Services immediately.
- The monitor should be handled with care. Dropping or other mishandling may cause it to malfunction.
- The monitor should be transported in its carrying case or another secure container.
- **DO NOT** store the monitor below -4°F/-20°C or above 158°F/70°C.
- **DO NOT** store the monitor below 15% or above 90% humidity.

### Testing environment

- Room temperature for testing should be between 50°F and 90°F (10°C and 32°C).
- The monitor and test strip must be at room temperature before use.
- Relative humidity should be between 15% and 90%, without condensation.
- Atmospheric pressure should be between 700 hPa and 1060 hPa.



## Collecting a fingerstick blood sample

- ⚠ Use only fresh fingerstick (capillary) whole blood for testing.
- ⚠ Squeezing the fingerstick site excessively, or milking the finger, 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.

## Performing a Test

- ⚠ Running a test with an incorrect strip code may cause inaccurate results. Confirm the strip code in the monitor 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 it during testing 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 (within 15 seconds) after collection. Failure to apply blood immediately may cause blood to begin clotting and may cause inaccurate results.
- ⚠ Test strips are for single use only. **DO NOT** reuse them or re-apply blood to them. This will cause inaccurate results or a testing error.
- ⚠ **DO NOT** move or touch the monitor while it is running a test.

# Set Up Your Alere INRatio®2 PT/INR Professional Monitoring System

## 8. Install and Replace Batteries

### When

- Install batteries when you first receive the monitor.
- Replace batteries when you see the Low Battery symbol with the flashing Caution symbol (see *Troubleshooting* section).

### What you need

- Alere INRatio®2 PT/INR Professional Monitor
- 4 standard AA Alkaline batteries

**⚠ CAUTION: DO NOT** use rechargeable batteries.

### Power Supply vs. Batteries:

All test results are stored in the monitor memory whether you use a power supply or batteries (unless you decide to clear the memory). However, the date, time, display format, and target range settings are stored in the monitor using battery power.

- If the monitor does not have a power source, the monitor will lose stored settings within approximately two hours. It is recommended to use both a power supply and batteries. To save your settings, install or replace the batteries as needed, even when using a power supply.

**⚠ CAUTION:** Only use the power supply provided with your monitor. The use of other power supplies may damage the monitor.

### Save Battery Power

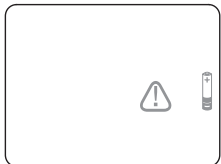
The monitor will turn off automatically after 10 minutes of inactivity. To maximize battery life, press and hold the OK button for 2 seconds to turn off the monitor.





## When you see this:

## Do this:



1. Turn off the monitor and disconnect the power supply.  
**⚠ CAUTION:** Never turn the monitor off by disconnecting the power supply from the wall or the monitor. Always turn the monitor off by pressing and holding the OK button for 2 seconds, then disconnect the power supply.
2. Turn the monitor over and find the battery compartment.
3. Use your thumb to press and lift up the tab of the battery compartment door until it releases.



- Set the door aside.
4. If old batteries are present, remove all 4 batteries by gently pressing each battery against the coil, and lifting.

- ⚠ CAUTION: Do not touch the batteries and the patient at the same time.**
- ⚠ CAUTION: If batteries are leaking or corroded please take proper precautions for removal or call Alere™ Technical Services.**

Hint: Never tap the monitor against a hard surface. A key or coin may be helpful to remove the first battery.



**NOTE:** Used batteries are special waste and should not be disposed of in general household waste. Please dispose of used batteries according to applicable local guidelines and regulations.

When you see this:

Do this:



5. Locate the plus (+) and minus (-) signs in the battery compartment and insert new batteries to match.

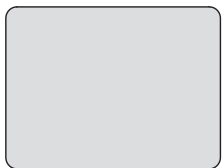
Hint: Push the flat end of each battery against the coil spring.



6. Insert the top tabs of the battery door, and gently push the door into place.

**⚠ CAUTION:** Ensure battery door is properly closed prior to use. You'll hear a click when the door is secured.

Turn the monitor over and set it on a flat, vibration-free surface.

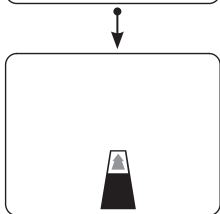
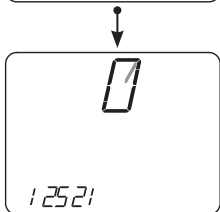
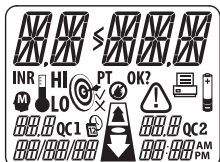


7. Check that monitor is working: Press and hold the OK button for 2 seconds to turn the monitor on.

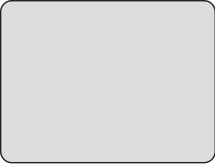


When you see this:

Do this:



8. The monitor is working.

If you see this:	Then:
 <p data-bbox="562 484 704 536">Or Anything Else</p>	<ul data-bbox="856 284 1322 378" style="list-style-type: none"><li>• The monitor is not working.</li><li>• Repeat steps 1-6, making sure the batteries are correctly aligned.</li></ul>

Hint: If the new batteries are installed correctly, the battery symbol will only appear during the monitor start-up display check and not while testing.

## 9. Setup or Change Monitor Settings

### Purpose

To have each result displayed and stored in the monitor memory with the correct date and time.

**⚠ CAUTION:** Failure to set the correct date and time could result in inability to retrieve the correct results.

This section helps you set up the Alere INRatio®2 PT/INR Professional Monitor with the display formats and functions you prefer including:

- Date and format (MM/DD/YY or DD/MM/YY)
- Correct time in 12 hour (AM / PM) or 24 hour format
- Test results as INR or INR + calculated PT, with /without QC results displayed.
- Displaying or not displaying the target (therapeutic) range.


### When

Do this after you've installed batteries or have connected the power supply and want to set up the monitor, or anytime you want to change these settings, such as during daylight savings time changes in the spring and fall.

### What you need

Alere INRatio®2 PT/INR Professional Monitor

### Helpful Hint

If during this sequence of steps you need to change an entry, press the SETUP (  ) button twice and begin the sequence again from Step 1.

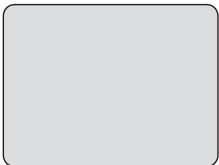
### Display Options -Step 4

You may choose to display QC. Whether or not you choose to see the QC results on your display, the Alere INRatio®2 PT/INR Professional Monitoring System always automatically runs two levels of integrated QC (QC1, QC2) with every test, and stores them in the Memory with the result. Please see the **Quality Control** section for more information about this important Alere INRatio®2 PT/INR Professional Monitor safety feature.

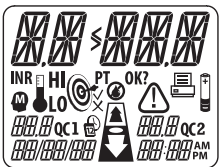


When you see this:

Do this:



1. To begin Setup, with the monitor off, press and hold the OK button for 2 seconds.



2. Decide if monitor is working properly.

If you see this:

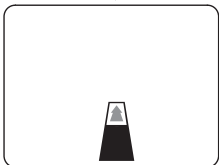
Display changes quickly: from self-check, to software version, to insert test strip symbol

Then:

- The monitor is working.
- Go to step 3.

Anything else

- The monitor is not working.
- Go to the section **Troubleshooting** section.



