

Nellcor™

Bedside Respiratory Patient Monitoring System Respiration Rate Version 1.0



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1 Nellcor™ Respiration Rate

Version 1.0

1.1 Overview

This *Operator's Manual* addendum describes the operation of the Nellcor™ Respiration Rate Version 1.0 parameter when used with the Nellcor™ Bedside Respiratory Patient Monitoring System.

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™ Respiratory Sensor. The parameter provides alarms for high and low respiration rate. The upper threshold is fixed at 28 breaths per minute, while the lower threshold is fixed at 8 breaths per minute. 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.

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 and intended use statements, New monitoring screen fields included in Operation section.
3	Installation	Refer to separate Activation Instructions
4	Operation	Additional monitoring screen views, additional alarm conditions, additional sensor type
5	Product Data Output	Additional data fields in data output
6	Performance Considerations	Additional sensor 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

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 26 healthy volunteers and 53 hospitalized patients. Hospital studies were conducted using convenience sampling and 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:

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.



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:**
Respiration rate may present inaccurate respiration rate values when respiration rate exceeds 50% of heart rate. This situation, though rare, may occur under conditions including, but not limited to, any of the following: patients with high respiration rate and low heart rate, patients taking beta blockers, or patients with specific medical conditions such as sick sinus syndrome.
- ◆ **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.

1.2.2 Related Documents

Documentation is available online at www.covidien.com.

- **The 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.
- **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*.
- **Saturation Accuracy Grid** — Provides sensor-specific guidance related to desired SpO₂ saturation accuracy measurements. Available online at www.covidien.com.
- **The 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 1.0 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 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 intend-

ed 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.

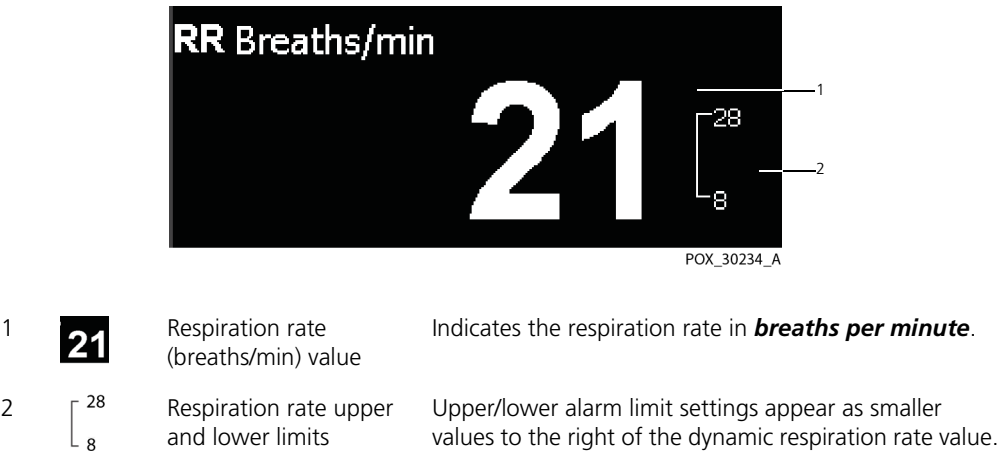
The Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Respiratory Sensor is intended for the continuous, non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

1.3.3 Updated Monitoring Screen

The front panel, back panel, and parameter module remain the same as those listed in the *Operator’s Manual*. 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.

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 fixed at 28 and 8, respectively.

Figure 1-1. Respiration Rate Fields

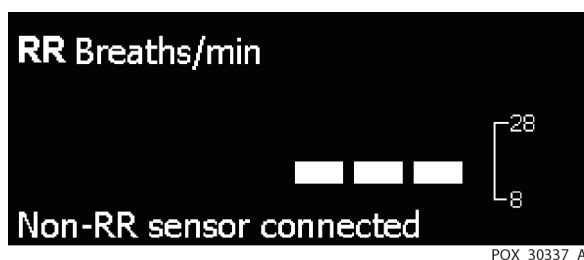


1.4 Operation

1.4.1 Required Pulse Oximetry Sensor Usage

To obtain respiration rate, caregivers must use a Nellcor™ Respiratory Sensor. If caregivers use alternate sensors, listed in the *Operator's Manual*, the monitoring system continues to post both SpO₂ and pulse rate data, with the user message, NON-RR SENSOR CONNECTED, and dashes in the RR field.

Figure 1-2. RR field with Non-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 UNABLE TO CALCULATE 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-19.

