

Nellcor™

Bedside Respiratory Patient Monitoring System Respiration Rate Version 2.0



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1 Nellcor™ Respiration Rate

Version 2.0

1.1 Overview

This *Operator's Manual* addendum describes the operation of the Nellcor™ Respiration Rate Version 2.0 parameter when used with the Nellcor™ Bedside Respiratory Patient Monitoring System.

This addendum applies to the following products:

REF GR101704-RR*

REF PM1000N-RR

The parameter provides caregivers with respiration rate information on patients. The parameter does not require modification of other monitoring system settings. Continue to use the monitoring system as before for monitoring SpO₂ and pulse rate, while also monitoring for respiration rate. The parameter does not in any way replace SpO₂ and pulse rate data, but augments it.

To obtain respiration rate data, caregivers must use a Nellcor™ Adult Respiratory Sensor. The parameter provides alarms for high and low respiration rate. Settings for the alarm thresholds are user-adjustable. The parameter has an operating range of 4 to 40 breaths per minute, with an accuracy of ± 1 breath per minute, relative to a capnography-based reference.

For first time activation of the parameter, review the activation kit instructions or contact Covidien for more details.

Use this addendum after thoroughly reading the *Operator's Manual*. All instructions, other than those listed here, remain the same as those listed in the *Operator's Manual*. This addendum only contains information relevant to Respiration Rate parameter usage.

* with the PMMOD30N and PMSW-1000N-V2.0 upgrade kits applied

Table 1-1. Additions to the *Operator's Manual*

Chapter	Title	Respiration Rate Addition
1	Introduction	Additional warnings and cautions
2	Product Overview	Additional product description, indications for use statements, and monitoring screen examples
3	Installation	Refer to separate Activation Instructions
4	Operation	Additional sensor usage information, safety messages, menu options, and alarm information
5	Product Data Output	Additional data fields in data output
6	Performance Considerations	Additional monitoring system constraint and patient condition considerations
7	Product Maintenance	---
8	Troubleshooting	Additional error conditions
9	Accessories	Additional sensor
10	Theory of Operations	Additional parameter
11	Product Specifications	Additional sensor accuracy and range data
Appendix A	Clinical Studies	Additional clinical study data specific to Respiration Rate

1.2 Introduction

1.2.1 Safety Symbol Definitions

This section contains safety information requiring users to exercise appropriate caution while using the monitoring system.

Table 1-2. Safety Symbol Definitions

Symbol	Definition
	WARNING Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.
	Caution Cautions alert users to exercise appropriate care for safe and effective use of the product.
	Note Notes provide additional guidelines or information.



WARNING:

The monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.



WARNING:

Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.



WARNING:

External factors, including certain ambient conditions, sensor application errors, and certain patient conditions, may compromise the accuracy of the displayed respiration rate value. Always consider clinical signs and symptoms when assessing the patient and before intervening in response to a respiration rate alarm.



WARNING:

Respiration Rate is not intended for use as an apnea monitor. During apnea, Respiration Rate may post a non-zero number.



Caution:

Accuracy of Respiration Rate was established using bench-top testing and clinical studies in 30 healthy volunteers and 75 hospitalized patients. Hospital studies did not necessarily include all patient conditions found in hospitals and hospital-type settings. These clinical study results may not generalize to all patient conditions. Use caution in patient populations in which a displayed respiration rate value outside of the stated accuracy specification could present a serious risk or hazard.



Caution:

Respiration Rate provides an indicator of central ventilatory drive and not a direct indication that air is moving through the upper airway. Always consider clinical signs and symptoms when assessing the patient and before intervening in response to a respiration rate alarm.



Caution:

Respiration Rate should be used only in conjunction with the SpO₂ and pulse rate information provided by the monitoring system. Reliance on respiration rate information alone is not recommended. Health care personnel should always consider clinical signs and symptoms when assessing the patient and before intervening in response to a respiration rate alarm.



Caution:

Periods of continuous patient motion may impact device performance. During prolonged periods of motion, Nellcor Respiration Rate may not report a respiration rate value. In situations where respiration rate is not reported, and is the only measurement affected by signal quality, the monitoring system will indicate "RR Interference."



Caution:

The operating range for Respiration Rate is 4 to 40 breaths per minute. Use on patients with respiration rates outside this range may result in inaccurate displayed respiration rate values.



Caution:

Respiration Rate should not be used on patients with significantly irregular cardiac rhythms (defined as three or more events of irregularity observed within 30 seconds) because the presence of these irregular cardiac rhythms may cause inaccurate respiration rate values or the loss of displayed respiration rate information. Safety and effectiveness of Respiration Rate in

patients with significantly irregular cardiac rhythms have not been established. Use an alternate means of monitoring ventilatory status for patients with significant cardiac dysrhythmia or an implanted pacemaker.



Caution:

Safety and effectiveness of Respiration Rate in pediatric and neonatal patients have not been established.



Caution:

Safety and effectiveness of Respiration Rate in pregnant or lactating women have not been established.



Caution:

Safety and effectiveness of Respiration Rate in patients on mechanical ventilation have not been established.



Caution:

An SpO₂ alarm may be the first indication of hypoventilation.



Caution:

A low SpO₂ alarm limit of at least 90% is recommended when monitoring patients on supplemental oxygen.



Caution:

Use of the Respiration Rate parameter does not change the need to set threshold limits appropriate to the patient being monitored.



Caution:

Nellcor Respiration Rate performance has not been established during cases of extreme motion (for example seizure) or poor perfusion (for example shock). In cases of extreme motion or poor perfusion other forms of respiration rate monitoring are recommended.

1.2.2 Related Documents

- **Nellcor™ Respiration Rate Upgrade Kit Version 2.0 - Activation Instructions** — Provides instructions for activating the Respiration Rate parameter on the Nellcor™ Bedside Respiratory Patient Monitoring System. The activation procedure must be performed by a qualified technician.
- **Nellcor™ Bedside Respiratory Patient Monitoring System Operator's Manual** — Provides basic information on operating the monitoring system and troubleshooting errors or malfunctions. Before using the monitoring system, thoroughly read this manual.
- **Nellcor™ Pulse Oximetry Sensor Instructions for Use** — Guides sensor selection and usage. Before attaching any of the various Covidien-approved Nellcor™ sensors to the monitoring system, refer to their *Instructions for Use*.
- **Nellcor™ Oxygen Saturation Accuracy Specification Grid** — Provides sensor-specific guidance related to desired SpO₂ saturation accuracy measurements. Available online at www.covidien.com.
- **Nellcor™ Bedside Respiratory Patient Monitoring System Service Manual** — Provides information to qualified service technicians for use when servicing the monitoring system.

