

NELLCOR DIGITAL™ AT THE HEART OF OUR MISSION



Nellcor Digital™ Technology

- Pulse Qualification
- Cardiac Gated Averaging (CGA)
- Digital Calibration

Evolving With You



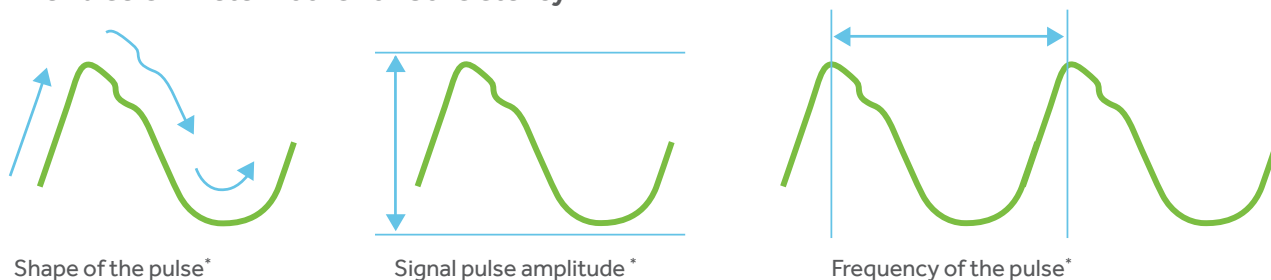
Medtronic

PULSE QUALIFICATION

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We believe the cardiac signal is key to mitigating interference and achieving an accurate reading because arterial pulses are essential to pulse oximetry. Our cardiac-base algorithm use Pulse Qualification to reject, for example, pulses with abnormal shapes or periods that would be indicative of signal interference, while accepting those that are of physiological origin, including regular pulses with or without dicrotic notches and arrhythmias. Because we qualify individual pulses, you can be confident that the values posted are accurate.

The Pulse Oximeter Looks For Consistency



*Qualifies a pulse on a beat-by-beat basis

Figure 1. Nellcor™ pulse oximeter examine each individual pulse – its shape, amplitude and frequency – to determine whether it is true physiological pulse and to ensure that it is not caused by noise or interference.

Our Technology

- Determines real-time cardiac activity
- Processes sensor signals to compute SpO₂ and pulse rate
- Qualifies when conditions are appropriate for posting the computed SpO₂ and pulse rate



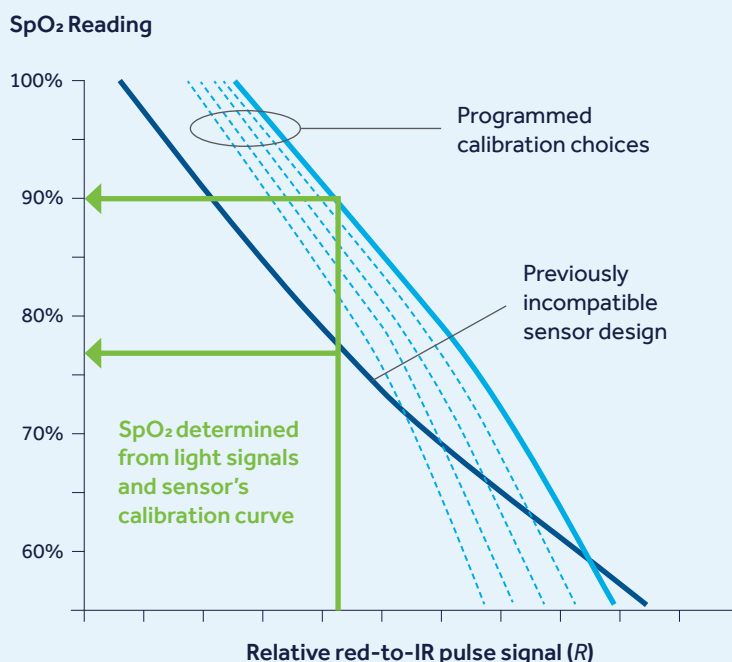
"Because we qualify individual pulses, you can be confident that the values posted are accurate."

DIGITAL CALIBRATION

Sensor Calibration

Every Nellcor™ OxiMax™ sensor incorporates a small digital memory chip. Now, instead of relying on a limited number of preprogrammed curves within the monitor, the OxiMax™ system relocates the sensor's individual calibration curve into the sensor itself. In this new design, every OxiMax™ sensor is digitally programmed with the specific coefficients that define its proper calibration curve.

The OxiMax™ platform has enabled Nellcor™ to expand the accuracy specifications of certain OxiMax™ sensors to an industry-leading $\pm 3\%$ in the 60% - 80% SpO₂ range. This LoSat expanded accuracy feature helps clinicians better manage patients in the challenging lower saturation ranges.



CARDIAC GATE AVERAGING (CGA)

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CGA averages multiple waveforms synchronous with the heart rate to enhance “good” cardiac pulse signals and reduce the effects of random interference.

