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Xltek® Trex / Trex HD

User & Service Manual

Publisher's Notice

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XLTEK Trex / Trex HD User & Service Manual

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1. Introduction

The Xltek® Trex amplifier, with its leading-edge mechanical design, provides you with maximum reliability and performance for clinical electroencephalographic (EEG) and polysomnographic (PSG) recordings. It is designed to be used with Natus SleepWorks™ or NeuroWorks® software to assist with diagnosis.

The Trex HD is equipped with a Bluetooth module which communicates wirelessly with a Trex Video Interface that communicates with a video camcorder. The content in this manual applies equally to both Trex and Trex HD devices unless explicitly stated.

The Trex offers these features:

- Connects to ***XLTEK*** computer
- 24 referential AC inputs
- 4 differential AC inputs
- 4 non-isolated DC inputs for connection to ***XLTEK*** patient-worn transducers
- Internal memory for up to 96hr of EEG recording
- Battery powered by two AA alkaline batteries (see Section *12 - Guaranteeing Sufficient Battery Power*)
- Bluetooth module for wireless synchronization with HD video (Trex HD only)
- Isolated serial port
- Patient-event switch interface

WARNING: We strongly recommend that you read the **Warnings and Cautions** section of this manual before operating this amplifier.

1.1. Intended Use

The Trex HD is intended to be used as an electroencephalograph: to acquire, digitized, store and archive electroencephalographic signals.

The Trex HD is intended to be used by either trained medical professionals or someone instructed by a trained medical professional. It is designed for use in clinical environments such as hospital rooms, epilepsy monitoring units, intensive care units, and operating rooms. It can be used with patients of all ages, but is not designed for fetal use.

The sale, distribution, or use of this device is restricted to, by, or on order of a physician.

The Trex HD is supplied with a standard label displaying markings for EEG studies; for convenience when performing Sleep studies, the user may apply the “Trex HD Sleep” label with markings designed for Sleep studies (provided). See “*Section 8 - Unpacking*” for pictures of the labels.

NOTE: The functionality of the Trex HD is not affected by the label and all instructions, warnings and cautions described in this manual still apply.

WARNING: The Trex HD should NOT be used as an apnea monitor.

1.2. Using the Manual

This manual provides basic information and instructions that will enable you to set up and operate the **Trex HD** amplifier. When going through the procedures, we recommend that you read the whole section first, before starting the sequence. In order to achieve the optimal use, Trex HD must be installed and operated according to the instructions provided in this user manual. Please follow all instructions carefully.

NOTE: In addition to reading this manual, we encourage you to explore the online **Help** of the software to enable you to take advantage of everything that **XLTEK** has designed the Trex HD amplifier to do. More detailed instructions relating to the operation and customization of the system are provided in the online Help.

1.3. Manual Conventions

Various symbols and typographical conventions are used throughout the manual. The following table illustrates them and describes their meanings and functions.

Symbol/ Convention	Description/Function
	This symbol denotes a warning or important information that should not be missed. Read all warnings and cautions carefully before starting the system for the first time.
	This symbol indicates a note that contains important supplemental information.
Bold	Names of control keys, function keys, options, and labels are shown in bold. Bold text is also used to emphasize important names or ideas.
Italic	Italic text is used for captions.

2. Safety and Standards Conformity

2.1. Safety and Standards Conformity for XLTEK Trex HD

The following section applies to Trex HD only. For Safety and Standards Conformity for Trex, see *Section 2.2*.

2.1.1. Standards of Compliance and Normative References

Electroencephalograph system, model **Trex HD**; rated two AA 1.5V batteries, 0.065A, 0.170W.

1. Type of protection against electric shock: Internally Powered Equipment
2. Degree of protection against electric shock: Type BF
3. Degree of protection against ingress of water: IPX0
4. Mode of operation: Continuous
5. Environmental Conditions: Normal: 5-40°C, 15-93% rH, 700-1060hPa

Trex HD Video Interface.

1. Type of protection against electric shock: Class II
2. Degree of protection against electric shock: No applied parts
3. Degree of protection against ingress of water: IPX0
4. Mode of operation: Continuous
5. Environmental Conditions: Normal: 5-40°C, 15-93% rH, 700-1060hPa

The **Trex HD** and its accessories have been designed to comply with the following national and international standards.

Table 1 - Safety Standard of Compliance and Normative

CAN/CSA-C22.2 No. 60601-1: 08(R2013) + C2:2011 ANSI/AAMI ES60601-1:2005/(R)2012 + C1:2009/(R)2012 and A2:2010/(R)2012 IEC 60601-1:2005 + C1:2006 and C2:2007, Third Edition CENELEC EN 60601-1:2006 + A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
CAN/CSA C22.2 No 601.1-M90 UL 60601-1:2003 IEC 60601-1:1988 + A1:1991 + A2:1995	Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 60601-2-26:2012, Edition 3 CENELEC EN 60601-2-26 L2003, Edition 2 CAN/CSA C22.2 No. 60601-2-26-04 IEC 60601-2-26: 2002	Medical Electrical Equipment - Part 2-26: Particular Requirements for the Safety of Electroencephalographs
CAN/CSA C22.2 No. 60601-1-4-02 IEC 60601-1-4: 1996 + A1: 1999	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems

EN ISO 80601-2-61:2011, Edition 1	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 60601-1-6:2010, Edition 3.0 CAN/CSA C22.2 No. 60601-1-6-05 IEC 60601-1-6: 2004	Medical Electrical Equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
IEC 62366:2007, Edition 1.0	Medical devices – Application of usability engineering to medical devices
IEC 60601-1-11:2010, Edition 1.0	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
CAN/CSA C22.2 No. 60601-1-1-02 IEC 60601-1-1: 2000	Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems

Table 2 - EMC Standard of Compliance and Normative References

IEC 60601-1-2:2007, Edition 3.0 IEC 60601-1-2:2001 +A1:2004 / EN 60601-1-2:2001 +A1:2006	Medical Electrical Equipment Part 1-2:General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 61000-4-2:2008 / EN 61000-4-2:2009	Electromagnetic Compatibility (EMC) Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test
IEC 61000-4-3:2006 +A1:2007 +A2:2010 / EN 61000-4-3:2006 +A1:2008 +A2:2010	Electromagnetic Compatibility (EMC) Part 4-3: Testing and Measurement Techniques - Radiated, Radio-frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:2012, ed 3.0 IEC 61000-4-4:2004 +A1:2010 / EN 61000-4-4:2004 +A1:2010	Electromagnetic Compatibility (EMC) Part 4-4: Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:2014, ed 3.0 IEC 61000-4-5:2005 / EN 61000-4-5:2006	Electromagnetic Compatibility (EMC) Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6:2008 / EN 61000-4-6:2009	Electromagnetic Compatibility (EMC) Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-frequency Fields
IEC 61000-4-8:2009 / EN 61000-4-8:2010	Electromagnetic Compatibility (EMC) Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:2004 / EN 61000-4-11:2004	Electromagnetic Compatibility (EMC) Part 4-11: Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests

IEC 61000-3-2:2014, ed 4.0 IEC 61000-3-2:2005 +A1:2008 +A2:2009 / EN 61000-3-2:2006 +A1:2009 +A2:2009	Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits for Harmonic Current Emissions
IEC 61000-3-3:2013, ed 3.0 IEC 61000-3-3:2008 / EN 61000-3-3:2008	Electromagnetic Compatibility (EMC) Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
CISPR 11:2009 +A1:2010 / EN 55011:2009 +A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement

2.1.2. Declaration of Compliance for IEC 60601-1-2

Table 1 - Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The **Trex HD** is intended for use in the electromagnetic environment specified below. The customer or the **Trex HD** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Trex HD uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Trex HD is suitable for use in all establishments, including domestic establishments and those directly connected to public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The **Trex HD** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Trex HD** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines N/A – lines <3m	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Line to Line ±2 kV Line to Earth	±1 kV Line to Line ±2 kV Line to Earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% *UT* (>95% dip in *UT*) for 0.5 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles <5% *UT* (>95% dip in *UT*) for 5 sec	<5% *UT* (>95% dip of *UT*) for 0.5 cycle 40% *UT* (>60% dip of *UT*) for 5 cycles 70% *UT* (>30% dip of *UT*) for 25 cycles <5% *UT* (>95% dip of *UT)* for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Trex HD** requires continued operation during power mains interruption, it is recommended that the **Trex HD** to be powered from a suitable uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *UT* is the AC supply voltage prior to application of the test level.			

Table 3 - Electromagnetic Immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The **Trex HD** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Trex HD** should assure that it is used in such an environment.			
Immunity test	**Test Level IEC60601-1-2**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Trex HD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d=1.2 \times \sqrt{P}$ 150kHz to 80MHz $d=1.2 \times \sqrt{P}$ 80MHz to 800MHz $d=2.3 \times \sqrt{P}$ 800MHz to 2.5GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic Site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:  .
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Trex HD** is used exceeds the applicable RF compliance level above, the **Trex HD** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Trex HD**.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Trex HD

The **Trex HD** is intended for use in the electromagnetic in which radiated RF disturbances are controlled. The customer or user of the **Trex HD** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Trex HD** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to the frequency of transmitter (m)**		
	from 150kHz to 80MHz **d= 1.2 x √P**	**from 80MHz to 800MHz** **d= 1.2 x √P**	**from 800MHz to 2.5GHz** **d= 2.3 x √P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

2.1.3. Electromagnetic Immunity (EMI) Information – FCC

NOTE: This equipment has been tested and found to comply with the limits for Class B digital devices, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

WARNING: Changes or modifications not expressly approved by ***XLTEK*** may void the user's authority to operate the equipment.

2.2. Safety and Standards Conformity for XLTEK Trex

The following section applies to Trex only. For Safety and Standards Conformity for Trex HD, see *Section 2.1*.

2.2.1. Standards of Compliance and Normative References

Electroencephalograph system, model Trex; rated two AA 1.5V batteries, 0.065A, 0.170W.

1. Type of protection against electric shock: Internally Powered Equipment
2. Degree of protection against electric shock: Type BF
3. Degree of protection against ingress of water: IPX0
4. Mode of operation: Continuous
5. Environmental Conditions: Normal: 10-40°C, 30-75% rH, 700-1060hPa

The Trex and its accessories have been designed to comply with the following national and international standards.

