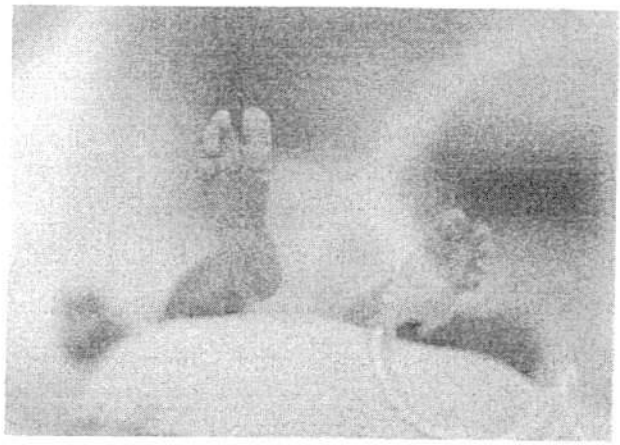
Effective Monitoring When Parents are Counting on You

Pediatric and Neonatal Surgery

Cerebral oximetry is used in critical care environments to reduce potential complications in pediatric and neonatal surgery. Premature infants, and children with congenital heart disease (CHD), are vulnerable to neurologic complications due to cerebral hypoxia-ischemia.



These patients can have a broad range of brain development and associated tissue differences. But technologies that are not designed to account for these differences can provide inaccurate readings.

Dynamic Compensation™ Algorithm

Dynamic Compensation, an exclusive, patent-pending Nonin algorithm, incorporates real-time information from the tissue being examined to eliminate the impact of myelin (a light chromophore) on the signal accuracy. This Dynamic Compensation algorithm along with sensors designed specifically for neonate and infant populations, ensures accurate information clinicians can trust without adjusting settings.

Read the Case Study at: **nonin.com/resource/dynamic-compensation**

NONIN

Responsive Readings for Improved Outcomes

Cerebral Oxygen Desaturation

Anesthesiologists and perfusionists protect oxygen levels in the brain during procedures such as cardiopulmonary bypass (CPB) surgery. Maintaining adequate perfusion is critical to protecting cognitive function in recovery. Regional oximetry helps specialists track and respond to changing patient needs.

A clinical study evaluated the use of rSO_2 monitoring during CPB surgery and effects of cerebral oxygen desaturation on postoperative neurological outcomes. The study involved 100 patients in two random groups.

Postoperative Outcomes

In one group, the anesthesiologist could not see the rSO_2 measurements; in the other, the anesthesiologist could see and respond to readings in case of cerebral desaturation. In both groups, rSO_2 declined during CPB.

Both groups were given tests one week and three months after surgery. In both a simplified antisaccadic eye movement test and a Mini-Mental State Examination, the intervention group had lower scores than the control group, indicating better cognitive performance.

36% DECREASE
IN INCIDENCE OF EARLY COGNITIVE IMPAIRMENT
AFTER OPEN HEART SURGERY*

The study conluded that rSO_2 monitoring during CPB can reduce the incidence of postoperative neurocognitive decline.*

Read the Clinical Study at: **nonin.com/resource/desaturation**

* Mohandas BS, Jagadeesh AM, Vikram SB. Impact of monitoring cerebral oxygen saturation on the outcome of patients undergoing open heart surgery. Ann Card Anaesth. 2013 Apr-Jun;16(2):102-5.

NONIN

Nonin Oximetry Solutions

Nonin designs and manufactures reliable oximetry and capnography solutions for use in a diverse range of settings, from prehospital emergencies to home care monitoring.

Our products are designed with durability to withstand repeated use for long-lasting peformance without workflow interruptions.

Full Suite of Measurements†

rSO_2

Cerebral & Tissue Oximetry

$EtCO_2$

Capnography & Capnometry

Pulse Oximetry

SpO_2 COHb MetHb

Respiratory Rate

Pulse Rate

Portfolio of Products

Fingertip
Rugged designs with clinically proven accuracy

Handheld
Proven durability for portable monitoring requirements

Patient Worn
Flexible design for stationary or ambulatory monitoring

Adult, Pediatric & Neonate Sensors
The most durable sensors on the market, with options for every patient

Tabletop
Simple and dependable monitoring across all care settings

Multi-Parameter Integration
Versatile technology available in a variety of monitoring products

†Not all parameters are approved in all countries. Respiratory rate, COHb and MetHb are not available in the USA.