3. Press the SETUP (Ⓢ) button.



When you see this:

Do this:



4. **Set the date format** to display either

**USA:** Month/Day/Year (MM/DD/YY) or

**Other:** Day/Month/Year (DD/MM/YY).



If you prefer:	Then:
The format you see on your display	<ul style="list-style-type: none"> <li>• Press OK.</li> <li>• Go to step 5.</li> </ul>
The other format	<ul style="list-style-type: none"> <li>• Press the UP (▲) or DOWN (▼) button to change the format.</li> <li>• Press OK.</li> <li>• Go to step 5.</li> </ul>

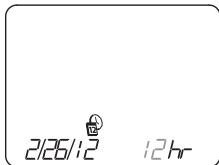
When you see this: Do this:

5. Set the correct date.



	When this flashes:	Then:
	The year	<ul style="list-style-type: none"> <li>• Press the UP (▲) or DOWN (▼) arrow to display the correct year.</li> <li>• Press OK.</li> <li>• Go to next step (month).</li> </ul>
	The month	<ul style="list-style-type: none"> <li>• Press the UP (▲) or DOWN (▼) arrow to display the correct month.</li> <li>• Press OK.</li> <li>• Go to next step (day).</li> </ul>
	The day	<ul style="list-style-type: none"> <li>• Press the UP (▲) or DOWN (▼) arrow to display the correct day.</li> <li>• Press OK.</li> <li>• Go to step 6.</li> </ul>

**When you see this:**      **Do this:**

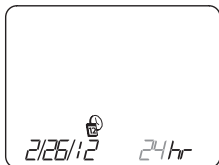


6. **Set the time format** to display 12 or 24 hours.

Example: 2 hours and 15 minutes after 12 noon would be:

12 hr: **2:15 PM** (morning as AM; afternoon as PM)

24 hr: **14:15** (no AM or PM displayed)

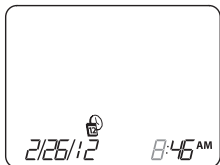


If you prefer:	Then:
The format you see on your display	<ul style="list-style-type: none"> <li>• Press OK.</li> <li>• Go to step 7.</li> </ul>
The other format	<ul style="list-style-type: none"> <li>• Press the UP (▲) arrow button to change the format.</li> <li>• Press OK when you see the format you want.</li> <li>• Go to step 7.</li> </ul>



When you see this:

Do this:

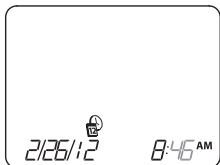


**Hour Flashing**

### 7. Set the correct time.

Hint: If you chose the 12 hour format, select the hour WITH AM or PM: Scroll through the hours until the correct hour appears with either AM or PM.

If you chose the 24 hour format, just select the hour.



**Minutes Flashing**

When this flashes:	Then:
The hour	<ul style="list-style-type: none"><li>• Press the UP (▲) or DOWN (▼) arrow to display the correct hour.</li><li>• Press OK.</li><li>• Go to step 8.</li></ul>
The minutes	<ul style="list-style-type: none"><li>• Press the UP (▲) or DOWN (▼) arrow to display the correct minutes.</li><li>• Press OK.</li><li>• Go to step 8.</li></ul>



### 8. Set the results reporting format.

INR Only (recommended): The monitor always displays INR.

- Press the UP (▲) or DOWN (▼) arrow to display INR only. (same display as shown at left)
- Press OK.
- Go to step 10.

Other: To display other information (PT, QC) as well, do NOT press OK: Go to step 9.

**When you see this:**      **Do this:**



9. To display QC and/or PT along with the INR result, follow these steps:

If you prefer:	Then:
<p data-bbox="361 239 598 263">One of these displays:</p> <div data-bbox="361 298 575 456"> </div> <div data-bbox="361 467 575 625"> </div> <div data-bbox="361 646 575 804"> </div>	<ul data-bbox="675 232 1234 373" style="list-style-type: none"> <li>• Press the UP (▲) or DOWN (▼) arrow to display the option you want.</li> <li>• Press OK.</li> <li>• Go to step 10.</li> </ul>

When you see this:

Do this:



OK?

10. **The Target Range feature** (steps 10 – 14) is for **home self-test patients** whose health care provider wants their specific target range entered into their Alere INRatio®2 Monitor. Entering a target range enables the monitor to compare each INR result with the target range recommended by your doctor or health care provider.

**Note:** *If the Alere INRatio®2 PT/INR Professional Monitor is being used at the point-of-care with multiple patients and multiple target ranges, this feature may not be desired.*

Step 11 shows you how to turn the Target Range feature OFF or ON.





**⚠ CAUTION – Unexpected results**

**An unexpected result may include any result that falls outside the target therapeutic range, or a result that falls inside the target range but is not consistent with the patient's clinical symptoms (e.g., such as bleeding or bruising when an INR is low).**

**See the Alere INRatio®2 PT/INR Professional Test Strips Package Insert to learn what may cause unexpected results, and what to do if you get an unexpected result.**

When you see this: Do this:

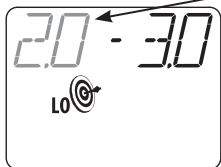
### 11. Turn Target Range feature OFF or ON:

	If you prefer:	Then:
 <p>OK?</p>	<p><b>Target Range OFF:</b></p> <p><b>Not</b> to have each INR result compared with your target range</p>	<ul style="list-style-type: none"> <li>• Press the UP (▲) arrow, if necessary, to display the target with the “x” mark: </li> <li>• Press OK</li> <li>• Skip to step 15</li> </ul>
 <p>OK?</p>	<p><b>Target Range ON:</b></p> <p>To have each INR result compared with your target range every time you test</p>	<ul style="list-style-type: none"> <li>• Press the UP (▲) arrow, if necessary, to display the target with the “✓” mark: </li> <li>• Press OK</li> <li>• Go to step 12 to set range.</li> </ul>

When you see this:

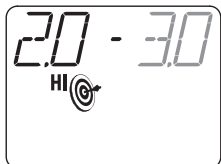
Do this:

12. Set the lower limit of the target range.



If flashing number is:	Then:
<b>Correct</b>	<ul style="list-style-type: none"><li>• Press OK</li><li>• Go to step 13</li></ul>
<b>Not correct</b>	<ul style="list-style-type: none"><li>• Press the UP (▲) or DOWN (▼) arrow to display the correct number</li><li>• Press OK</li><li>• Go to step 13</li></ul>

13. Set the upper limit of the target range.



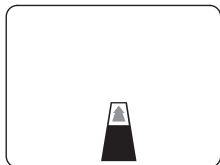
If flashing number is:	Then:
<b>Correct</b>	<ul style="list-style-type: none"><li>• Press OK</li><li>• Go to step 14</li></ul>
<b>Not correct</b>	<ul style="list-style-type: none"><li>• Press the UP (▲) or DOWN (▼) arrow to display the correct number.</li><li>• Press OK</li><li>• Go to step 14</li></ul>

When you see this: Do this:



#### 14. Accept or change target range numbers.

If target range numbers are:	Then:
<b>Correct</b>	<ul style="list-style-type: none"> <li>• Press OK</li> <li>• Go to <b>Step 15</b></li> </ul>
<b>Not correct</b>	<ul style="list-style-type: none"> <li>• Press the UP (▲) or DOWN (▼) arrow return to the LO number flashing (step 12) and follow steps 12 – 14, as necessary</li> </ul>



#### 15. Decide what to do next.

If you want to:	Then:
Change any entry in the sequence	<ul style="list-style-type: none"> <li>• Press the SETUP (ⓘ) button once.</li> <li>• Repeat sequence beginning with step 4.</li> </ul>
Perform an INR test	<ul style="list-style-type: none"> <li>• Go to <b>Prepare to Test</b> (next section).</li> </ul>
Review past test results, if available	<ul style="list-style-type: none"> <li>• Go to <b>Use the Monitor Memory</b> section.</li> </ul>
Turn the monitor off	<ul style="list-style-type: none"> <li>• Press and hold the OK button for 2 seconds.</li> </ul>

# Using Your Alere INRatio®2 PT/INR Professional Monitoring System

## 10. Prepare to Test

### Purpose

---

To prepare the monitor and lancet for a PT test.