1.2.3 Warranty Information

To obtain information, if any, contact Covidien or a local Covidien representative.

Covidien Technical Services: Patient Monitoring

15 Hampshire Street

Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635 (toll)
or contact a local Covidien representative

www.covidien.com

Purchase of this instrument confers no express or implied license under any Covidien patent to use that instrument with any sensor not manufactured or licensed by Covidien Inc.

1.3 Product Overview

1.3.1 Product Description

The Covidien Nellcor™ Respiration Rate Version 2.0 parameter as featured on the Nellcor™ Bedside Respiratory Patient Monitoring System allows for continuous noninvasive monitoring of arterial oxygen saturation (SpO₂), pulse rate and respiration rate of adult patients using a single sensor. The pulse oximeter collects the photoplethysmography signal from the patient via the Covidien Nellcor™ Adult Respiratory Sensor attached to the patient. This signal is processed by the pulse oximeter to determine patient SpO₂ and pulse rate data, which are displayed on the monitor user interface along with trending, system status, and alarm information. These data are stored on the monitor and available for subsequent export.

1.3.2 Indications for Use

The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO₂) and pulse rate of adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The Nellcor™ Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Adult Respiratory Sensor, is intended for the continuous, non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

1.3.3 Updated Monitoring Screens

The user interface components remain the same as those listed in the *Operator's Manual*, with the addition of the new respiration rate field at the lower right of the monitoring screen. In trend views, respiration rate data is shown as a white trend line.

The current respiration rate value (in breaths per minute) is shown as a large white numeral on the right side of the display. Upper and lower alarm limits are user-adjustable.

Figure 1-1. Respiration Rate (RR) Fields



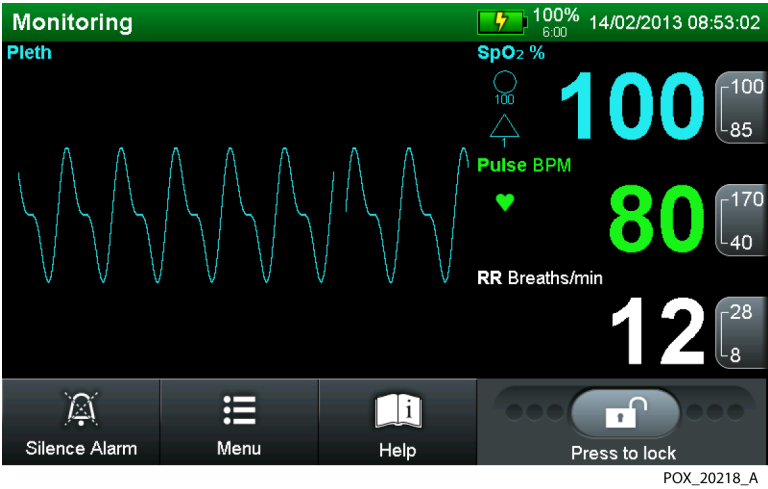
1	12	Respiration rate (breaths/min) value	Indicates the respiration rate in <i>breaths per minute</i> .
2		Respiration rate upper and lower limits	Upper/lower alarm limit settings appear as smaller values to the right of the dynamic respiration rate value.



Note:
The monitoring system displays respiration rate levels from 4 to 40 breaths/min. Detected breaths/min above 40 appear as 40. Detected breaths/min below 4 appear as 4.