Figure 1-3. RR field with Calculating Message



The current respiration rate value (in breaths per minute) is shown as a large white numeral on the right side of the display. Respiration rate is also shown in a trend view with rate values on the vertical axis and time (in 24-hour format)

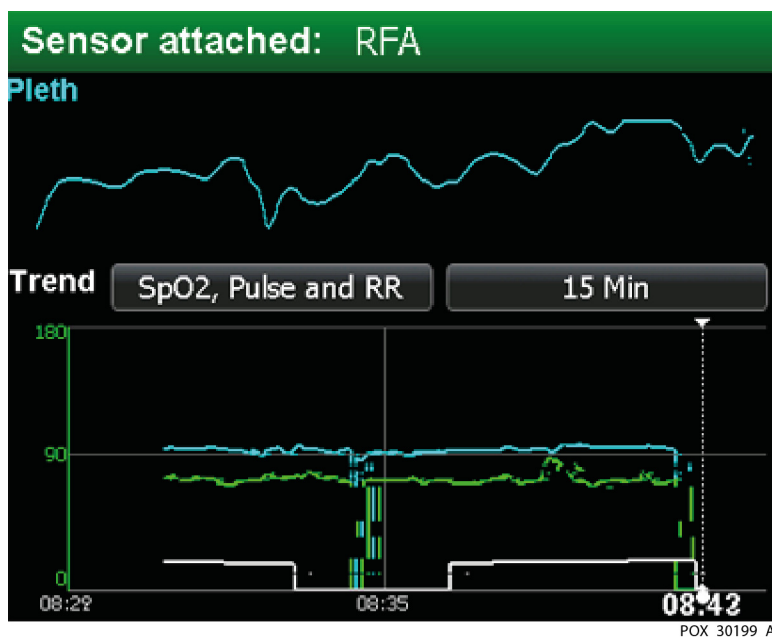
on the horizontal axis. The trend view shows the patient's respiration rate over time, with the most current reading on the right.

1.4.2 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.
- 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*. The monitoring system reports the appropriate sensor type in the message field when it detects the sensor.

Figure 1-4. Sample Sensor Type Message



1.4.3 Respiration Rate Views

Figure 1-5. Pleth View with Respiration Rate

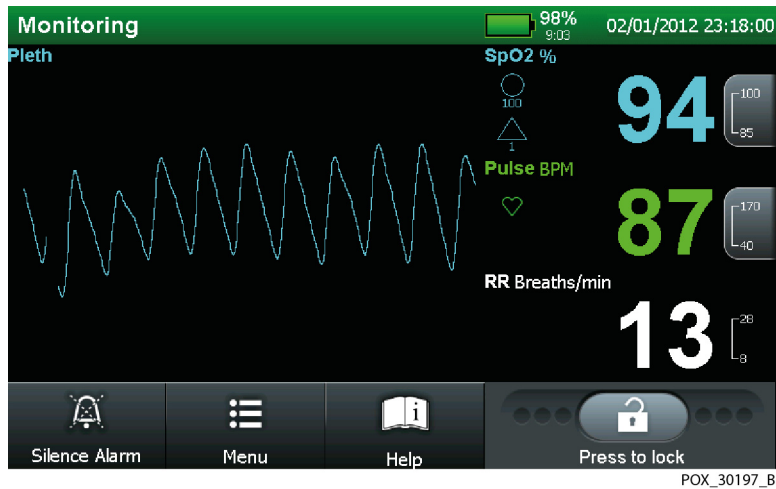


Figure 1-6. Trend View with Respiration Rate

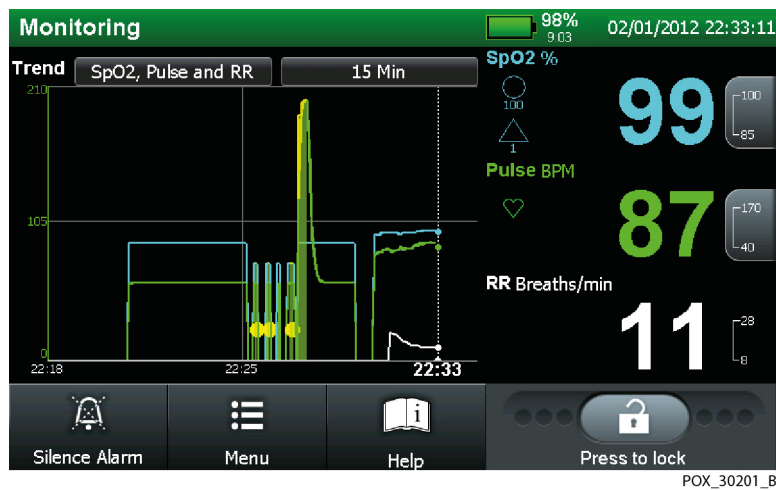
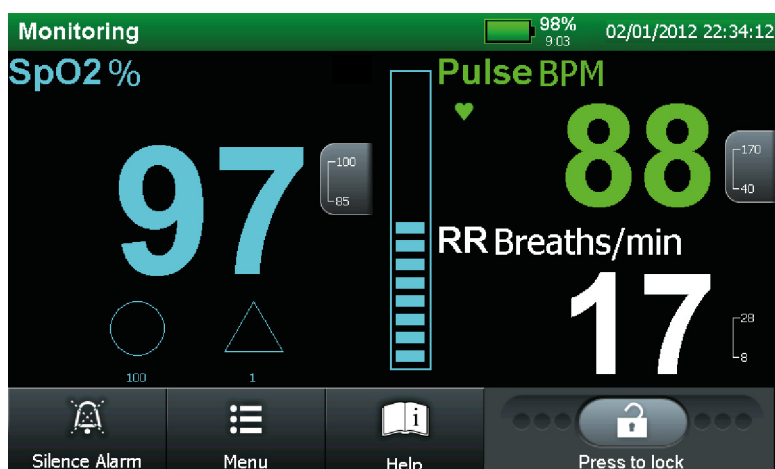


