NORAXON

MEASURING FOR EXCELLENCE

TeleMyo Clinical DTS®

User Manual

P-5848 Rev C (May 2013)

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0473 Notified Body:
Clearance to market this product in the European Community has been certified by Notified Body #0473, AMTAC of the UK.

Table of Contents

Section 1: Introduction
- Brief Description 1
- Intended Use 1
- Contraindications 1

Section 2: Definitions
- Graphic Symbols and Meanings 2
- Glossary of Terms 3

Section 3: Identification
- Model Designation 4
- Product Versions and Configurations 4

Section 4: General Warnings and Cautions
- Risks and Benefits 5
- Safety Information Summary 5

Section 5: Getting Started
- Quick Start Guides 6

Section 6: Preparing the Product for Use (Setup Instructions)
- Unpacking and Component Identification 10
- Component Inputs, Outputs and Indicators 11
- Component Interconnections 12
- Device Communication (Driver) Software Installation 12
- Companion Software Installation 13
- Companion Software Configuration 13

Section 7: Pre-use Check-out
- Normal Appearance of Signals 19
- Attaching to Patient or Subject 19
- Calibration 19

Section 8: Operating Instructions
- Safety Information Summary 20
- Normal Functions with Interface in PC 20
- Secondary Functions without PC Interface 20
- Exceptional Functions/Situations (error messages) 21
- Shutdown after Use 21
- Storage and Protecting Between Usages 21

Section 9: Accessories and Optional Modules
- Accessories 22
- Options 24
- Interfaces to Other Devices 25

Section 10: Cleaning
- Safety Precautions When Cleaning 26
- Cleaning by Users 26

Section 11: Maintenance
- Safety Precautions When Performing Maintenance 27
- Maintenance by Users 27
- Maintenance by Qualified Individuals 27

Section 12: Trouble-shooting, Fault Diagnosis
- Troubleshooting Chart 30
- Website Link to FAQ 30
- Radio Considerations 31
- Setting the Sensor RF Channels 31

Section 13: Service and Repair
Availability of Circuit Diagrams and Component Lists 32
Warranty Information 32
Submitting Service Requests 32
Returning Equipment 32
Section 14: List of Spare Parts and Consumables
Consumable Items (electrodes and sensor elements) 33
Replaceable Items (fuses, batteries, lead sets) 33
Section 15: Taking Product Out of Operation
Disposal of Equipment and Batteries 34
Section 16: Specifications of the Product
Expected Useful Lifetime 35
Dimensions and Weight 35
Performance Characteristics 35
Energy Consumption, Condition of Use 36
Environmental Conditions for Storage and Transport 32
IP (Ingress Protection) Rating 36
Section 17: Technical Information
Block Diagram 37
Theory of Operation 38
Electro-Magnetic Compatibility (EMC Tables) 39
Section 18: Appendices
Appendix A—Interference Between WiFi & Sensor Radio Frequency Channels 42
Appendix B—Sensor RF Channel Frequencies 33
Appendix C—Use of Disposable Electrodes 44
Appendix D—Radiation Exposure Information Regarding Use of DTS Sensors 46
Appendix E—Radio Regulatory Statements 47

Section 1: Introduction

Brief Description

The TeleMyo™ Clinical Direct Transmission System (DTS) for EMG and other biomechanical sensors directly transmits data from the electrode or sensor site to a receiver connected to the PC via a USB cable.

This direct transmission concept greatly simplifies the arrangement of EMG measurements by eliminating cable connections between the EMG electrodes and EMG amplifier. The small lightweight sensors are also beneficial for small subjects like children and small animals.

This unique concept gives the user flexibility to operate the DTS system without limitations. The TeleMyo Clinical DTS system is designed for up to 4 EMG channels and an additional 4 Biomechanical Sensor channels.

The default system is equipped with EMG sensors but can be upgraded with other biomechanical sensors, e.g. goniometers, Inclinometers, foot switches, and accelerometers.

Intended Use

The TeleMyo Clinical DTS system is intended to measure and quantify muscle biopotential signals separately or in combination with other kinematic or kinetic signals. This information can be used to affect muscle training and reeducation.

Intended Users
Individuals trained in physical medicine, physical therapy or ergonomics

Subject Populations – Medical
Individuals with cerebral palsy, physical injuries, post surgical or post stroke conditions

Subject Populations – Non medical
Athletes, workers at their worksite, subjects in new product trials

Common Applications
Gait analysis; tracking over time the outcome of surgical, therapeutic or orthotic interventions; identification of ergonomic stress factors in the workplace or new product designs

Contraindications

Use of the TeleMyo Clinical DTS is contra-indicated in individuals who have implanted pacemakers.

SECTION 2: DEFINITIONS

Graphic Symbols and Meaning

The following international icons and symbols are found on the TeleMyo Clinical DTS enclosures and in this user manual. Their meaning is described below.

CE 0473	Approval to market this product in the European Community was certified by Notified Body #0473 AMTAC of the UK.
	The device generates radio frequency energy during operation.
⎓ 5V DC	A 5 Volt DC power source is applied to this connection.
	The USB cable is applied to this connection.
	The device is suitable for a direct electrical attachment to the body.
	Read material in the Instruction Manual wherever this symbol appears.
	Identifies the manufacturer of the device.
SN	Identifies the serial number of the device.
DOC	Additional information available in a separate document

Glossary of Terms

DTS – (Abbreviation for Direct Transmission System) A network of short-range wireless sensors where measured data is transmitted directly from each sensor into a receiver for subsequent display and analysis on a computer or intelligent handheld device.

DTS Sensor -- A small individual radio transmitter typically worn on the body used to measure and transmit bio-potential signals (such as EMG) or motion related signals (such as position or acceleration). The Clinical DTS System can accommodate up to 8 body worn DTS Sensors in one network.

DTS Sensor Type – Refers to different models of DTS Sensors. Each sensor model measures a given type of physical parameter. Different DTS Sensor Types can be combined in the same DTS network. The most common DTS Sensor Type is EMG. Examples of other types include Accelerometers, Goniometers and Force sensors.