Table 1 – Safety Standard of Compliance and Normative References

CAN/CSA C22.2 No 601.1-M90	Medical Electrical Equipment Part 1: General Requirements for Safety
CAN/CSA C22.2 601.1S1:1994	Supplement No 1-94 to CAN/CSA C22.2 601.1-M90 Medical Electrical Equipment Part 1: General Requirements for Safety
CAN/CSA C22.2 601.1B-90:1998	Amendment 2 to CAN/CSA C22.2 601.1-M90 Medical Electrical Equipment Part 1: General Requirements for Safety

UL 60601-1:2003	Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 601-1:1988 + A1:1991 + A2:1995	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-2-26:1994	Medical electrical equipment Part 2-26: Particular Requirements for the Safety of Electroencephalographs
IEC 60601-1-4:2000 (1.1 Ed.)	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems

Table 2 – EMC Standard of Compliance and Normative References

IEC 60601-1-2:2001 / EN 60601-1-2:2001 (2nd Ed)	Medical Electrical Equipment Part 1-2:General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 61000-4-2:1995 / EN 61000-4-2:2001	Electromagnetic Compatibility (EMC) Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test
IEC 61000-4-3:1995 / EN 61000-4-3:2001	Electromagnetic Compatibility (EMC) Part 4-3: Testing and Measurement Techniques - Radiated, Radio-frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:1995 / EN 61000-4-4:2001	Electromagnetic Compatibility (EMC) Part 4-4: Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:1995 / EN 61000-4-5:2001	Electromagnetic Compatibility (EMC) Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6:1996 / EN 61000-4-6:2003	Electromagnetic Compatibility (EMC) Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-frequency Fields
IEC 61000-4-8 / EN 61000-4-8	Electromagnetic Compatibility (EMC) Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:1994 / EN 61000-4-11:2000	Electromagnetic Compatibility (EMC) Part 4-11: Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
IEC 61000-3-2:1995 / EN 61000-3-2:2001	Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits for Harmonic Current Emissions
IEC 61000-3-3:1994 / EN 61000-3-3:1998	Electromagnetic Compatibility (EMC) Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
EN50082-1:1997	Electromagnetic compatibility. Generic immunity standard. Part 1: Residential, commercial and light industry

EN50082-2:1995	Electromagnetic compatibility. Generic immunity standard. Part 2: Industry
CISPR 11:2003 / EN 55011:2003 Class B, Group 1	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement
ANSI C63.4:2004	American National Standard for Methods of Measurement of Radio-noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9KHz to 40 GHz
CISPR 16-1-1:2004	Specification for Radio Disturbance and Immunity Measuring Apparatus and Methods. Part 1-1: Measuring Apparatus

2.2.2. Declaration of Compliance for IEC 60601-1-2

Table 1 - Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The **Trex** is intended for use in the electromagnetic environment specified below. The customer of the **Trex** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The **Trex** uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The **Trex** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Table 2 - Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The **Trex** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Trex** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% *UT* (>95% dip in *UT*) for 0.5 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles <5% *UT* (>95% dip in *UT*) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Trex** requires continued operation during power mains interruption, it is recommended that the **Trex** to be powered from a suitable uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *UT* is the AC supply voltage prior to application of the test level.			

Table 3 - Electromagnetic Immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The Trex is intended for use in the electromagnetic environment specified below. The customer or the user of the Trex should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>Test Level IEC60601-1-2</th><th>Compliance Level</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>Conducted RF IEC 61000-4-6

Radiated RF IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>Complies</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Trex, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance:
d=1.2 ×√P 150kHz to 80MHz
d=1.2 ×√P 80MHz to 800MHz
d=2.3 ×√P 800MHz to 2.5GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic Site[c], should be less than the compliance level in each frequency[d].
Interference may occur in the vicinity of equipment marked with the following symbol:  .</td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Trex** is used exceeds the applicable RF compliance level above, the **Trex** should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the **Trex**.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Trex

The **Trex** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Trex** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Trex** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to the frequency of transmitter (m)**		
	from 150kHz to 80MHz	**from 80MHz to 800MHz**	**from 800MHz to 2.5GHz**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3. Warnings and Cautions

3.1. General Warnings

NOTE: It is recommended that all data be stored using redundant storage capabilities. This can help to minimize data loss in the event of a failure of the primary drive.

⚠	Proper use of this device depends on the careful reading of all instructions and labels that come with or on the system. Inaccurate measurements may be caused by incorrect application or use.
⚠	The amplifier is classified as an IP0 – ordinary degree of protection against ingress of water according to IEC 529. The amplifier is classified as a class II device according to IEC601-1.
⚠	The computer used with a Trex HD amplifier must either be approved by ***XLTEK*** and supplied as part of an IEC 601 approved system, or it must be approved to IEC 950 or similar and kept outside of the patient environment, (that is, at least 1.5 meters from the patient laterally and not within a height of 2.5 meters from the floor in the area occupied by the patient).
⚠	Only use the Trex/Trex HD in conjunction with approved devices and accessories. Use of cables other than those specified or sold by the manufacturer on the equipment, may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2007
⚠	To ensure the validity of signals, do not operate the device near any sources of electromagnetic interference.
⚠	**Electrostatic Discharge (ESD) Precaution:** Be sure to take the appropriate Electrostatic Discharge (ESD) precautions. Disconnect the cables before moving, cabling, or performing any set up procedures. Connectors marked with the ESD protection symbol should not be touched. For detailed handling procedures, see *Section 3.6*.
⚠	Turn off all system power and disconnect the power cord from the system and the wall before attempting to clean the unit. The Trex HD unit can be wiped clean with a soft, damp cloth using non-conductive distilled water, electrically non-conductive inert surfactants or an ***XLTEK*** -approved cold sterilizing agent. It is important to dry off the unit quickly. Avoid letting liquid seep into any of the internal electronics of the system. Do not use any abrasive cleaner on the system.
⚠	When the Trex amplifier is in the IPX2-certified pouch, it is offered protection from dripping water from above the device for up to 10 minutes in duration.

	***XLTEK*** systems are not AP or APG rated. **DO NOT USE** an ***XLTEK*** system in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
	Device accessories may include several kinds of disposable, sterile needle electrodes. These needles are labeled as **STERILE** and the method of sterilization is documented on the packaging. These electrodes should not be used if the sterile packaging has been tampered with.
	The two AA batteries used to operate the Trex HD should be removed if the Trex HD is not likely to be used for some time.
	Dispose of used, non-rechargeable batteries in accordance with local regulations.
	The Trex HD needs special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and operated according to EMC guidelines (see *Section 2.1.2*).
	Using the Trex HD with cables and accessories not approved by ***XLTEK*** may negatively affect EMC performance, including electromagnetic immunity (see *Section 2.1.3*).
	External equipment may interfere with the performance of the **Trex HD,** even if that other equipment complies with CISPR Emission requirements (see *Section 2.1.3*).
	The Trex HD should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the amplifier should be observed to verify normal operation in the configuration in which it will be used. See *Section 2.1.2* for minimum recommended separation distances.
	Do not connect items which are not specified as part of the Trex HD system to the system.
	Never use equipment that has parts missing or equipment that might contain loose parts inside of it (that is, inside an enclosed portion of the equipment). If you suspect a piece of equipment has missing or loose parts, contact ***XLTEK***. Routinely inspect system cables and components for regular wear and tear.
	**WARNING:** Third-party software installed on the acquisition computer may interfere with the operation of the ***XLTEK*** software. Please consult Technical Support before installing third-party software on the computer.
	**WARNING:** No modification of this equipment is allowed.
	The Trex HD is IPX2 marked when inside the carrying case.

3.2. Electrical Warnings and Cautions

	***XLTEK*** systems are intended for connection to a properly grounded electrical outlet only.
	Conductive parts of electrodes and their connectors are not to contact other conductive parts including earth.
	Do not place MULTIPLE PORTABLE SOCKET-OUTLETS (MPSOs) on the floor.
	Do not connect additional MPSOs or extension cords to the Trex HD system.
	Do not use the MPSO with the Trex HD system for supplying power to any equipment that is not part of the system.
	To avoid the possible hazards caused by the summation of leakage currents when all the parts of the system are interconnected, no equipment other than devices connected to the Trex HD may be powered by the isolation transformer.
	The current rating of the isolation transformer must be sufficient to operate all of the devices powered by it. Refer to the current ratings of the isolation transformer and current rating for each individual device connected.
	Do NOT connect non-medical equipment which has been supplied as part of the system directly to the wall outlet when the system is supplied, via MPSO, with a separating transformer.
	Do NOT connect electrical equipment which has not been supplied as a part of the system to the MPSO.
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** turn on the system power until all cables have been connected, verified and visually inspected for any damage. Failure to inspect the cables may result in electrocution. Verification of electrical safety should be performed routinely.
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** service the system. Refer servicing to qualified personnel only. Do **NOT** use repaired components without proper testing.

3.3. Wireless Option Warnings and Cautions*

**Trex HD only, not applicable to Trex*

	The wireless feature of the **Trex HD** presents a synchronization of the EEG signal with the video recording. This feature is not a substitute for other means of patient monitoring and supervision.
	Like other wireless devices, this feature is limited in operating range. The range will also be reduced substantially if there is any physical interference between the Digital Camcorder unit and the **Trex HD**. In either of these situations, the wireless data will not be received by the acquisition computer.
	The **Trex HD** contains FCC ID: **R47F2M03GL** which complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
	The **Trex HD** contains F2M03GLA which has passed the Bluetooth Qualification/Certification process as specified within the Bluetooth Specifications and as required within the PRD 2.0. **QDID: B012541**.
	Mobile RF communications equipment may affect the **Trex HD** and interfere with wireless operation. See Section 2.1.3 for guidelines.

3.4. Patient Environment Warnings and Cautions

NOTE: The patient environment is defined as the area within 1.5 meters of the patient laterally and within 2.5 meters of the floor in the area occupied by the patient.

	The Trex HD amplifier is **NOT** intended for use with High Frequency Surgical Equipment.
	Connect all patient electrodes to fully electrically isolated physiological devices only. Connecting patient electrodes to any other device or external outlet may result in personal injury.
	The amplifier accepts only touchproof style electrode inputs. Do **NOT** attempt to use any other style of patient electrode input.
	The patient event switch attached to the Trex HD is **NOT** intended for critical patient-safety-related incidents.

	Patient connections are **NOT** intended for direct cardiac contact.
	As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
	Connecting other medical equipment, such as an electrical stimulator, simultaneously to the same patient may constitute a safety hazard.
	Do **NOT** touch any Trex HD system accessible metal parts and the patient simultaneously.
	If a computer is located in the patient environment, it must be 60601-1 approved or 60950-1 approved and powered by a 60601-1 approved isolation transformer.
	Do not use the Trex HD system in the vicinity of MRI or CT systems.
	Do not allow loose electrodes to contact metal parts.
	As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
	User is not to position ME equipment in such a way as to make it difficult to operate the disconnection device.
	Potential allergic reactions could occur. Consult clinician on any allergies before use.
	Do not use the Trex HD system when outside its carrying case as the device is not IPX certified when used outside of the case.

3.5. Pulse Oximeter Warnings

	The Nonin XPOD pulse oximeter is to be operated by qualified personnel only. This manual, the instructions for use for any pulse oximeter sensor or cable extender, the accessory directions for use, all precautionary information, and specifications should be read prior to use.
	**EXPLOSION HAZARD:** Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

	A pulse oximeter should **NOT** be used as an apnea monitor.
	A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
	Significant levels of dysfunctional hemoglobins (HbCO or MetHb) may cause inaccurate measurements.
	Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate measurements.
	Excessive illumination may cause inaccurate measurements or loss of pulse signal.
	Excessive patient movement may cause inaccurate measurements.
	Venous pulsations may cause inaccurate measurements.
	Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.
	Loss of pulse signal can occur when the patient has hypotension, severe vasoconstriction, severe anemia or hypothermia.
	Loss of pulse signal can occur when there is arterial occlusion proximal to the sensor.
	Loss of pulse signal can occur when the patient is in cardiac arrest or is in shock.
	Do not immerse the sensor in water, solvents, or cleaning solutions. Do not sterilize the sensor by irradiation, steam or ethylene oxide.
	Do not immerse patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize patient cables by irradiation, steam or ethylene oxide.
	As with all medical equipment, carefully route cables and connections to minimize the possibility of entanglement or strangulation.

