

Addendum

Root<sup>®</sup>  
with Pathway



 **MASIMO**<sup>®</sup>



## Not for Sale in the USA - For Export Only

These operating instructions provide the necessary information for proper operation of all models of the Root. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Root are prerequisites for its proper use. Do not operate Root without completely reading and understanding these instructions.

**Notice:** Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

**Note:** Cleared Use Only: The device and related accessories are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

**CAUTION:** Use of this device must follow the order of a physician.

**For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.**

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ANSI/AAMI ES 60601-1, CAN/CSA C22.2 No. 60601-1, and applicable Particular (IEC 60601-2-49, IEC 80601-2-30, ISO 80601-2-56) and related Collateral (IEC 60601-1-8:2006) Standards for which the product has been found to comply by Intertek.

Patents: [www.masimo.com/patents](http://www.masimo.com/patents)

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# Addendum, Root Operator's Manual: Root with Pathway

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This addendum provides updates to the following:

## **Operator's Manual, Root®**

- 37365/LAB-8425 and equivalent translations
- 37503/LAB-8542 and equivalent translations

## **Operator's Manual, Root® with noninvasive blood pressure and temperature**

- 37705/LAB-8747 and equivalent translations
- 38280/LAB-9274 and equivalent translations

This addendum covers the Pathway feature of the Root device. For all other information, refer to the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature.***





# Product Description, Features and Indications for Use

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The following information is an addendum to be used with the content in **Product Description, Features and Indications for Use** of the **Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature**.

## Key Feature Update

The following added feature is available for Root:

- Pathway is an optional continuous monitoring mode which allows clinicians to set a visual indicator of the preferred oxygen saturation range during the first 10 minutes after birth.



# Safety Information, Warnings, and Cautions

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The following information is an addendum to be used with the content in **Safety Information, Warnings and Cautions** of the **Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature**.

**CAUTION:** Before using Pathway on Root, completely read and understand the **Operator's Manual, Radical-7, Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature**. This addendum to the Operator's Manual provides specific instructions about using Pathway.

## Performance Warnings and Cautions

### Pathway

**WARNING:** Monitoring in the Pathway mode is not intended to direct or prescribe a clinical treatment or therapy decision. The clinical treatment and therapy decision should be evaluated in conjunction with the patient's clinical status and confirmed with additional diagnostic tests consistent with each hospital's policy. Any concern about a patient's clinical condition should prompt an urgent clinical review, irrespective of monitoring results.

**WARNING:** Visual indicator of the glide path should be adjusted according to the hospital's policy and should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

**Note:** The time scrub button should be adjusted to reflect the actual elapsed time. The default time indicated is based upon the elapsed time from the start of use of the mode.



# Operation

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The following information is an addendum to be used with the content in **Chapter 3: Operation** of the *Operator's Manual, Radical-7, Operator's Manual, Root@* or *Operator's Manual, Root@ with noninvasive blood pressure and temperature*.

## Accessing Main Menu Options for Pathway

To access the Pathway Main Menu options, press the Main Menu icon at the bottom right corner of the touchscreen:



The Main Menu options include Root specific settings as well as Root settings.

Options in the **Main Menu** include the following:



### Pathway Settings

See *Pathway Settings* on page 12.



### Sounds\*



### Device Settings

See Device Settings.



### About\*

\* For Root settings not related to Pathway, refer to **Chapter 3: Operation** of the *Operator's Manual, Root@* or *Operator's Manual, Root@ with noninvasive blood pressure and temperature*.

## Pathway Settings



Pathway settings include the following:



### Parameter Settings\*, \*\*

See *Parameter Settings* on page 12.



### Additional Settings

See *Additional Settings* on page 13.



### SpO2 Pathway Alarms\*\*

See *SpO2 Pathway Alarms* on page 13.



### SpO2 Target Range

See *SpO2 Target Range* on page 14.



### PR Threshold

See *PR Threshold* on page 15.

\* Only displays when Radical-7 is docked to Root.

\*\* The *SpO2 Pathway Alarms* control the alarm limits during the first 10 minutes of Pathway operation. After 10 minutes of Pathway operation, the *SpO2 Parameter Settings* control the alarm limits.

## Parameter Settings



*Parameter Settings* display only when Radical-7 is docked to Root.