DTS Serial Number – A unique four-character tag used to identify each DTS Sensor. The members of any DTS network are determined by their serial numbers. Also DTS Sensor Types are grouped into a predefined range of serial numbers. Thus by serial number the DTS system can automatically determine the type of signal parameter being transmitted from any DTS Sensor in the network.

Multi-Channel Sensor – Certain DTS Sensor Types provide more than one signal. Thus a Multi-Channel DTS Sensor behaves like two or three standard DTS Sensors. An example is a 3-D Accelerometer that provides acceleration data for the x, y and z directions.

Probe – A generic term for any DTS Sensor.

Processed EMG – Refers to the nature of the EMG signal acquired by the Clinical DTS System. It is a compressed format revealing the amplitude ‘envelop’ of a muscle contraction rather than the actual grass patch like EMG signal. In general a stronger EMG contraction produces a larger value or amplitude for the processed EMG.

RF – (Abbreviation for Radio Frequency) Wireless communication takes place on assigned radio frequencies or channels. For the TeleMyo Clinical DTS System, RF transmissions occur at frequencies between 2.4 GHz and 2.5 GHz. Other wireless systems including WiFi and Bluetooth commonly operate at the same frequencies and can be a source of interference.

RF Channel – RF transmissions for the Clinical DTS System can be selected to occur on one of 24 different radio frequencies. The ability to operate over several different frequencies allows the DTS System to reposition its radio operation if needed to avoid interference.

RF Traffic – The presence of radioactivity present on a given frequency similar to the number of cars on an expressway. Several users (wireless devices) may be communicating using the same frequency. Best operation of the DTS System occurs when the RF Traffic is low (no other users) on the selected RF Channel.

Section 3: Identification

Model Designation

The basic Clinical DTS System consists of two primary components:

Model 584 Clinical DTS Receiver (1 per system)
Model 546 Clinical DTS EMG Sensor (2 to 8 per system)

Product Versions and Configurations

The model 584 Clinical DTS Receiver can accommodate up to 8 DTS Sensors. The standard model 546 Clinical DTS EMG Sensors can be combined with any of the following DTS Sensor Types.

Model 500 DTS Footswitch
Model 504 DTS 1D Fixed Axis (Mechanical) Goniometer
Model 508 DTS 2D Flexible Axis Goniometer
Model 511 DTS Universal Input Sensor
Model 517 DTS 3D Accelerometer
Model 520 DTS 500 LbF Force Sensor
Model 521 DTS 100 LbF Force Sensor
Model 524 DTS Local Pressure Sensor
Model 529 DTS Hand Dynamometer
Model 550 DTS ECG and Heart Rate Sensor

For additional equipment details refer to Section 9 of this manual.

As the Clinical DTS System requires software to perform its function, the equipment is offered in combination with the following computer program packages.

Model 131 MyoResearch-XP Clinical Applications Protocols
Model 432 myoMUSCLE Clinical

Section 4: General Warnings and Cautions

Risks and Benefits

There is **no identified risk of physical harm or injury** with use of the TeleMyo Clinical DTS product. The benefit provided by use of the device is the provision of objective measures to assess the severity of pathological human movement conditions and gauge any subsequent improvement offered by therapy, training, prosthetic alterations or ergonomic design changes.

Safety Information Summary

Cautions

- Never use the TeleMyo Clinical DTS System on a person with an implanted pacemaker
- Never operate the TeleMyo Clinical DTS System within 1 meter of any critical medical device

Warnings

- Do not immerse the DTS Sensors in any water or liquid
- Do not use the TeleMyo Clinical DTS equipment on individuals undergoing MRI, Electro Surgery or Defibrillation
- The TeleMyo Clinical DTS product produces results that are informative, not diagnostic. Qualified individuals must interpret the results

Attention

- The operator must be familiar with typical characteristics of the signals acquired by the TeleMyo Clinical DTS equipment and be able to detect anomalies that could interfere with proper interpretation.

SECTION 5: GETTING STARTED

Quick Start Guides

MR3 – Quick Start Tutorial Clinical MyoMuscle

Step 1: Home/Start Screen

1 **Select a module**

2 **Select/create a subject**

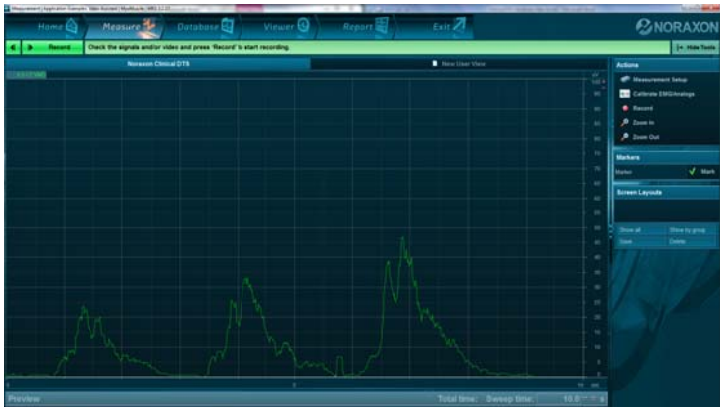
3 **Select a configuration**

(To create a new configuration see next page)

Continue to next step with:

Step 2: Measure

1 **Check the signals from the sensors and, if acceptable, follow the steps in green the tool bar.**



Step 3: Viewer

1 **Review/Replay the record**

2 **Set a marker at each start and end of a desired analysis period**

Continue to next step with:

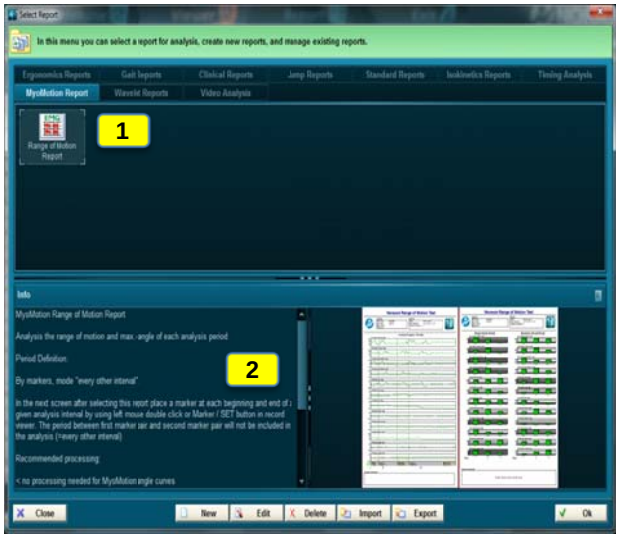
MR3 – General Quick Start Tutorial

Step 4: Report Selection and Analysis Period Definition

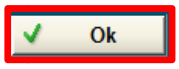
1 **Select a Report in one of the MyoMuscle tabs**

2 **Study report definition (Info)**

Each report comes with a pre-configured mode for analysis period definition which is explained here.



Continue to Period Definition Viewer with:



The Viewer is shown again: place marker at each start/end of analysis periods or confirm existing marker pairs (already placed in first viewer) and click:

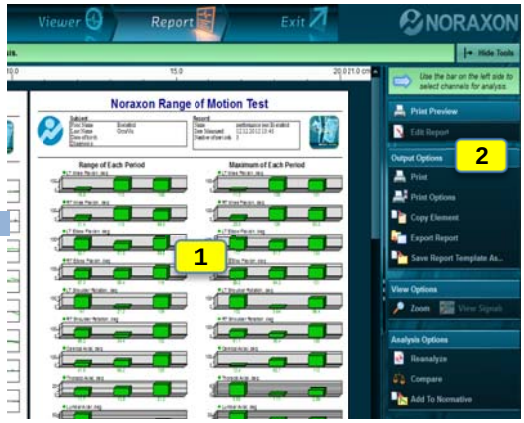
Confirm or change the analysis period defintion and continue with:

Step 5: Read and Print a Report

1 **Scroll through the report results**

2 **Use Print, View or Analysis Options**

Reports can be printed, copied to clipboard or exported to several files formats. The report can be Re-analyzed to adjust the period definition or to perform a comparison analysis. Averaged angle patterns can be stored as normative data or group data



Continue with:

To get back to the start screen or press measure to perform the next measurement:

Optional step in Home/Measure: Create or Edit a measurement configuration

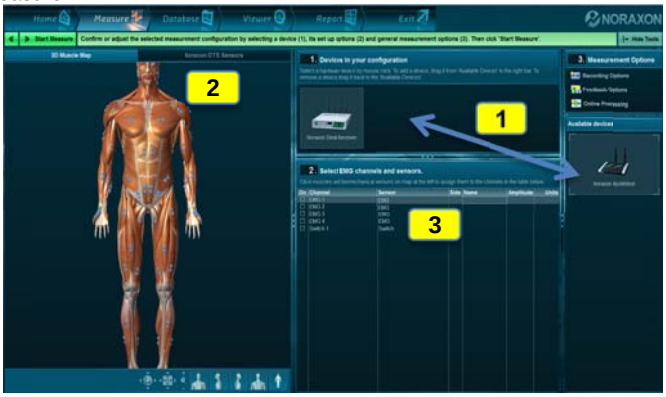
- click on New or Modify configuration in Home or Measure -

1 **Insert or delete a device**
by dragging a device in or from the list of "available devices

2 **Use Human model or sensor list to select or deselect DTS sensors**

3 **Measurement Options**

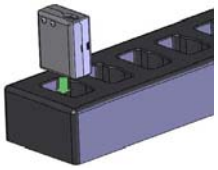
You can add Recording Options, Online Processing and Feedback Options if needed



Continue with:

Noraxon CDTS System Quick Start Tutorial

1) Charge all Clinical DTS EMG sensors and other DTS sensors, fully before initial start-up.
Page 10 of Clinical DTS User Manual



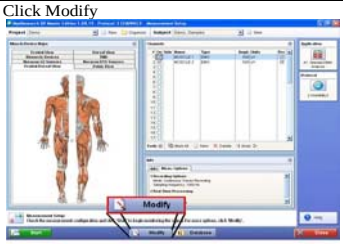
The amber Charge LED on the EMG Sensor will illuminate while charging. The LED will be extinguished when the charging cycle is complete.

2) Connect DTS Receiver to the PC via USB.

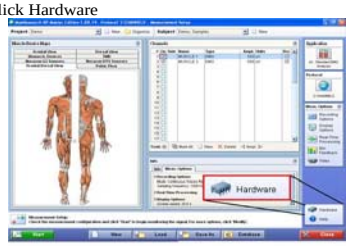
Refer to Page 11 of DTS User Manual for instructions

3) Open MRXP Application Protocols
Click Measure

4) Click Modify



Click Hardware

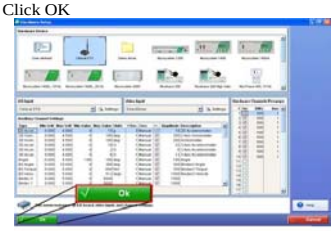


5) Click Clinical DTS then click settings

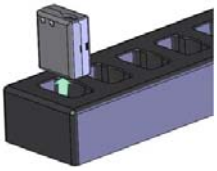
For questions, comments concerns contact Noraxon USA, Inc at:
Email: support@noraxon.com
Phone: (480)-443-3413
Address: Noraxon USA, Inc
15770 North Greenway-Hayden Loop
Suite #100
Scottsdale, AZ 85260 USA

6) The settings menu should appear. Input the Clinical EMG sensor Serial Numbers. When completed, click done

7) Click OK

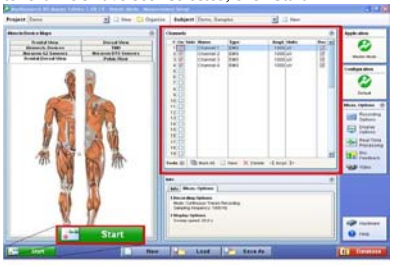


8) Remove any Clinical EMG sensors that will be used for measuring from charger block



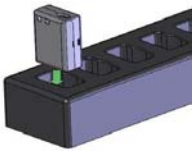
NOTE:
Charging the EMG sensors turns off the radio. If the EMG sensors are left charging, they will not communicate with the DTS Receiver.