	Operation of this module below the minimum amplitude of 0.3% modulation may cause inaccurate results.
	Oximeter readings may be affected by the use of an electrosurgical unit (ESU).
	Inspection of monitors, cables, and probes should be completed prior to each use to ensure compatibility and maintain patient safety.
	The Trex amplifier system does NOT include SpO_2 or Pulse Rate alarms.

3.6. Pulse Oximeter Sensor Warnings

	Before using, carefully read the sensor directions for use.
	Use only Nonin oximetry sensors, as required, for SpO2 measurements. These sensors are manufactured to meet the accuracy specifications for the pulse oximeter. Other oxygen transducers (sensors) may cause improper pulse oximeter performance.
	Tissue damage can be caused by incorrect application or use of a pulse oximetry sensor (i.e. by wrapping the sensor too tightly). Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity and correct positioning and adhesion of the sensor. Patient sensitivity may vary due to medical status or skin condition. Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.
	Do not use pulse oximetry sensors during MRI scanning as this could potentially cause burns. The pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
	Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may cause inaccurate measurements.
	Loss of pulse signal can occur when the sensor is too tight.
	Do not use damaged pulse oximetry sensors. Do not use sensors with exposed optical components. Do not immerse the sensor in water, solvents or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for the reusable pulse oximetry sensors.

	Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for reusable patient cables.
	The oximeter sensor may not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
	A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or its use with the Quantum system.
	Refer to sensor manufacturer instructions for use for recommended maximum application time.

3.7. Transportation Warnings

	Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the system and its components is adequate, sturdy, and safe. Natus is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces. Natus is not responsible for any injury or damage that may result from improper cable storage during transport.
	**TIPPING HAZARD:** During transport, the user should guide the cart using both hands, ensuring the wheel base is aligned so that a single caster leads in the direction of motion. Failure to lead the cart with one wheel could result in a tipping hazard when ascending or descending steps or thresholds.

3.8. Conducted Immunity Warnings

	In environments where parasitic electrical noise interferes with the electrical biologic signal, there is no risk of misinterpretation of EEG waveforms or ancillary data. Any abnormal pattern or out of range value is confirmed by trained medical professionals performing the test. In addition to ancillary data (e.g. SpO2), the accompanying EEG (Electroencephalograph) amplifier's signals will also be contaminated past the point where any clinical signal interpretation is possible. Trained electroencephalographers and technologists are well equipped to identify and disregard signals that are obscured by environmental noise.

4. Procedures and Warnings

4.1. Electrostatic Discharge (ESD) Handling Procedures and Warnings

Before performing any setup or placement procedures, read the precautions outlined in this section.

WARNING: Be sure to take the appropriate Electrostatic Discharge (ESD) precautions. Disconnect the cables before moving, cabling, or performing any set up procedures.

Some semiconductor (solid state) devices can be easily damaged by static electricity. Such components are commonly called Electrostatically Sensitive Devices (ESD). Do not touch the accessible conductive parts for the Connectors marked with the ESD symbol.

Follow these techniques to help reduce the incidence of component damage caused by static electricity:

- Immediately before handling any product components assemblies, drain the electrostatic charge from your body by touching a known earth ground.
- Minimize body motions when handling unpackaged replacement ESDs. Motions such as brushing clothes together or lifting your foot from a carpeted floor can generate enough static electricity to damage the product components.
- Avoid carpets in cool, dry areas. If provided, leave the product components in their anti-static packaging until ready to be installed.
- Take care when connecting or disconnecting cables. When disconnecting a cable, always pull on the cable connector or strain-relief loop, not on the cable itself.

WARNING: A damaged cable can cause a short in the electrical circuit. Prevent damage to the connectors by aligning connector pins before you connect the cable.

WARNING: Misaligned connector pins can cause damage to system components at power-on.

4.2. Conducted Immunity Procedures and Warnings

Conducted immunity is defined as the ability of an electronic product to tolerate the influence of electrical energy from other electronic products or electromagnetic phenomena.

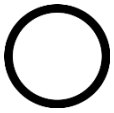
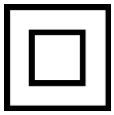
The electrical energy from other electronic devices located in nearby equipment are usually propagated through the connecting cables. The functionality of some Semiconductor devices and high sensitivity amplifiers (EEG, EMG ECG) may be affected by induced parasitic signals.

This effect could be described as noise and/or channel saturation on the EEG waveforms, which are coupled together with off the scale values for auxiliary sensors.

Follow these techniques to help identify the sources, and to increase the immunity towards parasitical noise:

- Verify the power supply and all portable multiple socket-outlets are off the floor and in a dry location.
- If parasitic noise is present on the EEG waveforms, try to identify possible culprits by disconnecting nearby equipment from the common power source.
- Lay out the interconnection cables as far as possible from the cables being used by nearby equipment.
- Verify the Power cord integrity. Do not use portable multiple socket outlets that are not properly grounded.
- Do not use power outlets without a protective ground
- When isolation transformers are used, ensure that the Medical System is properly grounded.

5. Description of Symbols

Symbol	Description
	**ATTENTION:** **Consult Accompanying Documents**
	Consult Accompanying Documents
	Protective Earth (Ground)
	Type BF Equipment
	Dangerous Voltage
	Alternating Current
	Direct Current
	Power On
	Power Off
	EU only: Do Not Dispose as Unsorted Municipal Waste
	CE Mark
	Class II Equipment (non-grounded enclosure)

Symbol	Description
	ESD Sensitive Or Static Sensitive
	RF Equipment for Non-ionizing Radiation

6. Specifications

6.1. XLTEK Trex HD

Specification	Value(s)
Patient Electrical Connections	
24 Referential Inputs (+ ground, + reference)	± 10 mV
Resolution	16 bit A/D
4 Differential Inputs	± 10 mV
Resolution	16 bit A/D
Common Mode Rejection Ratio	-113 dB @ 60 Hz
DC Removal	± 500 mV
Common Mode Input Impedance	> 10 MOhms
Input Noise (peak to peak)	6.4 µV
Input Noise (RMS)	1.08 µV
Input Bias Current	< 10 pA
Channel Crosstalk	56 dB
Electrode Connections (including common input)	Touchproof
4 Non-Isolated DC Inputs	± 5 Volts
Resolution	16 bit A/D
Impedance (kOhm)	<2.5, <5, <10, <25
Channel Test Signal	Software selectable
Sampling Frequency	200 Hz, 256 Hz, 512 Hz
Physical Capabilities	
Oximeter/Photic Stim Connection	Yes (either/or)
Patient Event Button	Yes
Interface Cable	USB 2.0
USB Cable Standard Length	1.8 m (5.9 ft)
Main Unit Weight (g)	300
Main Unit Size (cm)	10 x 15.5 x 2.5 (h x w x d)
Batteries	2 AA
Safety	
Leakage Current	<10 µA with 240 VAC on all electrode inputs

Specification	Value(s)
Operating Parameters	
Operating Environmental Limits	Temperature: 5°C to 40°C
	Humidity: 15% to 93%
	Atmospheric Pressure: 700 hPa to1060 hPa
Transport and Storage Temperature Range	- 40°C to 70°C
Transport and Storage Humidity Range	10% to 100%, including condensation
Transport and Storage Atmospheric Pressure Range	500 hPa to 1060 hPa
Wireless Transceiver - F2M03GLA (Trex HD only)	
Protocol	Bluetooth V2.0 EDR
Operating frequency	2.402 – 2.480 GHz
Transmission power	20dBm
Modulation	GFSK
FCCID	R47F2M03GL

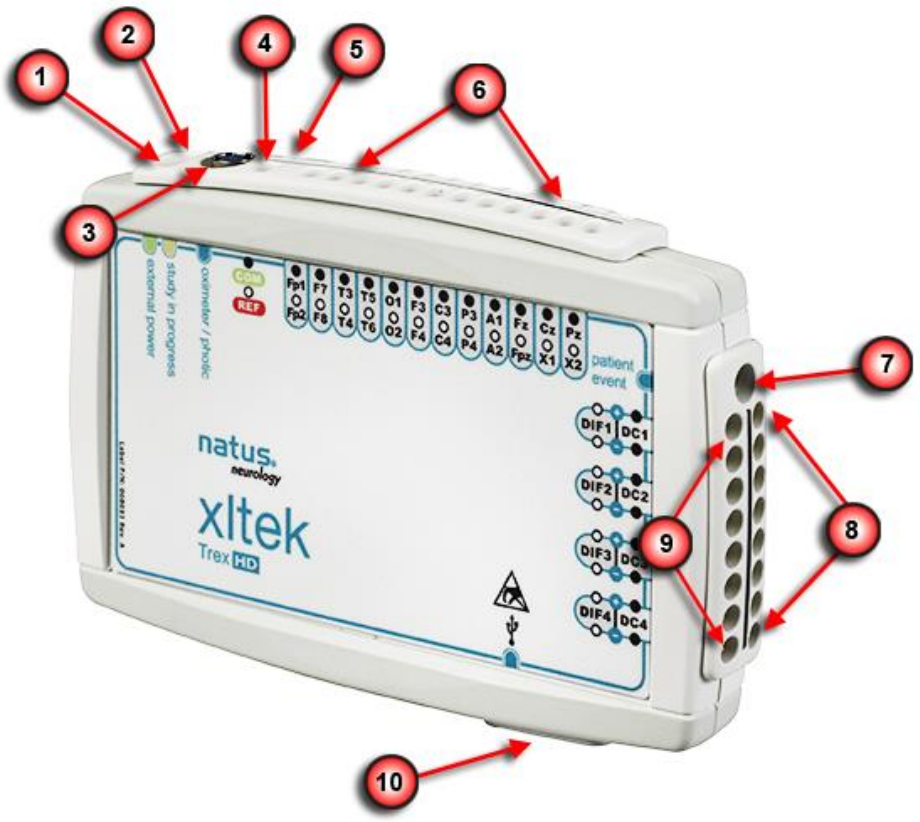
6.2. XLTEK Trex

Specification	Value(s)
Patient Electrical Connections	
24 Referential Inputs (+ ground, + reference)	± 10 mV
Resolution	16 bit A/D
4 Differential Inputs	± 10 mV
Resolution	16 bit A/D
Common Mode Rejection Ratio	-113 dB @ 60 Hz
DC Removal	Infinite
Common Mode Input Impedance	> 10 MOhms
Input Noise (peak to peak)	6.4 µV
Input Noise (RMS)	1.08 µV
Input Bias Current	< 10 pA
Channel Crosstalk	56 dB

Specification	Value(s)
Electrode Connections (including common input)	Safety Touch
4 Non-Isolated DC Inputs	±5 V
Resolution	16 bit A/D
Impedance (kOhm)	<2.5, <5, <10, <25
Channel Test Signal	Software selectable
Sampling Frequency	200 Hz, 256 Hz, 512 Hz
Physical Capabilities	
Oximeter/Photic Stim Connection	Yes (either/or)
Patient Event Button	Yes
Interface Cable	USB 2.0
USB Cable Standard Length	1.8 m (5.9 ft)
Main Unit Weight (g)	300
Main Unit Size (cm)	10 x 15.5 x 2.5 (h x w x d)
Batteries	2 AA
Safety	
Leakage Current	<10 µA with 240 VAC on all electrode inputs

7. Product Images

7.1. Trex HD (Front View)



Trex HD Amplifier

1	Power LED
2	Status LED
3	Oximeter / Photic Connection
4	Reference Input (forward)
5	Common Input (rear)
6	24 Referential Inputs (two rows)
7	Patient Event Switch Connection
8	DC Inputs (rear row)
9	Differential Inputs (forward row)
10	USB Connection (bottom)

7.2. Trex HD (Rear View)

NOTE: Dispose of used, non-rechargeable batteries in accordance with local regulations.

