

User Manual for NIRScout™, NIRScoutX™, and NIRScoutXP™ Systems

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NOTICE OF INTENDED USE: NIRx NIRS imaging systems are NOT intended for use as a clinical diagnostic or treatment guidance tool. Neither the system hardware (NIRSport, NIRScout, NIRScoutX) nor system control software (NIRStar) has FDA Approval. Use of these resources is for **investigational use only** and requires IRB approval **prior** to performing measures on human subjects.

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1 General Information

	Attention, consult accompanying documents.
	Type BF equipment.
	Warning, high voltage.
	Protective earth (ground).
	Do not dispose of in household garbage. Contact Manufacturer for proper disposal information.
	Mains disconnect OFF.
	Mains disconnect ON.
	Visible and invisible laser radiation
	Device or component sensitive to electrostatic discharge (ESD)

1.1 Intended Use

The NIRScout/NIRScoutX/NIRScutXP NIRS measurement system is not a medical device and may be used in the context of non-medical applications in order to carry out fundamental research on the basis of neurophysiological methodology and data.

The device is intended to be used for the Quantification of relative concentration changes of oxy- and deoxy-hemoglobin in tissue blood based on superficial diffuse near-infrared spectroscopic measurements.



Use of the device for diagnosis, therapy, monitoring of vital life functions (such as cardiovascular functions etc.) or other medical purposes is expressly forbidden.

The user is solely liable for any risks to test subjects (patients) associated with the investigation if the device is not used in accordance with the correct use described.

1.2 Correct Use

Application environment

- The device is permitted to be used in hospitals, clinics, other medical environments, research institutes and other environments, provided that all the other stipulations regarding correct use (e.g. with respect to the user) are met and that the device is used in accordance with its intended use.
- The device is not permitted to be used in the vicinity of explosive gases as may be the case in operating theaters, for example.

Target group

The device is permitted to be used on healthy and sick adults, children and animals.

Users

- The device is permitted to be used by physicians and medical experts.
- The device is not permitted to be used by unqualified persons.
- The device is not to be used by people who personally cannot read or understand the User Manual (e.g. due to insufficient language knowledge, due to blindness).

1.3 Electric Safety

Properly ground the instrument.



This instrument is grounded through the power cord. It is a Class 1 device. Use only the power cord specified for your instrument (see section “Specifications”). Use only a power cord that is in good condition.



WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Do not operate without covers and panels installed



To avoid personal injury and equipment damage, the user needs to turn off the mains disconnect before removing covers, panels, or grounding connections. Reinstall covers, panels, or grounding connections before turning the mains disconnect back on.



WARNING! Modification of the equipment is not permitted.

1.4 Intended Readership

This document is required reading for operators of NIRx NIRS imaging devices of the NIRScout™ product family in order to avoid instrument misuse potentially leading to hardware malfunctions or data corruption.

We furthermore recommend this document to any user concerned with the experimental planning or data analysis of NIRScout measurements.

All references to 'NIRScout' or 'NIRScout devices' in this manual include NIRScoutX and NIRScoutXP instruments unless otherwise specified.



Important notes and warnings are indicated with this symbol throughout the document.

1.5 Related Documents

The following user manuals and documents may contain additional information pertinent to the topic matter of this user manual:

- NIRx API Design Document for the real-time data streaming Software Development Kit (SDK)
- NIRx NIRStar Software User Manual
- Headgear and optode placement Manuals
- NIRx troubleshooting and quick start guides

1.6 Problem Reporting Instructions

You may use the following ways of contacting NIRx for additional support and bug reports:

E-mail: support@nirx.net

Web: www.nirx.net/contact

2 Handling and Maintenance

2.1 Transport and Storage

NIRScout devices are mobile instruments and may be moved by the user between different investigation sites (i.e., labs, exam rooms, etc.) within the institution of the original installation. When storing the instrument, it should be covered to protect it from dust. NIRx recommends its dedicated hardcase containers for prolonged storage and transport.



The equipment must not be exposed to fluids or condensation humidity conditions.



During storage or transport, the equipment should be kept at a temperature between -15°C to +70°C and at a relative humidity of 20% to 80% (non-condensing). Ambient pressure should be within 700 hPa and 1060 hPa.

2.2 Safe Performance

The equipment should only be handled and operated by trained personnel. Operators must familiarize themselves with the latest revision of the user's manual before using the device.

The NIRScout instruments are intended for continuous operation.

2.3 Cleaning, Sterilization, and Disinfection

The outside of the instrument may be cleaned with a damp cloth. A mild soap or a window cleaner may be used to aid cleaning; do not use solvents. Allow the instrument to thoroughly dry before use.

The fiber optic probe ends that come in contact with the skin can be cleaned and disinfected by wiping them after use with isopropyl alcohol 70%.



DO NOT USE ETHANOL OR METHANOL OR ACETONE FOR CLEANING OF THE FIBER-OPTIC SURFACES. THE FIBERS MUST NOT BE STERILIZED IN AN AUTOCLAVE.

2.4 Routine Maintenance

The fiber optic probes are delicate optical devices. Any strain, kinking, pinching, and tight bending (bending radius < 2 cm) should be avoided since this can damage the fibers. Before each measurement, the fibers should be visually inspected for signs of physical damage. In the case of suspected fiber damage, please contact the manufacturer.

No regular service, calibration, or inspection of the instrument by the user, vendor, manufacturer, is required for proper operation of the instrument. In order to maintain adequate signal quality, the user is advised to regularly perform the system check procedures such as a Dark Noise Check (see, NIRStar Software User Manual) and a static phantom stability measurement.

2.5 Waste Products and Disposal

There are no waste products from the equipment

Please contact the manufacturer for help with the disposal of the instrument or its components at the end of its useful life.

2.6 Operating Environment



NIRScout Instruments are for indoor use only.

NIRScout instruments are not safe for the use in presence of inflammable anesthetics. NIRScout instruments are not to be used in an operating room.



The equipment should be operated at a temperature of -10°C to +40°C and at a relative humidity of 20% to 80% (non-condensing). Ambient pressure should be within 700 hPa and 1060 hPa.

2.7 Use of Device

The NIRx NIRScout Near Infrared Spectroscopy (NIRS) imaging system is intended for non-invasive transcranial Near-Infrared Spectroscopy (NIRS) of blood perfusion dynamics in the human head. NIRScout is a research instrument. The instrument and all accessories are to be used for research purposes only.



NIRx products are NOT “medical devices” intended to be used for the purpose of diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or used as a life support device. Use of NIRx products are solely for research purposes.