---

### When

Do this whenever you are going to perform a PT test.

---

### What you'll need

- Alere INRatio®2 PT/INR Professional Monitor
- A lancet that uses, or has, a 21 or 23 gauge lancet.
- Alere INRatio®2 PT/INR Professional Test Strips
  - Refer to the package insert that came with your Alere INRatio®2 PT/INR Professional Test Strips for product updates and performance characteristics
- Find a place to perform the test that is:
  - Flat, stable and level
  - Free of vibrations
  - At room temperature – between 50°F-90°F (10°C-32°C)
  - Relative humidity – between 15% and 90% without condensation
  - Atmospheric pressure – between 700 hPa and 1060 hPa

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

---

## Helpful Hints

- 
- Refer to the instructions that came with your lancet for more details about preparing it to get a large hanging blood drop.
  - Test Strip – You may store the test strips at room temperature so they are always ready for testing. However, if you store your test strips in the refrigerator, take one out now so it's at room temperature at least 5 minutes before you open the pouch to test.
  - The monitor will time-out and turn off automatically if there is no activity for 10 minutes, so have your supplies ready.
- 





## 10. Prepare to Test (Continued)

When you see this:

Do this:



**Pre-loaded,  
single-use lancet**

1. Make sure you have a new, single-use lancet device ready (21 or 23 gauge lancet).

**⚠ CAUTION: Failure to use a 21 or 23 gauge lancet may produce too small a blood sample and cause an error message (Not Enough Sample).**

If using a preloaded single-use (auto-disabling) lancet, little or no preparation is needed: Check the package insert that comes with it, and make sure it is a 21 or 23 gauge.

If you have trouble, refer to the lancet instructions (package insert) for obtaining larger blood drops.

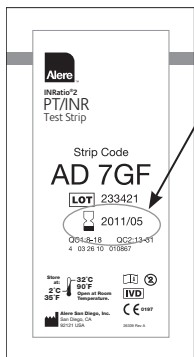
2. **Check the expiration date** to make sure the test strip has not expired. Do not use expired test strips. The expiration date is shown as year/month: YYYY/MM. The test strip is good through the last day of the month shown.

Example: **2011/05** means the test strip is good through the last day of May 2011 (May 31, 2011); do not use it June 1, 2011, or later.

Do not use expired test strips.

Tear open test strip foil pouch at the notch (bold line) and pull the test strip from the pouch.

**NOTE: You must use the test strip within 10 minutes of removing it from its foil pouch.**



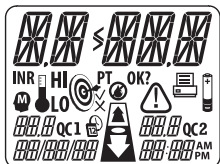
**When you see this:**      **Do this:**



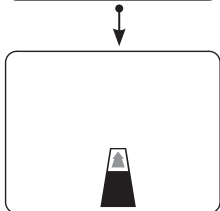
3. Press and hold the OK button for 2 seconds to turn on monitor.

OR

You may turn on the monitor simply by inserting a test strip.



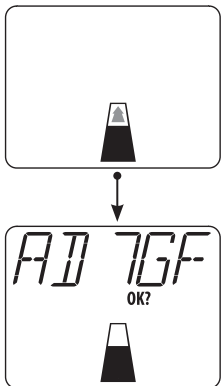
4. Decide if monitor is working properly.



If you see this:	Then:
Display changes from self-check to software check to insert test strip prompt	<ul style="list-style-type: none"> <li>• The monitor is working (and ready to do a test)</li> <li>• Go to step 5</li> </ul>
Anything else	<ul style="list-style-type: none"> <li>• The monitor is not working.</li> <li>• Go to the <b>Troubleshooting and Error Messages</b> section</li> </ul>

When you see this:

Do this:



5. **Insert Test Strip Display:** Steady the monitor with one hand and insert the test strip into the monitor so you can read 'INRatio®' on the test strip:

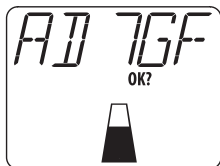
When the strip is inserted correctly you will hear a beep 🎵 and the display will show a five (5) digit code with "OK?" flashing.

- If it does not beep, check to make sure the test strip is inserted correctly. The monitor won't recognize the strip if it is upside down or backwards.



When you see this:

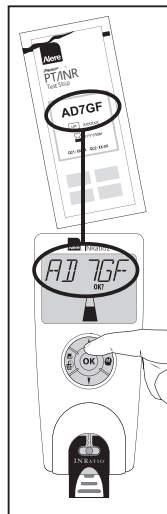
Do this:



**⚠ CAUTION:** Always match the code on the monitor display to the Strip Code on the test strip pouch. Failure to do so may cause inaccurate results.

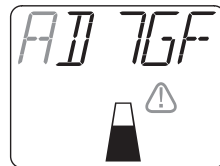
6. Match the 5-digit Strip Code on the display with the **Strip Code** printed on the test strip pouch.

- If every digit in the displayed Strip Code matches the pouch, press OK, and go to step 8.
- If any digit of the Strip Code does **not** match, follow these steps to make sure it matches:



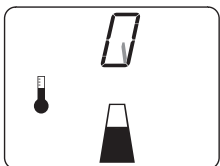
If flashing digit is:	Then:
<b>Correct</b>	<ul style="list-style-type: none"> <li>• Press OK</li> </ul>
<b>Not correct</b>	<ul style="list-style-type: none"> <li>• Press the UP (▲) or DOWN (▼) arrow to find the number or letter you need</li> <li>• Press OK when you have that number or letter matching the one on the pouch. It will advance to the next digit.</li> <li>• Repeat until every digit matches</li> <li>• Press OK to confirm the entire code matches.</li> </ul>

**NOTE:** If you enter an invalid code, the Caution symbol ⚠ will flash. You need to check the code on your test strip pouch and adjust each digit on the display to match the pouch.



When you see this:

Do this:



7. Wait for monitor to warm up.

Do not add blood until you go to **Perform a Test** section.

**NOTE:** If you apply a blood sample before the monitor is ready (before the Apply Sample symbols are displayed), the CAUTION symbol  $\triangle$  will flash on the display. Remove the test strip. DO NOT add more blood to the test strip. Go back to step 5 and start with a fresh test strip, new lancet, new fingerstick site.

The monitor will be ready when you:

- SEE: the display shows a flashing blood drop above a test strip;
- HEAR: the monitor beep;
- SEE: the sample light under the test strip well is green.

## 11. Perform a Test

### Purpose

To apply enough blood to the sample well, within 15 seconds of sticking the finger to get an accurate test result.

### When

After you prepare the lancet device, insert the test strip, enter the correct Strip Code and see the display change from “warming up” to the “Apply Sample” display (test strip with the drop of blood). The light under the sample well will turn green.