Figure 1-7. Combined View with Respiration Rate



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Figure 1-8. Blip View with Respiration Rate

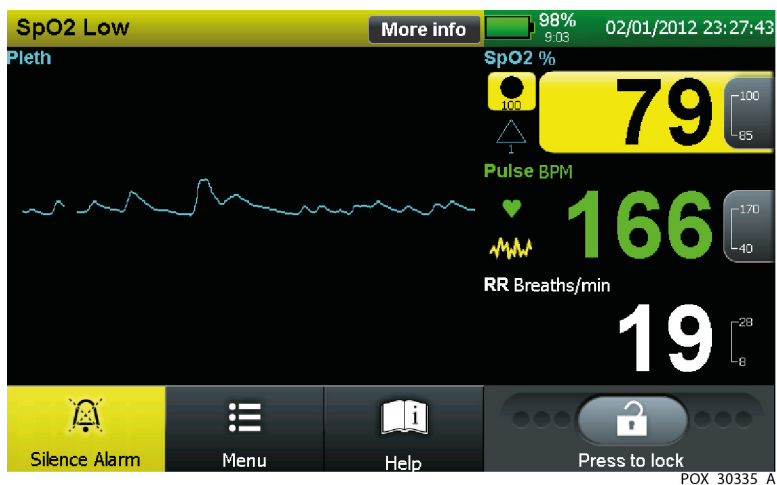


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1.4.4 Additional Alarm Messages

Existing alarm behaviors remain the same as those listed in the *Operator's Manual*. Several new alarms accompany the respiration rate parameter. When an alarm is active, the value in that field turns black on a yellow background. Reference [Troubleshooting](#), p. ADD-23.

Figure 1-9. Sample Alarm Condition



1.4.5 Additional Respiration Rate Parameter



WARNING:

Use only Nellcor-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.



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.

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 signifi-

cant changes in respiration rate over time may indicate that patient status is deteriorating and additional assessment is warranted. Reference the *Reference Theory of Operations*, p. ADD-24, for the theory behind how the Respiration Rate parameter works. Reference *Monitoring System Constraints*, p. ADD-19, for information on related alarm limits.



Note:

Respiration Rate values are calculated 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.

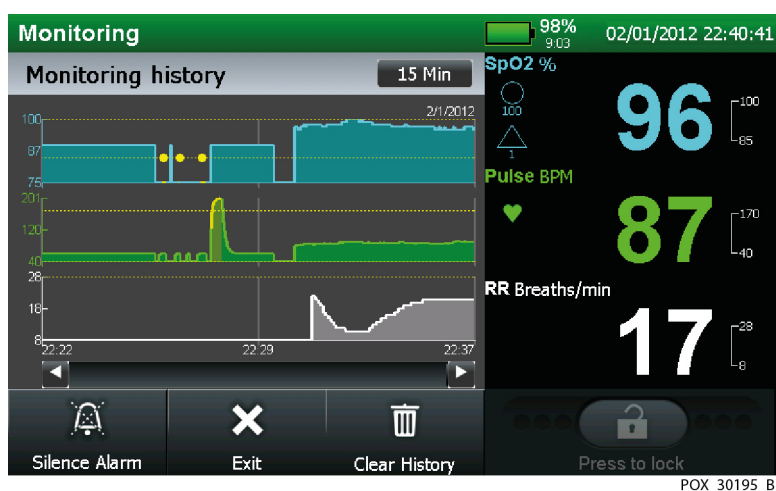
1.4.6 Menu Options and Defaults

Menu options and default settings remain the same as those listed in the *Operator's Manual*. The respiration rate alarm limit thresholds are fixed; they are not user-selectable.

In addition to the new respiration rate field on all monitoring screens, trend information also includes respiration rate data.

1. The MONITORING HISTORY trend data also includes respiration rate historical trends below the SpO₂ and pulse rate historical trends.