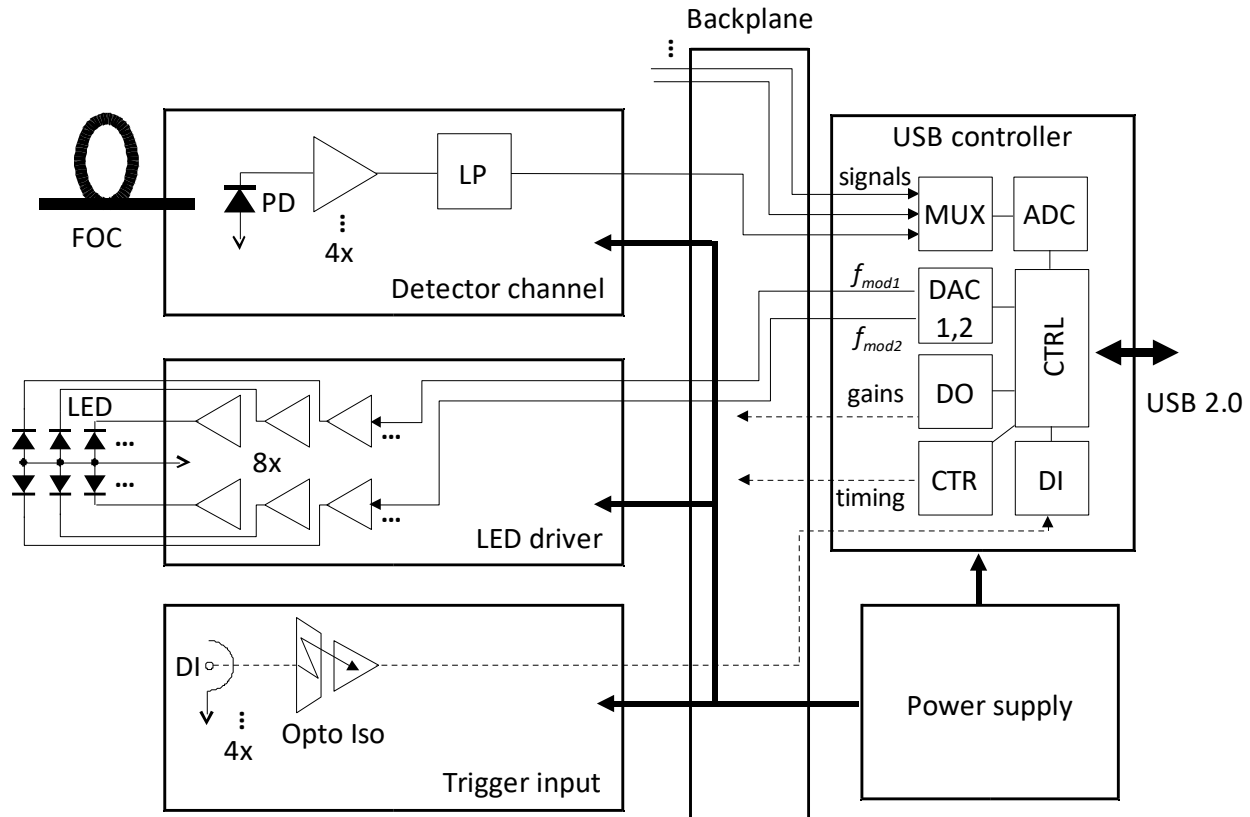


Fig. 1: Block diagram of NIRScout functional components and interconnections. FOC: Fiber optic cable; PD: Photo diode; LP: Low-pass filter; LED: Light emitting diode; DI: Digital input; Opto Iso: Opto-isolator; USB: Universal serial bus; MUX: Multiplexer; DAC: Digital-to-analog converter; DO: Digital out; CTR: Counter; CTRL: Controller; $f_{mod1,2}$: Modulation frequencies 1, 2.

3 Functional Description

NIRScout performs dual-wavelength continuous-wave (CW) near infrared (NIR) diffuse tomographic measurements on large tissue structures at high (= several Hz) sampling rates. The system facilitates NIR illumination of multiple target locations in a time-multiplexed, scanning fashion. Using LED emitters at two distinct wavelengths allows discrimination of the two oxygenation states of tissue hemoglobin. Both wavelengths are emitted simultaneously and are distinguished by modulating and demodulating each at distinct frequencies in the low kHz-range.

The instrument employs parallel readout of multiple optical detector channels, each of which uses adaptive gain switching to maximize the dynamic measurement range ($>10^9$). The device features four parallel, optically isolated digital input channels (TTL level) for the acquisition of event trigger signals. The NIRScout instrument is operated through a graphical user interface (GUI) on a personal computer (PC), to which it is connected by USB 2.0.

Fig. 1 shows a block diagram depicting the NIRScout hardware components and main signal connections. All components except for the power supply plug into the instrument front and interconnect through a backplane. The USB controller establishes data and control signal connection with a host PC and contains

all data acquisition and control hardware necessary for instrument operation. This includes digital I/O lines, counters, an analog-to-digital converter, and digital-to-analog converters.

The LED driver card provides multiple parallel precision current sources which allow the desired intensity control of the LED emitters. Each optode incorporates two LED wavelengths, which receive distinct current modulation frequencies in the low kHz range. A tissue scan is facilitated by sequentially turning on and off LED optodes under digital control of the LED driver, at a rate of about 60 Hz.

Detection fiber optics are used to guide the transmitted and back reflected light from the target to the detection card, each of which houses 4 detector channels. The optical signal transmitted by the fiber optic cable is converted to a voltage proportional to light intensity by means of a photo detector (photo diode) followed by electrical amplification. The gain of the amplifier is automatically adjusted by the instrument to provide optimal signal-to-noise ratio depending on the intensity of the received light. The instrument is therefore capable of dealing with optical intensities over an extremely large dynamic range ($>10^9$), which allows diffuse transmission measurements on tissue over distances from under 1 cm to about 4 cm. This makes the instrument suitable for optical tomographic ('multi-distance') imaging. The amplifier output is low-pass filtered and converted to a digital signal with 16-bit resolution by the controller board.

To allow time stamping of the measured data for the purpose of event synchronization with concurrent measurements or experimental protocols, the instrument provides four parallel digital input channels. Each of these is optically isolated from the rest of the system. Each input is over-voltage protected and contains a comparator circuit ('Schmitt Trigger') to improve noise immunity. The inputs are TTL/CMOS compatible and are positive-edge triggered.

4 Hardware Components

4.1 Main Frame

The instrument's form factor is based on an industry standard modular rack enclosure. All main functional components are implemented as modular electronic cards, which can be inserted as required by the system's configuration. The back of the enclosure contains the AC mains power entry as well as the main On/Off switch. Also situated in the rear panel is a cooling fan exhaust.