**Note:** The Neonatal profile is selected by default for all Radical-7 parameter settings during Pathway operation.

For information about configuring the *Parameter Settings* related to *Pathway*, refer to **Chapter 3: Operation** of the *Operator's Manual, Radical-7 Pulse CO-Oximeter*.

## Additional Settings



From the *Additional Settings* screen, change any of the following options:

Option	Description	Factory Default Settings	User Configurable Settings
SmartTone	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

## SpO<sub>2</sub> Pathway Alarms



The SpO<sub>2</sub> Pathway Alarms allow the user to optionally adjust alarm limits during the first 10 minutes when used in Pathway mode. After 10 minutes, the alarm limits revert to the ones set as part of the SpO<sub>2</sub> Parameter Settings.

From the *SpO<sub>2</sub> Pathway Alarms* settings screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	99	2 to 99 in steps of 1, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	88	1 to 98 in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	2 minutes	30 seconds, 1 or 2 minutes
Rapid Desat	Sets the Rapid Desat limit threshold to the selected amount below the Low Alarm Limit. When SpO <sub>2</sub> value falls below rapid desat limit the audio and visual alarm are immediately triggered without respect to the alarm delay.	-10	Off, -5, or -10

Options	Description	Factory Default Settings	User Configurable Settings
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	10	0, 5, 10, or 15

## SpO2 Target Range



Use the SpO2 Target Range settings screen to configure the Glide Path visualization. See **Pathway Screen** on page 20.

Option	Description	Factory Default Settings*	User Configurable Settings**
1 Min	SpO <sub>2</sub> Max	60	60 to 98 in steps of 1
	SpO <sub>2</sub> Min	65	61 to 99 in steps of 5
2 Min	SpO <sub>2</sub> Max	65	60 to 98 in steps of 1
	SpO <sub>2</sub> Min	70	61 to 99 in steps of 1
3 Min	SpO <sub>2</sub> Max	70	60 to 98 in steps of 1
	SpO <sub>2</sub> -axis Min	75	61 to 99 in steps of 1
4 Min	SpO <sub>2</sub> Max	75	60 to 98 in steps of 1
	SpO <sub>2</sub> Min	80	61 to 99 in steps of 1
5 Min	SpO <sub>2</sub> Max	80	60 to 98 in steps of 1
	SpO <sub>2</sub> Min	85	61 to 99 in steps of 1
10 Min	SpO <sub>2</sub> Max	85	60 to 98 in steps of 1
	SpO <sub>2</sub> -axis Min	95	61 to 99 in steps of 1

\* Default settings are established based upon the recommendation made by Wyckoff MH, Aziz K, Escobedo MB, Kapadia VS, Kattwinkel J, Perlman JM, Simon WM, Weiner GM, Zaichkin, JG. Part 13: neonatal resuscitation: 2015 American Heart Association Guidelines Update for



*Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015; 132(suppl 2):S543–S560.*

\*\* Visual indicators only. Audible alarms only occur when the Radical-7 high and low alarm limits are reached. Refer to the **Operator's Manual, Radical-7® Pulse CO-Oximeter®**.

## PR Threshold



From the PR Threshold settings screen, change any of the following options. Default settings are established based upon the recommendation made by the *International Liaison Committee on Resuscitation (ILCOR)*.

Options	Description	Factory Default Settings*	User Configurable Settings**
Low Limit	Adjusts the low limit threshold visual indicator.	100	35 to 235 in steps of 5
Critical Limit	Adjusts the critical limit threshold visual indicator.	60	30 to 230 in steps of 5

\* Default settings are established based upon the recommendation made by *Wyckoff MH, Aziz K, Escobedo MB, Kapadia VS, Kattwinkel J, Perlman JM, Simon WM, Weiner GM, Zaichkin, JG. Part 13: neonatal resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015; 132(suppl 2):S543–S560.*

\*\* Visual indicator only. Audible alarms only occur when the Radical-7 high and low alarm limits are reached. Refer to the **Operator's Manual, Radical-7® Pulse CO-Oximeter®**.

## Device Settings



On Root equipped with Pathway, some *Device Settings* options change and are reflected below:



### Access Control

See **Access Control** on page 16.

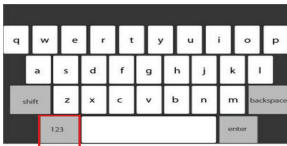
## Access Control



Access Control contains configurable options and settings that require a password.