8. Unpacking

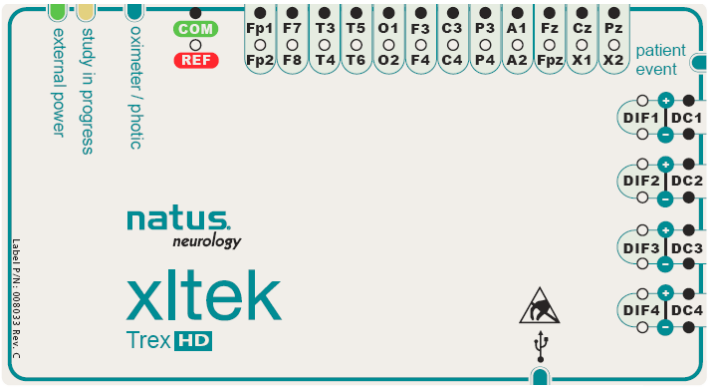
The following applies to both Trex and Trex HD standard amplifier packages but the Trex EEG and Sleep labels state “Trex” and “Trex Sleep”, respectively.

8.1. Trex HD Package Items

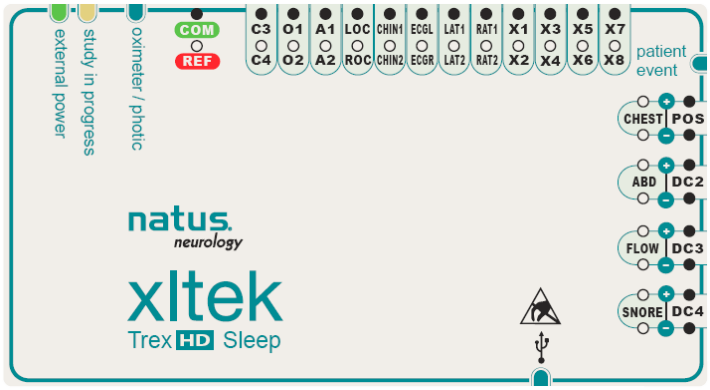
- The Trex HD amplifier package includes the following items:
- Trex HD amplifier
- Mini-USB 2.0 cable (1.8 m / 5.9 ft)
- Pouch for Trex HD amplifier
- 4 AA batteries
- Trex / Trex HD User & Service Manual
- Trex Warning Document
- Patient Instructions Booklet & Diary (English)
- Trex HD Sleep Label

NOTE: The Trex HD is supplied with a standard label displaying markings for EEG studies; for convenience when performing Sleep studies, the user may apply the “Trex HD Sleep” label with markings designed for Sleep studies (provided).

NOTE: The functionality of the Trex HD is not affected by the label and all instructions, warnings and cautions described in this manual still apply.



Trex HD label with markings for clinical EEG study (standard)



Trex HD Sleep label with markings for Sleep study

8.2. Optional Accessories

The Trex HD Video Ambulatory Desktop System includes (Trex HD only, not available in all markets):

- Trex HD package
- HD Camcorder kit (camcorder, carrying case, tripod, clamp)
- Trex Video Interface kit (Trex Video Interface, LANC cable (7.0 in / 0.18 m))
- Acquisition desktop and monitor
- Software license

The Trex HD Video Ambulatory Laptop System includes (Trex HD only, not available in all markets):

- Trex HD package
- HD Camcorder kit (camcorder, carrying case, tripod, clamp)
- Trex Video Interface kit (Trex Video Interface, LANC cable (7.0 in / 0.18 m))
- Acquisition laptop
- Software license

Other optional accessories (Trex and Trex HD):

- XLTEK trolley with optional video
- Sleep accessory kit
- EEG accessory kit
- Patient event switch (2.4 m / 7.9 ft)
- SD flash card for camcorder (Trex HD only)
- Nonin Xpod® Oximeter
- Natus Photic Stimulator Trex Cable for Natus Photic Stimulator (2.4 m / 7.9 ft)

NOTE: The Trex HD amplifier should only be used with cables, transducers, electrodes, sensor, and switches that are supplied or approved by ***XLTEK***.

9. Setting Up

The Trex / Trex HD is designed to work with an ***XLTEK*** computer system running XLTEK Database (XLDB) and NeuroWorks or SleepWorks software.

9.1. Getting Started

NOTE: In the event of a power failure, the current recording will resume using the last programmed settings upon the restoration of power.

9.1.1. Placement of the Operator and Patient

- **Clinical Environment:** It is expected that the operator of the system will stand or sit in front of the computer, but not continuously. The patient is typically lying in a bed located beside the system and is in no way supported by the equipment.
- **Home Environment:** It is expected that the operator of the system will sleep with the Trex HD System and non-patient worn accessories on a bedside table, as required. The patient is in no way supported by the equipment.
- Trex HD system units are patient-worn.
- Refer to the corresponding Instructions for Use for all system components prior to use. This should include, but is not limited to: pulse oximeters, computers, and software.

NOTE: There is a risk of injury if the Trex unit is not properly fitted to the patient.

NOTE: Prior to sending the Trex HD system home with a patient, please ensure that the patient has been provided with the proper contact information.

At no point should the system be leaned against or rested upon. Refer to the *Transport System Specifications and Maintenance* section for placement, details, and cautions for the different cart transportation options.

Refer to the corresponding *Instructions for Use* for all system components prior to use. This should include, but is not limited to: cameras, computers, stimulators, and software.

9.1.2. Beginning a study

Once the equipment has been installed by your Natus qualified representative and a patient has been connected to the Trex system, a new EEG study can be started. For details on beginning a new EEG study, consult the *NeuroWorks* manual directly.

9.1.3. Powering Down the System

Utilize the following steps to ensure your system is powered down completely and safely.

1. Close any active studies in the *NeuroWorks* software.
2. Shut the computer down; ensuring to follow the proper shut down procedure.
3. Remove the batteries from the Trex HD system.

9.2. Adding the Trex HD unit to a belt or a lanyard

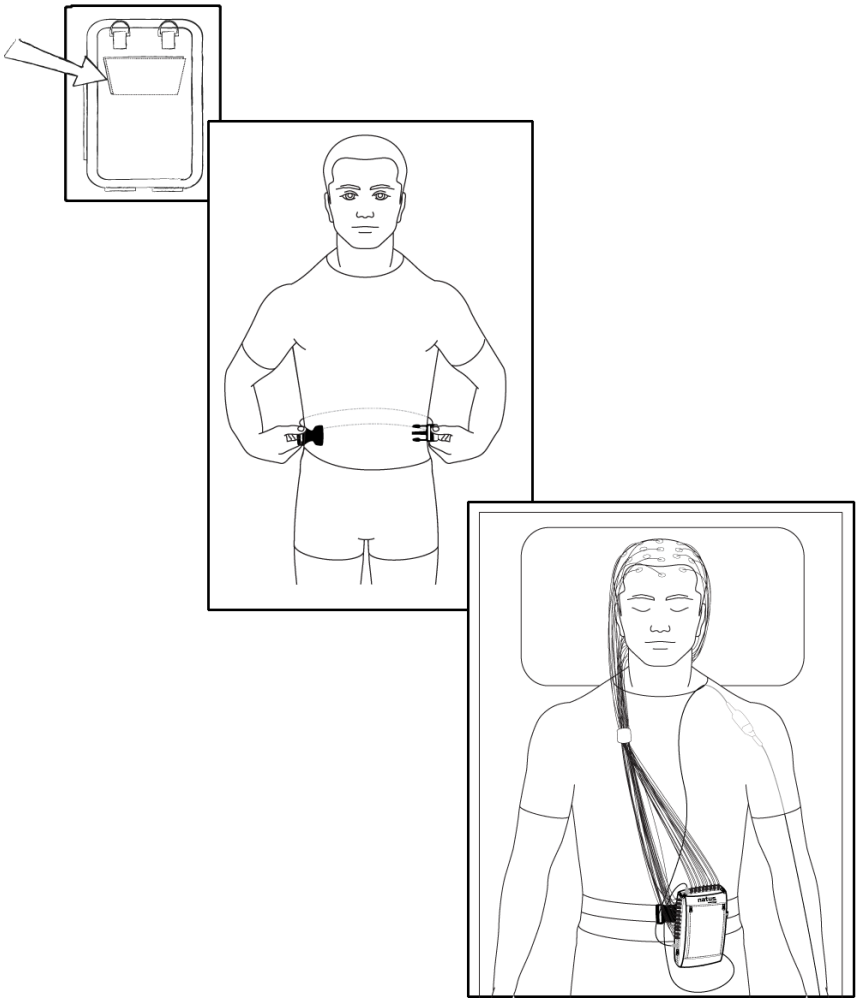
Placing the Trex HD unit on the patient, can be accomplished by using either the belt or the lanyard setup.

NOTE: The pouch and belt or lanyard system must be worn over top of the patient's clothes or hospital garment.

9.2.1. Belt Setup

To use the belt setup:

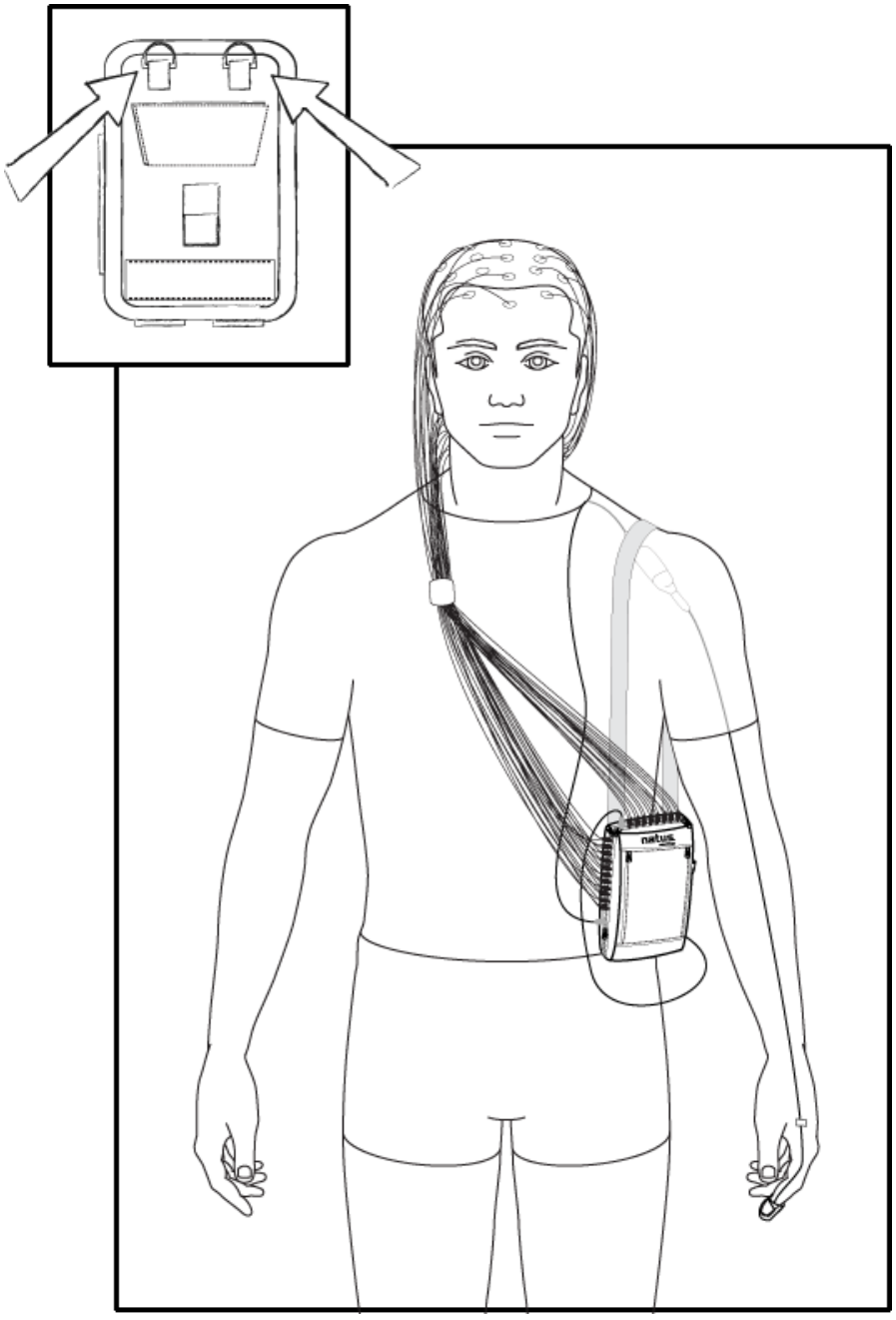
1. Attach the pouch to the belt, by threading it through the back of the pouch.
2. After attaching the electrodes to the patient, place the Trex HD into the pouch with the electrode wires exiting at the top or on the sides, as required.
3. Close the zippers as much as possible so that the Trex HD is secured.
4. Once the Trex HD is enclosed in the pouch, fit the belt snugly around patient's mid-section. Ensure the belt is neither too tight, nor too loose and the patient is comfortable.
5. Insert the patient event button into the holder on the side of the pouch and the gather the electrodes into a ponytail.