Fig. 2 shows the front and rear view of the instrument.



Fig. 2: (a) Front view of the NIRScout imaging system. (1) Quad-channel detection cards QDC-10; (2) USB controller card USB-1618 with Trigger input (3); (4) Led driver card LED-16. (b) Rear View showing AC power inlet and power main On/Off switch (1).

4.2 USB Controller Card

The USB controller (front panel shown right) performs all functions of instrument control and signal acquisition and provides connections for experimental timing signals through various digital I/O lines. Communication to the host PC and instrument operation software is established through USB 2.0 connection (1). Once connected the system goes through a startup sequence during which the green status indicator (2) lights up and then starts to blink. At this point, the data link to the host PC is established.

The indicator (3) signals the power on state of the instrument. Only when the status indicator is blinking *and* the power LED is lit is the instrument ready for operation.

A rectangular 10-pin connector (4) provides four parallel, positive-edge triggered digital TTL input lines. In addition, a coaxial miniature SMB coaxial connector (5) outputs a digital frame marker pulse for timing purposes. This pulse is generated with the beginning of each scan, or measurement frame. Details about the timing I/O signals can be found in sections 4.8 and 4.9.

All inputs and the output are optically isolated from the instrument electronics to enhance electrical safety and signal integrity.

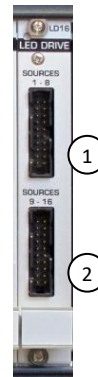


The USB should be connected before powering the system.

4.3 LED Driver Card

The LED driver card (front panel, shown right) exists in an 8-channel version with one rectangular connector, and a 16-channel version (shown here) with two identical connectors (1, 2). For the 16-channel version, the upper connector serves sources 1...8, and the lower connector drives source 9...16.

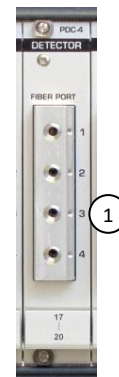
One 8-channel source optode set (NIRx LED-POD-8) can be plugged into each 20-pin connector.



Connection should be established before powering up and operating the instrument. Connecting and disconnecting the optode set during operation should be avoided.

4.4 Detector Card

The Quad-Channel-Detector (QCD) card front pane (shown right) provides one fiber port connector (1) to accommodate four individual fiber optic cables, which are secured by set screws. The instrument can be configured with 1...6 QCD modules, offering 4...16 optical detection channels in increments of four.



4.5 Optical Probes

Spectroscopic measurements of the cerebral hemodynamics are performed by placing optical emitters ('sources') and receivers ('detectors') on the scalp. As illumination sources for the NIRScout systems serve dual-wavelength LED emitters, which are placed directly on the skin.

The detectors are formed by fiber optic cables whose input ends make contact with the scalp and, whose output lead to the fiber port connector of the QCD, and an optical sensor placed inside the instrument.



Fig. 3: Sensors used with the NIRScout system. (a) Detection fiber optical cables, bundle of four. The black plastic tips are placed on tissue, the metal end ferrules are inserted into the detection card. (b) Bundle of eight dual-wavelength LED emitters. Black plastic ends with LED lens are placed on the skin, and the ribbon cable connects to the LED driver card. (3) Example of optode placement on a Phantom head.

4.5.1 Connecting Fiber Optics to the Imager

Insert the metal ferrule of the fiber optic cable into the appropriate fiber port input. Carefully push in the fiber until mechanical resistance is met. Do not exert strong force. It may help to perform slight turning motions to ease the fiber connector into the port. Once the fiber is seated, turn the set screw next to it clockwise to lock in the ferrule. A small amount of torque is sufficient to prevent the fiber from slipping back out. Do not use strong force as this can damage the fiber ferrule. To release fiber, turn set screw counterclockwise (a fraction of a turn will suffice) and carefully extract the ferrule.

Hints: All fiber ferrules should protrude into the port by the same amount. If some fibers are observed to protrude out more than others, these may not be connected properly. Make sure the set screw is not blocking the path for the ferrule before connecting the fiber optic cable.

4.5.2 Connecting the LED POD Emitters to the Imager

The LED POD emitter flat ribbon cable is connected to the instrument through a flat ribbon cable. The connector in the LED driver card is polarized to prevent reversed connection. Carefully insert the cable until it is fully seated.



The cable should only be connected or disconnected while the instrument is powered down. Otherwise damage may occur to the LED optodes.

4.6 Optodes and Head Gear

A variety of fiber optic and LED-based optodes as well as probe placement systems are available for NIRScout. An example of a fabric-cap based solution is shown in Fig. 7c. For detailed instructions and handling advice, please refer to the specific operators' manuals.

4.7 Experimental Setup

Fig. 4 shows an example of a complete NIRScout measurement setup (no control PC shown). The target under investigation is a head phantom (Dynamical Optical Tissue Simulator – DOTs). To organize the probe cables and to serve as a strain relief an articulated arm with cable clamp is used.



Fig. 4: Complete measurement setup (control PC not shown). (1) NIRScout-1624 imaging system, configured for a 16-source-by-16-detector measurement. (2) Source optode cables; (3) Fiber optic detector cables; (4) articulating arm with (5) base plate and (6) cable clamp for strain relief; (7) Head phantom.

4.8 Trigger Inputs

The digital input to the instrument has the following specification:

Connector: IDC shrouded pin header, dual-row, 2.54 mm pitch (pinout, see right)

Logic level: *Positive edge triggered* (i.e. low-to-high transitions) TTL level.

Minimum pulse duration: Timing pulses should be at least 10 ms long.

Maximum pulse duration: There is no restriction on the maximum duration, but timing pulses should be separated by at least 100 ms to be distinguished.

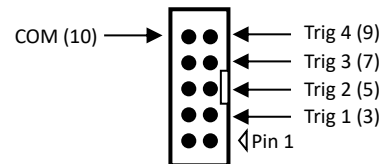


Fig. 5: Pinout of trigger input connector. Trig 1...4 denote the Trigger input lines, and numbers in parentheses denote pin numbers. COM: common (= Ground).

4.9 Trigger Output

A digital output signal is available for external timing purposes, accessible through a coaxial connector in the front panel of the USB controller. The connector is a SMB, 50-Ohm, Jack (Male connector) that can be readily interfaced with a standard SMB (Female) receptacle. This output provides a 0.1 ms positive 5-V pulse with the beginning of each scan frame of the imaging sequence.

5 Accessories

All accessories and replacement parts are to be obtained only through NIRx directly, or from authorized sales partners. Disposables may only be used if obtained from NIRx or authorized dealers, or with the expressed approval by NIRx.