9) Select EMG channels needed by using muscle map on left of page. Refer to software user manual for more information.
After channels have been selected, click Start



STORAGE:

When recording is complete, and you are ready to store the DTS System, put the EMG sensors charging.
It is best to store the EMG sensors in the charging condition.



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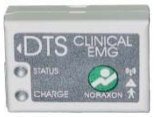
Section 6: Preparing the Product for Use

(Set-up Instructions)

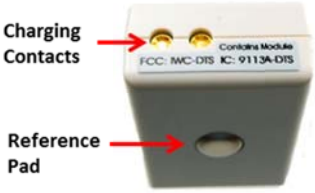
Unpacking and Component Identification

	The TeleMyo Clinical DTS System is provided with a padded suitcase for protection during transport and for storage. The contents are secured in recessed areas of the padding as illustrated. Carefully remove all contents and verify the following components are present.
	Clinical DTS Receiver (part #584)
	Antenna (part #ANT3) (shipped attached to receiver)
	A to mini-B USB Cable (part #CBL17)
	Clinical DTS EMG Sensor (part #546) Qty: 2 or 4 (shipped inside charging station)
	DTS EMG Lead Set (part # 542AP) Qty: Matches number of EMG Sensors
	DTS Sensor Charging Station (part #543)

	DTS Sensor Charger Power Source (part #PSU1)
Additional contents not illustrated	
Double side tape samples (part #542CS)	
Sample electrodes (typically dual electrodes part #272)	
Clinical DTS User Manual (part #5848) *This document*	

If additional accessories have been included please see Section 9, Accessories for component identification.

Component Inputs, Outputs and Indicators

1 Receiver (Rear) 	Sync – TTL (on-off) compatible 3.5 mm stereo jack connection to other devices. See Section 9, Interfaces for representative devices. Antenna – Screw on connector for attachment of external antenna. USB Port – Mini B style USB connection
2A EMG Sensor (front) 	Status – Sensor operational indicator flashes green. Flash rate is faster when measuring, slower when idle. Charge – Indicator illuminates steady amber while sensor is charging. When the battery is fully charged the indication is off.
2B EMG Sensor (back and bottom edge) 	Charging Contacts – Sensor battery is charged through these two points. Reference Pad – Metal pad must be applied to bare skin for stable EMG readings. All three above contact points must be kept clean and free of tape residue.
2C EMG Sensor (top edge) 	Serial Number – Unique 4 character serial number which identifies each DTS sensor. Lead Set Socket – Attachment point for various styles of EMG electrode lead sets.

Component Interconnections

Step 1

Screw on the antenna (ANT3) to the antenna connector located on the rear of the TeleMyo Desktop DTS Receiver (586). If the antenna is already attached, check that it is securely tightened.

Step 2

Insert the mating (smaller) end of the USB cable (CBL17) into the USB connector on the rear of the receiver.

Insert the opposite end of the USB cable into an available USB port on the computer.

Step 3

Insert one EMG lead set (542AP) into each EMG probe (542).

Step 4

For charging the sensors, insert power supply (PSU1) barrel connector into the jack of the Sensor Charging Station (543)

Device Communication (Driver) Software Installation

No driver installation is needed. The CDTS Receiver uses the standard Windows HID driver for communication over the USB port.

Companion Software Installation

The CDTS System is compatible with several different software programs. Identify the companion software that accompanied the equipment (MyoResearch or MR3) and follow the appropriate instructions given next.

MyoResearch XP Clinical Applications Protocols Installation

1. Insert the MyoResearch XP Software CD into the PC.
2. A menu will automatically pop up.
3. Click on “Install MRXP” and follow the Wizard’s instructions.
4. When the Wizard requests a password, enter the password printed on your CD case.
5. After installing MRXP exit (close) the MRXP software.
6. Click on “Install Patch” and follow the Wizard’s instructions.

The installed companion software must be *activated* before unrestricted use is possible.

1. Open MRXP.
2. A dialog box will indicate how many more times MRXP can be opened.
3. Click on “Enter Activation Code”.
4. Call or email Noraxon Support with the provided Activation Key.
5. Please include the following: Your name, Company/Organization Name, Serial Number on TeleMyo Clinical DTS Receiver and the Activation Key.
6. Noraxon Support will email or respond by phone with the Activation Code
7. Enter the provided Activation Code to remove any restrictions on use.

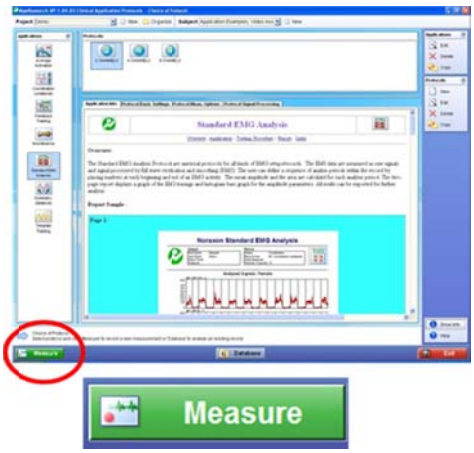
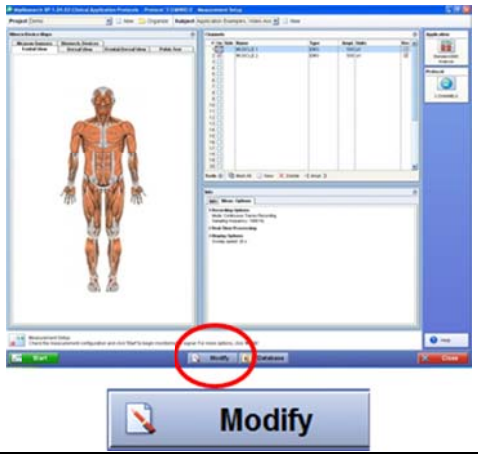
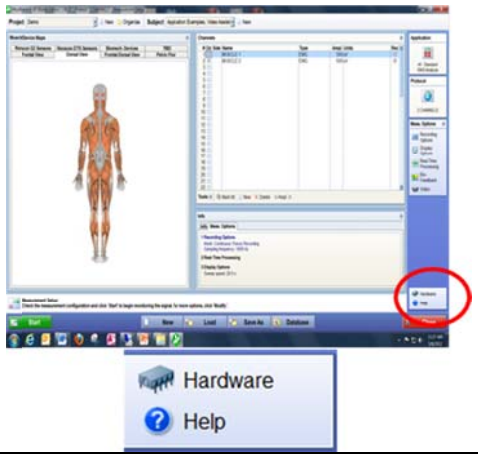
MR3 Installation