9.2.2. Lanyard Setup

To use the lanyard setup:

1. Attach the lanyard to the two (2) rings on the back of the pouch.
2. After attaching the electrodes to the patient, place the Trex HD into the pouch with the electrode wires exiting at the top or on the sides, as required.
3. Close the zippers as much as possible so that the Trex HD is secured in the pouch.
4. Once the Trex HD is enclosed in the pouch, place the lanyard around the patient's neck or shoulder, or hang it on the bedside post.
5. Insert the patient event button into the holder on the side of the pouch and the gather the electrodes into a ponytail.



9.3. Setting up Trex Amplifier for a non-Video Study

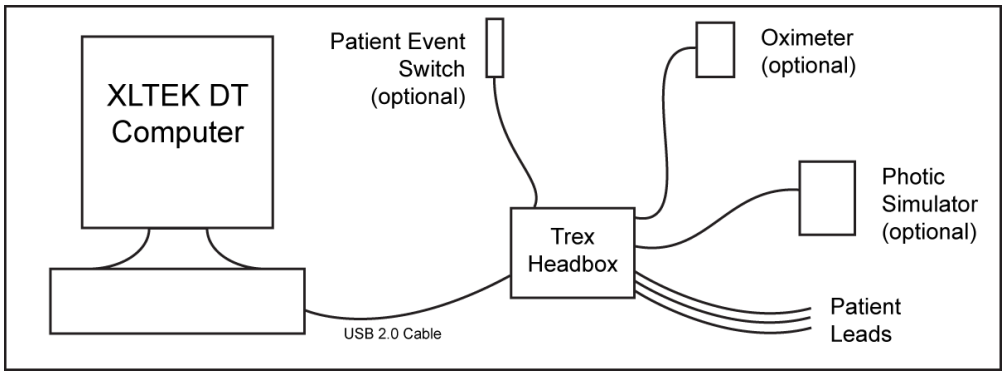


Figure 1: Hardware Connections for a Trex

To connect the Trex to the XLTEK computer:

1. Use the supplied USB 2.0 cable to connect the Trex to the computer.
2. If a Patient Event Switch is needed, insert the Patient Event Switch into the Patient Event connection on the headbox.
3. If a Photic Stimulator is needed, insert the Photic Stimulator into the Photic Stimulator connection on the base unit.
4. When you are ready to run a study, connect the patient leads and transducers to the Trex.

Trex amplifier LED color functionality:

- Flashing **amber** indicates the Trex is storing data in its flash memory.
- **Green** indicates the Trex is connected to the main computer via USB.
- Flashing **green** indicates the battery is running low.

9.4. Setting up Trex HD Amplifier for an Ambulatory Video Study

1. Connect the Trex HD and camcorder to the acquisition computer using the supplied (or XLTEK approved) cables. Use the supplied USB to mini-USB cable to connect the camcorder to the computer (see *Figure 2*).
2. Using the software, prepare the camcorder for wireless connection with the Trex HD amplifier. For detailed instructions, see the Trex HD Technical Guide (P/N 009318).

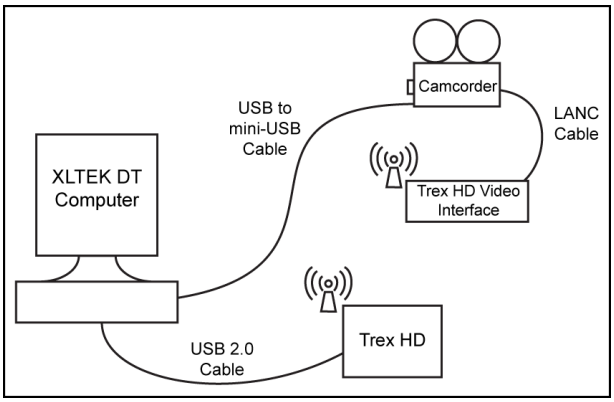


Figure 2: Setting up the Trex HD for a Video Study (No Patient Connected)

3. Following successful completion of a video test using the software, disconnect camcorder from the acquisition computer.
4. Connect additional external devices as required (Patient Event Switch, Pulse Oximeter, Photic Stimulator) to the Trex HD (see *Figure 3*).
5. When you are ready to run a study, connect the patient leads and transducers to the Trex HD.

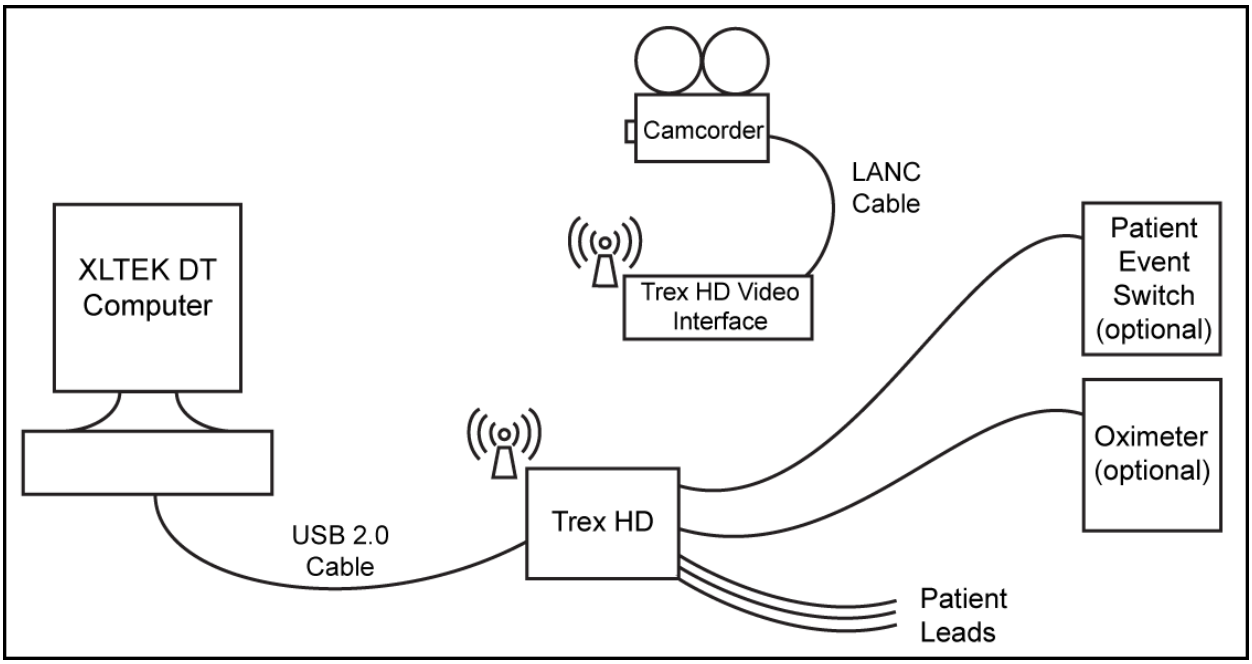


Figure 3: Trex HD and Video Hardware Connections for Device Operation

NOTE: The Trex HD camcorder can be used for ambulatory video recordings only. Video data is recorded to the camcorder's internal memory or SD memory card and uploaded to the acquisition station after the study has ended. Video cannot be monitored or reviewed on a computer prior to its upload.

NOTE: For detailed instructions on starting, stopping and uploading an ambulatory video study using the Trex HD, see the Trex HD Technical Guide (P/N 009318).

Trex HD amplifier LED color functionality:

- Flashing **amber** indicates the Trex is storing data in its flash memory.
- **Green** indicates the Trex is connected to the main computer via USB.
- Flashing **green** indicates the battery is running low.

9.4.1. Setting up Camcorder and Trex HD Video Interface (TVI)

This video functionality is available only with the Trex HD. The Trex HD contains a Bluetooth module which communicates wirelessly with the Trex HD Video Interface (TVI) attached to the camcorder.

NOTE: Only use the camcorder model and accessories supplied or approved by XLTEK.

Trex Video Adaptor LED color functionality:

- **Green** indicates that the TVI is powered on.
- Periodically flashing **blue** light flashes indicates the TVI is 'paired' with a nearby Trex HD amplifier.