5.1 Fiber optic probes and Led illuminators

A wide range of fiber optic probes and LED illuminators is available for the NIRScout Series to suit a diverse range of intended user applications. To provide up-to-date information about available products, please inquire with NIRx or one of its authorized vendors.

5.2 Probe holders / Head Gear

A wide range of head caps and probe holders is available for the NIRScout Series to suit the diverse range of intended user applications. To provide up-to-date information about available products, please inquire with NIRx or one of its authorized vendors.

5.3 Cables

For the USB connection to the controller board, a generic cable of suitable length conforming to USB 2.0 guidelines may be used (a suitable cable is included with the instrument).

For power mains connection, a generic power cord may be used that adheres to the following: Three-wire cable with neutral, live phase, and protective earth wires of sufficient cross-section (1mm² minimum for each wire), IEC C13 type connector for instrument connection, and applicable approvals or certification (e.g., EU: VDE, TÜV, GS,... US: CSA, UL, ... etc.).

A 3-m long trigger cable is included with the instrument, which connects a standard PC parallel port (25-pin sub-D female connector) to the 10-pin rectangular connector at the USB controller front panel. The cable connections are shown for reference in the following figure.

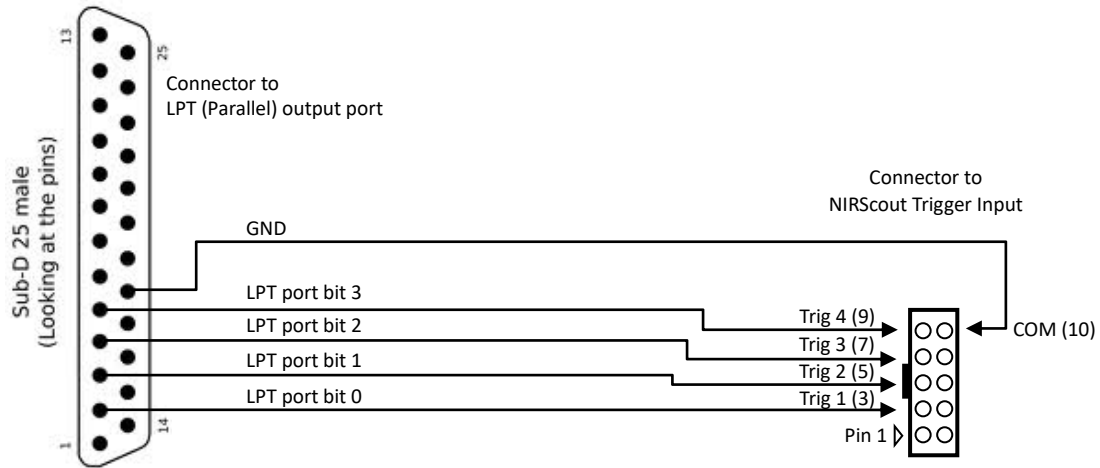


Fig. 6: Connection schematic of the NIRScout trigger cable.

5.4 Disposables

Third-party disposables such as spatulas (for parting hair), contact gel, etc. may be used as long as the applicable directives for medical safety (biocompatibility, etc.) are complied with. To assure uncompromised data quality, we strongly advise use of disposables recommended by NIRx.

6 NIRScout Extended (NIRScoutX) Devices

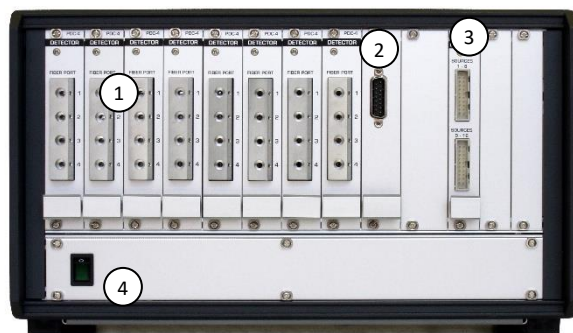


Fig. 7: Front view of the NIRScoutX 816 imaging system. (1) Quad-channel detection cards QDC-10; (2) Trigger input/output card; (3) Led driver card LED-82; (4) Mains On/Off switch.

6.1 Overview

NIRScoutX is functionally identical to the NIRScout products but offers the following extended capabilities:

- Up to 32 fiber-based detection channels
- Up to 48 LED illumination sources
- Up to 8 digital input channels
- Up to 8 digital output channels

NIRScoutX is operated through the same acquisition software NIRStar. For details please refer to the NIRStar User Manual.

6.2 Hardware Components

6.2.1 Main Frame

The instrument's form factor is based on the 19-inch rack enclosure industry standard. The NIRScoutX front panel is 63 horizontal partitions wide (= 320 mm (12.6")) and 4 height units high (= 177.8 mm (7")). All the main functional components are implemented as modular electronic cards, which can be inserted as required by the system's configuration. The back of the enclosure contains the AC mains power entry, USB connector, and cooling fan exhaust. The main On/Off switch is located to the lower left of the instrument front. Fig. 7 shows the front view of the instrument

6.3 USB Connection

The USB connection achieves all functions of instrument control and signal acquisition. The USB connection will activate several seconds after turning on the instrument. The USB cable may remain in place while the device is not in use and during powering the system on or off. There is no status indicator for USB connectivity to the host on the instrument.

6.4 LED Driver Card

Up to three 8-channel or 16-channel LED driver cards may be used in the three leftmost slots of the instrument front. These **must** be populated in order from left to right. Any combination of 8- or 16-channel cards may be used. LED optodes connect in groups of eight to each of the available square 20-pin connectors (Fig. 7). If multiple LED connectors are used, the sources are numbered in order from top to bottom, then left to right (i.e., from the top left to the lower right connector). All LED connections should be established before powering up and operating the instrument. Connecting and disconnecting the LED optode set during operation should be avoided. For details about the LED driver please also refer to section 4.3

6.5 Detector Card

The quad-channel detector (QCD) card is shown in Fig. 3. The fiber port connector accommodates four individual fiber optic cables, which are secured by individual set screws. The instrument accommodates between one and eight QCD modules, or 4 – 32 optical detection channels. For proper operation, detector cards must be populated continuously, starting at the leftmost position of the front panel. Individual detector channels are numbered consecutively from top to bottom within a card, and then left to right across cards. For details about the detector card driver please also refer to section 4.4

6.6 Digital I/O Trigger Card

Fig. 8 shows the trigger card front panel. Eight parallel digital inputs (TTL level, **positive** edge triggered) are available for synchronizing the NIRS measurement with external event trigger markers. All inputs are optically isolated from the instrument electronics to enhance safety and signal integrity. The digital input is a male 15-pin, D-Sub connector with the following pinout (see Fig. 8): Pins 1..8 correspond to digital input channels 1..8 (or, bits 0..7). Pin 12 is signal return (GND). The instrument is supplied with a 3-m long, 15-lead flat ribbon cable which may be used to connect the trigger input to a standard PC parallel (LPT) port, mapping LPT output lines (bits) 0..7 to trigger inputs 1..8.