### To enter Access Control

1. Press the **123** key.



2. When the numeric screen displays, enter the following numbers: **6 2 7 4**  
Asterisks (\*\*\*\*) will be displayed.  
To undo an entry, press **Backspace**.
3. Press **Enter** to access the password protected screen.

**Note:** The password will have to be entered every time this screen is accessed.

Option	Description	Factory Default Setting	Configurable Settings
All Mute Enabled	Enables or disables parameter Alarm Silence menu option. See Sounds.	Off	On or Off
Lock Alarm Volume	Sets the lowest alarm volume level.	Off	3, 4, or Off
USB Port 1* baud rate	Enables option to change baud rate of device.	921600	9600, 19200, 38400, 57600, 115200, 230400, or 921600
USB Port 2* baud rate	Enables option to change baud rate of device.	921600	9600, 19200, 38400, 57600, 115200, 230400, or 921600
Data Collection Enabled	Enables or disables physical data collection mode.	Off	On or Off

Option	Description	Factory Default Setting	Configurable Settings
Factory Defaults	Options are restored to factory value.	N/A	Press <b>Restore</b> .

\*Changes to USB Ports baud rate will take effect after Root is power cycled (turned off then on again).

**Note:** Restore Factory Defaults can only be performed during non-monitoring and when no cable connections are present.



# Pathway

Before using Pathway on Root, completely read and understand the ***Operator's Manual, Radical-7, Operator's Manual, Root@*** or ***Operator's Manual, Root@ with noninvasive blood pressure and temperature.***

Select the appropriate Masimo sensor and completely read and understand the *Directions for Use* of the Masimo sensor.

See ***Safety Information, Warnings, and Cautions*** on page 9.

## About the Pathway Main Screen

The *Main Screen* consists of different areas.

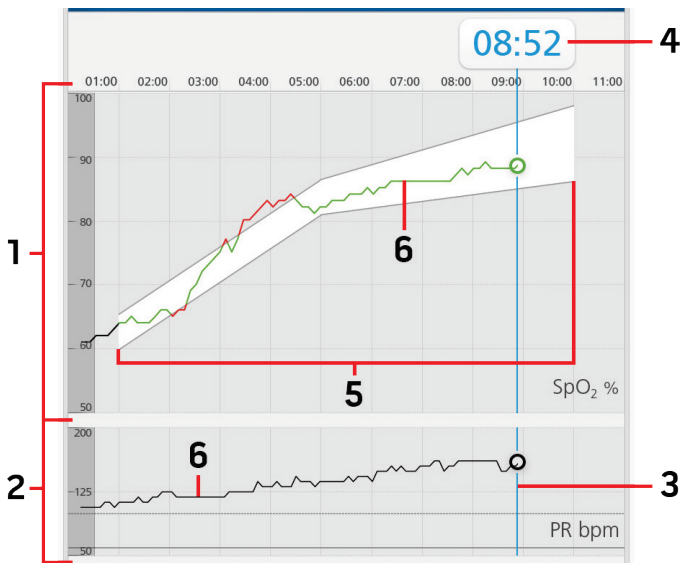


Ref.	Feature	Information
1	Status Bar	See <b><i>Operator's Manual, Root@</i></b> or <b><i>Operator's Manual, Root@ with noninvasive blood pressure and temperature.</i></b>

Ref.	Feature	Information
2	Pathway Operation Start Button	See <b>Pathway Procedure</b> on page 21.
3	Main Menu	See <b>Accessing Main Menu Options for Pathway</b> on page 11.

## Pathway Screen

The *Pathway* screen details are described below.



Item	Name	Description
1	SpO <sub>2</sub> Measurement Window	Displays the <i>Glide Path</i> and SpO <sub>2</sub> measurements.
2	PR Measurement Window	Displays the PR measurements.
3	Time Rule	Current location of the SpO <sub>2</sub> and PR measurements.

Item	Name	Description
4	Time Scrub Button	Displays the elapsed time and allows adjustment to the time. See <b>Time Adjustment</b> on page 26.
5	Glide Path	The set Min and Max <i>SpO2 Target Range</i> . See <b>SpO2 Target Range</b> on page 14.
6	Trend	Displays the trends for SpO <sub>2</sub> and PR. See <b>Trend</b> on page 23.