*Camcorder Mounting Configurations**The Trex HD camcorder with TVI can be mounted on a tripod or a clamp.***

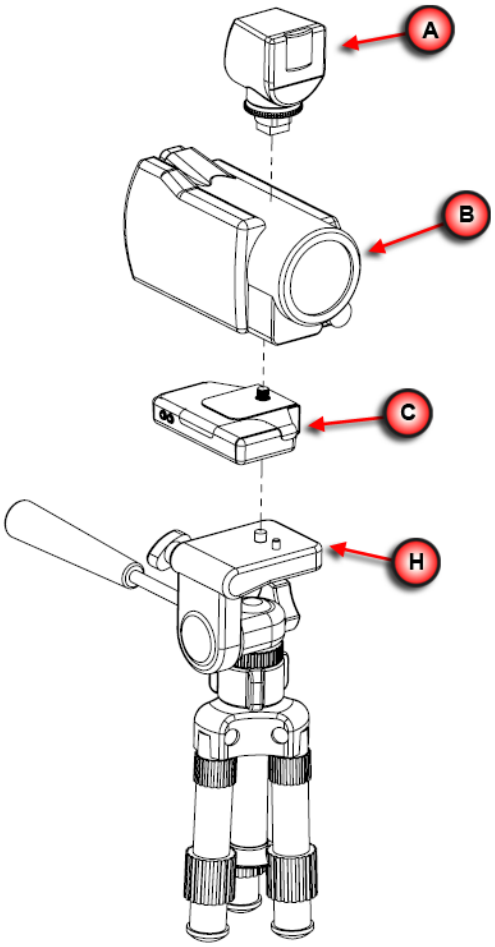
Camcorder Mounting Options

Camcorder with Infrared Light (IR) Attachment

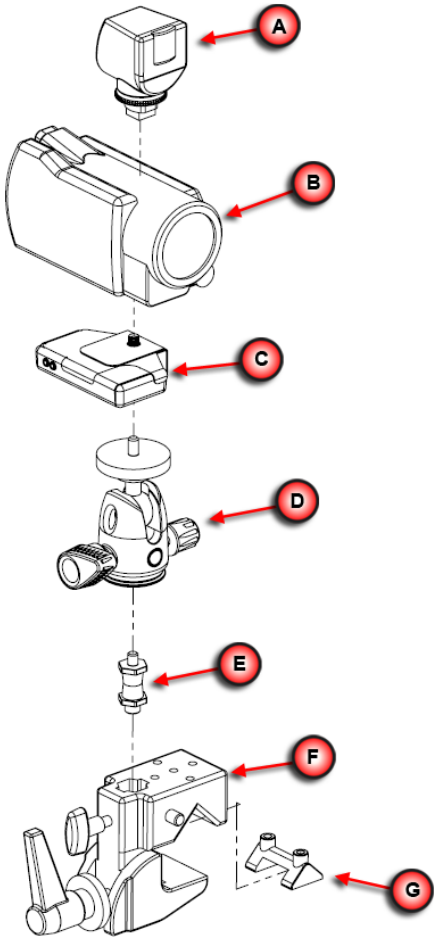
The infrared light illuminator provided with the camcorder can be attached to the camcorder during operation to extend recording range during dark or night conditions.

Optional Infrared Light (IR) Attachment

9.4.1.1. Tripod and Clamp Mounting Overview



Tripod Configuration



Clamp Configuration

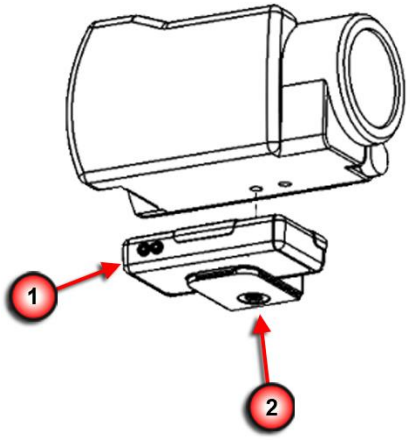
Camcorder Mounting

A	IR Illuminator
B	Camcorder
C	Trex HD Video Interface
D	Camera Ball Pivot
E	Mounting Clamp Stud
F	Mounting Clamp
G	Mounting Clamp Wedge
H	Tripod

NOTE: Refer to manufacturer instructions for operation and installation of components A, B, D, E, F, G and H.

9.4.1.2. Trex HD Video Interface Mounting

The TVI may remain secured to the camcorder as it is moved from the carry case to the tripod or clamp.



1. Orient the TVI such that the LEDs are to the rear of the camcorder.
2. Use a coin to turn the bolt on the TVI to thread and tighten the device on to the bottom of camcorder.

9.4.1.3. LANC Cable Connections

1. Connect this end to the Trex HD Video Interface. Use the port with the camcorder symbol .
2. Connect this end to the camcorder. Use the port labeled “LANC”.

9.5. Testing the Trex HD Amplifier

The Trex HD amplifier is fully assembled, tested, and calibrated before being shipped to you. The following sections describe some tests you can perform to verify the performance of the Trex HD amplifier connections. The tests described in this section should be performed regularly to ensure that the device is functioning as intended.

9.5.1. Calibration and Verification

There is no need to calibrate the software or the Trex amplifier. All calibration is done at the factory before the system is shipped. To verify that the Trex amplifier is correctly calibrated, perform the following procedure:

1. Connect the Trex HD to an ***XLTEK*** computer and turn on the system.
2. Start Natus Database (XLDB).
3. To start a new study, click **New EEG** or **Sleep**.
4. Choose **Edit > Settings > Acquisition**.

5. On the Acquisition tab, set the **Reference Electrode** to **Common**.
6. Design four bipolar montages that take the difference of adjacent channels; for example, C3 CZ, C4 T4, T5 P3, etc.
7. Apply a sine wave of 50 microvolts, peak-to-peak amplitude, 10 Hz to all channels of the group using a signal generator. Ensure there is a 50 Ohm load on the generator output if the generator is designed to deliver the specified level into this load.
8. Set the LFF filter to 0.1, the HFF filter to OFF, and the Notch filter to OFF.
9. Verify that no sine wave is greater than 50 microvolts peak-to-peak. 50 microvolts represents gain match to 1%.

NOTE: For more information on setting up a montage, consult online Help.

9.5.2. Channel Test

While in **Acquisition** mode, a channel test may be performed to check whether a signal is being properly processed from the amplifier to the display. A channel test applies a test signal to all channels. This allows you to examine the waveforms on the screen to see if all channels are working.

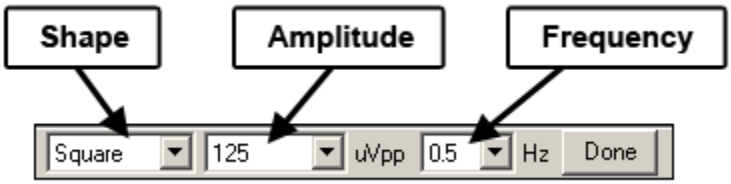
NOTE: A channel test does not validate the connection from the patient electrode to the amplifier input.

To Run a Channel Test

1. Choose **Controls > Channel Test Signal**. The **Channel Test** toolbar appears above the waveform window.
2. Use the Channel Test toolbar to select the desired wave **shape**, **amplitude**, and **frequency**.
3. To stop the channel test and save the current settings, click **Done**.

Channel Test Signal Control

The Channel Test Signal control turns on the channel test signal according to the last settings saved and displays a Test Signal toolbar. The **Test Signal** toolbar is located above the trace display. The toolbar has controls for shape, amplitude and frequency.



Channel Test Signal Toolbar

9.5.3. Impedance Check

An impedance check is performed to ensure that the electrode contact with the patient is satisfactory. You can perform an impedance check at any time during a study.

To Run an Impedance Check from the Software

When an impedance check is initiated, the software scans all channels (in auto scan mode).

To…	Do this…
Start the impedance check	Choose **Controls > Impedance Check**
Lock onto a channel	Click **Lock Channel**. Then, make adjustments to the electrode connection until satisfactory levels are achieved
Proceed to a full impedance check	Click **Release Lock**
End the impedance check	Click **End**
Save the impedance check as part of the study	Click **End and Start Recording**

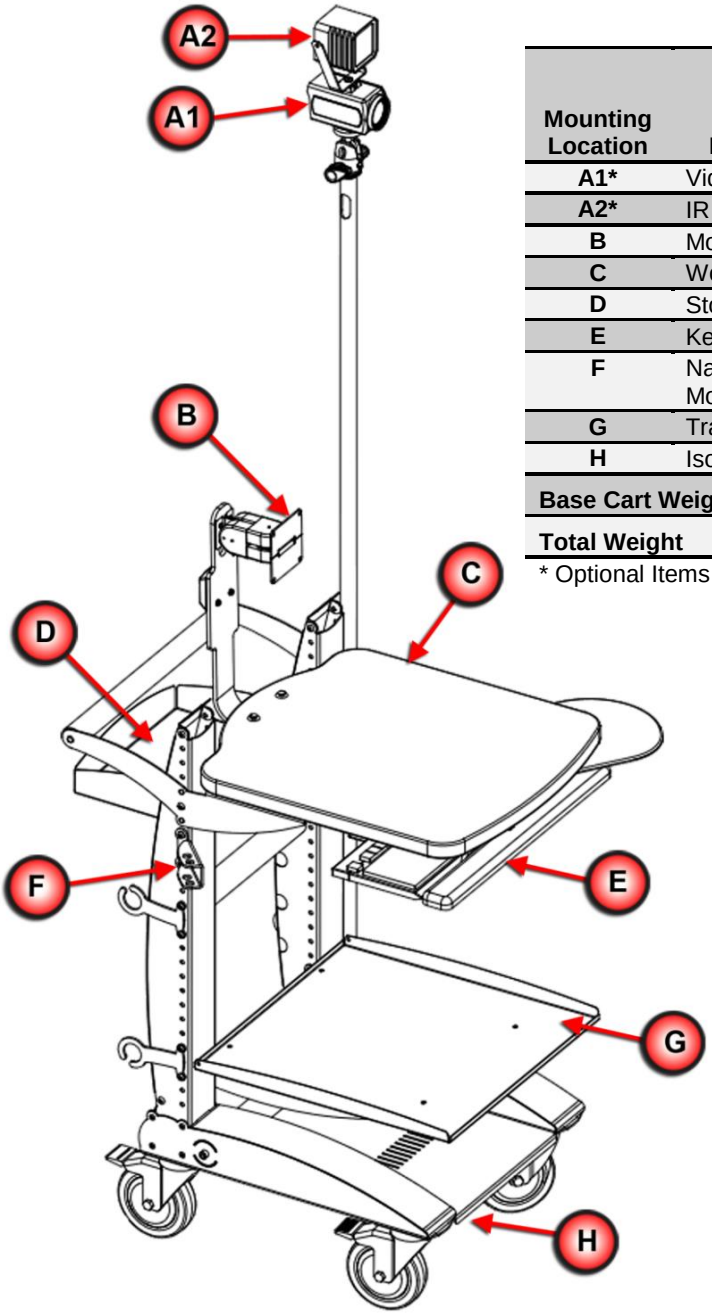
An impedance check displays bar graphs that show the impedance of each electrode connection. A **green** bar indicates that the reading is below the set threshold. A **red** bar indicates the reading is above the threshold. To set the impedance threshold, click one of the **Threshold** buttons in the **Threshold Group** box on the right side of the **Check Impedance** box.

10. Transport System Specifications and Maintenance

Refer to the corresponding *Instructions for Use* for all system components prior to use. This should include, but is not limited to: cameras, computers, stimulators, and software.

NOTE: Transportation System setup and installation should be performed by Natus qualified personnel only.