Connector: Sub-D 15-pin male connector (pinout, see Fig. 8)

Logic level: *Positive* edge triggered (i.e. low-to-high transitions) TTL level.

Minimum pulse duration: Timing pulses should be at least 1 ms long.

Maximum pulse duration: There is no restriction on the maximum duration or repetition rate.

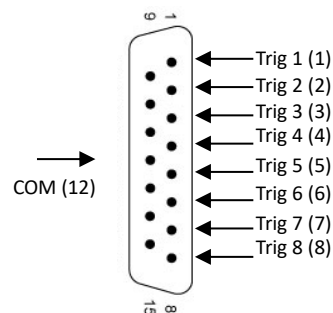
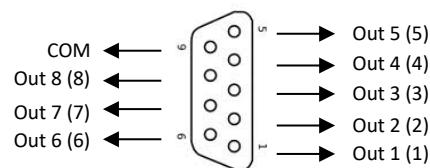


Fig. 8: Pinout of trigger input connector. Trig 1...8 denote the Trigger input lines, and numbers in parentheses denote pin numbers. COM: common (= Ground).

The Trigger Card is available with a second connector (9-pin female D-sub) for the generation of digital output signals for synchronization purposes. All outputs are optically isolated from the instrument electronics to enhance safety and signal integrity. The digital output is a female 9-pin, D-Sub connector with the following pinout (see Fig. 9): Pins 1..8 correspond to digital output channels 1..8 (or, bits 0..7). Pin 9 is signal return (GND).



Connector: Sub-D 9-pin female connector (pinout, see Fig. 8)

Logic level: TTL, program-specified pulsed or levels

Minimum pulse duration: 1 ms

Maximum pulse duration: N/A.

Fig. 9: Pinout of the trigger output connector. Trig 1...8 denote the trigger output lines, and numbers in parentheses denote pin numbers. COM: common (= Ground).

6.7 Optical Probes

Fiber optical detection probes and LED illumination sources are identical to those used with NIRScout. For details of use and proper handling, please refer to Section 4.5.

7 Accessories

All accessories and replacement parts are to be obtained only through NIRx directly, or from authorized sales partners. Disposables may only be used if obtained from NIRx or authorized dealers, or with the expressed approval by NIRx.

7.1 Fiber optic probes and Led illuminators

A wide range of fiber optic probes and LED illuminators is available for the NIRScout Series to suit a diverse range of intended user applications. To provide up-to-date information about available products, please inquire with NIRx or one of its authorized vendors.

7.2 Probe holders / Head Gear

A wide range of head caps and probe holders is available for the NIRScout Series to suit the diverse range of intended user applications. To provide up-to-date information about available products, please inquire with NIRx or one of its authorized vendors.

7.3 Cables

For the USB connection to the controller board, a generic cable of suitable length conforming to USB 2.0 guidelines may be used (a suitable cable is included with the instrument).

For power mains connection, a generic power cord may be used that adheres to the following: Three-wire cable with neutral, live phase, and protective earth wires of sufficient cross-section (1mm² minimum for each wire), IEC C13 type connector for instrument connection, and applicable approvals or certification (e.g., EU: VDE, TÜV, GS,... US: CSA, UL, ... etc.).

A 3-m long trigger cable is included with the instrument, which connects a standard PC parallel port (25-pin sub-D female connector) to the 15-pin sub-D connector at the Trigger I/O card front panel. The cable connections are shown for reference in the following figure:

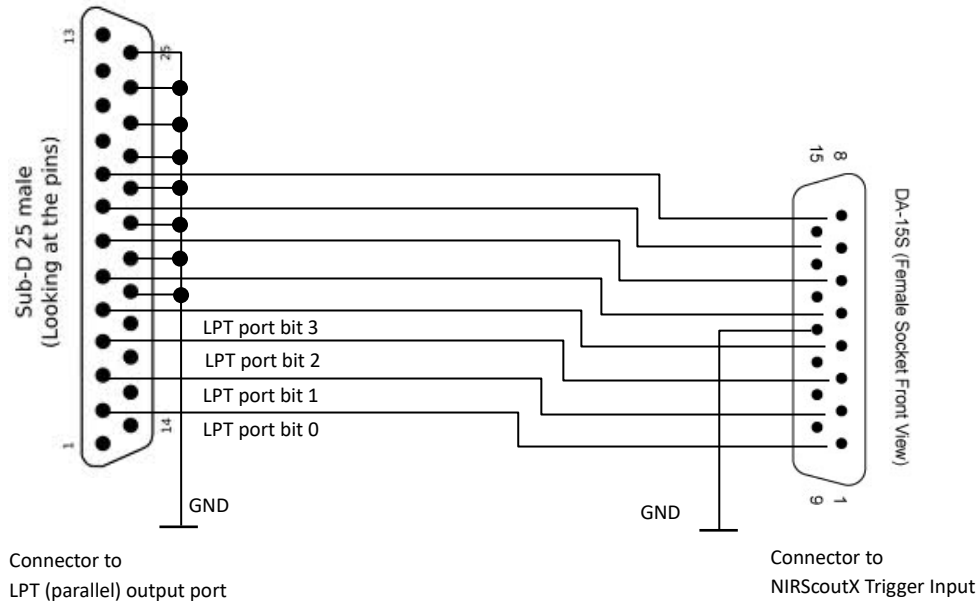


Fig. 10: Connection schematic of the NIRScoutX trigger cable.