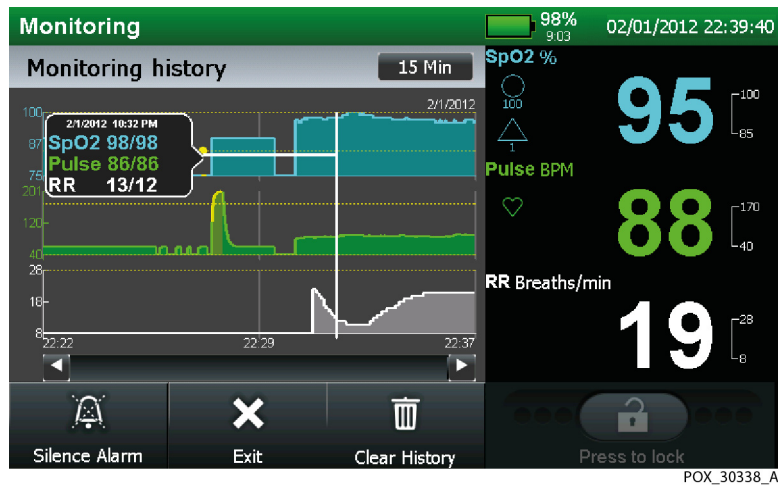
Figure 1-10. MONITORING HISTORY Screen



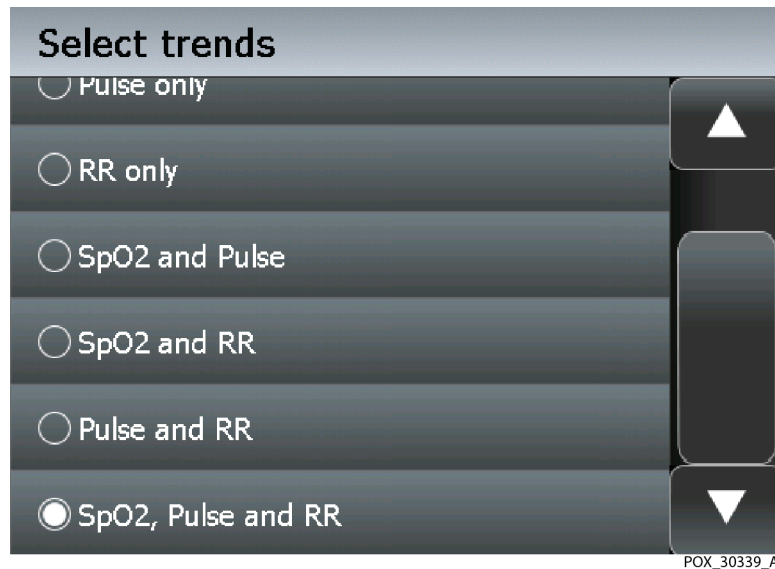
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2. The trend data pop-up window also includes respiration rate data whenever the Respiration Rate parameter is enabled.

Figure 1-11. MONITORING HISTORY Pop-up



3. Trend data types in the SELECT TRENDS option also include variations of the three main variables of SpO₂, pulse, and respiration rate.
 - a. SpO₂ only
 - b. Pulse only
 - c. Respiration rate only
 - d. SpO₂ and pulse
 - e. SpO₂ and respiration rate
 - f. Pulse and respiration rate
 - g. SpO₂, pulse, and respiration rate

Figure 1-12. Initial Select Trends Screen

1.5 Additional Data Output Fields

The following trend data fields are available to users after activating respiration rate. Not all remote monitoring software will report respiration rate data.

- SpO2 (Saturation) trend data
- Pulse rate (BPM) trend data
- Pulse amplitude trend data
- Respiration rate trend data

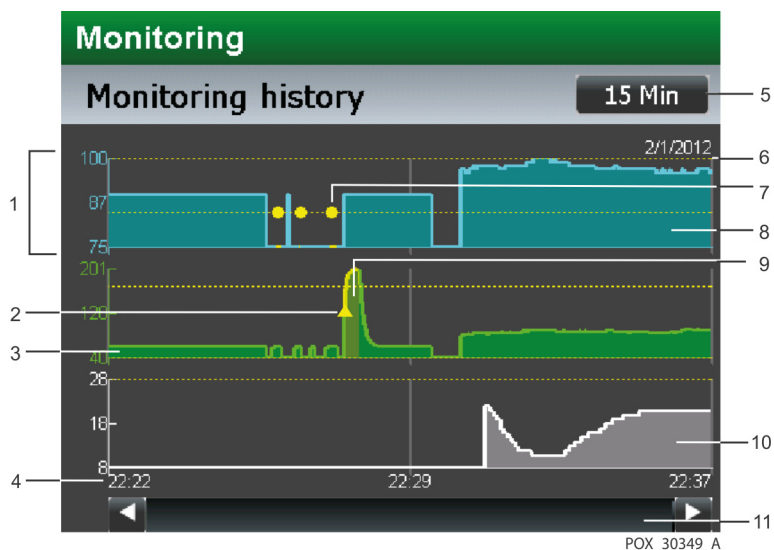
1.5.1 Real-time Trend Data

Users may view the trend display at any time. Users may choose to view trend data in a tabular or graphical format.