To manage signal interference, we measure the cardiac rhythm’s characteristic frequency and follow its progression over time. CGA processing attenuates signal that does not occur synchronously with the average rhythm of the heartbeat. Figure 2 and 3 illustrate the principle of CGA.

Pulse Without Interference

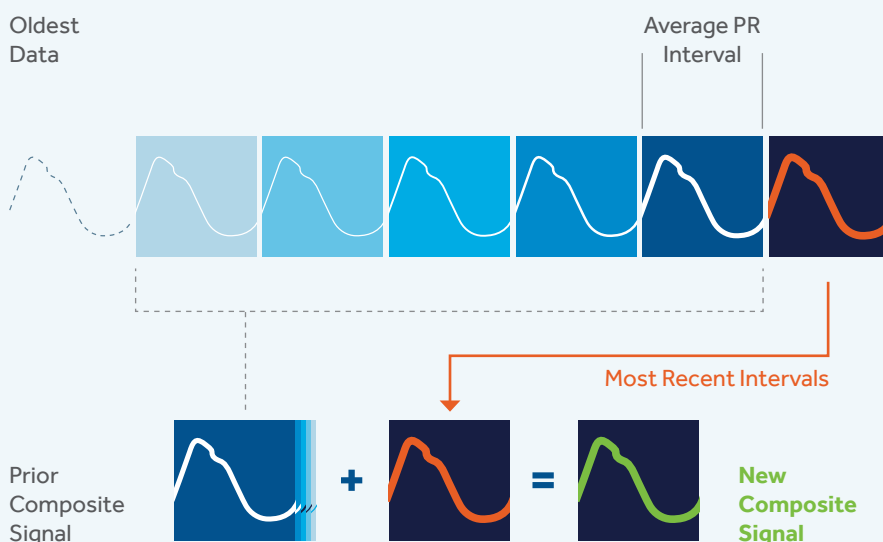
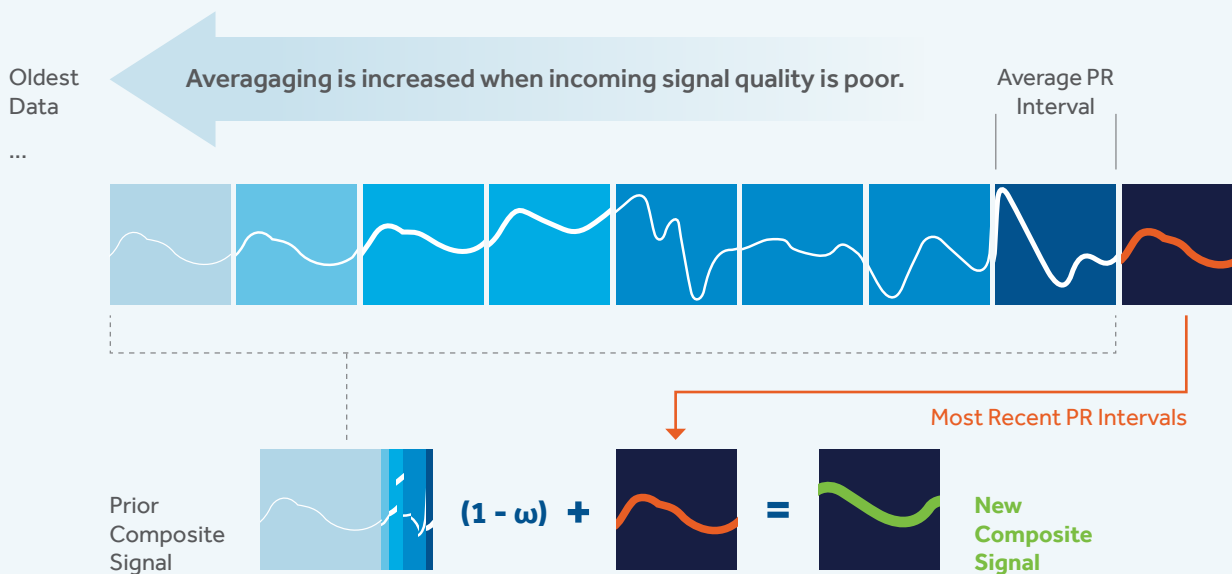


Figure 2. Cardiac Gated Averaging breaks the incoming signal into segments corresponding to the average heart rate. These segments are numerically combined to create a composite “pulse” signal.

Pulse With Interference



Weighing (ω) ranges between approximately 0 and 1

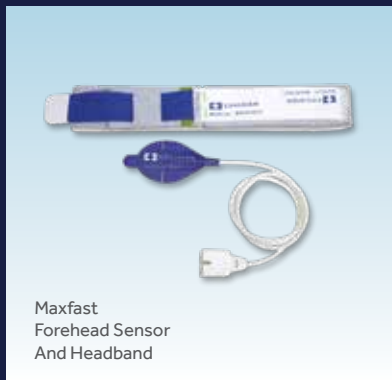
Figure 3. Weighting is adjusted when signal interference is present. When characteristics of the incoming signal indicate that the pulses may be distorted by interference, more weight is given to the prior composite signal in the averaging process, further reducing the influence of the interference. The parts of the waveform that are synchronous with the average heart rate pass through the CGA process unaffected.