NONIN

Count on Nonin.

Performance

Responsive, reliable measurements you can trust in any situation

Product

Durable devices built to withstand repeated use for long-lasting peformance

People

Dedicated sales, engineering and service support for over 30 years

To learn more about our technologies and products, visit
nonin.com/technologies/cerebral-tissue-oximetry

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, MN • 55441-5443 • USA

Tel: +1.763.553.9968 1.800.365.8874
Fax: +1.763.577.5521
Email: info@nonin.com

Nonin Medical B.V.
Doctor Paul Janssenweg 150
5026 RH Tilburg • Netherlands

Tel: +31 (0)13 – 45 87 130

Email: infointl@nonin.com

NONIN

nonin.com

U.S.A MADE

Monitoring Screen – Procedures 4.11

Set All rSO_2 Channel Baselines to Current $\%rSO_2$ Values

1. (OPTIONAL STEP) Press **Event Mark** to mark an event. Record the letter of the event in the hospital records.
2. While in the monitoring screen, press **Baseline**. "Update baselines for rSO_2 channels" screen displays with the patient's baseline values.
3. Press **Baseline** or **Select**.
4. rSO_2 channel baseline values are set to the current baseline readings and the display returns to the monitoring screen.

Mark an Event

1. While monitoring, momentarily press **Event Mark**.
2. The event mark letter appears on the screen and is stored in memory.

NOTE: It may take up to 4 seconds for the event mark to appear on the display.

View the Event Mark Table

1. While monitoring, press **Event Mark** for approximately 2 seconds.
2. The event mark table (figure 17) displays on the monitor.
3. The event mark table screen automatically closes after 2 minutes. To quickly exit the event mark table, momentarily press **Event Mark**, **Menu**, **Select**, or **On/Standby**.

Change the Timescale

While monitoring, press **Up/Down** to change the timescale to the desired setting.

Available settings are:

- 7.5 minutes
- 15 minutes
- 30 minutes (default)
- 1 hour
- 2 hours
- 4 hours
- 8 hours
- 12 hours
- 24 hours

Scroll Through the Timescale

1. While monitoring, press **Left** to display the cursor above the graph(s).
2. When the scrolling cursor displays, the color-coded cursor values display on the left side of the monitoring screen below the timescale rate.
3. To quickly exit scrolling mode and return to the current time in the case, press **Menu** twice or momentarily press **On/Standby**.

Graph Set-up

Graphs are set up on the Settings Menu screen. See "Graph Position" on page 32 or "Set Graph Position(s)" on page 35 for more information.

Brightness

This setting determines the display screen brightness. The brightness slider has 15 steps. The default brightness is maximum brightness (15). This setting can be saved as a preset parameter.

Alarm Volume 4.13

This setting determines the volume of audible alarms. The alarm volume slider has 15 steps. The default alarm volume is maximum volume (15). This setting can be saved as a preset parameter.

If the alarm volume is at step 5 or higher, the slider is green. If the alarm volume is at step 4 or lower (less than 45 decibels), the slider is yellow, and the yellow Alarm Silence indicator is lit solidly on the monitoring screen.

rSO_2 Low Alarm Mode

This setting determines how the low alarm limit will be calculated. This setting can be set to either "% Below Baseline" or "Absolute." Default is "% Below Baseline."

Once set, either $\%rSO_2$ Low (% BL) or $\%rSO_2$ Low (Abs) will display on the Settings Menu screen. See page 31 for more information about rSO_2 low alarm limits.

This setting can be saved as a preset parameter.

% Below Baseline

To have the rSO_2 low alarm limit value automatically calculated as a percentage below the baseline, set the rSO_2 Low Alarm Mode to "% Below Baseline" (default). The factory default is the baseline value minus 25% of the baseline value (table 8 on page 31).

Example: if the BL is 60, then the low alarm limit is 45 (60 minus 25% = 45).

When starting a new case and the rSO_2 Low Alarm Mode is set to "% Below Baseline," the rSO_2 low alarm limit values are the institution's or preset's default $\%rSO_2$ Low (Abs) value. Once the user sets the baseline, the rSO_2 low alarm limit will become a percentage of the baseline.