Graphical Trend View

The graphical trend view provides users with 15 minutes to 48 hours of continuous trend data. Status codes remain the same as those listed in the *Operator's Manual*.

Figure 1-13. Graphical trend data monitoring history components

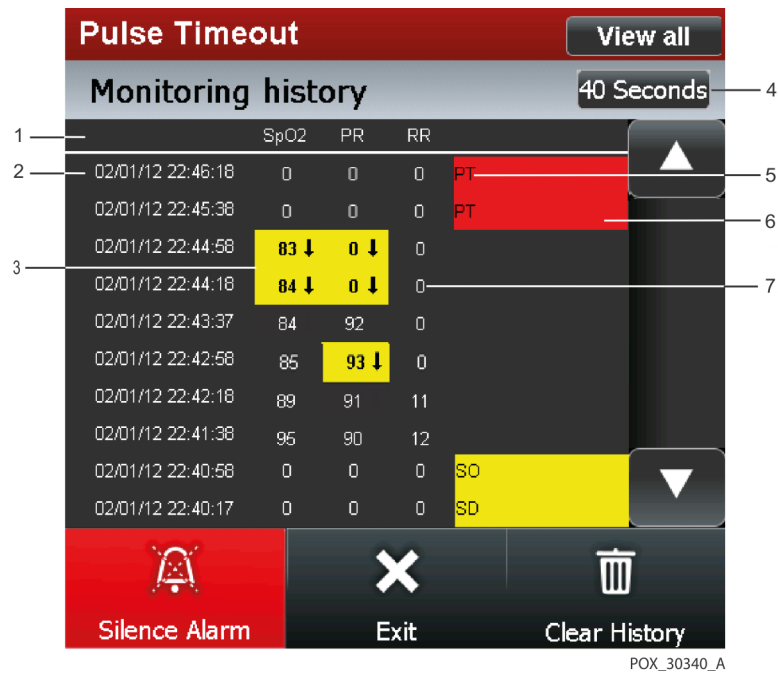


- 1 Graph x-axis contains time divisions, depending on specified time scale
- 2 Yellow triangle icon for period of SPD alert
- 3 Green pulse trend data for specified time scale
- 4 Graph y-axis contains signal amplitude values
- 5 Trend scale button for adjusting time scale to view more or less data
- 6 Dashed horizontal yellow lines for upper and lower thresholds
- 7 Yellow circle icon for period of SatSeconds alarm
- 8 Cyan SpO2 trend data for specified time scale
- 9 Yellow fill for period of limit threshold violation
- 10 **White respiration rate data for specified time scale**
- 11 Scroll bar for access to additional trend data

Tabular Trend View

The tabular trend view provides users with data from 20 to 40 seconds of continuous trend data in a tabular format. Status codes are constrained to five types and are the same as those listed in the *Operator's Manual*.

Figure 1-14. Tabular trend data components



- 1 Column heading(s)
- 2 Time and date stamp
- 3 Yellow highlight, indicating an upper or lower limit threshold violation
- 4 Trend scale button for adjusting time scale to view more or less data
- 5 Status message, indicating an alarm condition
- 6 Red highlight, indicating a high priority alarm
- 7 **Respiratory trend data (Zeroes indicate missing trend data)**

1.5.2 Historical Trend Data

The methods used to obtain historical trend data or to erase historical trend data remain the same as those listed in the *Operator's Manual*, including respiration rate readings.

Figure 1-15. Historical Trend Data with Respiration Rate Values

1	2		3		4		5		6		7												
	SpO2	SpO2	SpO2	SpO2	Pulse	Pulse	Pulse	Pulse	RR	RR	RR	RR	SatSec	SatSec	SatSec	SPD	SPD	SPD		%Mod	%Mod		First
Time Stamp	Max	Min	LL	UL	Max	Min	LL	UL	Max	Min	LL	UL	Min	Max	Limit	Max	Min	Limit	Alarms	Max	Min	Interval	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	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	23.6	23.6	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

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- | | | | |
|---|------------------------------|---|-------------------------------------|
| 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 | | |

1.6 Performance Considerations

1.6.1 Monitoring System Constraints

- **Pulse Rates** — The monitoring system only displays pulse rates between 20 and 250 bpm. Detected pulse rates above 250 bpm appear as 250. Detected pulse rates below 20 appear as a zero (0).
- **Saturation** — The monitoring system displays saturation levels between 1 % and 100%.
- **Respiration Rate** — The monitoring system displays respiration rate levels between 4 and 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.

1.6.2 Nellcor™ Sensor Performance Considerations



WARNING:

Incorrect application or inappropriate duration of use of a sensor can cause tissue damage. Inspect the sensor site as directed in the *Instructions for Use*.



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:

Pulse oximetry readings and pulse signal can be affected by certain ambient conditions, sensor application errors, and certain patient conditions.



WARNING:

Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements. Readings and pulse signals can be affected by certain environmental conditions, pulse oximetry sensor application errors, and certain patient conditions.