The resulting CGA composite signal retains the contributions from the underlying cardiac-induced pulsations while reducing the relative influence of random interference. SpO₂ and PR values determined from the composite signal thus are more reliable.

SENSOR SELECTION INFORMATION

At the Heart of our Mission | Nellcor Digital™ Technology

Adult And Paediatric Forehead SpO₂ sensor



- For patients with low perfusion
- Our latest technology responds up to 90 seconds faster than a finger sensor — and responds 0.6 seconds faster than an arterial line¹
- Suitable for long-term monitoring
- Can be used with mechanically ventilated patients
- Single-patient use
- Sterile sensor

Part Number	Weight Range	Units Per Case	Accuracy 70 - 100%	Accuracy 60 - 80%
MAXFASTI	>10 Kg	24	±2	±3

Adult, Paediatric, Infant, Neonatal Adhesive SpO₂ sensors



- Suitable for continuous monitoring
- Comfortable, form-fitting sensors
- Single-patient use
- Sterile sensor

Part Number	Weight Range	Units Per Case	Accuracy 70 - 100%	Accuracy 60 - 80%
MAXAI/ MAX-AL-I	Adult >30 kg	24	±2	±3
MAX-N-I	Neonatal/adult <3 kg or >40 kg	24	±2	±3
MAX-I-I	Infant 3-20 kg	24	±2	±3
MAX-P-I	Pediatric 10-50 kg	24	±2	±3

Adult And Neonatal Non-adhesive SpO₂ sensors



- For patients with fragile skin
- Nellcor™ non-adhesive SpO₂ sensor specifications show the same accuracy in neonates as the Nellcor™ MAX-N-I and MAX-I-I sensors.²
- Suitable for long-term monitoring
- Single-patient use
- Sterile sensor

Part Number	Weight Range	Units Per Case	Accuracy 70 - 100%
SC-A-I	Adult > 40 KG	24	±2
SC-NEO-I	Neonatal 1.5-5 kg	24	±2
SC-PR-I	Preterm Infant <1.5 kg	24	±2

SENSOR SELECTION INFORMATION

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Adult

Respiration rate sensor



- Measures SpO₂, pulse rate and respiration rate
- For patients with low perfusion
- Suitable for long-term monitoring
- Use with Nellcor™ Respiration Rate enabled monitor
- Single-patient use
- Sterile sensor

Part Number	Weight Range	Units Per Case	Accuracy 70 - 100%	Accuracy 60% - 80%	Accuracy 4 - 40 Breaths Per Minute
10068119	>30 KG	24	±2	±3	±1 breath per minute

Nellcor™ SpO₂ A04 Module



- Compatible with the full line of Nellcor™ sensors with Digital™ technology, including the Nellcor™ SpO₂ forehead sensor
- Produces the numerics for the arterial oxygen saturation value and the pulse rate and a real-time wave for the plethysmogram for display on Philips IntelliVue® patient monitors
- Designed to be used in a range of critical care environments
- Rugged design to withstand the stresses of the clinical environment
- Single-patient -use and specialty sensor Accurac y^{3,4,5} (Adult - Neonate)

Saturation (% SpO₂ ± 1 SD):

70% to 100% ± 2 digits
60% to 80% ± 3 digits

Low perfusion:

70% to 100% ± 2 digits

Pulse rate:

25 to 250 bpm ± 3 digits

Low perfusion:

25 to 250 bpm ± 3 digitss

Compatible With
Philips IntelliVue® Systems†

MP40	MP90
MP50	MX400/450
MP60	MX500/550
MP70	MX700
MP80	MX800

Part Number	Dimensions	Weight	Contents
10076644	99.6 x 36 x 102.5mm (3.9 x 1.4 x 4.0 in.)	210g (8.2oz)	Nellcor™ SpO ₂ Module, instructions for use and M1943NL Cable

† Revision C.0 or higher software

References:

1. MaxFast video – internal protocol on file.
2. Nellcor™ Oxygen Saturation Accuracy Specification Grid. Part No. 10091796 Rev B 01/2013.
3. FDA 510(k).
4. MAX-N-I: Clinical functionality has been demonstrated on a population of hospitalized neonate patient. The observed SpO₂ accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weighing from 750 to 4100 grams, and 63 observations made spanning a range of 85 to 99% SaO₂ while monitored with Nellcor™ OxiMax™ N-595 pulse oximeters. The accuracy specification has been determined between saturations of 80%–100%.
5. MAX-R-I ± 3.5 digits determined between saturations of 80%–100%.

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