## Parameter Window

Below the *Pathway Screen* is the *Parameter Window*. The *Parameter Window* displays parameters available on Radical-7.



## Pathway Procedure

To use Pathway, perform the following:

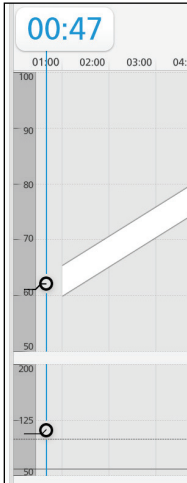
1. Select the appropriate Masimo sensor and completely read and understand the *Directions for Use* of the Masimo sensor.
2. Attach a cable and sensor to Radical-7 and the patient.
3. From the *Pathway Main Screen*, press the **Start** button to begin.



**Note:** If Radical-7 is not attached to Root, *Please Connect a Device* displays on the screen below the **Start** button.

Once the sensor signal is acquired, measurement begins automatically.

4. During the first minute of measurement, the glide path is not displayed. The glide path only displays from one (1:00) minute to ten (10:00) minutes. The *Time Scrub Button* displays the elapsed time.



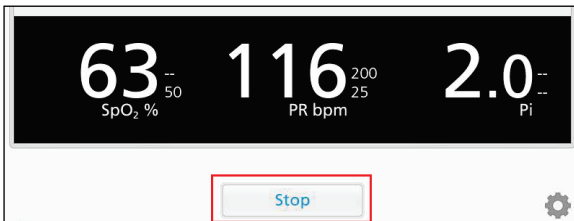
5. After ten (10:00) minutes of measurement the following occurs:
  - The glide path moves off the screen as the time advances past ten minutes.
  - Panning is allowed and will have a one minute no touch timeout. After the timeout, the view returns to the current location in the measurement time.
  - Panning forward beyond the current time will snap back to the current location in the measurement time.
  - Panning backward beyond zero will snap to zero.
  - The current Pathway session continues until manually ended.



- After 96 hours the *Time Scrub Button* displays >96:00:00.



6. To stop the Pathway procedure, select the **Stop** button at the bottom of the screen. Confirm by selecting the **Stop** button again in the confirmation window. The screen returns to the *Pathway Main Screen*. To continue with the Pathway procedure, select **Cancel** in the confirmation window.



## Trend

The SpO<sub>2</sub> and PR trends display on the Pathway screen.

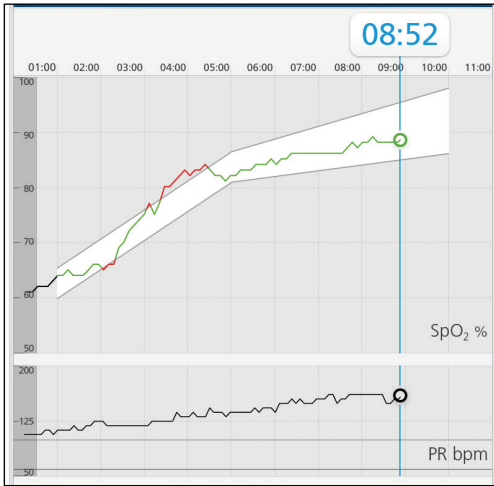
**Note:** Panning left/right on the screen is disabled during the first 11 minutes of monitoring.

The SpO<sub>2</sub> trend changes colors depending on location in relation to the glide path (target range). See **SpO<sub>2</sub> Target Range** on page 14. SpO<sub>2</sub> trend colors include:

- Black - before and after the glide path.
- Green - within the glide path.
- Red - above or below the glide path.

The PR trend changes colors depending on relation to the PR Threshold Settings. See **PR Threshold** on page 15. PR trend colors include:

- Black - above the set PR Threshold Low Limit.
- Yellow - below the set PR Threshold Low Limit but above the set Critical Limit.
- Red - below the set PR Threshold Critical Limit.



## Visual Indicators

In Pathway mode, visual indicators are provided under the following circumstances, based upon the hospital's established Glide Path visualization settings. See **SpO<sub>2</sub> Target Range** on page 14.