**NOTE:** *If the blood drop is too small, the monitor will not detect a blood sample. The monitor will remain on the Apply Sample display for 3 minutes, count down and then turn OFF.*

### What you need

- Alere INRatio®2 PT/INR Professional Monitor
- Lancet with a 21 or 23 gauge lancet
- Alcohol wipe
- Gauze
- Gloves
- Sharps or other puncture-proof container

### Tips for a good fingerstick

- A large hanging blood drop is required to perform the test. Increased blood flow to the finger tip helps get a good blood drop.
- More blood is needed for PT testing than for other tests, such as blood glucose for diabetics, so before you stick a finger for PT testing for the first time, read these tips and this section carefully:
  - Warm the hand (wash hands in warm soapy water, rub hands together or use a hand warmer).
  - Make sure the hand is held below heart level (i.e. near waist level), fingers pointing towards the floor.
  - Massage the arm with downwards strokes, from elbow to wrist to finger tip, until you see more color in the patient's finger tips.
- Clean the patient's finger tip with alcohol; dry thoroughly with gauze or allow to air dry.



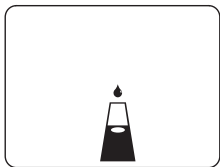
## NOTE


To save battery power, when there is no activity for 10 minutes the monitor beeps, “times out” (10 second count down), then turns OFF.

- Check the monitor display before each step to make sure it is ready.
- If it has “timed out” (counting down), press any button to keep it ON.
- If the screen is blank, it may already have “timed out”. You will have to turn the monitor on and start over.

When you see this:

Do this:



**You may also  
HEAR the monitor  
beep   
and  
SEE the sample light  
under the test strip  
turn green.**

**The monitor is ready to do a test.**

**Prepare to collect a fingerstick blood sample:**

1. Make sure your hands are clean.
2. Put on a new pair of gloves prior to testing each patient.
3. Choose where to stick the finger.

Find a spot that is:

- a. On a middle finger on either hand. If you stick a finger on the less dominant hand it is less painful afterwards. For example, if the patient is right handed, stick a finger on their left hand.
- b. Away from any calluses or scars.
- c. Near the finger tip, on the side that faces towards the little (“pinky”) finger, between the edge of the nail and the middle of the pad, so it’s easy to bring the blood drop to the test strip sample well.

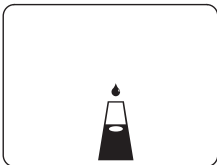


Right Hand

Left Hand

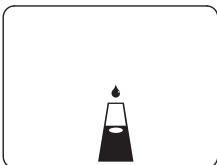
When you see this:

Do this:



4. Clean the fingerstick site with an alcohol pad and dry thoroughly with gauze or allow to air dry.

**⚠ CAUTION: Make sure the finger tip is completely dry to avoid inaccurate results**



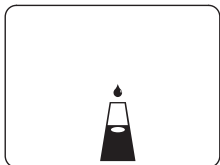
5. With a **pre-loaded** single use lancet device, please check its package insert to prepare it for use.





When you see this:

Do this:



6. Stick the finger by holding the lancet firmly against the test site, then press the button.



**⚠ CAUTION:** Lancets are for single patient use. **DO NOT** use on multiple patients!

**⚠ CAUTION:** Only auto-disabling, single-use lancet devices should be used.

**⚠ CAUTION:** All parts of the kit are considered biohazardous after contact with human blood, and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

**WARNING:** Please observe the following practice guidelines published on the Centers for Disease Control website: Biosafety in Microbiological and Biomedical Laboratories (BMBL) and “Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition” Clinical and Laboratory Standards Institute (CLSI) M29-A3.

**NOTE:** If you apply a blood sample before the monitor is ready (before the Apply Sample symbols are displayed), 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 5 and start with a fresh test strip, new lancet, and new fingerstick site.

When you see this:

Do this:



7. Gently squeeze the finger tip to obtain a hanging drop of blood (about the size of a small green pea).

**⚠ CAUTION: DO NOT excessively squeeze or milk the finger or you may get inaccurate results.**

**NOTE:** Apply the first hanging drop to the test strip sample well.



8. **DO NOT** touch the test strip directly: Lightly touch and hold the bottom of the blood drop to the oval sample well above the green light until you hear a beep 🎵 and you see the 'testing sample' display.

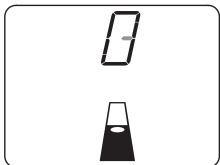
**⚠ CAUTION: Apply blood drop immediately, within 15 seconds after collection, to avoid inaccurate results.**

**NOTE:** Never smear the blood onto the test strip or touch the sample well or you may not get enough blood to enter the channel.



When you see this:

Do this:



(you may also hear  
a beep 🎵)

9. Wait for the monitor to perform the test. The result will appear in about 1 minute.

**DO NOT** move the test strip or touch the monitor during testing. You may:

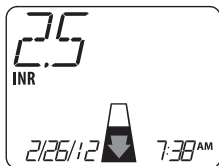
- Pull the finger away from the test strip.
- Wipe the finger tip and apply gauze and pressure to stop bleeding, as needed.
- Go to Step 9.

If this happens:	Then:
You do <b>not</b> hear a beep or see the countdown	The blood sample was too small. <ul style="list-style-type: none"><li>• Do <b>not</b> add more blood</li><li>• Discard the used strip</li><li>• Go back to step 1 to repeat the test with a fresh test strip, new lancet, and new fingerstick site.</li></ul>


**NOTE:** If the blood drop is too small, the monitor will not detect a blood sample. The monitor will remain on the Apply Sample display for 3 minutes, count down and then turn OFF.

When you see this:

Do this:



**Example**  
Actual result may be  
any number.

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

10. Remove the used test strip.
11. Safely dispose of used lancet into a Sharps or other puncture proof container (also biohazard).
12. Remove gloves and wash hands thoroughly with soap and water to prevent the transmission of potential bloodborne pathogens before testing the next patient.

**WARNING:** If testing multiple patients follow the disinfection procedure outlined in Section 14, *Clean and Disinfect the Monitor* in this user guide.

13. Go to the **Record Results** section.
14. Go to the **Troubleshooting and Error Messages** section.

**Any other display**



## 12. Record Results

### When

Whenever you get any test result or error message.

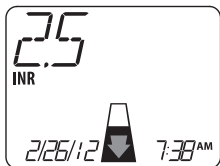
### What you need

- Alere INRatio®2 PT/INR Professional Monitor
- Package Insert for the Alere INRatio®2 PT/INR Professional Test Strips

Hint: Depending on whether or not you set up the monitor to display PT, QC, or a target range, your display may have more, or less, information. See examples below.

### When you see this:

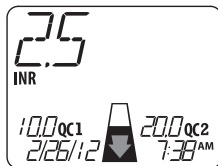
### Do this:



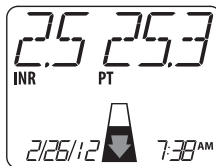
*Example result if you chose to display INR only during SETUP*

**Record the result**, date and time as required by your institution.

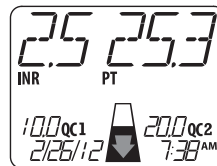
Go to the **Clean the Monitor** section.



INR + QC



INR + PT



INR + PT + QC

### Turn Monitor OFF

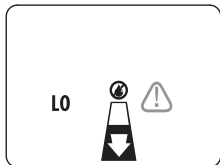
If you are using an external power supply, the monitor will stay on indefinitely.