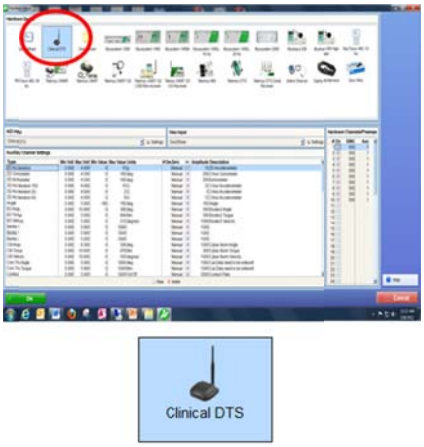
1. Insert the MR3 Software CD into the PC
2. A menu will automatically pop up
3. Click on “Install MR3” and follow the Wizard’s instructions

Companion Software Configuration

Before the Clinical DTS system can be used, the companion software must be configured to recognize the different components that make up the system. Refer to the following configuration instructions for the particular program (MyoResearch or MR3) supplied with the Clinical DTS System.

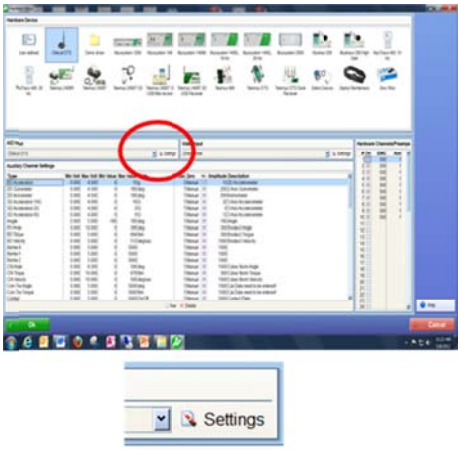
MyoResearch XP Clinical Applications Configuration

	**Step 1** Open the MyoResearch XP Clinical Applications program and click on the Measure button.
	**Step 2** Click on the Modify button
	**Step 3** Click on the Hardware button



Step 4

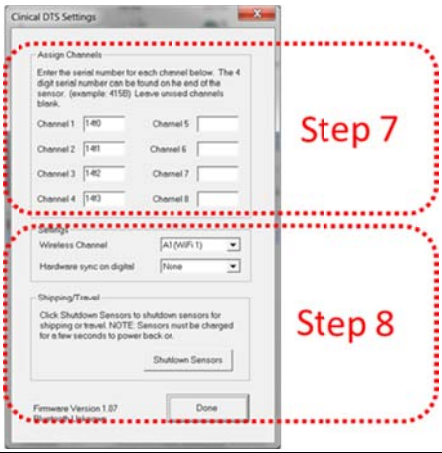
Select (click on) the Clinical DTS Icon from the various devices at the top of the screen.



Step 5

Click on the Settings Icon.

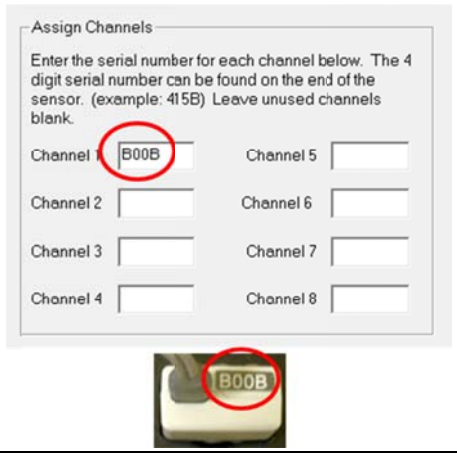
Note: If the CDTS Receiver is not connected to the computer the following message will appear instead of the dialog in step 6.



Step 6

When the CDTS Receiver is attached to the computer's USB port, the Clinical DTS Settings Dialog will appear.

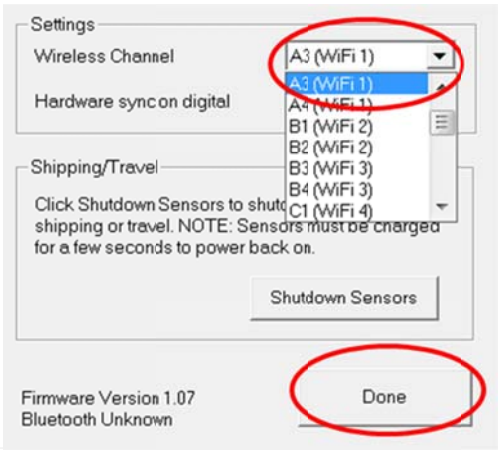
Continue with steps 7 and 8 using this dialog screen.



Step 7

For each CDTS Sensor identify its 4-character serial number and enter the value into a corresponding channel number field.

After this assignment there is no need to refer to sensor serial numbers any more. Channel numbers 1-8 are used to specify sensors.