- SpO<sub>2</sub> is Low. See description of **SpO<sub>2</sub> Low** on page 24.
- SpO<sub>2</sub> is High. See description of **SpO<sub>2</sub> High** on page 25.
- PR is Low. See description of **PR Low (Below 100 bpm)** on page 26.
- PR is Critical. See description of **PR Critical (Below 60 bpm)** on page 26.

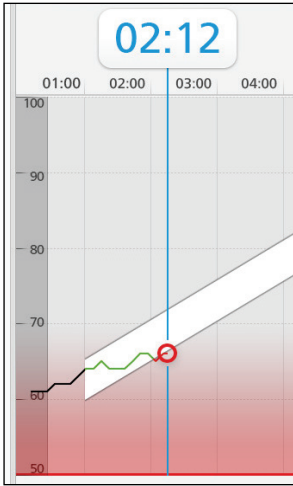
**Note:** Visual indicators of deviations of the SpO<sub>2</sub> and PR from the Glide Path are not alarms and therefore will not generate audible alarms.

## SpO<sub>2</sub> Low

When SpO<sub>2</sub> is below the glide path:

- Red SpO<sub>2</sub> indicator and red glow from the bottom edge of the trend.
- No message displays in the header.

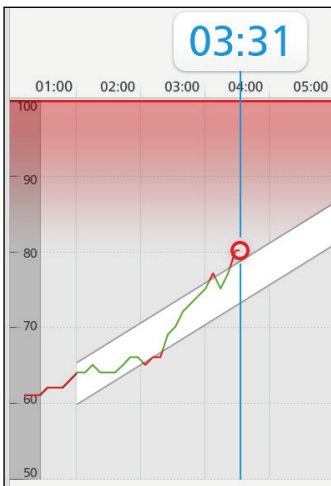
- No audible alarms.



## SpO2 High

When SpO<sub>2</sub> is above the glide path:

- Red SpO<sub>2</sub> indicator and red glow from the top edge of the trend.
- No message displays in the header.
- No audible alarms.



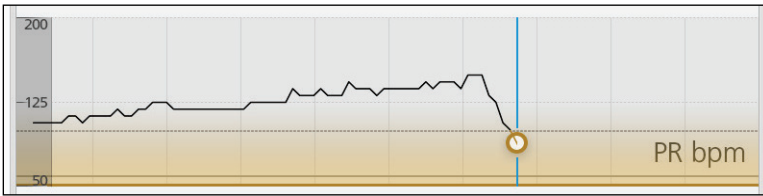
## PR Visual Indicators

PR thresholds are configurable in the *PR Threshold* settings menu. See **PR Threshold** on page 15.

### PR Low (Below 100 bpm)

The PR trend and current indicator display yellow after breaching the 100 bpm dashed limit. A visual indicator displays immediately.

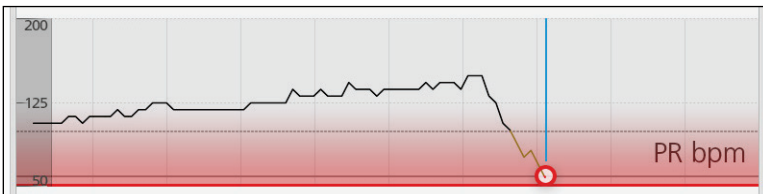
- Yellow glow from the bottom of the PR trend.
- No message displays in the header.
- No audible alarms.



### PR Critical (Below 60 bpm)

The PR trend and current indicator display red after breaching the 60 bpm solid limit. A visual indicator displays immediately.

- Red glow from the bottom of the PR trend.
- No message displays in the header.
- No audible alarms.



## Time Adjustment

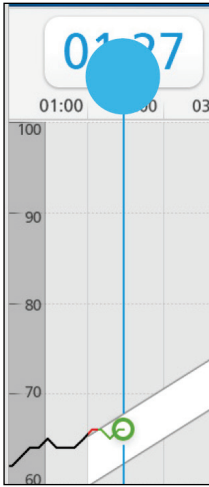
Time adjustment allows the measurement start time to be adjusted in relation to actual birth time.

- Time adjustment can only be initiated within the first ten minutes of a session.
- No time adjustment can be made to less than 0 minutes.