If you are using batteries, to save battery power, you can turn the monitor off when it is not being used: Press and hold the OK button.

**CAUTION:** Never turn the monitor off by disconnecting the power supply from the wall or the monitor. Always turn the monitor off by pressing and holding the OK button for 2 seconds, then disconnect the power supply.

**When you see this: Do this:**

Any other display,  
such as:



*Example*

- Record the display (use the reference letters in the ***Troubleshooting and Error Messages*** section).

Go to the ***Troubleshooting and Error Messages*** section to understand and correct the problem.

**⚠ CAUTION: Unexpected results**

An unexpected result may include any result that falls outside the target therapeutic range, or a result that falls inside the target range but is not consistent with the patient's clinical symptoms (e.g., such as bleeding or bruising when an INR is low).

See the Alere INRatio®2 PT/INR Professional Test Strips Package Insert to learn what may cause unexpected results, and what to do if you get any unexpected result.

## 13. Troubleshooting and Error Messages

---

**Purpose**

This table helps identify and resolve most problems you might encounter.

---

**When**

Use this information whenever you see a display you don't understand.

---

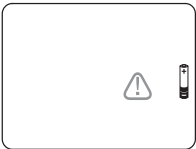


**What you need to do**

- Compare your monitor display with the displays shown below so you can match it to the correct reference letter in the troubleshooting table. The reference letter makes it easier to describe the display to Alere™ Technical Services, should you need help.
  - If you need to repeat a test, repeat it only once (maximum 2 tests): do not waste test strips. If the error repeats, call Alere™ Technical Services.
- 


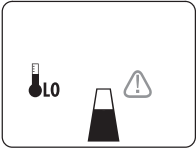

**Displayed information**

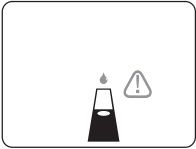
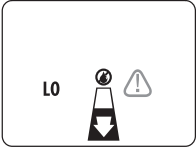
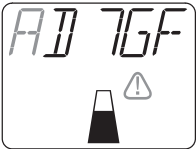
During **Setup or Change Monitor Settings** (Section 9) you may have chosen to show INR only, or one of the other 3 display options. If you chose a display option showing other information (PT, QC), then your display will have more information than is displayed in this **Troubleshooting and Error Messages** section.

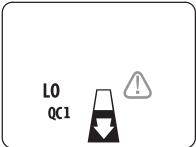


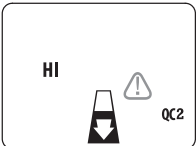
---




Reference	Display	What it Means	Action to Take
A	 <p><b>Caution flashing</b></p>	Battery power is low. However, there is still enough power to perform a test.	Replace batteries as soon as possible.
B	 <p><b>Caution + Battery flashing</b></p>	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.
C	 <p><b>LO flashing</b></p>	Room temperature is too <u>cold</u> (below the operating range) for the monitor to work properly.	Move the monitor to a <u>warmer</u> location and try again in a few minutes.



Reference	Display	What it Means	Action to Take
D	 <p><b>HI flashing</b></p>	Room temperature is too <u>warm</u> (above the operating range) for the monitor to work properly.	Move the monitor to a <u>cooler</u> location and try again in a few minutes.
E	 <p><b>Caution flashing</b></p>	The monitor, test strip and/or room temperature is too <u>cold</u> (below the operating range) to continue with the test.	<p>Make sure the monitor and test strip are within the operating range of the monitor.</p> <p>Move the monitor and strips to a <u>warmer</u> location, then repeat the test in a few minutes with a fresh test strip, new lancet, and new fingerstick site.</p>
F	 <p><b>Caution flashing</b></p>	The monitor, test strip and/or room temperature is too <u>warm</u> (above the operating range) to continue with the test.	<p>Make sure the monitor and test strip are within the operating range of the monitor.</p> <p>Move the monitor and strips to a <u>cooler</u> location, then repeat the test in a few minutes with a fresh test strip, new lancet, and new fingerstick site.</p>

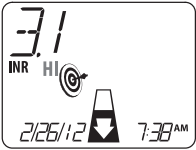
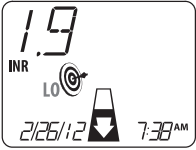
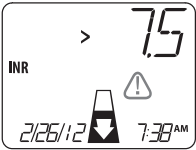
Reference	Display	What it Means	Action to Take
G	 <p><b>Drop + Caution flashing</b></p>	<p>You applied a blood sample to the test strip <u>before</u> the monitor warm up was complete, or you inserted a used test strip.</p>	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site</p> <p>Make sure to wait until the monitor prompts you to apply a blood sample.</p>
H	 <p><b>Caution flashing</b></p>	<p>You did not apply enough blood to fill the sample well area.</p>	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site</p> <p>Hold the blood drop to the sample well until you hear a beep and see the display change.</p> <p><b>DO NOT</b> add more blood to the test strip.</p>
I	 <p><b>Digit + Caution flashing</b></p>	<p>The strip code you entered is invalid.</p>	<p>Re-enter the correct strip code to match your test strip pouch, beginning with the first digit.</p>

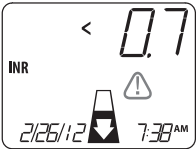
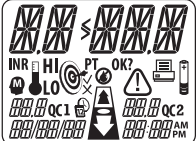

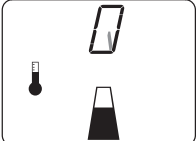
Reference	Display	What it Means	Action to Take
J	 <p><b>Caution flashing</b></p>	The QC1 test result is below the control range of this strip code.	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site.</p> <ul style="list-style-type: none"> <li>– Check to make sure the test strips have not expired.</li> <li>– Make sure the test strips have been stored properly.</li> <li>– Make sure you match the strip code on the monitor display to that on the test strip pouch.</li> </ul> <p>If this message continues, call Alere™ Technical Services for assistance.</p>
K	 <p><b>Caution flashing</b></p>	The QC1 test result is above the control range of this strip code.	
L	 <p><b>Caution flashing</b></p>	The QC2 test result is below the control range of this strip code.	
M	 <p><b>Caution flashing</b></p>	The QC2 test result is above the control range of this strip code.	

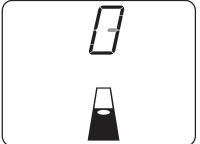

Reference	Display	What it Means	Action to Take
N	 <p><i>N = Any number</i> <b>Caution flashing</b></p>	There is an error in calculating PT or INR for this test. There may be a problem with the monitor and test strips.	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site.</p> <p>Make sure the monitor is on a flat level surface free of vibrations, and that it is not being moved during testing.</p> <p>If this message continues, call Alere™ Technical Services for assistance.</p>
O	 <p><i>N = Any number</i></p>	<p>There is a problem with the monitor. It will shut down if:</p> <ul style="list-style-type: none"> <li>You press the OK button.</li> <li>The message has been displayed for 60 seconds.</li> </ul>	Call Alere™ Technical Services.
P		The printer is not connected.	Connect the printer to the Alere INRatio®2 data port.

**The next 4 displays are NOT Errors.** These represent results outside the Alere INRatio®2 System measuring range, or outside the therapeutic range you set in the Alere INRatio®2 Monitor during SETUP. Follow the “Action to take” and contact the health care provider if needed.