Caution:

Accuracy of respiration rate was established using bench-top testing and clinical studies in 26 healthy volunteers and 53 hospitalized patients. Hospital studies were conducted using convenience sampling and 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:

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 may present inaccurate respiration rate values when respiration rate exceeds 50% of heart rate. This situation, though rare, may occur under conditions including, but not limited to, any of the following: patients with high respiration rate and low heart rate, patients taking beta blockers, or patients with specific medical conditions such as sick sinus syndrome.



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 the respiration rate parameter 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.

Inaccurate Sensor Measurement Conditions

A variety of conditions can cause inaccurate sensor measurements.

- Incorrect application of the recommended sensor
- Placement of the recommended sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Failure to cover the sensor site with opaque material in high ambient light conditions
- Excessive patient activity
- Dark skin pigment
- Intravascular dyes or externally applied coloring, such as nail polish or pigmented cream
- Excessive patient talking
- Respiration rate outside the range of 4 to 40 breaths per minute
- Significantly irregular cardiac rhythms (three or more events of irregularity observed within 30 seconds)

Signal Loss

Loss-of-pulse signal can occur for several reasons.

- Recommended sensor applied too tightly
- Inflation of a blood pressure cuff on the same extremity as the attached sensor
- Arterial occlusion proximal to the recommended sensor
- Poor peripheral perfusion

Recommended Usage

Select an appropriate recommended sensor, apply it as directed, and observe all warnings and cautions presented in the *Instructions for Use* accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the recommended sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and

direct sunlight can interfere with sensor performance. To prevent interference from ambient light, ensure the recommended sensor is properly applied and cover the sensor with opaque material.

If patient activity presents a problem, try one or more of the following remedies to correct the problem.

- Verify the sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that improves patient skin contact.
- Use a new sensor with fresh adhesive backing.
- Keep the patient quiet and still, if possible.

1.6.3 Patient Conditions

Application issues and certain patient conditions can affect the measurements of the monitoring system and cause the loss of the pulse signal.

- **Anemia** — Anemia causes decreased arterial oxygen content. Although SpO₂ readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The pulse oximeter may fail to provide an SpO₂ reading if hemoglobin levels fall below 5 gm/dl.
- **Dysfunctional hemoglobins** — Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulphhemoglobin are unable to carry oxygen. SpO₂ readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.
- **Additional possible patient conditions** may also influence measurements.
 - Poor peripheral perfusion
 - Excessive patient activity
 - Venous pulsations
 - Dark skin pigment
 - Intravascular dyes, such as indocyanine green or methylene blue
 - Externally applied coloring agents (nail polish, dye, pigmented cream)
 - Defibrillation

- Excessive patient talking
- Respiration rate outside the range of 4 to 40 breaths per minute
- Significantly irregular cardiac rhythms (three or more events of irregularity observed within 30 seconds)

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.

Table 1-3. 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.
Non-RR Sensor Connected	Error: A non-respiration rate 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 1-3. Additional Alarm, Error, and Status Messages (Continued)

Message	Description
Unable to Calculate	Error: The monitoring system is unable to calculate a respiration rate value. Resolution: • Ensure that the patient is still and quiet. • Check for the presence of significantly irregular cardiac rhythms (three or more events of irregularity observed within 30 seconds).

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-19.

Table 1-4. Additional Sensor Model and Patient Size

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

1.9 Theory of Operations

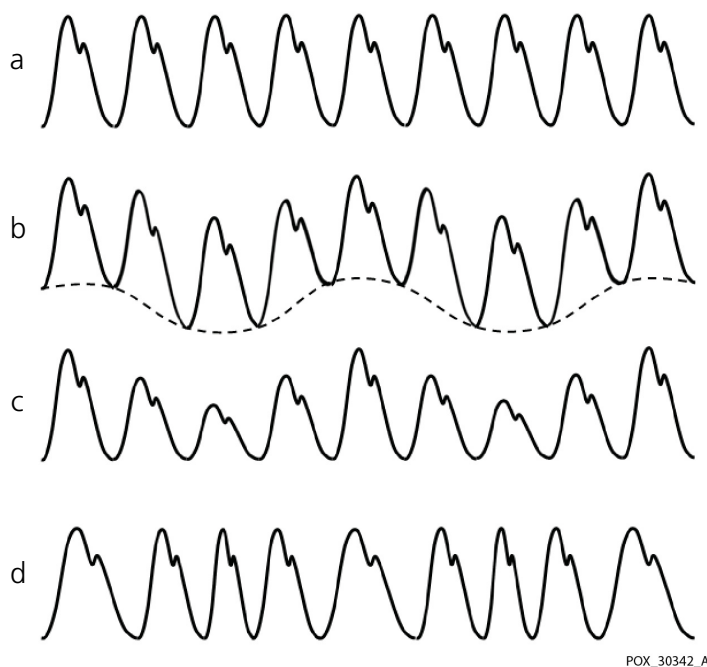
The Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Respiratory Sensor, provides continuous non-invasive monitoring of arterial oxygen saturation, pulse rate and respiration rate using a single sensor. The Respiration Rate 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 1-16](#) (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 1-16](#) (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 1-16](#) (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 1-16](#) (d).