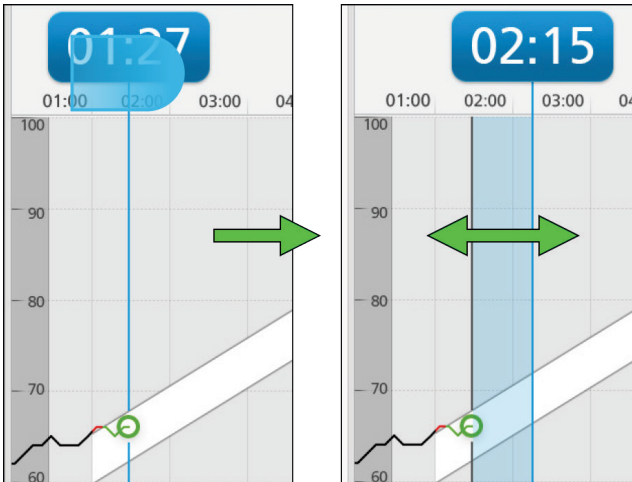
- No time adjustment can be made to greater than 10 minutes.
- No time adjustment can be made after 10 minutes of the session elapses.

To adjust the time during Pathway operation, perform the following:

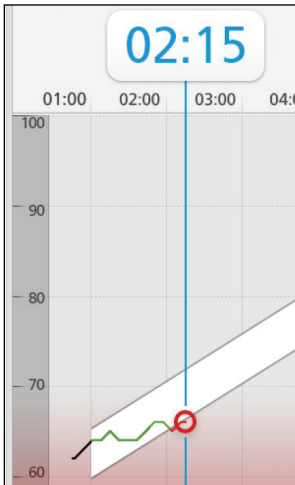
1. Press and hold the *Time Scrub Button* to activate the time adjustment.



2. The *Time Scrub Button* is blue when adjustment can be made. Drag the *Time Scrub Button* left or right on the screen to the desired location. As the *Time Scrub Button* is moved, the time adjusts in relation to the new location. Release the *Time Scrub Button* at the new time.

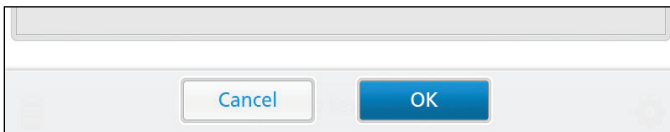


**Note:** SpO<sub>2</sub> visual indicators may display if the trend is not within the glide path.



3. Select the **OK** button to confirm the new time or **Cancel** to return to the previous time.

**Note:** After one (1) minute with no interaction, the adjustment times out and continues with the previous time.



# Messages

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The following information is an addendum to be used with the content in the **Messages Chapter** of the **Operator's Manual, Root®** or **Operator's Manual, Root® with noninvasive blood pressure and temperature**.

The following messages are specific to Pathway operation:

Message	Explanation	Next Step
<i>Please connect a Device</i>	Radical-7 is not docked to Root.	Connect a Radical-7 to Root.
<i>Radical-7 displays: "Root software is not fully compatible. Please contact support to upgrade now."</i>	Radical-7 Software needs to be upgraded to v1.5.8.4 or higher to work properly with the Pathway feature on Root.	Contact Masimo.





# Troubleshooting

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The following information is an addendum to be used with the content in **Troubleshooting** chapter of the **Operator's Manual, Root@** or **Operator's Manual, Root@ with noninvasive blood pressure and temperature**.

## Root Troubleshooting

Symptom	Possible Cause	Correction
<i>Radical-7 Not Docked Before Pathway Operation</i>	When Radical-7 is not docked to Root, the Pathway main screen displays <i>Please Connect a Device</i> .	Dock a Radical-7 device to Root prior to performing the Pathway operation.
<i>Radical-7 Not Docked During Pathway Operation</i>	The Pathway feature can be started without a Radical-7 docked to Root. If the Pathway operation is started with a Radical-7 docked, the session time is displayed but without trend data. Once a Radical-7 is docked to Root with a sensor connected to the patient, available trend data displays on the screen. The top of the Pathway window displays <i>Please Connect a Device</i> message.	Ensure a Radical-7 device is docked to Root prior to performing the Pathway operation.
<i>Radical-7 Un-Docked During Pathway Operation</i>	If Radical-7 is un-docked (removed) from Root during Pathway operation, the session time continues to be displayed but without trend data. The top of the Pathway window displays <i>Please Connect a Device</i> .	Do not undock a Radical-7 device from Root during Pathway operation.







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