**WARNING:** Failure to take action on any of the following display messages could result in physical injury or death.

Reference	Display	What it Means	Action to Take
--	 <p><b>HI flashing</b></p>	<p>This is not an error.</p> <p>Test result is above the high target you set up in the monitor.</p>	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site.</p> <p>If result is still above the high target, follow your health care provider's procedure for a high INR.</p>
--	 <p><b>LO flashing</b></p>	<p>This is not an error.</p> <p>Test result is below the low target you set in the monitor.</p>	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site.</p> <p>If result is still below the low target, follow your health care provider's procedure for a low INR.</p>
--	 <p><b>Caution flashing</b></p>	<p>This may not be an error.</p> <p>Test result is outside the measuring range of the monitor.</p>	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site.</p> <p>If the message repeats, or the repeated test remains above the measuring range, contact your health care provider.</p>

Reference	Display	What it Means	Action to Take
--	 <p><b>Caution flashing</b></p>	<p>This may not be an error.</p> <p>Test result is outside the measuring range of the monitor.</p>	<p>Repeat the test with a fresh test strip, new lancet, new fingerstick site.</p> <p>If the message repeats, or the repeated test remains below the measuring range, contact your health care provider.</p>
<p><b>The following displays are NOT errors.</b> They are transition displays to tell what the monitor is doing.</p>			
--		<p>This is the full segment display, shown during the self-check after the monitor is turned on.</p>	<p>If <u>any</u> segment is missing: Something may be wrong with your monitor's display.</p> <p>Call Alere™ Technical Services.</p>
--		<p>Software Version Display.</p> <p>The numbers in the lower left indicate the software version.</p>	<p>Do nothing. This display only flashes quickly after the full segment screen display (above) and before the insert strip display.</p>
--		<p>The monitor is warming up.</p>	<p>Wait until the Apply Sample screen appears before adding blood to the test strip.</p>

Reference	Display	What it Means	Action to Take
		<p>The monitor is performing a test (counting down until test is completed).</p>	<p>Wait until the test result is displayed.</p>
--		<p>The monitor has “Timed out” while waiting for an action from you. It will turn off at the end of the 10 second count down to save battery power.</p>	<p>Press any button to keep monitor on; otherwise the monitor turns off.</p>
<p><b>NOTES:</b></p>			

# Maintenance and Memory

## 14. Cleaning and Disinfecting the Monitor

### Purpose

To keep the monitor clean and disinfected. Disinfecting the monitor will minimize the transmission of bloodborne pathogens when testing multiple patients.

### When

- **Clean** the monitor when it is visibly dirty and **before disinfection**. Disinfect the monitor after each use in a multi-patient setting with the Clorox Dispatch® towel. (See page 1 of this guide for ordering information.)

**NOTE:** *No maintenance is required other than routine cleaning and disinfection.*

**Health Care Professionals (i.e. clinic / point-of-care settings)** are required to clean and disinfect the outside of the monitor **after each patient test** with disinfectant towels to assist with infection control.

Alere has validated and recommends the use of Clorox Dispatch® Hospital Cleaner Disinfectant Towels for cleaning and disinfection of the Alere INRatio®2 PT/INR Professional Monitor. See the CDC publication: *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* for information on the validation of alternate cleaning measures.





## What you need

- Alere INRatio®2 PT/INR Professional Monitor
- Two pre-moistened towels with disinfectant such as Clorox Dispatch® Disinfectant Towels
- Lint free tissues
- Gloves

**NOTE:** 1,200 cleaning and disinfection cycles showed no effect on the monitor. Depending on the actual usage, lifespan of the monitor will vary.

One (1) cycle = One (1) cleaning towel + One (1) disinfection towel

**Example for professionals testing multiple patients:**

10 cycles per week x 52 weeks x 1 year = 520 cycles

Monitor life span: 1,200 cleaning and disinfection cycles / 520 cycles = 2.3 years

**NOTE:** The Clorox Dispatch® with Sodium Hypochlorite, as an active ingredient, has been shown to be safe for use with the Alere INRatio®2 Monitor.

When you see this:

Do this:



### To Clean Monitor:


1. While wearing gloves, remove one towel. Allow any excess liquid from towel to drip over a sink or container so the towel is damp but not dripping. **Follow all towel manufacturers' instructions.**

**⚠ CAUTION: DO NOT** allow any liquid to spill on the monitor. If this should occur, unplug the monitor (if it is plugged in) and call Alere™ Technical Services immediately. **DO NOT** spray liquid onto the monitor.

2. Wipe the outside of the monitor with the towel. Take special care not to allow liquid to enter monitor around the buttons and around the Test Strip Guide. It is important to gently wipe the top and side of the buttons. Wipe entire Test Strip Guide just enough until wet. Avoid pressing down too hard.
3. If monitor plastic becomes slightly cloudy, wipe with a water-dampened cloth.
4. Wipe the monitor dry with a lint free tissue. Take special care to ensure the Test Strip Guide (entry area) is dry including near seams/edges.



5. Discard used towel.
6. No other maintenance is needed.



When you see this:

Do this:

7. If any of the following should occur please stop using the device and contact Alere™ Technical Services at **+1 877 866 5313** or **INRatio.Support@alere.com**:
  - Error messages appear when a test has not been performed
  - Strip code changes without prompting
  - Alere INRatio®2 Monitor does not turn on
  - Any other unusual errors not specified in this user guide

When you see this:

Do this:



### To Disinfect Monitor:

1. While wearing gloves, remove one towel. Allow any excess liquid from towel to drip over a sink or container so the towel is damp but not dripping. **Follow all towel manufacturers' instructions.**

**⚠ CAUTION: DO NOT** allow any liquid to spill on the monitor. If this should occur, unplug the monitor (if it is plugged in) and call Alere™ Technical Services immediately. **DO NOT** spray liquid onto the monitor.

2. Wipe the outside of the monitor with the towel. Take special care not to allow liquid to enter monitor around the buttons and around Test Strip Guide. It is important to gently wipe the top and side of the buttons. Wipe entire Test Strip Guide just enough until wet. Avoid pressing down too hard.
3. Allow the monitor to sit moistened for **1 minute (not less than 1 minute)** to allow the disinfectant to work fully.
4. If monitor plastic becomes slightly cloudy, wipe with water-dampened cloth.



5. Wipe the monitor dry with a lint free tissue. Take special care to ensure the strip guide (entry area) is dry including near seams/edges.

When you see this:

Do this:

6. Discard used gloves and towel.
7. No other maintenance is needed.
8. If the following should occur please stop using the device and contact Alere™ Technical Services at **+1 877 866 5313** or **INRatio.Support@alere.com**:
  - Error messages appear when a test has not been performed
  - Strip code changes without prompting
  - Alere INRatio®2 Monitor does not turn on
  - Any other unusual errors not specified in this user guide

## 15. Use the Monitor Memory

---

**Purpose**

To review previous results, show results to others, or erase all results

---

**When**

After each test or whenever you want to review past results.