Absolute

To have the $\%rSO_2$ low alarm limit be a specific value, set the rSO_2 Low Alarm Mode to "Absolute."

When starting a new case and the rSO_2 Low Alarm Mode is set to "Absolute," the rSO_2 low alarm limit values are the selected preset's $\%rSO_2$ Low (Abs) values.

Pulse Tone Volume

This setting determines the volume of the pulse beep. The pulse tone volume slider has 15 steps. The default pulse tone volume is off (0). This setting can be saved as a preset parameter.

4.1 SenSmart® X-100 System Test Schedule

Test	Standard & Clause Reference	Test Report
PERFORMANCE		
Declared Range	IEC 60601-1:2005 FDA Guidance on SW V&V IEC 62304:2006	QATR8552
System Noise	ISO 80601-2-61:2011 Sub-clause 201.12	QATR8560
Low Perfusion	ISO 80601-2-61:2011 Sub-clause 201.12.1.103	QATR8634
Battery Life & Charge Time	Performance	QATR8503
Pulse Rate Accuracy (motion)	ISO 80601-2-61:2011 Sub-clause 201.12.1.102	QATR8559
Pulse Rate Accuracy (non-motion)	ISO 80601-2-61:2011 Sub-clause 201.12.1.104	QATR8558
Sound Level / Audible Alarms	IEC 60601-1-8:2006 201.3.3.2 IEC 60601-1:2005 Sub-clause 12.3	QATR6472
Insertion/Removal	Internal / EDS	QATR8644 QATR8645
Abnormal Position	IEC 60601-1:2005 Sub-clause 15.4.7.2	QATR8505
Cable Flex Testing	Internal	QATR8415
Cable Stiffness Testing	Internal	QATR8416
Flex Resilience	Internal	QATR8641
Retention Strength	Internal / EDS	QATR8635 QATR8644
Rotation Retention (X-100HH)	Internal	QATR8639
Sensor Compatibility (Backward and Forward)	Internal	QATR8635
Strain Relief Pull Strength	Internal / EDS	QATR8647
EMC		
Conducted Immunity	IEC 60601-1-2:2014	QATR8538
EFT	IEC 60601-1-2:2014 ISO 80601-2-61:2011	QATR8541
ESD	IEC 60601-1-2:2014 IEC 61000-4-2:2008	QATR8542
Emissions	IEC 60601-1-2:2014 CISPR 11:2010	QATR11292 QATR10800
MFI	IEC 60601-1-2:2014	QATR11292
Radiated Immunity	IEC 60601-1-2:2014 ISO 80601-2-61:2011	QATR11292
Surge	IEC 60601-1-2:2014 ISO 80601-2-61:2011	QATR8539
VDD	IEC 60601-1-2:2014 IEC 61000-4- 11:2004 ISO 80601-2-612-61:2011	QATR8540