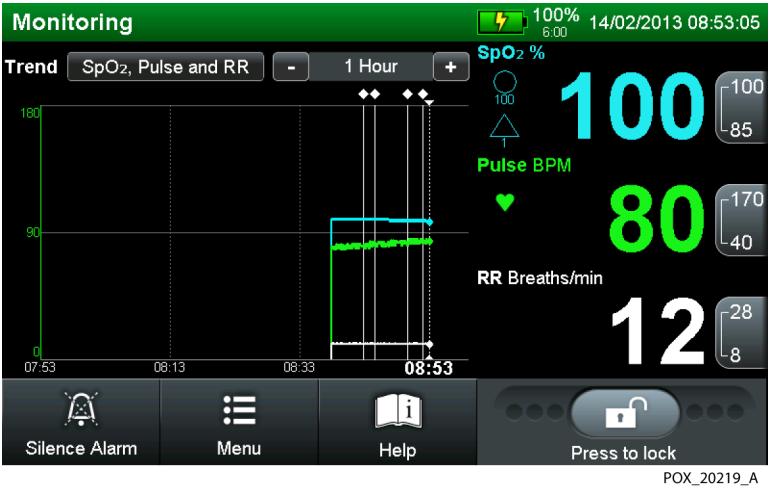
Pleth View

Figure 1-2. Pleth View with Respiration Rate



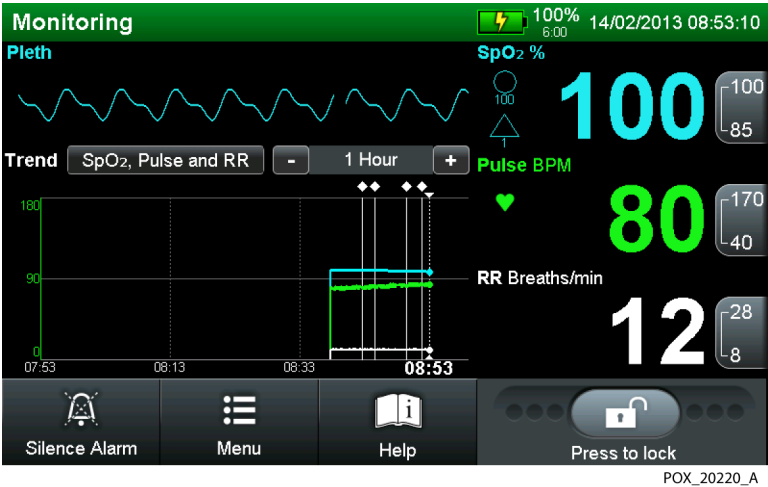
Trend View

Figure 1-3. Trend View with Respiration Rate



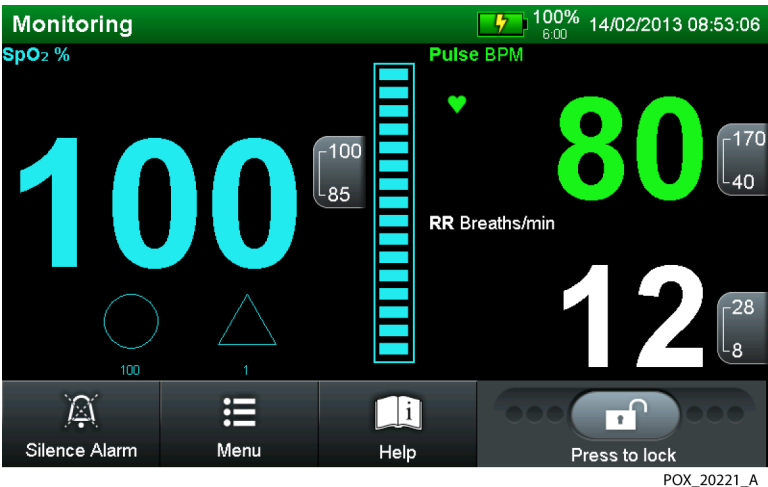
Combined Pleth and Trend View

Figure 1-4. Combined View with Respiration Rate



Numbers Only (Blip) View

Figure 1-5. Blip View with Respiration Rate

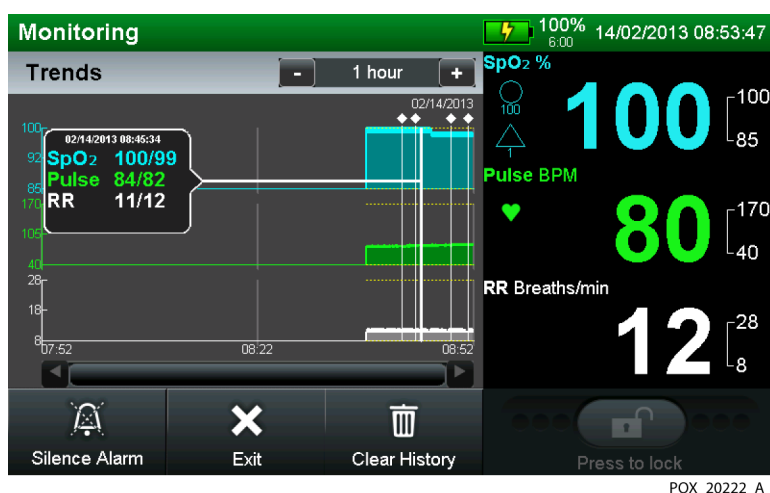


1.3.4 Updated Monitoring History Screens

Similar to the real-time trend views, the monitoring history trend views include the new respiration rate field at the lower right and respiration rate trend data in white below the SpO₂ and pulse rate data. Respiration data is also documented in the clinical log and histogram view.

Monitoring History - Trends

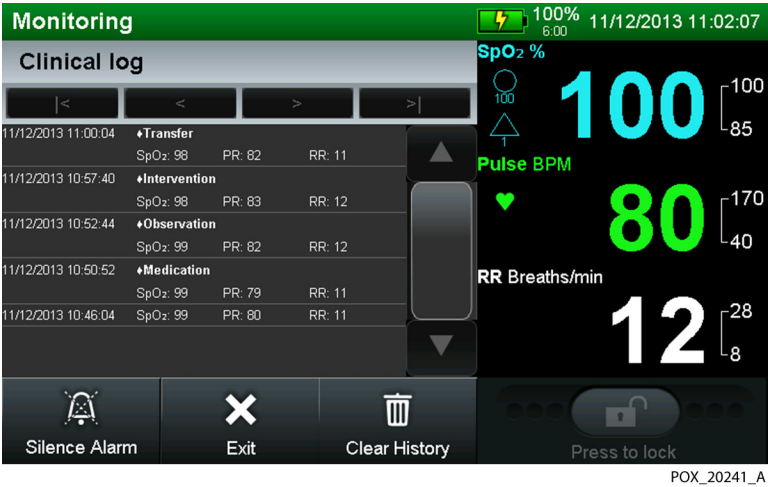
Figure 1-6. MONITORING HISTORY - Trends with Data Pop-up



Note that trend data pop-up windows (in both real-time and historical trend data views) also include respiration rate data.

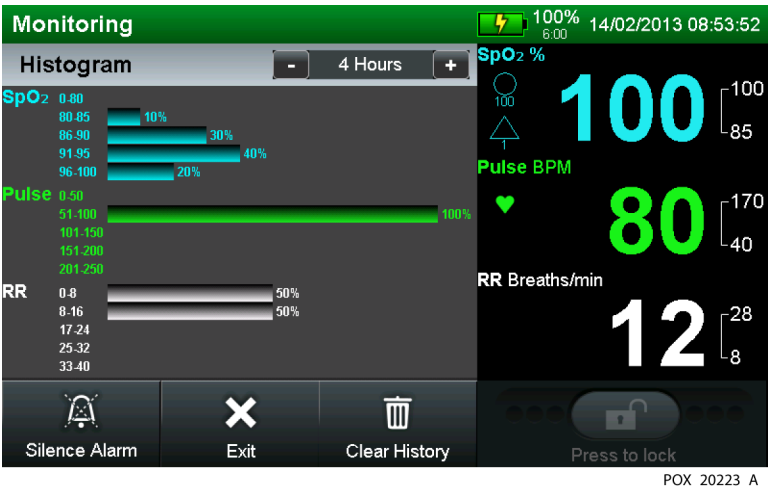
Monitoring History - Clinical Log

Figure 1-7. MONITORING HISTORY -Clinical Log



Monitoring History - Histograms

Figure 1-8. MONITORING HISTORY - Histograms



1.4 Operation

When used with a respiratory sensor, the Respiration Rate parameter provides a continuous, non-invasive measurement of respiration rate, in breaths per minute, for adults in hospitals or hospital-type facilities. Respiration rate is derived by analysis of changes in the photoplethysmogram (PPG) signal that occur during the respiratory cycle. Extremes of respiration rate and/or significant changes in respiration rate over time may indicate that patient status is deteriorating and additional assessment is warranted. Reference [Theory of Operations](#), p. ADD-25, for the theory behind how the Respiration Rate parameter works. Reference [Monitoring System Constraints](#), p. ADD-22, for information on related alarm limits.