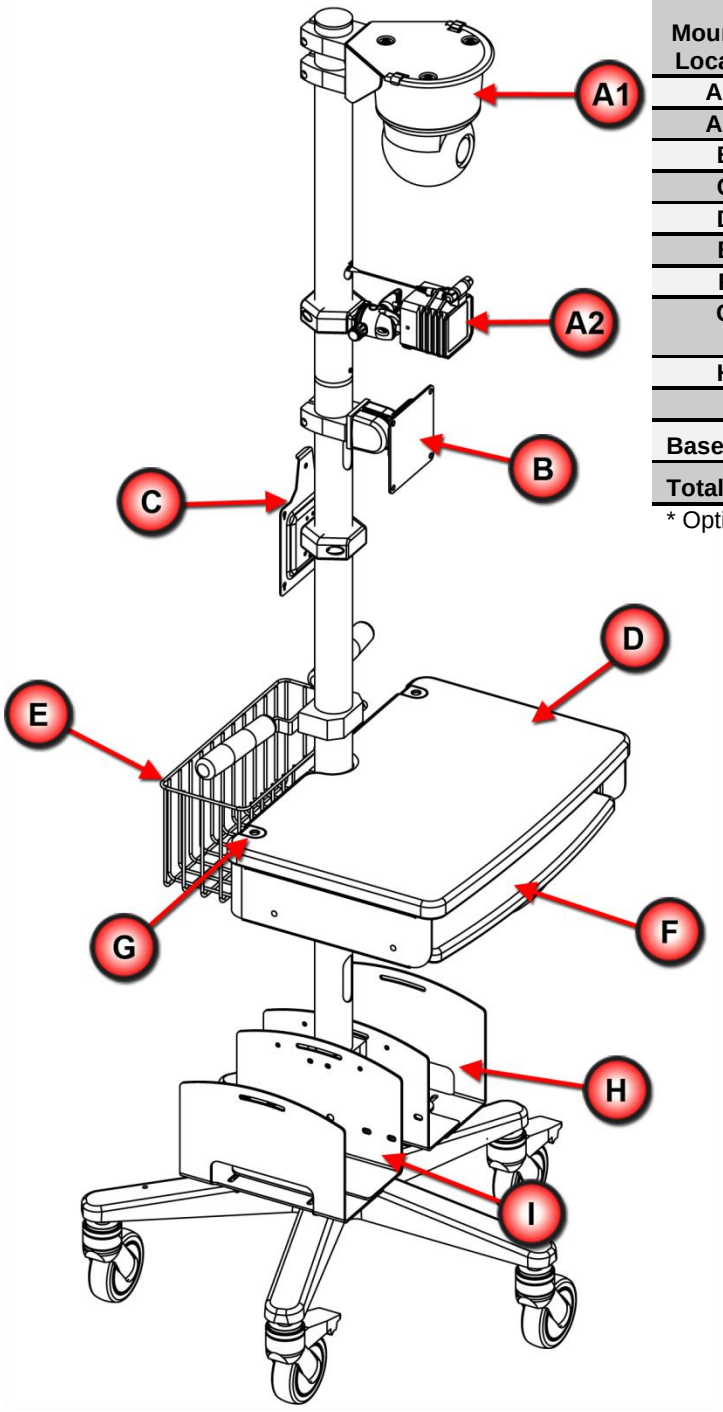
10.1. XLTEK Trolley Specifications



Mounting Location	Default Equipment	Equipment Weight [lbs]	Maximum Load [lbs] (including equipment)
A1*	Video Camera	1	3
A2*	IR Illuminator	2	2
B	Monitor Mount	10	10
C	Work Surface	0	10
D	Storage Bin	0	10
E	Keyboard Tray	3	5
F	Natus Photic Stimulator Mount	5	5
G	Tray for Acquisition DT	20	50
H	Isolation Transformer	22	60
Base Cart Weight		**100**	
Total Weight		**163**	**255**

* Optional Items

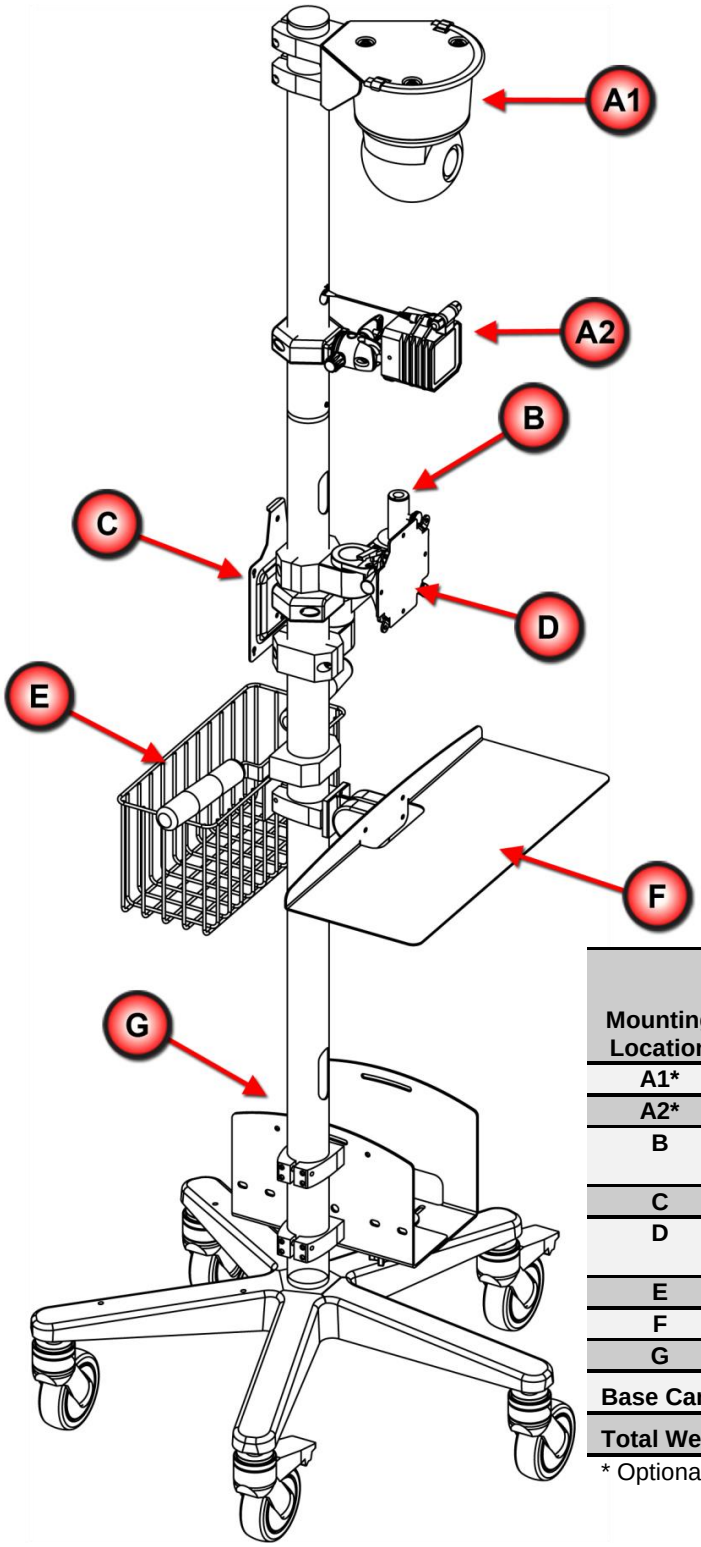
10.2. Cyclops cart with Minitower PC Specifications



Mounting Location	Default Equipment	Equipment Weight [lbs]	Maximum Load [lbs] (including equipment)
A1*	Video Camera	4	4
A2*	IR Illuminator	2	2
B	Monitor Mount	10	25
C	Amplifier Mount	5	5
D	Work Surface	0	10
E	Storage Bin	0	10
F	Keyboard Tray	3	5
G	Natus Photic Stimulator Mount	5	5
H	Tray for Acquisition DT	20	40
I	Isolation Transformer	23	40
Base Cart Weight		**97**	
Total Weight		**169**	**243**

* Optional Items

10.3. Cyclops cart with All-in-One PC Specifications



Mounting Location	Default Equipment	Equipment Weight [lbs]	Maximum Load [lbs] (including equipment)
A1*	Video Camera	4	4
A2*	IR Illuminator	2	2
B	Natus Photic Stimulator Mount	5	10
C	Amplifier Mount	5	5
D	All-in-one Computer Mount	26	30
E	Storage Bin	0	10
F	Keyboard Tray	3	7
G	Isolation Transformer	23	40
Base Cart Weight		**48**	
Total Weight		**116**	**156**

* Optional Items

10.4. ErgoJust Cart Specifications

See Natus ErgoJust Installation & Functionality Guide (p/n 019667).

10.5. Maintenance

1. Regularly inspect the trolley to ensure that casters, bolts, equipment mounting and shelf fasteners are secured tight at all times.
2. Regularly inspect all wires and cables for cuts and damages.
3. Regularly inspect all electrical plugs to ensure they are securely inserted into their mating receptacles.

10.6. Warnings and Cautions

WARNING: Only use XLTEK approved equipment on the trolley/cart. Non-approved equipment may compromise the function and safety of the system.

Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the system and its components is adequate, sturdy, and safe. Natus is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces. Natus is not responsible for any injury or damage that may result from improper cable storage during transport.

WARNING: Do not tilt the trolley/cart more than 10° incline as this will compromise the stability of the trolley/cart.

TIPPING HAZARD: During transport, the user should guide the cart using both hands, ensuring the wheel base is aligned so that a single caster leads in the direction of motion. Failure to lead the cart with one wheel could result in a tipping hazard when ascending or descending steps or thresholds.

10.7. Electrical Input and Isolation Transformer Details

EU	
Electrical input	200-240V AC, 2.24A @ 50 Hz
Isolation Transformer	Powervar ABC500-22MED
North America	
Electrical input	120V AC, 3.10A @ 60 Hz
Isolation Transformer	Powervar ABC300-11MED

11. Nonin Xpod Pulse Oximeter

NOTE: Refer to the Instructions for Use for any pulse oximeter, sensor, or cable extender prior to use.

The following topic lists the specifications for the Nonin Xpod board that is built into the Quantum Amplifier. The board connects to sensors and provides oxygen saturation, pulse rate, pulse waveform, and other output information via the NeuroWorks software. The Quantum Amplifier provides power and isolates the board from the main power and ground.

The user of this medical equipment can verify the operation of the pulse oximeter by appropriately applying the proper sensor, and viewing the generated SpO2 signal and pulse rate display using the *NeuroWorks* software.

NOTE: The SpO2 and pulse rate waveforms are not normalized.

11.1. No Implied License

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in any combination with this device, fall within the scope of one or more of the patents relating to this device.

11.2. Indications for Use

The Xpod is intended to provide medical device manufacturers with a small, low-power oximeter that can be easily attached to a host device externally. The Xpod measures functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate (BPM) for adult, pediatric, infant and neonatal patients. When integrated with a medical device manufacturer's host system, the Xpod may be used in any environment where pulse oximetry measurements are made.

Additional safety information can be found in the labeling provided with each Nonin sensor.

11.3. Accessories

The following Nonin accessories may be used with the Xpod module. See the respective sensor instructions for detailed information regarding specified sensor use (patient population, body/tissue, and application).

