



TECHNICAL SERVICE BULLETIN

Product Name:

Masimo Rad-8

Symptom:

Inability to retain user default settings on Rad-8 device after power cycle

Cause:

The Rad-8 device has been noted to revert back to factory default settings after power cycle. Device functions as intended once user settings are configured or verified after power cycle. There is no impact to performance.

Impact Assessment:

The directions for use for the Rad-8 device indicate that user settings shall be verified at each use. If the end user fails to verify user settings after a power cycle, it is possible that an end user may unintentionally monitor a patient with a Rad-8 device that has reverted back to factory default settings, which may or may not be appropriate for the patient's clinical condition.

Effectivity:

This Technical Service Bulletin is effective Nov 15, 2010

Keywords:

Rad-8; Return to Default;

Test Instructions: *Select the device which looks most like your monitor and follow the test instructions*

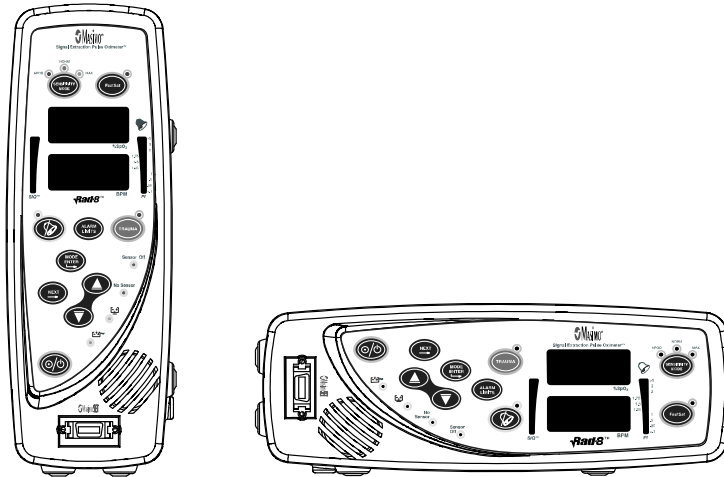


- 1 Remove the Rad-8 monitor from service
- 2 Disconnect the cable or direct connect sensor if attached and power on the unit by pressing the ON/OFF button
- 3 Observe and record the set defaults from the start up display; SpO2 Low/High; Pulse Rate (BPM) Low/High respectively
- 4 From the Standard Mode (Std) set the monitor to Factory Defaults by pressing the Enter button for 5 seconds until *DEF NO* is displayed
- 5 Press the arrow up/down button until *DEF FAC* is displayed and press the Enter button to confirm
- 6 Next change the user defined Alarm Limits to the following settings
- 7 Press the Alarm Limits button 1 time to set the low SpO2 alarm limit
 - a. Press the arrow up/down buttons to change the low SpO2 alarm limit to 92
- 8 Press the Alarm Limits button 2 times to set the high SpO2 alarm limit
 - a. Press the arrow up/down buttons to change the high SpO2 alarm limit to 99
- 9 Press the Alarm Limits button 3 times to set the low Pulse Rate (BPM) alarm limit
 - a. Press the arrow up/down buttons to change the low Pulse Rate (BPM) alarm limit to 55
- 10 Press the Alarm Limits button 4 times to set the high Pulse Rate (BPM) alarm limit
 - a. Press the arrow up/down buttons to change the high Pulse Rate (BPM) alarm limit to 135
- 11 Verify Alarm Limits LED is illuminated and *NO SEN* is displayed (may take up to 10 seconds)
- 12 Save the set User defaults by pressing the Enter button for 5 seconds until *DEF NO* is displayed
- 13 Press the arrow up/down button until *DEF uSr* is displayed and press the Enter button to confirm
- 14 Verify that the Alarm Limits LED is off.
- 15 Press the ON/OFF button for 2 seconds to turn the Rad-8 Off
- 16 Turn on the monitor by pressing the ON/OFF button
- 17 Verify the Alarm Limits at start up are: SpO2 Low = 92, High = 99, BPM Low = 55, High = 135
 - a. If this step was missed at start up the alarm limits can be displayed by pressing the Alarm Limits button 1 through 4 times to cycle through each of the respective alarm limits
- 18 If the alarm limits are as stated above continue to the next step. If they are different segregate the instrument and contact Masimo Technical Services*



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- 19 Repeat steps 15 through 18 an additional 39 times
- 20 If the monitor retains the alarm limits in the steps above return the alarm limits back to the initial settings as recorded in step 3 and place the monitor back into service.
- 21 Refer to steps 7-13 to set and save the alarm limits



- 1 Remove the Rad-8 monitor from service
- 2 Disconnect the cable or direct connect sensor if attached and power on the unit by pressing the ON/OFF button
- 3 Observe and record the set defaults from the start up display; SpO2 Low/High; Pulse Rate (BPM) Low/High respectively
- 4 From the Standard Mode (Std) set the monitor to Factory Defaults by pressing the Mode/Enter button 2 times or until 888 888 is displayed
- 5 Press the Next button 2 times until *FAC DEF* is displayed
- 6 Press the Up arrow 2 times until *DEF YES* is displayed and press the Mode/Enter button and wait until *NO SEN* is displayed
- 7 Next change the user defined Alarm Limits to the following settings
- 8 Press the Alarm Limits button 1 time to set the low SpO2 alarm limit
 - a. Press the arrow up/down buttons to change the low SpO2 alarm limit to 92
- 9 Press the Alarm Limits button 2 times to set the high SpO2 alarm limit
 - a. Press the arrow up/down buttons to change the high SpO2 alarm limit to 99
- 10 Press the Alarm Limits button 3 times to set the low Pulse Rate (BPM) alarm limit
 - a. Press the arrow up/down buttons to change the low Pulse Rate (BPM) alarm limit to 55
- 11 Press the Alarm Limits button 4 times to set the high Pulse Rate (BPM) alarm limit
 - a. Press the arrow up/down buttons to change the high Pulse Rate (BPM) alarm limit to 135
- 12 Wait until *NO SEN* is displayed (may take up to 10 seconds)
- 13 Save the set User defaults by pressing the Mode/Enter button 2 times or until 888 888 is displayed
- 14 Press the Next button 3 times until *SAV DEF* is displayed
- 15 Press the Up arrow 2 times until *SAV YES* is displayed and press the Mode/Enter button
- 16 At the *Ent PAS* prompt press the following button sequence: Next button, Up arrow, Down arrow, Next button
- 17 The display will return to reading *NO SEN*
- 18 Press the ON/OFF button for 2 seconds to turn the Rad-8 Off
- 19 Turn on the monitor by pressing the ON/OFF button
- 20 Verify the Alarm Limits at start up are: SpO2 Low = 92, High = 99, BPM Low = 55, High = 135
 - a. If this step was missed at start up the alarm limits can be displayed by pressing the Alarm Limits button 1 through 4 times to cycle through each of the respective alarm limits



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- 21 If the limits are as stated above continue to the next step. If they are different segregate the instrument and contact Masimo Technical Services*
- 22 Repeat steps 18 through 21 an additional 39 times
- 23 If the monitor retains the alarm limits in the steps above return the alarm limits back to the initial settings as recorded in step 3 and place the monitor back into service
- 24 Refer to steps 8-17 to set and save the alarm limits

Final Action:

If the Rad-8 does not pass the above screening, please discontinue use of the device in use case scenarios where custom settings are required. Contact Technical Services to obtain a free software upgrade which will restore user default retention functionality of your device.

This upgrade will require sending the Rad-8 to Masimo.

*Please visit our website for contact information; <http://www.masimo.com/contact.htm>