**Note:**

Respiration rate values are updated every five seconds. Users should be aware that the reported respiration rate represents an average over a period of time and does not necessarily represent the instantaneous respiration rate. Low and high respiration rate alarms are triggered immediately when the reported rate falls outside the alarm limits and no further alarm delay is applied.

1.4.1 Prerequisites

Before starting a monitoring session, confirm the following:

- The monitoring system is powered on, has successfully completed its power-on self-test, and has the Respiration Rate parameter enabled. Contact a qualified service technician to have the monitoring system upgraded if the Respiration Rate parameter does not appear on the screen.

Note: If the Respiration Rate parameter is enabled and a parameter module that does not support Respiration Rate is subsequently installed in the monitoring system, the following error is displayed at power-up:

“Parameter module does not support RR. Replace with compatible parameter module or deactivate RR in Service Mode.”

- The monitoring system is connected to power or the battery is fully charged.
- An interface cable is connected to the monitoring system sensor port as described in the *Operator's Manual*.
- A respiratory sensor is connected to the interface cable and correctly applied to the patient as described in the *Instructions for Use*. Reference [Required Pulse Oximetry Sensor Usage](#), p. ADD-14 for additional information.

1.4.2 Required Pulse Oximetry Sensor Usage

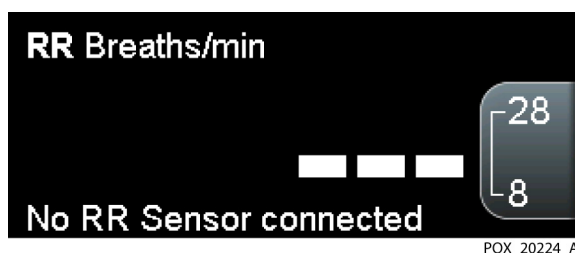
To obtain respiration rate, caregivers must use a Nellcor™ Adult Respiratory Sensor. The monitoring system reports the appropriate sensor type in the message field when it detects the sensor.

Figure 1-9. Sample Sensor Type Message



If caregivers use non-respiratory sensors, listed in the *Operator's Manual*, the monitoring system continues to post both SpO₂ and pulse rate data, with the user message, NO RR SENSOR CONNECTED, and dashes in the RR field.

Figure 1-10. RR field with No RR Sensor Message



If caregivers use a respiratory sensor, the monitoring system will post both SpO₂ and pulse rate and the message CALCULATING until enough data are available to post respiration rate. The monitoring system posts a status message for instances where it is unable calculate a respiration rate. If such is the case, examine all possible performance considerations. Reference [Performance Considerations](#), p. ADD-22.

Figure 1-11. RR field with Calculating Message



1.4.3 Respiration Rate Safety Information

Upon connection of the respiratory sensor to the monitoring system, you are prompted to review on-screen Respiration Rate safety information.

To review the safety information

1. Press EXIT, then press HELP.
2. Select RR Safety Information from the Help options, and review the safety information.
3. Press Exit.

1.4.4 Menu Options

Most menu options remain the same as those listed in the *Operator's Manual*. Menu options specific to Respiration Rate are described below.

ALARM LIMITS Menu - Respiration Rate Alarm Limits

The ALARM LIMITS menu includes an option for setting upper and lower respiration rate alarm limits. An alarm is indicated each time a patient's respiration rate violates either limit.

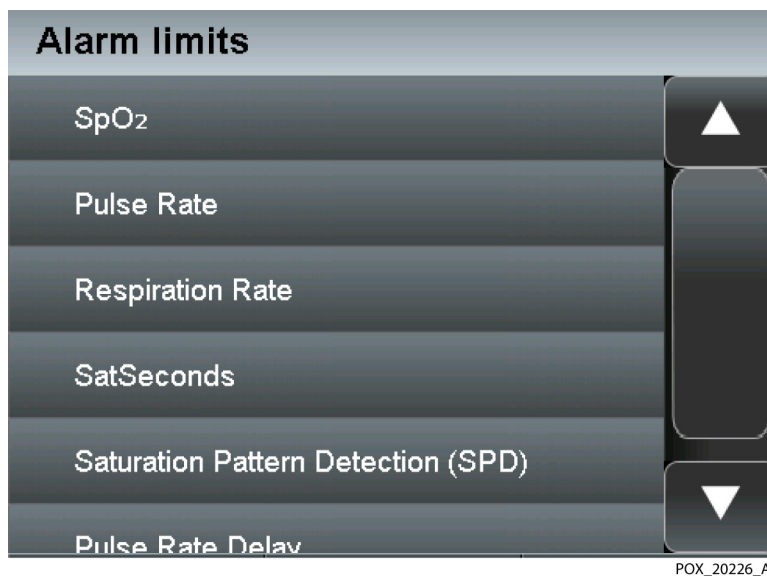
By default, the upper alarm limit is 28 breaths per minute, and the lower alarm limit is 8 breaths per minute. If changing these values, be sure to observe all warnings and cautions presented in the *Operator's Manual* regarding setting appropriate alarm limits.



Note:

The ability for users to adjust alarm limit settings can be enabled or disabled by qualified service personnel as described in the *Service Manual*.

Figure 1-12. ALARM LIMITS Menu Options



Note:

The initial alarm limits are the factory default settings or the institutional default settings set by qualified service personnel. Any changes to these settings are temporary. Limit changes remain in effect as long as the monitoring system retains power, but return to the factory or institutional default settings at power off.

To temporarily change respiration rate alarm limits



1. While in normal monitoring mode, press MENU.
2. Press ALARM LIMITS.
3. Press RESPIRATION RATE.
4. For each limit, use the arrow keys or slide the bar up or down until reaching the desired value. There must be a minimum of 5 breaths per minute between the high and low limits.