11.3.1. Cables

Model Number	Description
UNI-RA-0	7.5" 90-degree Patient Cable
UNI EXT-X	Patient Extension Cable (select 1, 3, 6, or 9 meters)

11.3.2. Available Oximetry Sensors

Model Number	Description
8000AA-1	Adult Articulated Internal Spring Finger Clip, 1 m (3 ft) cable
8000AA-3	Adult Articulated Internal Spring Finger Clip, 3 m (9.8 ft) cable
8000AP-1	Pediatric External Spring Finger Clip, 1 m (3 ft) cable
8000AP-3	Pediatric External Spring Finger Clip, 3 m (9.8 ft) cable
8000J-1	Adult Flex, 1 m (3 ft) cable
8000J-3	Adult Flex, 3 m (9.8 ft) cable
8001J	Neonatal Flex, 1 m (3 ft) cable
8008J	Infant Flex, 1 m (3 ft) cable
8000Q2	Ear Clip, 1 m (3 ft) cable
8000R	Reflectance, 1 m (3 ft) cable
8000SS	Sensor, Reusable, Soft, Small, 1 m (3 ft) cable
8000SS-3	Sensor, Reusable, Soft, Small, 3m (9.8ft) cable
8000SM	Sensor, Reusable, Soft, Medium, 1 m (3 ft) cable
8000SM-3	Sensor, Reusable, Soft, Medium, 3 m (9.8 ft) cable
8000SL	Sensor, Reusable, Soft, Large, 1 m (3 ft) cable
8000SL-3	Sensor, Reusable, Soft, Large, 1 m (3 ft) cable
7000A	Flexi-Form® III Adult, 1 m (3 ft) cable, 24-pack 7000P
7000I	Flexi-Form III Infant, 1 m (3 ft) cable, 24-pack
7000N	Flexi-Form III Neonate, 1 m (3 ft) cable, 24-pack
6000CA	Sensor, Disposable, Adult, 45 cm (17.5 in) cable
6000CP	Sensor, Disposable, Pediatric, 45 cm (17.5 in) cable
6000CI	Sensor, Disposable, Infant, 90 cm (35.5 in) cable
6000CN	Sensor, Disposable, Neonate, 90 cm (35.5 in) cable
6500SA	Sensor, Durafoam Disposable, Standard, 1 m (3 ft) cable

Model Number	Description
6500MA	Sensor, Durafoam Disposable, Small, 1 m (3 ft) cable

11.4. Measurements

This pulse oximeter module is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin.

Pulse rate and SpO2 values are updated every 1/3 second and consist of a 4-beat average.

Measurement Wavelengths and Output Power[5]

- Red: 660 nanometers @ 0.8 mW max. avg.
- Infrared: 910 nanometers @ 1.2 mW max. avg. (using Nonin PureLight® sensor)

Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

- excessive ambient light
- excessive motion
- electrosurgical interference
- blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
- moisture in the sensor
- improperly applied sensor
- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiogreen or other intravascular dyes
- carboxyhemoglobin
- methemoglobin
- dysfunctional hemoglobin
- artificial nails or fingernail polish
- a sensor not at heart level

11.5. Displayed Ranges

Displayed ranges for the Nonin Xpod 0 to 100% for SpO2, 18 to 321 BPM for pulse rate

[5] This information is especially useful to clinicians.

12. Guaranteeing Sufficient Battery Power

Your new Trex HD amplifier comes standard with on-board DC channels and optional pulse oxygen monitoring. It is powered by two AA alkaline batteries during ambulatory mode. However, in order to guarantee:

- Sufficient battery power for 24 hours of consecutive ambulatory recording with two new AA batteries, and
- Sufficient on-board storage for a 96-hour recording (or 48-hour with a Trex 48)

Then:

a. All DC channels, differential channels 2 to 4, pulse rate (PR) and oxygen saturation (OSAT) must be **turned off** on the acquisition station, and
b. Sampling frequency must be set to **200 Hz**.

This will ensure that your ambulatory amplifier has enough onboard memory and battery power to record for the duration of the study. It is recommended that batteries be replaced every 24 hours with a set of new AA batteries.

NOTES: It is strongly recommend that you use **major brand name AA alkaline batteries** such as Duracell® Coppertop®, Duracell Procell® or equivalent. Do not use rechargeable batteries.

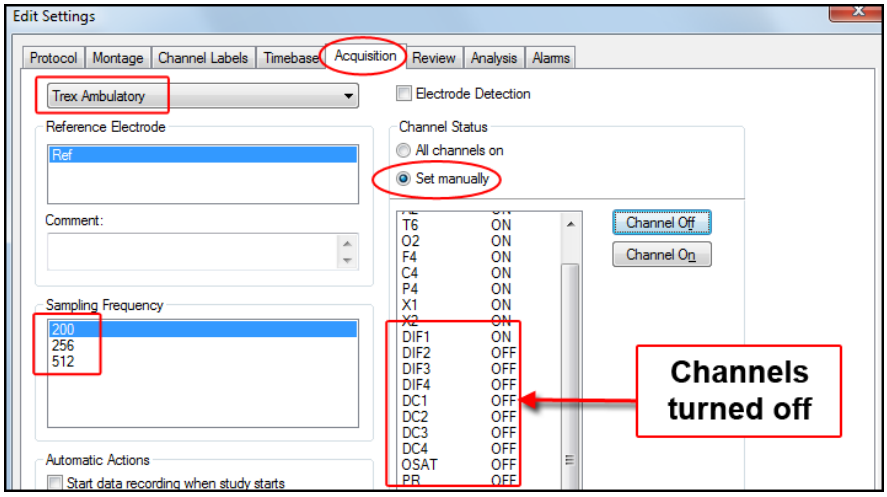
With a Pulse Oximeter sensor connected to it, the Trex HD can run for 17 hours with a set of new AA batteries recording to Flash memory.

NOTES: When the **settings described in this section** are applied, it is recommended that patients be advised to replace the internal batteries according to a fixed schedule:

- **Standard ambulatory EEG studies:** Every 24 hours (at the same time once a day)
- **PSG studies with pulse oximeter sensor connected:** Every 12 hours (twice a day - once in the morning and again at night)

13. How to Disable Channels and Set Frequency

1. In NeuroWorks or SleepWorks, choose **Edit > Settings > Acquisition**.
2. Select **Trex Ambulatory** in the first drop-down box.
3. In the **Channel Status** section, select **Set manually**.
4. In the pane below, select the following channels:



- All DC channels: **DC1**, **DC2**, **DC3**, and **DC4**
- Differential Channels **DIF2**, **DIF3** and **DIF4***
- Pulse Rate (**PR**) and Oxygen Saturation (**OSAT**)

5. Click the 

button.
6. In the **Sampling Frequency** section, select **200**.

* **DIF1** should not be turned off because it is needed in order to perform the impedance check.

14. Maintenance, Cleaning, & Disposal

To keep the Trex HD amplifier in good working condition, follow a regular schedule of maintenance. Regular maintenance performed by the user does not involve access to the interior of the Trex HD amplifier and components. For servicing problems that require corrective maintenance and/or internal component service, call Technical Support at **1-800-303-0306**, or contact your local ***XLTEK*** representative.

Periodically check cable connections and electrodes for damage and wear. Inspect cables for bent pins. Replace frayed or worn cables. Also, regularly inspect and clean all system components, including:

- Connectors and jack ports
- Amplifier and USB 2.0 cable
- Electrodes and accessories

The Trex HD amplifier and its components should not be immersed in water or any other fluid. To clean, use a damp cloth to wipe all surfaces.

The Trex HD amplifier is designed to be extremely portable. As such, the Trex HD is subject to increased daily wear and tear. Taking basic care of the system and avoiding extreme physical abuse helps prolong the lifespan of the Trex HD.

14.1. Recommendations

	Disconnect all cables from the Trex HD before wiping. Wipe using a soft, damp cloth using non-conductive distilled water, electrically non-conductive inert surfactants or an ***XLTEK*** - approved cold sterilizing agent. Do not use any abrasive cleaner on the system.
	It is important to dry off the unit quickly. Be careful not to allow any fluid to seep into the internal electronic components of the system.
	Do NOT leave the amplifier attached to the computer when transporting the unit.
	Do NOT autoclave, pressure sterilize, or gas sterilize this amplifier.
	Do NOT soak or immerse the amplifier in any liquid.
	A cleaning solution of 70% isopropyl alcohol is recommended.

	Use cleaning solution sparingly. Excessive solution can flow into the amplifier and cause damage to internal components.
	Do NOT use petroleum-based or acetone solutions, or other harsh solvents, to clean the amplifier.

14.2. Disposal

At the end of the expected service life, when disposing of the Trex HD amplifier and its components, it is recommended that federal, state, and local laws be followed for proper disposal of printed circuit boards, plastics, and metal parts. For disposal of non-Natus accessories, please follow the instructions provided with these items.

14.3. Expected Service Life

The expected service life of the Trex HD system is seven (7) years. Refer to the *Instructions for Use* for any accessories or sensors for their expected service life.

15. Troubleshooting

If you are experiencing problems, try the solutions listed below.

Troubleshooting Checklist

☑	Ask the patient to relax.
☑	Inspect your cables.
☑	Make sure there is a tight connection between the Trex HD and the computer.
☑	Make sure the patient electrodes are connected to the correct channel in the amplifier.
☑	Make sure the patient electrodes fit properly into the amplifier (not loosely).
☑	Make sure there are no apparent breaks in the patient electrode cables.
☑	Are any of the electrodes touching? If so, they are causing a short circuit and will develop an artifact.
☑	Check the impedance.
☑	Unplug any other devices on the same circuit such as printers, mechanical beds, vacuum cleaners, or other potential sources of interference.
☑	Install a medical grade ground to make sure that your clinic has a properly grounded electrical system.
☑	Change the acquisition cable. You should always have a backup acquisition cable.
☑	Check the gain and timebase settings to ensure that they are appropriate for the current test. You may also want to check the LFF, HFF, and Notch Filter settings. Choose **Edit > Settings > Montage**. Right-click a cell in the appropriate column and select a value.
☑	Disconnect and reconnect the amplifier. This will reset the amplifier
☑	Shut down for at least 10 seconds. Then set up the test again from the beginning. Shutting down the computer and starting over also resets the amplifier and sometimes solves the problem.
☑	Try inserting fresh batteries. If batteries become too low, the Trex HD will not operate.

16. Getting Help

XLTEK is committed to providing you with support so you can operate the Trex HD amplifier with ease and confidence. If you need help, follow these steps to find a solution:

Step 1: Document the Incident

Carefully document the incident. If possible, note error messages, dialog box names and what you did before the problem occurred.

Step 2: Search NeuroWorks/SleepWorks Online Documentation

Choose the following in the NeuroWorks/SleepWorks or the Database software:

- **Help >**

Alternately, the help documentation can be located using the Windows Start Menu:

1. Click the **Start** button on the Windows taskbar.
2. Navigate to the **Excel Tech | Documentation** folder

Step 3: Restart the Computer

Often restarting the computer will solve a problem.

3. Close all applications.
4. Click the **Start** button on the Windows taskbar.
5. Choose **Shut Down** from the Start menu.
6. Select **Restart** the computer and click **Yes**.

Step 4: Shut Down the Computer

Sometimes you need to shut down the computer completely in order to solve a problem.

1. Click the **Start** button on the Windows taskbar.
2. Choose **Shut Down** from the Start menu.
3. Select **Shut Down** and click **Yes**.
4. Turn off the power to the unit. Wait 10 seconds. Turn the power back on.

Step 5: Contact Technical Support

First, write down the serial number of your computer (located on the back) and the serial number of your Trex amplifier. Then contact your local XLTEK distributor or Technical Support at **1-800-303-0306** or OTS@natus.com.

We welcome your feedback and suggestions regarding the Trex HD amplifier and any aspect of our system and software, online Help, line of accessories, and support services.

17. EEG and Sleep Accessories

EEG and Sleep accessories which can be used with the Trex HD amplifier are available for you to browse the Natus Neurology Catalog online at www.natus.com or call Natus Sales and Support at 1-800-303-0306.

18. Index

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A Total Service Solution

Standing behind every XLTEK product is Natus Medical Incorporated, an internationally respected innovator of medical products and services.

Our Neurology systems are backed up by an in-house support team staffed with technical and clinical experts, 24/7 support, remote support via WebEx or VPN, the largest clinical and technical field support network in Neuro/Sleep and customized service contracts that include preventative maintenance visits and computer upgrades.

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