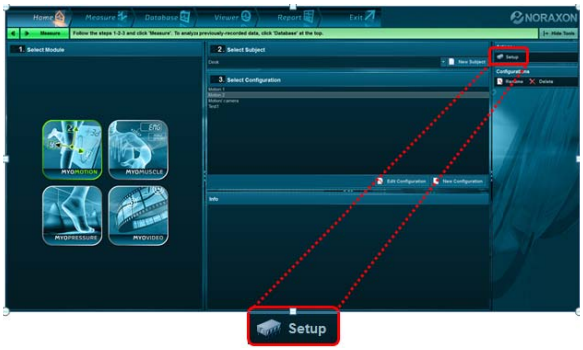
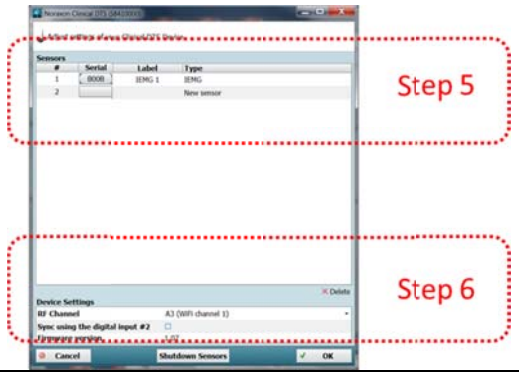
Step 8

Select a wireless radio channel from the pull down list. In most cases the default ‘A1 (WiFi 1)” will work.

Please refer to Appendices A and B for detailed information on radio channel selection.

Click on Done

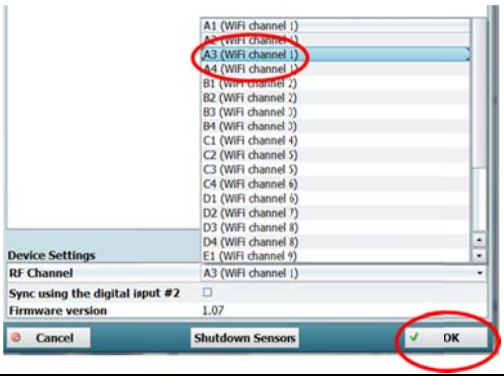
MR3 Configuration

	**Step 1** Open the MR3 program and click on the Setup button.
	**Step 2** Make sure the Clinical DTS Receiver is attached to the USB port of the computer. Click on the Insert Device button
	**Step 3** Double-Click on the Clinical DTS Icon to bring up the dialog of step 4. Note: The Clinical DTS Icon will not be displayed if the device is not attached to the USB port of the computer. If absent go back to step 2.
	**Step 4** When the CDTS Receiver is attached to the computer's USB port, the Clinical DTS Settings Dialog will appear as shown. Continue with steps 5 and 6 using the upper and lower parts of this dialog screen.

Step 5

For each CDTS Sensor identify its 4-character serial number and enter the value into the corresponding Serial column field.

After this assignment there is no need to refer to sensor serial numbers any more. Channel numbers 1-8 are used to specify sensors



Step 6

Select a wireless radio channel from the RF Channel list. In most cases the default ‘A1 (WiFi channel 1)” will work.

Please refer to Appendices A and B for detailed information on radio channel selection.

Click on OK

Section 7: Pre-Use Check-Out

Normal Appearance of Signals

The sensor's green STATUS indicator provides a means of communicating its operational state. In the idle state, the STATUS indicator will flash at a low, once per second rate. When the sensor is actively measuring an EMG signal, the STATUS indicator will flash recognizably faster.

If the STATUS indicator is not flashing at all, the EMG Sensor must be placed in a powered charger station to be reactivated. This could be due to a depleted sensor battery or if the sensor has been deliberately placed in a special shut down mode.

Attaching the EMG Sensor to a Patient or Subject

Do not depend on the wire connection to the disposable electrodes as a means to secure the EMG sensor.

For proper operation the EMG Sensor must be applied to the measurement site so that the reference electrode pad on the bottom side is in direct contact with bare skin. The skin area in contact with the reference pad generally does not require any special preparation prior to applying the sensor. (Some skin preparation for the reference pad site may be beneficial if the EMG signal exhibits a wandering baseline. See Appendix C)

The EMG Sensors can be secured in place using Noraxon supplied double-sided adhesive tape and/or elastic straps. Straps are recommended if dynamic movements are expected.

The EMG Sensor allows for interchangeable terminal lead wires for attachment to disposable electrodes. The two lead wires are offset with one longer than the other by an amount equal to the standard 2 cm spacing for surface EMG electrodes. The 2-pin lead wire connector can be inserted either way into the EMG Sensor to facilitate attachment to the surface electrodes.

Both snap (or button) style and pinch (or clip) style wire terminations are available. Noraxon also offers longer lead wires for special needs.

Calibration

Instruct the subject to relax all muscles for one second at the start of each measurement. (Data collected during the first second of a measurement is used to correct for any offset present in the electrodes or electronics.)

SECTION 8: OPERATING INSTRUCTIONS

Safety Information Summary

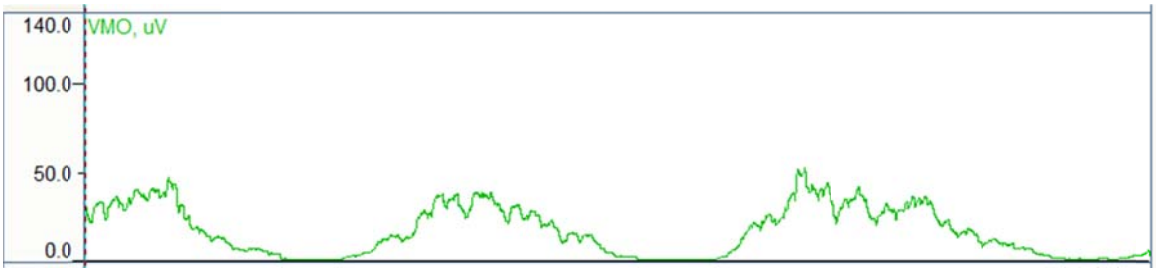
Strictly follow all safety practices given in section 4 of this manual. The most critical ones are repeated here.