Figure 1-13. Adjusting Respiration Rate Alarm Limits

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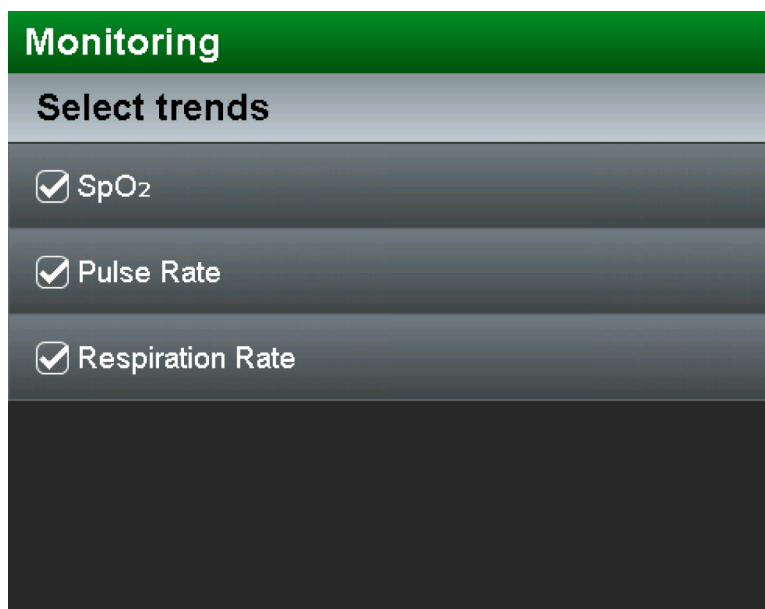
5. Press SAVE CHANGES.
6. Press EXIT.
7. Confirm that the new limits appear in the respiration rate limit area on the monitoring screen.

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MONITORING SETTINGS Menu - Real-Time Respiration Rate Data

For monitoring views that include real-time trend data, the SELECT TRENDS menu includes options to display SpO₂, pulse rate, respiration rate, or any combination of these selections.

Figure 1-14. Initial Select Trends Screen

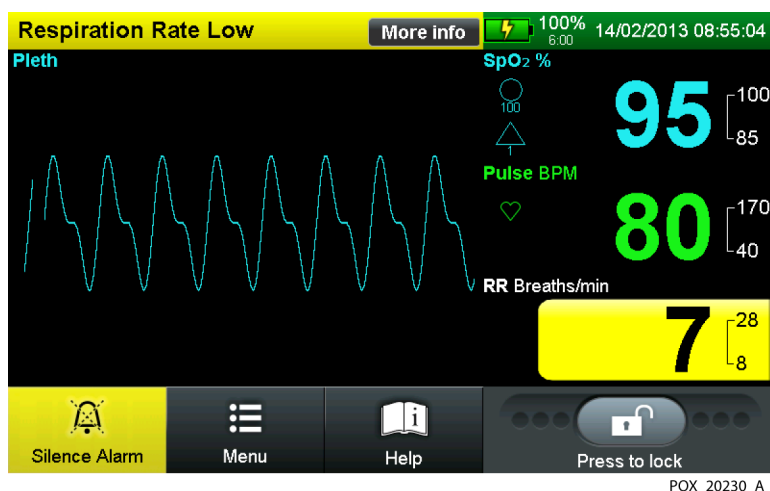


POX_20228_A

1.4.5 Additional Alarm Messages

As with SpO₂ and pulse rate alarms, when a respiration rate alarm is active, the value in that field turns black on a yellow background.

Figure 1-15. Sample Alarm Condition



Several new alarms and message accompany the Respiration Rate parameter. Reference [Troubleshooting](#), p. ADD-23 for descriptions and recommended resolutions.

1.5 Data Output

Respiration rate data is included in the trend data available via the monitoring system's USB data port. Respiration rate data is indicated by the column heading "RR" in tabular data format.



Note:

Not all remote monitoring software will report respiration rate data.

Figure 1-16. Historical Trend Data Export with Respiration Rate Values

1	2		3		4		5		6		7												
Time Stamp	SpO2 Max	SpO2 Min	SpO2 LL	SpO2 UL	Pulse Max	Pulse Min	Pulse LL	Pulse UL	RR Max	RR Min	RR LL	RR UL	SatSec Min	SatSec Max	SatSec Limit	SPD Max	SPD Min	SPD Limit	Alarms	%Mod Max	%Mod Min	Interval	First Sample
1/17/2012 11:49	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	0	0	0	1	255
1/17/2012 11:49	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	0	0	0	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	0	0	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	0.4	0.4	2	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	1.1	1.1	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	18.1	18.1	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	12.9	12.9	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	5.9	5.9	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	3.2	3.2	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	2.6	2.6	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	2.7	2.7	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	2.8	2.8	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	4	4	8	28	0	0	0	0	0	0	0	2.9	2.9	1	0
1/17/2012 11:51	82	82	85	100	0	0	40	170	4	4	8	28	18	18	0	0	0	0	16	3	3	1	0
1/17/2012 11:51	81	81	85	100	0	0	40	170	4	4	8	28	21	21	0	0	0	0	16	5.4	5.4	1	0
1/17/2012 11:51	79	79	85	100	0	0	40	170	4	4	8	28	25	25	0	0	0	0	16	11.1	11.1	1	0
1/17/2012 11:51	79	79	85	100	0	0	40	170	5	6	8	28	31	31	0	0	0	0	16	11	11	1	0
1/17/2012 11:51	80	80	85	100	0	0	40	170	7	8	8	28	37	37	0	0	0	0	16	7.9	7.9	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	9	10	8	28	42	42	0	0	0	0	16	23.6	23.6	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	11	12	8	28	47	47	0	0	0	0	16	23.8	23.8	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	13	14	8	28	52	52	0	0	0	0	16	25.5	25.5	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	14	14	8	28	57	57	0	0	0	0	16	25.5	25.5	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	14	14	8	28	62	62	0	0	0	0	16	24.9	24.9	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	0	0	8	28	67	67	0	0	0	0	16	24.9	24.9	1	0
1/17/2012 11:52	81	81	85	100	0	0	40	170	0	0	8	28	72	72	0	0	0	0	16	24.9	24.9	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	76	76	0	0	0	0	1040	25.5	25.5	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1040	2.3	2.3	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	2064	2	2	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	2064	1.7	1.7	1	0

POX_30341_A

- | | | | |
|---|------------------------------|---|-------------------------------------|
| 1 | Time stamp | 5 | Alarm type |
| 2 | High and low readings | 6 | Pulsatile strength minimum/maximum |
| 3 | Upper and lower limits | 7 | Sample interval (period in seconds) |
| 4 | Respiration rate data | | |

Table 1-3 describes the respiration rate data in the historical trend data output. Refer to the *Operator's Manual* for descriptions of the other data in the output.