8 NIRScout Extended Plus (NIRScoutXP) Devices

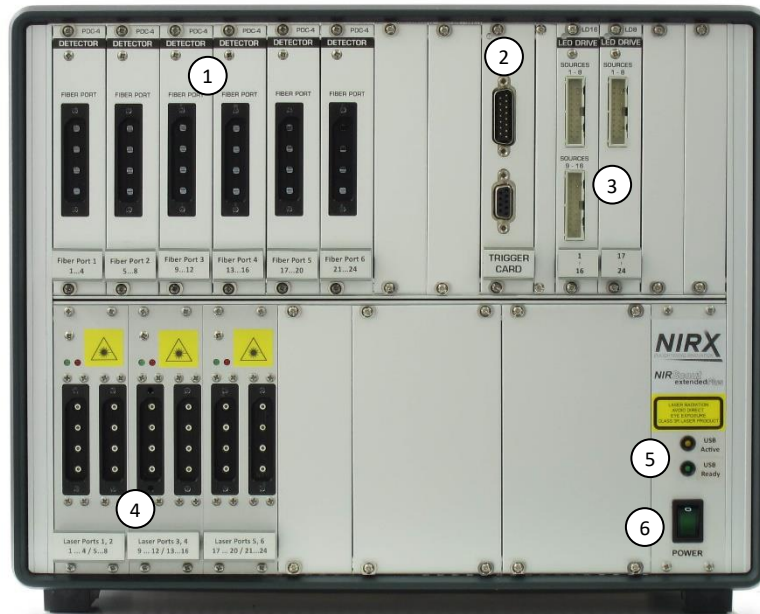


Fig. 11: Front view of the NIRScoutXP 2424 imaging system. (1) Quad-channel detection cards QDC-10; (2) Trigger input/output card; (3) Hybrid Led-Laser driver card; (4) Laser source cards; (5) USB status indicators; (6) Mains On/Off switch.

8.1 Overview

CLASS 1 LASER PRODUCT. Avoid Long-term viewing of laser.

The Device emits visible and invisible Laser radiation. Avoid direct eye exposure:



Class 1

- Do not stare into the expose illumination fiber end
- Do not leave the laser output disconnected from the illumination fibers during operation; do not stare into the open laser ports.
- Only operate instrument after all source fibers are connected, and the source fibers are placed and secured on the target or are otherwise covered by suitable means (e.g., inserted in test medium).

NIRScout Extended Plus is functionally identical to the NIRScoutX products but offers optional integrated, fiber-based laser illumination at up to 64 source channels at 2 wavelengths or up to 32 sources at 4 wavelengths.

The system can be software-configured to either be operated in laser or in LED illumination mode. For details, please see NIRStar™ recording software User Manual.

8.2 Hardware Component

8.2.1 Main Switch and Status Lights

The lower right of the system front panel contains the mains (AC) power switch to turn on the instrument. In the OFF position, a '0' symbol is visible on the upper face of the rocker switch. When turned to the 'ON' position, the switch is illuminated green.

Above the power switch, two indicator LEDs report the status of the USB link to the host PC. The lower (green) LED lights up as soon as a stable USB connection with the PC is established. The upper (yellow) LED turns on when there is data activity over the USB line (i.e., while running the NIRStar software).



8.2.2 Hybrid Laser/LED Driver Card

NIRScoutXP systems with Laser option are equipped with hybrid LED/Laser driver cards, which can be software-switched to operate either LED or Laser sources. Each hybrid LED-Laser driver card can supply up to 16 LED sources at 2 wavelengths or 16 Laser sources at 2 wavelengths (8 lasers/4 wavelengths optional). The driver is internally connected to the laser source cards. The selection of LED vs. Laser operation is made in the operator software (NIRStar™).

LED Operation

Connect LED bundles as you would normally to the front panel connectors labeled, 'SOURCES 1 – 8' or, 'SOURCES 9 – 16' (see, 4.5.2). Set NIRStar software to 'LED Illumination mode' and proceed with the measurement (see NIRStar™ User Manual).



Laser Operation

Be sure to connect the laser source fibers to the Laser Ports of the laser source card (see figure on the right).

Set NIRStar software to 'Laser Illumination mode' and proceed with the measurement (see NIRStar™ User Manual). When set to 'Laser' mode, the green indicator light on the upper left side of each laser card will light up to indicate laser mode operation.

The second (red) indicator will light up whenever the laser is activated (i.e., during the acquisition process).



Laser Connectors and laser Safety Interrupt

The fiberoptic Connectors for laser and detector fibers are keyed in different ways to prevent confusion when connecting these to the instrument. Fig. 12 illustrates the difference for the plugs and receptacles.



The laser fiber receptacle is equipped with a sensor which interrupts the laser radiation whenever the laser fiber plug is removed from the receptacle. This is a safety feature to avoid a freely propagating laser beam to be emitted by the instrument and to make sure that laser radiation is applied to the tissue only through the proper optical fiber bundles. The sensor is activated by a small magnet that is situated near the front edge of the laser fiber connector (see picture).

Fig. 12: Difference between the connections used for laser and detector fiberoptics. Left: Comparison of plug for laser (bottom) and detector(top) cable. Center: Receptacle for laser fiber. Right: Receptacle for detector fiber.

laser fiber plug is removed from the receptacle. This is a safety feature to avoid a freely propagating laser beam to be emitted by the instrument and to make sure that laser radiation is applied to the tissue only through the proper optical fiber bundles. The sensor is activated by a small magnet that is situated near the front edge of the laser fiber connector (see picture).



When operating the instrument in Laser mode it is critically important to make sure that:



- The full number of available source channels is specified in the Hardware Specification section of NIRStar's Hardware Configuration menu (see NIRStar™ manual)
- That all LED bundles are disconnected.
Failure to observe these guidelines may result in corrupted data.

CLASS 1 LASER PRODUCT. Avoid Long-term viewing of laser.

The Device emits visible and invisible Laser radiation. Avoid direct eye exposure:



Class 1

- Do not stare into the expose illumination fiber end
- Do not leave the laser output disconnected from the illumination fibers during operation; do not stare into the open laser ports.
- Only operate instrument after all source fibers are connected, and the source fibers are placed and secured on the target or are otherwise covered by suitable means (e.g., inserted in test medium).

Error Messages and Trouble Shooting

Error / Warning / Problem	Potential Cause	Recommended Action
Power LED does not light up	No power to instrument	Check if power switch is turned on
		Check if AC line is properly connected.
		Check fuses and replace if necessary
Status LED does is off or on continuously	No data connection to PC	Reconnect USB cable
		Try different cable or different port
		Make sure software and drivers are installed
Software error message: 'Device may not be connected'	No data connection to PC	Make sure USB connection is established (Status LED blinking)
Large number or all channels go to highest gain setting	Low or no signal in all channels	Check connection of LED POD
		Check if LEDs are blinking during scanning
		Check connection of the fiber optic bundles
		Check proper placement of probes on subject's head
		Check for damage on LED illuminator or fiber optic cable
All detectors show maximum gain for the same source	Low signal from the source	Check optical coupling of the affected source to the skin, if needed part hair, apply coupling gel, apply gentle pressure through outer cap or bandage
No or low reading for one source, at one wavelength	Damage to LED driver or LED optode	Restart instrument, and without performing performing calibration start scan and point affected LED directly into a detection fiber tip or detector channel port. If OK there should be a stable reading for both wavelength plots in the scan screen (display set to raw data)
All sources show maximum gain and low signal for the same detector channel	Low signal from the detector	Check optical coupling of the affected detector to the skin, if needed part hair, apply coupling gel, apply gentle pressure through outer cap or bandage
		Check connection of affected fiber optic cable to the instrument
Data overly noisy	Ambient light interference	Make sure head is well shielded and/or not directly illuminated by ambient light, in particular fluorescent tubes.