CAUTIONS

- Never use the TeleMyo Clinical DTS System on a person with an implanted pacemaker
- Never operate the TeleMyo Clinical DTS System within 1 meter of any critical medical device

Normal Functions with Interface to a PC

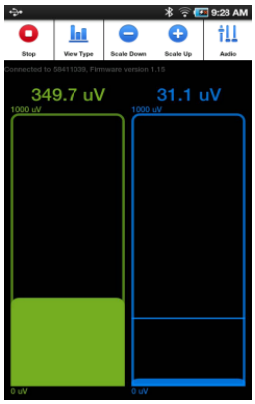
When used with the companion software the CDTS System displays and records processed EMG waveforms that will appear similar to the following.



Consult the user manual for the companion software for descriptions of the setup, playback and analysis of the data acquired by the CDTS system.

Secondary Functions without PC Interface

When used with optional Android software, signals from the CDTS sensors can be shown on a tablet style display in bar graph form. The height of the bar column varies with the strength or intensity of the EMG signal. An audible tone can be sounded when the height of the bar crosses a threshold line. The display is suitable for use in biofeedback training.



Exceptional Functions/Situations (error messages)

Error Message	Meaning
Channel n is not assigned	Channel n (1<n<8) was selected for a measurement but a sensor serial number for channel n has not yet been defined in the companion software.
Could not start all sensors Close the measurement window Check the sensors and try again	One or more DTS sensors failed to respond to a start measurement command. Check to see if any DTS sensors are still in the charging station. This can also happen if the subject is more than 30m away from the CDTS receiver.

Shutdown after Use

At the end of the day:

- Place all DTS sensors inside the sensor charging station
- Apply AC wall power to the charging station which disables the sensor radios
- Unplug the CDTS Receiver's USB cable or else turn off the computer

Storage and Protecting Between Usages

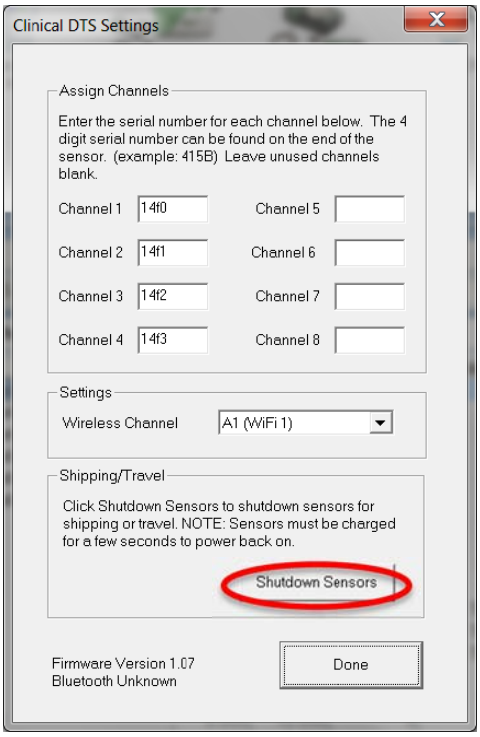
For extended storage or when travelling:

- Put the DTS sensors into sleep mode *****
- Place all sensors into the sensor charging station
- Position all components inside the system travelling case according to their prepared cavities. (see photo in section 6)

***** A special setting in the companion user software activates sensor sleep mode. (See section 6)

To access the shutdown mode in MRXP Clinical Application Protocols:

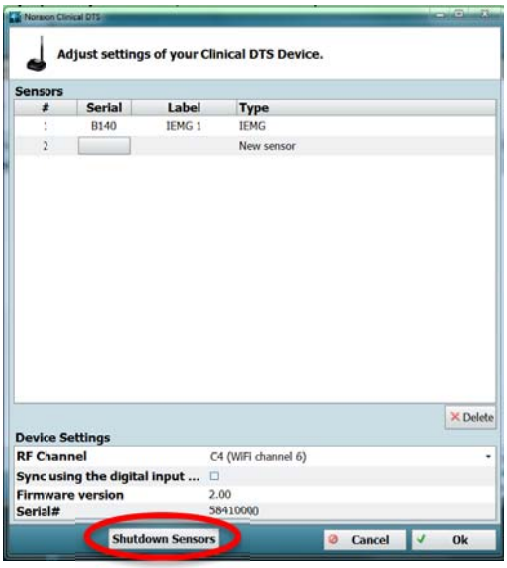
- Click on the **Measure** Button at lower left corner of the screen
- Click on the **Modify** Button at the lower middle of the screen
- Click on the **Hardware** Button at the lower right side of the screen
- Click on the **Settings** Button in the A/D Input section
- Click on the **Shutdown Sensors** Button



When the sensors are shutdown they will stop blinking completely. The sensors are reactivated by briefly charging them.

To access the shutdown mode in MR3:

- Click on the **Home** tab in the top navigation bar
- Click on the **Setup** button at the lower middle of the screen
- Click on the **Hardware** button in the right side Actions toolbar
- Click on the **Noraxon Desk Receiver** icon
- Click on the **Configure Device** button
- Click on the **Shutdown Sensors** Button



Section 9: Accessories and Optional Modules

Accessories

Part No.	Image	Description	More…
543		DTS Sensor Charging Station (8 sensors)	
PSU1		Sensor Charging Station Power Supply	
500		DTS Footswitch Sensor	DOC
504		DTS Single Axis Goniometer (knee and elbow)	DOC
508		DTS Dual Axis Goniometer (hip, shoulder, wrist, back)	DOC
517A		DTS 3-Axis Accelerometer (2G/6G user selectable)	DOC
520/521		DTS Force Sensor (specify 520 = 500Lb or 521 = 100Lb)	DOC
524		DTS Local Pressure Sensor (specify 1Lb, 25Lb or 100Lb)	DOC
529		DTS Hand Dynamometer (200Lb)	DOC

550		DTS Heart Rate Sensor	DOC
514		DTS 2D Inclinometer	DOC
511		DTS Analog Input	DOC
553		DTS Respiration Sensor	
910		Mobie Force Sensor	DOC
542FW		Fine Wire Leads	
500-IS		DTS Insoles-Pair	

As new accessories may be available after the time of printing, please check Noraxon's website at this link for the latest offerings.