---






**What you need**

- Alere INRatio®2 PT/INR Professional Monitor
- 

**Notes**

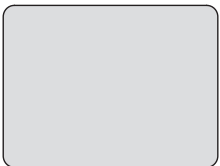
- The monitor will store up to 120 results. The most recent 60 results are available for review on the display.
  - Each stored result includes the INR with date, time, PT and QC.
  - After 120, the oldest result is automatically deleted to make room for the newest.
- 

**Note About****Display Options**

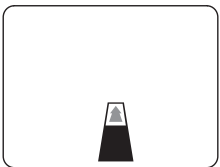
- The INR, PT seconds and QC results are always stored, with date and time, for every test.
  - The MEMORY will show the display selections you made during SETUP.
    - If you chose to display INR only, then you will see only INR results when you view the memory.
    - If you want to see the PT or QC values for any test result but can only see INR, do this:
      1. Exit MEMORY by pressing the MEMORY (  ) button.
      2. Press the SETUP (  ) button.
      3. Press OK to scroll past each display until you see the blood drop.
      4. Press the UP (  ) and DOWN (  ) arrows to find the display you want, then press OK.
      5. Press the SETUP (  ) button to exit SETUP.
      6. Follow the steps below to access memory.
- 



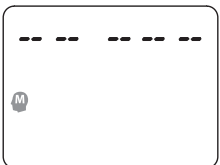
**When you see this:**      **Do this:**



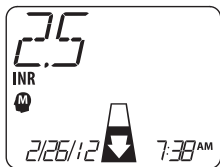
1. If the monitor is off, turn it on:  
Press and hold the OK button for 2 seconds.  
If the monitor is on, skip to step 2.



2. Press the MEMORY (M) button.



3. Do nothing: There is nothing in memory because you have either not performed a test or you have cleared the memory.

**When you see this:****Do this:****Example**

4. View result(s).

Hint: The MEMORY (M) symbol flashes to show you are reviewing results in the Monitor Memory

Press the DOWN (▼) arrow to scroll through previous results.  
Press UP (▲) if you want to see results you have scrolled past.



5. To exit Memory, press the MEMORY (M) to return to the insert strip display.





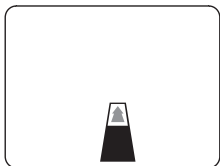
## To Clear Memory:

You can erase the monitor memory of all previous test results, but you cannot clear any specific result. Make sure to record previous results if you wish to keep them before you clear the monitor memory.

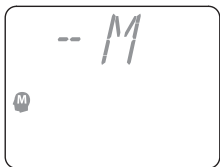
**When you see this:**      **Do this:**



1. With the monitor off, press and hold the OK button for 2 seconds.



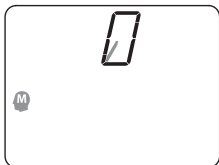
2. Press the MEMORY (M) button.
3. Press and hold the MEMORY (M) button for 2 seconds.



You will see this screen (Memory symbol and --M flashing) to confirm you want to clear the memory.

Hint: If you decide NOT to clear the memory, do NOT press the SETUP (S) button. To exit Memory, press any other button (UP (▲) or DOWN (▼), OK, or MEMORY (M)).

**Clear Memory confirmation  
(all flashing)**

**When you see this:****Do this:*****Memory is clearing***

4. If you want to clear the memory:

- Press and hold the SETUP (  ) button for 2 seconds
- Wait 3 seconds while memory clears



5. The memory is now cleared (empty).

## 16. Print Results

---

### Purpose

- Health Care Professionals who need to print results.

⚠ **CAUTION:** The printer is not recommended for near patient use.

---

### What you need

- Alere Universal Printer Kit (no other printer is recommended for use with the Alere INRatio®2 PT/INR Professional Monitor)
  - Printer Labels
- 

### Helpful Hints:

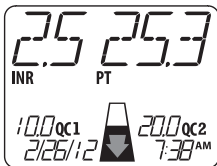
- Refer to the Alere Universal Printer User Guide for set-up instructions, routine maintenance procedures and troubleshooting guidelines.
- The printout provides the same information as on the Alere INRatio®2 PT/INR Professional Monitor display (date, time and result formats chosen during Setup).

**NOTE:** *Target Range information will not be printed (target range is also not shown on the display).*

- Patient identification (ID) can be hand-written in the space provided on the printout.
-

**When you see this:**

**Print  
Test  
Results:**



**Do this:**

1. Connect the printer to the Alere INRatio®2 Monitor data port **1**:
2. Turn printer on.



3. Press the Alere INRatio®2 Monitor's Printer /SETUP button:



4. Printing is in progress. Wait for result to be printed.

**If you see this instead:**

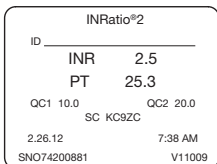


**Then:**

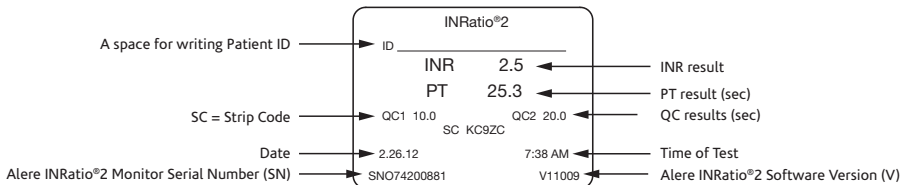
- The printer is not connected.
- Go back to step 1.

When you see this:

Do this:



5. Your Alere INRatio®2 test result is now printed. The printout will match the display chosen during Setup. In this example, INR + PT + QC are printed.



Print  
Error  
Results:



**Example**

If you get an error result, you may also print the error following steps 1-3 above.

"N" represents any number (0-9). Example Error "141".

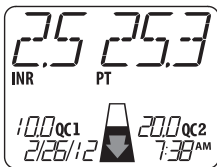
When you see this:

Do this:

### Print Results from the Memory

You can also print results from the Monitor Memory.

1. With the monitor **off**, press and hold the **OK** button for two (2) seconds to turn it on.
2. Press the Memory ( **M** ) button
3. Press the UP ( **▲** ) or DOWN ( **▼** ) arrows to scroll through previous results.
4. Once you see the result you want to print, press the Printer/SETUP button.



When you see this:

Do this:

INRatio®2			
ID	_____		
INR	2.5		
PT	25.3		
QC1 10.0	QC2 20.0		
SC KC9ZC			
2:26.12	7:38 AM		
SNO74200881	V11009		

5. Your Alere INRatio®2 result is now printed. The printout will match the display chosen during Setup.

In this example, INR + PT + QC are printed.

### Turn Monitor OFF

6. If you are using an external power supply, the monitor will stay on indefinitely.  
If you are using batteries, to save battery power, you can turn the monitor off when it is not being used: Press and hold the OK button.
- ⚠ **CAUTION:** Never turn the monitor off by disconnecting the power supply from the wall or the monitor. Always turn the monitor off by pressing and holding the OK button for 2 seconds, then disconnect the power supply.



## Additional Reference Information

### 17. Operating Conditions, Storage Conditions and Product Specifications

**Operating Conditions:**

---

Temperature 50 – 90°F (10 – 32°C)  
Humidity: 15 – 90% (without condensation)  
Atmospheric Pressure: 700 hPa – 1060 hPa

---

**Storage Conditions**

---

Temperature -4°F to 158°F (-20°C to 70°C),  
Humidity: 15-90% (without condensation)

---

**Memory:**

---

120 tests (60 available for review on the display)

---

**Power:**

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

---

**Size:**

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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

---

**Data Port:**

---

RS232


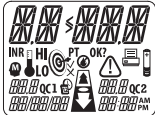















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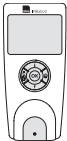
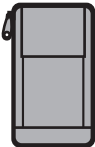

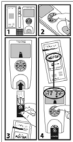


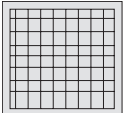






















## 18. Monitor Display Symbols

These symbols appear on the monitor display and throughout this User Guide.