8.3 List of Approved Accessories

#	Part No.	Name	Description
1	FOB-XX	Fiber optic bundle	Fiber optic cable for detection or illumination, various lengths, diameters, and tip designs
2	NLP-8-XX	LED POD	LED illuminator (8 channels, 2 wavelengths) various lengths and tip designs
3	L2F-8-XX	LED-to-fiber coupler	Couples LED light into illumination fiber bundles (8 channels, 2 wavelengths)
	P2B-8-XX	Parallel-to-BNC adapter	Adapter box to connect parallel (25-pin) to BNC trigger input connectors
	P2SUB-15-XX	Parallel-to15-pin	Adapter cable to connect parallel-cable (25-pin) to 15-pin Sub-D trigger input (NIRScoutX only)
	P2SUB-9-XX	Parallel-to9-pin	Adapter cable to connect parallel-cable (25-pin) to 9-pin Sub-D trigger output (NIRScoutX only)
	P2IDC-10-XX	Parallel-to10-pin	Adapter cable to connect parallel-cable (25-pin) to 10-pin IDC trigger input
4	NMA-XX	Mechanical arm	Articulated arm for support of fiberoptics and LED cables
5	NBP-XX	Base plate	Mounting plate to stabilize NIRScout and to provide mounting point for mechanical arm

9 NIRScout / NIRScoutX Technical Specifications

All specifications apply to NIRScout ('NSC') and NIRScoutX ('NSX') and NIREcsoutSP ('NSXP') instruments, unless otherwise indicated.

Optical Detection

No. of Channels	NSC: 4-24 (Parallel Digital Demodulation) NSX: 4-32 (Parallel Digital Demodulation)
Sensitivity	better 1 pW NEP (SiPD) better 200 fW NEP (APD)
Dynamic Range	>90dB _{opt} (SiPD) >70 dB _{opt} (APD)
Sensor Type	Si Photodiode (SiPD) or Avalanche Photodiode (APD)

Optical Illumination (LED)

No. of Illumination Sources	NSC: 8/16 (Time-Multiplexed) NSX: 8-48 (Time-Multiplexed)
Wavelengths	760 nm, 850 nm (Frequency-Encoded)
Power	25 mW _{max} / Wavelength
Multiplexing Rate	62.5 Hz / (No. of Sources) standard 100 Hz / (No. of Sources) optional
Emitter Type	LED

Optical Illumination (Laser)

No. of Illumination Sources	4-64 (Time-Multiplexed)
Wavelengths	785 nm, 830 nm (Frequency-Encoded) 808 nm, 850 nm added for 4-WL systems
Power	20 mW / Wavelength
Multiplexing Rate	62.5 Hz / (No. of Sources) standard 100 Hz / (No. of Sources) optional
Emitter Type	Laser diode
Laser Class.....	Class 1 (For minimum of 2 source switching steps; enforced by software)

Communication

Host	USB 2.0
Experiment	NSC: TTL (4x Trigger in, falling edge, 1x Frame out) NSX: TTL (8x Trigger in, rising edge, 8x programmable digital out)

Electrical

Supply Voltage	90-250 VAC (50-60Hz)
Power consumption.....	175 W, max
Phases	1

Physical

Size (W × L × H)	NSC: 257 mm (42HP) × 326 mm × 165 mm (3U)
	NSX: 365 mm (63HP) × 326 mm × 204 mm (4U)
	NSX+: 365 mm (63HP) × 330 mm × 280 mm (6U)
Weight	NSC: 6 kg, max
	NSX: 11kg, max
	NSX+: 13 kg, max.

Environmental

Temperature range	10°C to 40°C (operating)
	-15°C to +70°C (storage and transport)
Humidity.....	20 to 80% relative humidity non-condensing
Ambient pressure.....	700 hPa to 1060 hPa

Classification

Degree of electric shock protection	Class I
Type of electric shock protection	Type BF
Degree of liquid ingress protection	IPX 0 (not protected)
Mode of operation	Continuous
Marking	CE
Conformity	DIN EN 60601-1:2007, DIN EN 60601-1-2:2007

Optical Safety

The device uses low-power NIR LED illumination and is deemed eye safe ('Exempt').

The optional laser illumination falls under Laser Class 1 for the intended use and operation.

Methods of sterilization or disinfection

Applied parts (fiber optic probe tips) can be disinfected with diluted isopropyl ('rubbing') alcohol 70%. Fiber optics are NOT suitable for autoclaving. Fiber optics /LED probes and fabric caps are suitable for cold-gas sterilization. Please see also section "Cleaning, sterilization, and disinfection" on p.5.

Degree of safety in the presence of flammable anesthetics

The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Declaration of Electromagnetic Emissions/Immunity

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). The equipment needs to be installed and put into service in EMC environments compliant with the directives for Medical Electrical Devices.

Mobile and portable RF communications devices can affect the equipment.

Accessories and cables compliant with the EMC test results

- Unshielded power cord, 250VAC, 6A, 5 m length max.
- NIRx LED illumination probe Type NLP-8



WARNING! Accessories and cables other than those specified, with the exception of parts sold by NIRx as replacement parts for internal components, may result in increased emissions or decreased immunity of the NIRScout instrument.



WARNING! The NIRScout should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the instrument should be observed to verify normal operation in the configuration in which it will be used.

10 Appendices

NIRx Medizintechnik GmbH
Berlin, Germany



Konformitätserklärung Declaration of Conformity

“ NIRScout“

Bestellnummer / Article No.: NIRScout

Seriennummer / Serial No.: Wird bei Lieferung ergänzt/will be added when delivered

The product complies with the essential requirements and provisions of following standards and guidelines:

DIN EN 60601-1:2007	Medical devices: General safety requirements
DIN EN 60601-1-2:2007	Medical devices: Electromagnetic compatibility

Intended Use:

Quantification of relative concentration changes of oxy- and deoxy-hemoglobin in tissue blood based on superficial diffuse near-infrared spectroscopic measurements.

The product is marked with



Zusätzliche Angaben / Additional Information:

Das Produkt ist kein Medizinprodukt. This Product is not a medical device.