Table 1-3. Historical Trend Data Output Definitions (Respiration Rate Data Only)

Column	Description						
RR Max	Maximum respiration rate value observed within the 1-sec. duration of the record						
RR Min	Minimum respiration rate value observed within the 1-sec. duration of the record						
RR LL	Lower alarm limit for respiration rate as configured by the user						
RR UL	Upper alarm limit for respiration rate as configured by the user						
Alarms	Encoded number indicating which alarms were active during the 1-sec. duration of the record. Note: The alarm number is intended for interpretation by software such as the Nellcor™ Analytics Tool (NAT). It is encoded as a mathematical OR of 32 unique numbers, each indicating a unique alarm. Numbers indicating respiration rate alarms are listed below. Refer to the <i>Operator's Manual</i> for other alarms that can appear in the output. A value of 0 is reported if no alarms were active. <table> <tr> <td>0x00100000</td><td>RR Not Activated</td></tr> <tr> <td>0x04000000</td><td>Respiration Rate Low</td></tr> <tr> <td>0x08000000</td><td>Respiration Rate High</td></tr> </table>	0x00100000	RR Not Activated	0x04000000	Respiration Rate Low	0x08000000	Respiration Rate High
0x00100000	RR Not Activated						
0x04000000	Respiration Rate Low						
0x08000000	Respiration Rate High						

1.6 Performance Considerations

1.6.1 Monitoring System Constraints

In addition to the pulse rate and saturation constraints listed in the *Operator's Manual*, the following constraint applies:

- **Respiration Rate** — The monitoring system displays respiration rate levels from 4 to 40 breaths per minute (breaths/min). Detected breaths/min above 40 appear as 40. Detected breaths/min below 4 appear as 4. It calculates with an average accuracy of ± 1 breaths per minute, relative to a capnography-based reference.



Note:

Claims on motion and low perfusion conditions represented in the pulse oximetry indications for use are not applicable to Nellcor Respiration Rate.

1.6.2 Nellcor™ Sensor Performance Considerations

All sensor performance considerations described in the *Operator's Manual* apply to use of the Nellcor™ Adult Respiratory Sensor. Apply the sensor as directed in the accompanying *Instructions for Use*, and follow all warnings, cautions, and guidelines in the *Operator's Manual* to mitigate situations that may lead to inaccurate measurements or signal loss.

1.6.3 Patient Conditions

All patient conditions described in the *Operator's Manual* that can affect measurements made by the monitoring system also apply to respiration rate. In addition, the following patient conditions can cause inaccurate respiration rate measurements:

- Respiration rate outside the range of 4 to 40 breaths per minute
- Documented history of atrial fibrillation
- Implanted pacemaker

1.7 Troubleshooting

Existing troubleshooting and error codes remain the same as those listed in the *Operator's Manual*. Additional messages and errors related to the Respiration Rate parameter follow.



Note:

The Respiration Rate parameter is approved for use in the range 4 to 40 breaths per minute. When respiration rate falls below or exceeds alarm limits (user-configurable within the approved range), a respiration rate alarm is indicated. If the monitoring system detects a respiration rate below or above the 4 to 40 operating range, it continues to report 4 or 40 respectively. These values may indicate that the parameter has calculated a value outside the approved range.

Table 1-4. Additional Alarm, Error, and Status Messages

Message	Description
Low Respiration Rate	Alarm: The patient's respiration rate is below the low alarm limit. Resolution: Assess patient condition in conjunction with SpO₂ and pulse rate readings from the monitoring system to determine appropriate intervention.
High Respiration Rate	Alarm: The patient's respiration rate is above the high alarm limit. Resolution: Assess patient condition in conjunction with SpO₂ and pulse rate readings from the monitoring system to determine appropriate intervention.
No RR Sensor Connected	Error: A non-respiratory sensor is connected to the monitoring system. Resolution: Remove the sensor and replace it with a respiratory sensor.
Calculating...	Status: The monitoring system is attempting to calculate a respiration rate value. This message appears for a brief time at the beginning of each monitoring session. Resolution: No action required. The message disappears when calculation is complete. If a calculation cannot be made, the message UNABLE TO CALCULATE appears.

Table 1-4. Additional Alarm, Error, and Status Messages (Continued)

Message	Description
Unable to Calculate	Error: The monitoring system is unable to calculate a respiration rate value because the SpO2 or pulse rate value is unavailable. Resolution: • Check for correct application and placement of sensor, as described in the <i>Operator's Manual</i>. • Check for other environmental and patient conditions that can affect sensor performance, as described in the <i>Operator's Manual</i>.
Outside Range	Status: One of the following conditions has occurred: • The patient's pulse rate is outside the range of 40 -170 beats per minute. • The patient's respiration rate is >0.5 of pulse rate. Resolution: Assess patient condition in conjunction with SpO2 and pulse rate readings from the monitoring system to determine appropriate intervention. Use an alternate means of monitoring respiration rate.
RR Interference	Error: The monitoring system is unable to calculate a respiration rate value due to signal interference. Resolution: • Ensure that the patient is still and quiet. • Check for a documented history of atrial fibrillation or implanted pacemaker. • Use an alternate means of monitoring respiration rate.
Check Patient	Status: Respiration rate is not posted because a Low SpO2 alarm condition is present. Resolution: Take appropriate clinical actions in response to the Low SpO2 alarm.

1.8 Additional Nellcor™ Pulse Oximetry Sensor

When selecting a Nellcor™ sensor, consider the patient's weight and activity level, the adequacy of perfusion, and the available sensor sites, the need for sterility, and the anticipated duration of monitoring. Use the recommended sensor's *Instructions for Use* to guide sensor selection or contact Covidien or a local Covidien representative. Reference [Nellcor™ Sensor Performance Considerations](#), p. ADD-22.