SenSmart® X-100 System Test Schedule

Test	Standard & Clause Reference	Test Report
RADIO EMC		
Radio Immunity	EN 301 489-17:2002 EN 55024:1998 IEC 60601-1-2:2014	QATR10183
Spurious Radio Emissions	EN 300 328-2:2001 CISPR 22:2005/A2:2006 FCC Part 15, subpart B, Class B, FCC Part 15, subpart C, IC RSS-210 Issue 7	QATR8596
ENVIRONMENTAL		
Operating Temperature and Humidity	IEC 60601-1:2005 sub-clause 7.9.3.1	QATR8524
Storage Temp and Humidity	IEC 60601-1:2005 sub-clause 7.9.3.1 IEC 60601-1-11:2010 sub-clause 4.2.1 EN 1789:2007 sub-clause 6.3.2	QATR8599
Shock and Vibration	IEC 60068-2-6 IEC 60068-2-64 IEC 60068-2-27 clause 6.4.1 IEC 60068-2-34 clause 6.1 IEC 60068-2-29 clause 6.4.1 ISO 80601-2-61:2011 clause 201.15.3.5.101.2	QATR7697 QATR7497 QATR8527
Drop (Standard)	IEC 60601-1:2005 Sub-clause 15.3.4.1	QATR8593
Drop/Swing (EDS)	IEC 60601-1:2005 Sub-clause 15.3.4.1	QATR8613
Altitude	IEC 60601-1:2005 sub-clause 5.3	QATR8557
Hyperbaric (Pressure)	Internal / EDS	QATR8561
Thermal Shock	IEC 60601-1-11:2010 Sub-clause 4.2.3	QATR8601
Low Temperature Exposure	EN 1789:2007 Clause 6.3.2.3	QATR8600
Maximum Temperature	IEC 60601-1:2005 clause 11.1.1	QATR8590
Impact	IEC 60601-1:2005 Sub-clause 15.3.3	QATR8594
Castors and Wheels: Force for Propulsion	IEC 60601-1:2005 sub-clause 9.4.2.4	QATR8637
Connection to External DC Power Source - Reverse Polarity	IEC 60601-1:2005 Sub-clause 8.2.2	QATR8553
Defibrillator Proof	IEC 60601-1:2005 clause 8.5.5	QATR8528 QATR10896
Stability in Normal Use	IEC 60601-1:2005 Sub-clause 9.4	QATR8506 QATR10896
Grips/Handling Device Loading	IEC 60601-1:2005 sub-clauses 9.4.4	QATR8635
Rigidity of Enclosure	IEC 60601-1:2005 Sub-clause 15.3.2	QATR8450 QATR7825 QATR8510 QATR8580
Strength of Enclosure	IEC 60601-1:1988/A2:1995 Sub-Clause 21b	QATR8451 QATR8511 QATR8579
Incorrect Battery Installation (REF only)	IEC 60601-1:2005 Sub-clause 15.4.3.2	QATR8484
Shipping (ISTA)	ISTA 2A:2008	QATR8598

SenSmart® X-100 System Test Schedule

Test	Standard & Clause Reference	Test Report
SAFETY		
Biocompatibility	IEC 60601-1:2005 clause 11.7	QATR8605 QATR10152
Patient Leakage	IEC 60601-1:2005 clause 8.7	QATR8529
Dielectric Withstand	IEC 60601-1:2005 Sub-clause 8.8.3	QATR8529
Ingress Protection (IPXX)	IEC 60529:2013 clauses IEC 60601-1:2005 Sub-clause 6.3 ISO 80601-2-61:2011 clause 201.11. 6.5.101	QATR8608
Electrosurgical Interference Suppression	ANSI/AAMI EC13:2002/(R)2007 clause 4.1.2.1a & 4.2.9.14	QATR8602
Limitation of Voltage, Current, or Energy	IEC 60601-1:2005, sub-clause 5.9.2 and 8.4.2	QATR8577
Excessive Temperatures	IEC 60601-1:2005 clause 11.1.2	QATR8525
Cleaning Resistance (Standard)	IEC 60601-1:2005 Sub-clause 11.6.6	QATR8649 QATR8650 QATR8652
Components and General Assembly	IEC 60601-1:2005, Sub-clause 15.4	QATR8603
Surfaces, Corners and Edges	IEC 60601-1:2005 Sub-clause 9.3	QATR8452 QATR8509 QATR8597
Humidity Preconditioning	IEC 60601-1:2005 Sub-clause 5.7	QATR8529
Mains Voltage/Frequency	IEC 60601-1:2005 clause 4.10.2 IEC 60601-1-11:2010 sub-clause 4.1	QATR8507
Instability in transport: From unwanted movement and Overbalance	IEC 60601-1:2005 sub-clauses 9.4.2 and 9.4.3	QATR8638
Lithium Batteries	IEC 60601-1:2005, Sub-clause 15.4.3.4	QATR6498
Interruption of Power Supply	IEC 60601-1:2005 Sub-clause 11.8 IEC 60601-1-8:2003 clause 201.5.5 ISO 80601-2-61:2011 clause 201.11. 8.101	QATR8526
CLINICAL		
Accuracy	ISO 14155:2011 ISO 80601-2-61:2011 clause 201.12.1.101	QATR8102 QATR7341 QATR7754
USABILITY		
Usability	IEC 60601-1:2005 sub-clause 12.2	QATR8619
SOFTWARE		
SW Validation (SenSmart Download SW)	FDA 938:2002 IEC 62304:2016	QATR8726
SW Validation (X-100 Sensor Memory Image)	FDA 938:2002 IEC 62304:2016	QATR8392 QATR8391
SW Validation (X-100M)	FDA 938:2002 IEC 62304:2016	QATR8684
SW Validation (X-100SP)	FDA 938:2002 IEC 62304:2016	QATR8552
SW Verification (Nonin Universal Bus)	FDA 938:2002 IEC 62304:2016	QATR8709