Diese Erklärung wird abgegeben in alleiniger Verantwortung des Herstellers:
Aforesaid is declared under the sole responsibility of the manufacturer:

NIRx Medizintechnik GmbH
Gustav-Meyer-Allee 25
13355 Berlin, Germany

Berlin, 2017-11-20

DR. CHRISTOPH SCHMITZ
Geschäftsführer
Managing Director

Fig. 7: Declaration of CE Conformity for the NIRScout Imaging System

NIRx Medizintechnik GmbH
Berlin, Germany



Konformitätserklärung Declaration of Conformity

“ NIRScout Extended / NIRScoutX “

Bestellnummer / Article No.: NIRScoutX

Seriennummer / Serial No.: Wird bei Lieferung ergänzt / will be added when delivered

The product complies with the essential requirements and provisions of following standards and guidelines:

DIN EN 60601-1:2007	Medical devices: General safety requirements
DIN EN 60601-1-2:2007	Medical devices: Electromagnetic compatibility

Intended Use:

Quantification of relative concentration changes of oxy- and deoxy-hemoglobin in tissue blood based on superficial diffuse near-infrared spectroscopic measurements.

The product is marked with



Zusätzliche Angaben / Additional Information:

Das Produkt ist kein Medizinprodukt. This Product is not a medical device.

Diese Erklärung wird abgegeben in alleiniger Verantwortung des Herstellers:
Aforesaid is declared under the sole responsibility of the manufacturer:

NIRx Medizintechnik GmbH
Gustav-Meyer-Allee 25
13355 Berlin, Germany

Berlin, 2018-09-05

DR. CHRISTOPH SCHMITZ
Geschäftsführer
Managing Director

Fig. 8: Declaration of CE Conformity for the NIRScoutX Imaging System

NIRx Medizintechnik GmbH
Berlin, Germany



Konformitätserklärung Declaration of Conformity

“ NIRScout Extended Plus / NIRScoutXP “

Bestellnummer / Article No.: NIRScoutXP

Seriennummer / Serial No.: Wird bei Lieferung ergänzt / will be added when delivered

The product complies with the essential requirements and provisions of following standards and guidelines:

DIN EN 60601-1:2007	Medical devices: General safety requirements
DIN EN 60601-1-2:2007	Medical devices: Electromagnetic compatibility

Intended Use:

Quantification of relative concentration changes of oxy- and deoxy-hemoglobin in tissue blood based on superficial diffuse near-infrared spectroscopic measurements.

The product is marked with



Zusätzliche Angaben / Additional Information:

Das Produkt ist kein Medizinprodukt. This Product is not a medical device.

Diese Erklärung wird abgegeben in alleiniger Verantwortung des Herstellers:
Aforesaid is declared under the sole responsibility of the manufacturer:

NIRx Medizintechnik GmbH
Gustav-Meyer-Allee 25
13355 Berlin, Germany

Berlin, 2017-12-05

DR. CHRISTOPH SCHMITZ
Geschäftsführer
Managing Director

Fig. 9: Declaration of CE Conformity for the NIRScoutXP Imaging System





ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety

Akkreditierung Austria is Full Member of the International Laboratory Accreditation Cooperation ILAC and Signatory of the MRA for "Testing, Calibration and Inspection".

TEST REPORT NO. LE-L143/17

Subject: Laser classification according to IEC 60825-1:2014, Edition 3.

Ordered by: NIRx Medizintechnik GmbH

Address: Gustav-Meyer-Allee 25
13355 Berlin
GERMANY

On: NIRScoutXP

Conclusion: Within the scope of this test report the product „NIRScoutXP“ can be assigned to Laser Class 1 according to IEC 60825-1:2014, Ed. 3, if a minimum of two illumination (source) channels are activated.
If only the first source channel ("S1") is activated the product under test would be assigned to Laser Class 3R.

This report contains the pages 1 to 8.

Authorized person



Dr. Karl Schulmeister

Test performed by:




Dr. Georg Veés



Date: 11.12.2017
Internal Order Number: L-1734

Comments:
This test report refers exclusively to the test subject and to the configuration of the test subject at the date of test. Subsequent changes of the test subject are not covered by this test report.
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Fig. 10: Certification of Laser Class 1 for NIRScoutXP (2-wavelength)



ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety

TEST REPORT NO. LE-L105/18

Subject: Laser classification according to IEC 60825-1:2014, Edition 3.

Ordered by: NIRx Medizintechnik GmbH


Address: Gustav-Meyer-Allee 25
13355 Berlin
GERMANY

On: NIRScout Extended Plus (NIRScoutXP)
in 4-Wavelength configuration.

Conclusion: Within the scope of this test report the product „NIRScoutXP“ can be assigned to Laser Class 1 according to IEC 60825-1:2014, Ed. 3, if a minimum of two illumination (source) channels is activated.
If only the first source channel (“S1”) is activated the product under test would be assigned to Laser Class 3R.

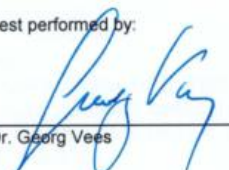
This report contains the pages 1 to 9.

Authorized person



DI Marko Weber

Test performed by:



Dr. Georg Vees

Date: 22.08.2018
Internal Order Number: L-1864

Comments:
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www.seibersdorf-laboratories.at | Landesgericht Wiener Neustadt | FN 319187v | DVR: 4000728 | UID: ATU64767504 | Steuernummer: 192/6571 | Zertifiziert nach ISO 9001:2000
Bankverbindung: Erste Bank der Österreichischen Sparkassen AG | BLZ 20111 | Konto Nr. 291-140-380/00 | IBAN AT112011129114038000 | BIC GIBAATWW

Fig. 11: Certification of Laser Class 1 for NIRScoutXP (4-wavelength)





ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED & Lamp Safety

TEST REPORT

NR. LE-L11/13

Scope: Risk group classification of a LED-product according to EN 62471: 2008

Ordered by: Berlin Cert
Prüf- und Zertifizierstelle für Medizinprodukte GmbH
an der Technischen Universität Berlin

Address: Dovestraße 6
D-10587 Berlin

Test Subject: "NIRScout Xtended" imaging system

Conclusions: According to EN 62471:2008, the device under test was classified as "Exempt Group" under the scope of the test.

This report contains the pages 1 to 8.

Technical responsibility:



Dr. Karl Schulmeister

Test performed by:



DI. Reinhard Gilber

Date: 31.01.2013
Internal Order Number: L-1011

Note:
This test report refers exclusively to the test subject and to the configuration of the test subject at the date of test.
Subsequent changes of the test subject are not covered by this test report.
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Fig. 12: Certification of LED safety (applies to all models)