Figure 1-16. 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™ Respiratory Sensor data.

Table 1-5. Nellcor™ Sensor Accuracy and Ranges

Type	Values
Measurement Ranges	
SpO2 saturation range	1 % to 100 %
Pulse rate range	20 to 250 beats per minute (bpm)
Respiration Rate	4 to 40 breaths per minute
Perfusion range	0.03 % to 20 %
Measurement Accuracy	
Pulse rate accuracy	20 to 250 beats per minute (bpm) ± 3 digits
SpO2 saturation accuracy ¹	70 % to 100 % ± 2 to ± 3 digits
Respiration Rate	± 1 breath per minute
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

- Monitoring system measurements are statistically distributed; about two-thirds of monitoring system measurements can be expected to fall in this accuracy (ARMS) range. For a complete listing and for test results of SpO2 accuracy across the full line of available Nellcor™ sensors, contact Covidien, a local Covidien representative, or locate it online at www.covidien.com.

1.11 Clinical Studies

Two (2) prospective, observational, non-randomized clinical studies were conducted to demonstrate the accuracy of the Respiration Rate Version 1.0 when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System, using the Nellcor™ Respiratory Sensor. One study was performed with healthy volunteers at a single clinical laboratory. A second study enrolled a convenience sample of hospitalized patients at two centers. Accuracy was established by comparison to respiration rate determined from capnography waveforms.

1.11.1 Methods

Data from 79 enrolled subjects were included in the analysis: 26 healthy volunteers and 53 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 the Respiration Rate Version 1.0 and from manual counting of breaths on the capnograph waveforms by an anesthesiologist blinded to all other data (the “reference”).

1.11.2 Study Population

Demographics for all study subjects are presented in [Table 1-6](#). For the hospitalized patients (N = 53), a listing of patient medical conditions is provided in [Table 1-7](#), p. ADD-28.

Table 1-6. Demographic Data

Demographics	Mean ± Standard Deviation (Range)
Age (Years)	43.7 ± 14 (22 - 79)
Gender (Male/Female)	31/48
BMI (kg/m ²)	28.3 ± 7.2 (15 - 48)

Table 1-7. Medical Conditions in Hospitalized Patients

Cardiovascular	N	Renal (continued)	N
Hypertension	24	Nephrolithiasis	2
Deep Venous Thrombosis (DVT)	4	Amyloidosis	1
Coronary Artery Disease	3	Hyperphosphatemia	3
Congestive Heart Failure	2	Metabolic Acidosis	1
Previous Myocardial Infarction	2	Adrenal Neoplasm	1
Fluid Overload and/or Venous Insufficiency	2	Genitourinary	N
Asymptomatic Bradycardia	1	Urinary Tract Infection	6
Diastolic Dysfunction	1	Gynecologic Tumor	4
Mitral Valve Endocarditis	1	Breast Cancer	3
Orthostatic Hypotension	1	Bladder Cancer	1
Superior Vena Cava Stenosis	1	Flank Pain / Hematuria	1
Respiratory	N	Epididymo-orchitis	1
Asthma	7	Testicular Cancer	1
Chronic Obstructive Pulmonary Disease	3	Pelvic Hematoma	1
Obstructive Sleep Apnea	2	Lymphocele	1
Previous Pulmonary Embolism	2	Hematology	N
Cystic Fibrosis	1	Anemia	6
Reactive Airway Disease	1	Avascular Necrosis	1
Endocrine/Metabolic	N	Idiopathic Thrombocytopenic Purpura	1
Obesity	19	Sickle Cell Pain Crisis	1
Morbid Obesity	6	Infections	N
Hyperlipidemia	9	Cellulitis	2
Hypothyroidism	9	Chronic Bulbar Poliomyelitis	1
Diabetes Mellitus (Type I or Type II)	7	HIV	1
Thyroid/Parathyroid Mass	5	Hepatitis C	1
Growth Hormone Deficiency	1	Hepatobiliary	N
Multiple Endocrine Neoplasm-1 Syndrome	1	Liver / Gallbladder Mass	3
Previous Pancreatic Transplant	1	Cholecystitis / Choledocholithiasis	2
Gastrointestinal	N	Cirrhosis	2
Gastroesophageal reflux disease	9	Musculoskeletal and Connective Tissue	N
Diverticulitis	5	Chronic Lower Extremity Ulcer	1
Bowel Obstruction	3	Degenerative Joint Disease	1
Crohn's Disease	3	Neurological	N
Gastroparesis	2	Migraine Headache	3
Intra-abdominal Abscess / Anal Fistula	2	Hepatic Encephalopathy	1
Rectal Cancer	2	Peripheral Neuropathy	1
Appendicitis	1	Multiple Sclerosis	1
Barrett's Esophagus / Carcinoma <i>in situ</i>	1	Seizure Disorder	1
Ulcerative Colitis	1	Peritoneal/Retroperitoneal	N
Renal	N	Primary Peritoneal Adenocarcinoma	1
Previous Renal Transplant	5	Retroperitoneal Liposarcoma	1
End-Stage Renal Disease	4	Psychiatric	N
Uremia / Renal Insufficiency	4	Anxiety/Depression	6
Chronic Kidney Disease	2	Bipolar Disorder	3
Renal Mass	2		