 <p>Temperature</p>	 <p>First Display: Shows All Segments</p>		 <p>Caution</p>
<p>Button &amp; Display:</p>  <p><b>SETUP</b></p>	<p>Button:</p>  <p><b>UP</b> Arrow</p>	<p>Button:</p>  <p><b>DOWN</b> Arrow</p>	<p>Button &amp; Display:</p>  <p><b>MEMORY</b></p>
 <p>Insert Strip</p>	 <p>Apply Sample</p>	 <p>Not enough blood, <b>DO NOT</b> add more blood</p>	 <p>Remove Strip</p>
 <p>Batteries are low</p>	 <p>Replace Batteries</p>	<p><b>QC1</b></p> <p>Quality Control 1</p>	<p><b>QC2</b></p> <p>Quality Control 2</p>
<p>Button &amp; Display:</p>  <p>Print Results</p>	 <p>Target Range</p>	 <p>Target Range Feature "On"</p>	 <p>Target Range Feature "Off"</p>

## Symbols Used in Alere INRatio®2 PT/INR Professional Monitoring System Instructions or Packaging

 <p>Alere INRatio®2 Monitor</p>	 <p>Carrying Case</p>	 <p>Consult Instructions for Use (User Guide) (blue)</p>	 <p>Quick Reference Guide</p>
 <p>Single Use Lancing Device</p>	 <p>Training Video</p>	 <p>Clorox Dispatch® Disinfecting Towels</p>	 <p>Multi-language User Guide</p>
 <p>Power Supply (For Professional Use Only)</p>	 <p>Consult Instructions for Use</p>	 <p>Biohazard (yellow)</p>	

 <p>Direct / Alternating Current</p>	 <p>Use by (date)</p>	 <p>Do Not Reuse</p>	 <p><i>In Vitro</i> Diagnostic Medical Device</p>
 <p>Direct Current</p>	 <p>Catalogue Number</p>	 <p>Temperature Limitation</p>	 <p>Serial Number</p>
 <p>Data Port</p>	 <p>Power Supply Port (Connect only the power supply provided with your monitor)</p>	 <p>Biological Risk: Disposable items pose biological risks.</p>	 <p>Special Waste (wheeled bin)</p>
 <p>Manufacturer</p>	 <p>Authorised Representative in the European Community</p>	 <p>CE Mark</p>	 <p>Type BF Applied Part: The monitor has conductive contact with the patient.</p>



Class II Equipment:  
The monitor is double insulated

The monitor is classified as ordinary equipment



### Classification

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



## 19. Hazards

- ⚠ 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 Alere™ Technical Services 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. 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. Please contact Alere™ Technical Services if you have any questions about connecting devices to the data port.
- ⚠ Use only the recommended Power Supply provided with your monitor or you may damage the monitor.
- ⚠ IEC 60601-1:2005 + A1:2012

### **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 60601-1-2:2007. 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

## 20. Warranty - Limited 2 Year Warranty

### Use of the Alere INRatio®2 PT/INR Professional Monitoring System

The Alere INRatio®2 PT/INR Professional 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

For the applicable warranty period, Alere warrants that each Product shall be (i) of good quality and free of material defects, (ii) function in accordance with the material specifications referenced in the Product Manual, and (iii) approved by the proper governmental agencies required for the sale of Products for their intended use (the “LIMITED WARRANTY”). If the Product fails to meet the requirements of the Limited Warranty, then as customer’s sole remedy, Alere shall either repair or replace, at Alere’s discretion, the Product. Except for the LIMITED WARRANTY stated in this section, Alere disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the Product. Alere’s maximum liability with any customer claim shall not exceed the net Product price paid by customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result.

The Limited Warranty above shall not apply if the Customer has subjected the Product to physical abuse, misuse, abnormal use, use inconsistent with the Product Manual or Insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by Customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.



## 21. Glossary of Terms (listed alphabetically)

**Biohazard / Biological Risk:** Used, disposable items (such as used lancet, test strip, gauze) have blood on them and pose biological risks so must be disposed of properly.

**Calculated Prothrombin Time (PT):** The monitor does not display raw PT time in seconds. The raw PT (seconds) value is measured and used internally by the monitor for calculation of INR based on lot specific parameters encoded in strip code. Only INR is reported in default mode on monitor. A *calculated* PT (sec) may be optionally displayed on the monitor in clinical settings. {The displayed, *calculated* PT (sec) is back calculated from INR with an ISI of 1.0 and normal geometric mean PT of 10.0 seconds using formula  $INR = (PT/MNPT)^{ISI}$ .}

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

**Coagulation:** Clotting of blood.

**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 finger tip. Collecting a hanging drop helps to ensure that an adequate sample (at least 9.5µL) 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 finger tip 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 clots to the electrical current produced by the electrodes. The Alere INRatio®2 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), for people taking oral anticoagulant therapy, that takes into account the different sensitivity of thromboplastins (reagents) used in various methods. INR results are comparable across PT measurement systems.

**International Sensitivity Index (ISI):** A mathematical value estimating sensitivity of the thromboplastin reagent used in the PT test.

**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® or warfarin) 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 Alere INRatio®2 power supply.

**Prothrombin Time (PT):** Test measures the clotting time of plasma. The Alere INRatio®2 Monitor measures raw PT (seconds) using a fresh sample of whole blood and uses this number to calculate INR using lot specific measurement.

**Quality Control (QC):** The testing done to show that the system (monitor and test strip) 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 oval hole (target) on the single-use test strip where the blood sample is applied.

**Strip Code:** Code entered and used by the Alere INRatio®2 Monitor that corresponds to the code printed on the test strip pouch and box. For your results to be accurate, the strip code entered into the monitor must match each new lot of test strips.

**Symbols:** See definitions of symbols and their meanings in Section 18, above.

**Test Strip:** A single-use test strip used to perform the Prothrombin Time (PT) test with the Alere INRatio®2 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.





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## Contact

### Alere™ Technical Services

Please read this entire User Guide to learn how to use the Alere INRatio®2 PT/INR Professional Monitoring System. If you have any questions, or have problems with the monitor or test strips, please contact Alere™ Technical Services or your local distributor in your region.

Region	Phone	E Mail Address
USA	+1 877 866 5313	INRatio.Support@alere.com
Canada	+1 613 271 1144	CANproductsupport@alere.com
Latin America	+57 2 6618797	LAprouductsupport@alere.com
Europe & Middle East	+44 161 483 9032	EMEprouductsupport@alere.com
Asia Pacific	+61 7 3363 7711	APprouductsupport@alere.com
Africa, Russia, & CIS	+972 8 9429 683	ARCISprouductsupport@alere.com

**Web:** [www.alere.com](http://www.alere.com)

### Alere™ Customer Service

Contact the following Alere™ Service Care Center or your local distributor for order and billing assistance. You may also contact us at [www.alere.com](http://www.alere.com).


#### Phone

+ 1.877.441.7440

#### E Mail Address

[clientservices@alere.com](mailto:clientservices@alere.com)



 Manufactured for:  
**Alere San Diego, Inc.**  
9975 Summers Ridge Road  
San Diego, CA 92121 USA  
+1.877.441.7440  
**[www.alere.com](http://www.alere.com)**



MDSS GmbH  
Schiffgraben 41  
30175 Hannover, Germany

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