Table 1-5. Additional Sensor Model and Patient Size

Nellcor™ Pulse Oximetry Sensor	SKU	Patient Size
Nellcor™ Adult Respiratory Sensor (Sterile, single-use only)	10068119	>30 kg

1.9 Theory of Operations

The Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Adult Respiratory Sensor, provides continuous non-invasive monitoring of arterial oxygen saturation, pulse rate and respiration rate using a single sensor. The Respiration Rate parameter provides an indication of central ventilatory drive by processing and interpreting the photoplethysmogram, or pleth.

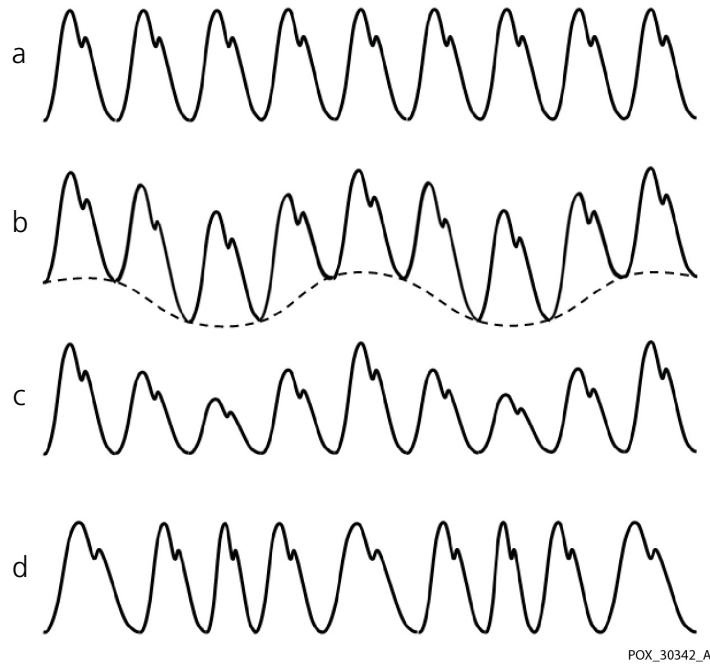
The pleth signal is used to measure arterial oxygen saturation (SpO₂). A typical pleth pattern includes a regular cardiac 'pulse' waveform on top of a large constant baseline component, or DC component. See [Figure 1-17](#) (a).

In clinical settings, both the cardiac pulse and baseline components may vary over time due to physiologic conditions and changes. In standard pulse oximetry, these variations are typically filtered out in order to accurately measure arterial oxygen saturation (SpO₂). These same subtle variations, however, may be used to derive respiration rate by tracking three types of changes associated with the respiratory cycle.

1. **Baseline (DC) variation** — Changes in intrathoracic pressure during the respiratory cycle influence venous return to the heart and result in baseline DC variation in the pleth. Reference [Figure 1-17](#) (b).
2. **Pulse amplitude variation** — Changes in intrathoracic pressure during inspiration also lead to variation in cardiac stroke volume and result in pulse amplitude variations. Reference [Figure 1-17](#) (c).

3. **Respiratory sinus arrhythmia (RSA)** — During the respiratory cycle, heart rate generally increases during inspiration and decreases during expiration. RSA results in pulse frequency variations. Reference [Figure 1-17](#) (d).

Figure 1-17. Variations of the pleth due to respiration



The Respiration Rate parameter utilizes these subtle pleth variations to measure respiration rate. Note that the Respiration Rate parameter is an indicator of central ventilatory drive and is not a direct measure of ventilation.

1.10 Specifications

Product specifications remain the same as those listed in the *Operator's Manual*, with the exception of the Nellcor™ Adult Respiratory Sensor data.

Table 1-6. Nellcor™ Adult Respiratory Sensor Accuracy and Ranges

Measurement Range		
Pulse Oximetry Saturation (SpO ₂)	1% to 100%	
Pulse Rate	20 to 250 beats per minute (bpm)	
Perfusion Range	0.03% to 20%	
Respiration Rate	4 to 40 breaths per minute	
Pulse Oximetry Saturation (SpO ₂) Accuracy		
Population, Condition	Range	Accuracy
Adult ^{1, 2}	70 to 100%	±2 digits
Adult, Low Saturation ^{1, 2}	60 to 80%	±3 digits
Adult, Low Perfusion ³	70 to 100%	±2 digits
Adult, Motion ^{1, 4}	70 to 100%	±3 digits
Pulse Rate Accuracy		
Population, Condition	Range	Accuracy
Adult ^{1, 2}	20 to 250 bpm	±3 bpm
Adult, Low Perfusion ³	20 to 250 bpm	±3 bpm
Adult, Motion ^{1, 4}	20 to 250 bpm	±5 bpm
Respiration Rate Accuracy ⁵		
Population	Range	Accuracy
Adult	4 to 40 breaths per minute	±1 breath per minute (Mean Error) ≤3 breaths per minute (RMSD)

1. SpO₂ and pulse rate accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All SpO₂ and pulse rate accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (A_{RMS}) range (refer to the Sensor Accuracy Grid for more details).
2. Specifications are shown for the Nellcor™ Adult Respiratory Sensor with the Nellcor™ Bedside Respiratory Patient Monitoring System.
3. Specification applies to Nellcor™ Bedside Respiratory Patient Monitoring System SpO₂ and pulse rate performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO₂ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.
4. SpO₂ and pulse rate performance in motion were validated during a controlled hypoxia blood study. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent modulation during quiescent periods was 1.63, during motion 4.14. Motion performance over the entire specified pulse rate range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components.
5. Respiration Rate performance was validated in a hospital study of both men and women ranging in age from 18-91 years old. Subjects were monitored for 30 minutes on the general care floor. Performance over the entire specified respiration rate range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components.

Table 1-7. Nellcor™ Adult Respiratory Sensor Operating Range and Power Dissipation

Operating Range and Dissipation	
Red Light Wavelength	Approximately 660 nm
Infrared Light Wavelength	Approximately 900 nm
Optical Output Power	Less than 15 mW
Power Dissipation	52.5 mW

1.11 Clinical Studies

Two (2) prospective, observational, non-randomized clinical studies were conducted to demonstrate the accuracy of Respiration Rate Version 2.0 when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System, using the Nellcor™ Adult Respiratory Sensor. One study was performed with healthy recruited volunteers at a single clinical laboratory. A second study enrolled volunteer subjects from a hospital population. Accuracy was established by comparison to respiration rate determined from capnography waveforms.