1.11.3 Study Results

Results for Respiration Rate Version 1.0 are shown in [Table 1-8](#). The observed respiration rate range in the studies was 4 to 34 breaths per minute. Accuracy was calculated using both root mean square difference (RMSD) and mean error. The results demonstrate that Respiration Rate Version 1.0 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.

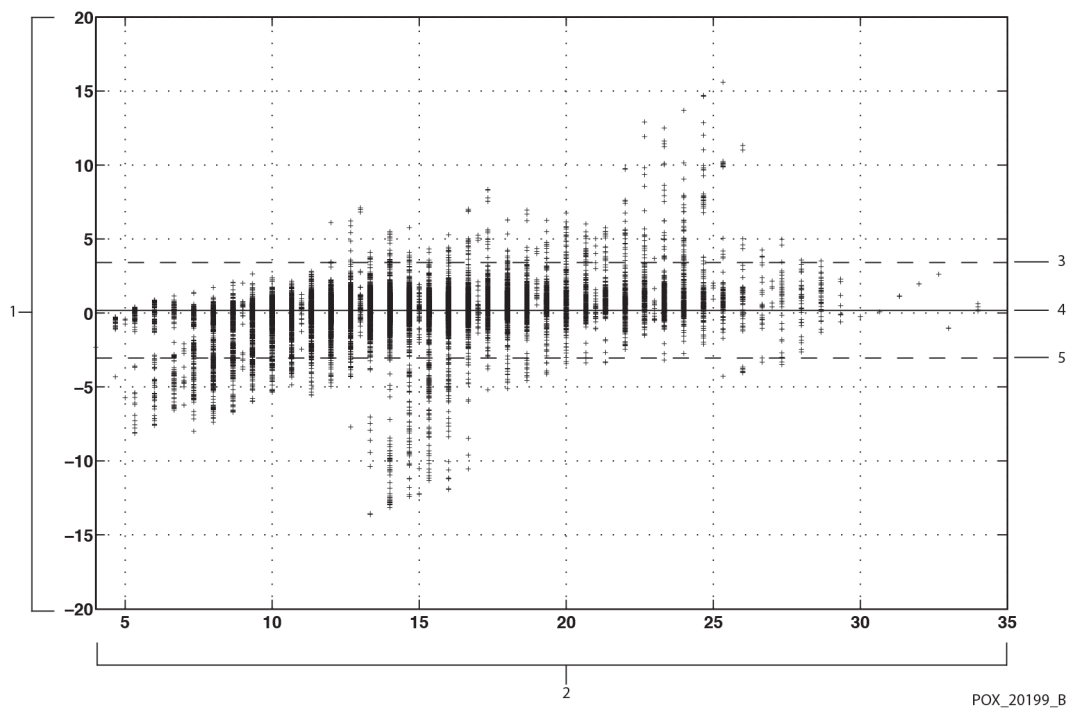
Table 1-8. Accuracy and Precision for Respiration Rate, Version 1.0 vs. Capnography-Based Reference

Population	N	Accuracy: Mean Error (Breaths Per Minute)	Precision: Standard Deviation (Breaths Per Minute)	Accuracy: RMSD (Breaths Per Minute)
Healthy Volunteers	26	0.37	± 0.78	0.84
Hospital Patients	53	0.07	± 1.98	1.60
All Subjects	79	0.18	± 1.65	1.35

Nine (9) subjects (11% of subjects) had RMSD accuracy measures of >2.29 breaths per minute and would be considered outliers because their RMSD exceeded the third quartile by $> 1.5x$ the interquartile range.

The clinical studies yielded 23,243 paired observations between Respiration Rate, Version 1.0 and the capnography-based reference method. [Figure 1-17](#), 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.

Figure 1-17. Modified Bland-Altman Plot of Nellcor Respiration Rate Software versus Reference (N=23,243 Paired Observations)



- | | | | |
|---|--|---|--------------------|
| 1 | Difference (Reference—Nellcor Respiration Rate Software) | 3 | Mean + (1.96 x sd) |
| | | 4 | Mean |
| 2 | Reference | 5 | Mean - (1.96 x sd) |

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 1.0 provided respiration rate with an accuracy of ± 1 breath per minute when compared to respiration rate derived from a capnography-based reference. Hospital studies were conducted using convenience sampling and 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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