SenSmart® X-100 System Test Schedule

Test	Standard & Clause Reference	Test Report
SW Verification (Smart Sensor Interface Module)	FDA 938:2002 IEC 62304:2016	QATR8757
PSP Software Equivalence to ISP3 Software	FDA 938:2002 IEC 62304:2016	QATR8781
SW Verification (Pulse Oximetry Processing Module)	FDA 938:2002 IEC 62304:2016	QATR8756
SW Verification (Regional Oximetry Processing Module)	FDA 938:2002 IEC 62304:2016	QATR8536
LABELING		
Accompanying Documents	IEC 60601-1:2005 sub-clause 7.9	QATR8606 QATR8575
Legibility of Markings	IEC 60601-1-6:2006 IEC 60601-1:2005 Sub-clause 7.1.2 ISO 80601-2-61:2011 clause 201.7. 2.101	QATR8607
Durability of Markings	IEC 60601-1:2005 Clause 7.1.3	QATR8651
USABILITY		
Usability	IEC 60601-1:2005 sub-clause 9.4.4	QATR8619
MISCELLANEOUS		
RoHS	2011/65/EU	QATR8604 QATR10165
Risk Management	ISO 14971:2012	8834-001

บริษัท เทค เอส จำกัด
德德有限公司
TECH ACE CO., LTD.

TO WHOM IT MAY CONCERN:

6.4

Nonin Medical, Inc., agrees to maintain in house, most frequently used (supply) replacement parts needed to service Nonin-branded pulse oximeters for a period of not less than ten (10) years.

Replacement parts will be new and not used or refurbished and will either be manufactured by, and/or meet the minimum specifications established by Nonin Medical, Inc. In the event replacement parts are not available, Nonin Medical, Inc., will provide replacement product of similar design.

Respectfully,
Nonin Medical, Inc.

Kim E. Aves
Regulatory Affairs Specialist
Telephone: + 763 577 3196
Email: Regulatory@nonin.com

บริษัท เทค เอซ จำกัด
TECH ACE CO.,LTD.
德億有限公司

www.techace.co.th

TECH ACE CO., LTD. 1341 SOI LADPRAO 94 (PANJAMIT) SRIVARA TOWN IN TOWN WANGTHONGLANG BANGKOK 10310 TEL: 0-2934-7360 FAX: 0-2530-3865

บริษัท เทคเอซ จำกัด 1341 ซอยลาดพร้าว 94 (ปัญจมิตร) ศรีวราทาวน์อินทาวน์ แขวงพลับพลา เขตวังทองหลาง กรุงเทพฯ 10310 โทร 0-2934-7360 แฟกซ์ 0-2530-3865

บัญชีเงินฝากของ บริษัท เทคเอซ จำกัด

ใช้สำหรับทำสัญญาซื้อขายเครื่องวัดปริมาณความอิ่มตัวของออกซิเจนในเนื้อเยื่อ จำนวน 1 เครื่อง ต่อทางโรงพยาบาลนครปฐม จังหวัดนครปฐมเท่านั้น

สำนักงาน Office รหัสสาขา 294

บัญชีเลขที่ Account No. 094-1-01855-5

สาขาประชาอุทิศ

ชื่อบัญชี Account Name

บจ. เทคเอซ จำกัด

ธนาคารกรุงไทย KRUNGTHAI BANK

ลายมือชื่อผู้มีอำนาจลงนาม Authorized Signature

SA H 1369686

รับรองสำเนาถูกต้อง

ธนาคารกรุงไทย จำกัด สาขาประชาอุทิศ
เลขที่ 603 อาคารอุษรินทร์ ชั้น 2 ถนนประชาอุทิศ
แขวง/เขตวังทองหลาง กรุงเทพฯ 10310
โทร. 0-2934-7418-20