1.11.1 Methods

Data from 105 enrolled subjects were included in the analysis: 30 healthy volunteers and 75 hospitalized patients. Subjects were studied for approximately 30 minutes during which data from capnography and the Nellcor pulse oximeter were collected. Respiration rate was derived every five seconds using Respiration Rate Version 2.0. The reference was obtained from counting breaths on the capnography waveforms by an anesthesiologist blinded to all other data.

1.11.2 Study Population

Demographics for all study subjects are presented in [Table 1-8](#).

Table 1-8. Demographic Data

Demographics	Mean ± Standard Deviation (Range)
Age (Years)	47.69 ± 17.94 (18 - 91)
Gender (Male/Female)	60/45
BMI (kg/m ²)	29.15 ± 8.10 (17.22 - 55.91)

1.11.3 Study Results

Results for Respiration Rate Version 2.0 are shown in [Table 1-9](#). The observed respiration rate range in the studies was 4 to 32 breaths per minute. Accuracy was calculated using both root mean square difference (RMSD) and mean error. The results demonstrate that Respiration Rate Version 2.0 calculates respiration rate with a mean error of less than 1 breath per minute when compared to respiration rate derived from the capnography-based reference.

Table 1-9. Accuracy and Precision for Respiration Rate, Version 2.0 vs. Capnography-Based Reference

Population	N	Accuracy: Mean Error (Breaths Per Minute)	Precision: Standard Deviation (Breaths Per Minute)	Accuracy: RMSD (Breaths Per Minute)
Healthy Volunteers	30	-0.05	± 1.04	1.04
Hospital Patients	75	-0.53	± 2.53	2.58
All Subjects	105	-0.22	± 1.77	1.74

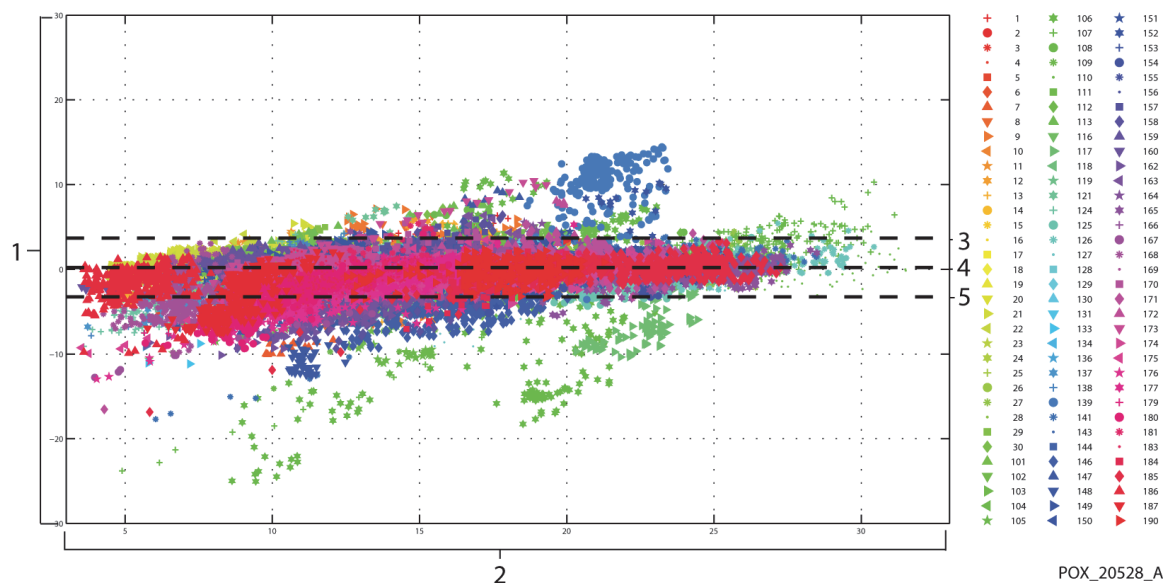
The clinical studies yielded 68,112 paired observations between Respiration Rate, Version 2.0 and the capnography-based reference method. [Figure 1-18](#), p. ADD-30, presents a modified Bland-Altman plot of these paired observations to provide another method of comparison between the two methods of measuring respiration rate.



Note:

Each individual subject is represented by a unique marker on the plot. Subject identification numbers are indicated in the legend next to the plot.

Figure 1-18. Modified Bland-Altman Plot of Nellcor Respiration Rate Software versus Clinician Overscored Respiration Rate



- | | | | |
|---|---|---|---------------|
| 1 | Difference (Clinician Overscored Respiration Rate - Nellcor Respiration Rate, BrPM) | 3 | Upper 95% LoA |
| 2 | Clinician Overscored Respiration Rate (BrPM) | 4 | Mean |
| | | 5 | Lower 95% LoA |

In [Table 1-10](#), *Local Bias with Respect to Reference Respiratory Rate*, the hospital data is broken into sub-ranges of respiration rate. A performance analysis is completed on each respiration rate sub-range. The limits of agreement were derived from data in each respiration rate sub-range and are provided in [Table 1-10](#).

Table 1-10. Local Bias with Respect to Reference Respiratory Rate

Reference Respiration Rate Range (Breaths/Min)	≥ 4-7	≥ 8-11	≥ 12-15	≥ 16-19	≥ 20-23	≥ 24-27	≥ 28-31	≥ 32
Mean Bias	-2.90	-1.82	-0.62	-0.04	0.50	0.49	2.28	N/A
Upper 95% LoA	1.99	3.70	3.26	3.86	7.33	3.27	7.14	N/A
Lower 95% LoA	-7.79	-7.35	-4.51	-3.95	-6.32	-2.29	-2.58	N/A

1.11.4 Adverse Events

No adverse events were reported during the studies.

1.11.5 Conclusion

In clinical studies of healthy subjects and hospitalized patients, Respiration Rate, Version 2.0 provided respiration rate with an accuracy of ± 1 breath per minute when compared to respiration rate derived from a capnography-based reference.

Hospital studies did not necessarily include all patient conditions found in hospitals and hospital-type settings. These clinical study results may not generalize to all patient conditions.

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