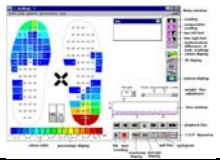
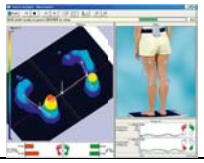
http://noraxon.com/products

Options

Part No.	Image	Description
584B		Android MyoFeedback Software (install on Android Tablets)
TAB1		Samsung Galaxy Tablet (for viewing signals without a PC)

PSU6		CDTS Receiver alternate power supply (when not attached to PC) Required when using a Tablet.

Interfaces to Other Devices

Package	Image	Description
Medilogic Insoles		Measures foot pressure profiles using insoles
Pressure Plate (Stationary)		Measures foot pressure profiles using a plate (Can be used to assess balance)
Pressure Plate (Treadmill)		Measures foot pressure and center of gravity while walking
MyoMotion		Measures human motion in thee degrees of freedom (3 DOF)
MyoVideo		2D motion capture system
Digital camera		For recording the test subject while they perform trials

Section 10: Cleaning

Safety Precautions When Cleaning

WARNING

Only use a damp cloth with mild soap and water or isopropyl alcohol to clean the bottom of the EMG Sensors.

Do not immerse EMG Sensors in any water or liquid.

Cleaning by Users

Clean the bottom of the EMG Sensors on a regular basis. The EMG Sensors can be cleaned with a cloth slightly dampened with a solution of mild soap and water or isopropyl alcohol.

The EMG Sensors are not constructed to withstand repeated application of any disinfectant solution. Likewise, the EMG Sensors are not warranted against exposure to any of the conventional forms of sterilization.

Section 11: Maintenance

Safety Precautions When Performing Maintenance

No precautions required.

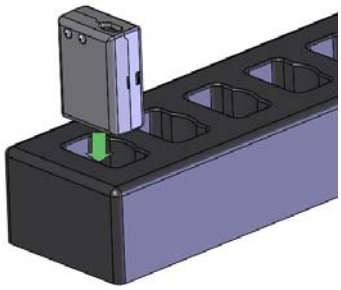
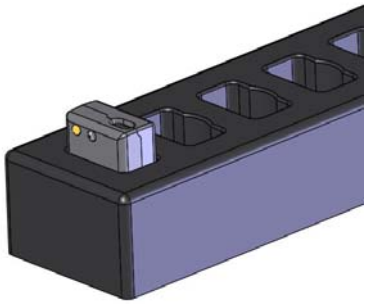
Maintenance by Users

Routine maintenance recommended for the TeleMyo Clinical DTS is cleaning the bottom pad of the EMG Sensor periodically. Because the DTS sensor batteries are Li-Ion, the only battery maintenance required is recharging.

Charging the DTS Sensors

The Clinical DTS Sensors may be charged using the DTS Sensor Charging Station

- Verify that all the sensors are correctly inserted into the DTS Sensor Charging Station (543).
- Plug the DTS Sensor Charger Power Source (PSU1) into the DTS Sensor Charging Station jack (Match blue color-coded connectors).
- Insert the DTS Sensor Charger Power Source into a Power Strip (recommended) or into the wall outlet (mains).
- Verify that the “charge” indicator on all sensors glows amber (yellow).
- Charge for approximately 3 hours or until each sensor “charge” indicator turns off.

1) Insert the DTS Sensor Charger Power Source (PSU1) into the charger jack on the DTS Sensor Charging Station (Part #543)  **2)** Insert the DTS Sensor(s) into the DTS Sensor Charging Station slots.	**3)** The Charge Indicator on the DTS Sensor will show an amber light while charging. The indicator will turn off when the charging cycle is complete. 

Maintenance by Qualified Individuals

The following activities should only be undertaken by PC support (IT) personnel, equipment technicians or those with suitable training.

Companion Software Updates

- Perform a backup of the data folders to a separate drive as a precaution.
- Click on the Patch/Update link provided in the email or as given on the Noraxon website
- http://noraxon.com/software-downloads

- Download the Patch/Update file.
- To install the Patch/Update, click “Run” on the dialog box. No password is required.

Device Software (firmware) Updates

The internal program (firmware) inside the various DTS devices can be updated through the use of a special utility program available at this link:

http://noraxon.com/drivers-and-firmware

The installed program will permit updates to both the CDTS Receiver and the DTS Sensors

Attention

All DTS sensors should be fully charged before firmware update is performed.

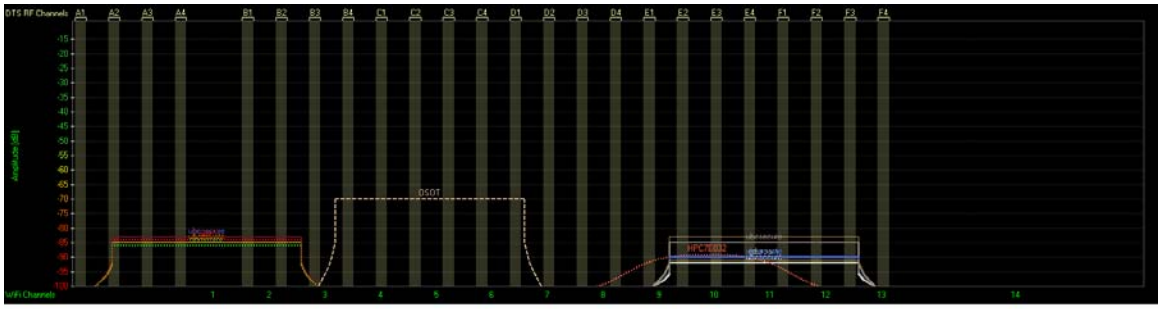
Maintaining an Optimal Wireless Connection

As wireless devices are increasingly more commonplace, the radio traffic in any given location can change often abruptly. The Clinical DTS system operates in the 2.4 GHz band which is shared by wireless networks and personal communication devices. The CDTS system can be set to operate at one of 24 different frequencies within the 2.4 GHz band as given in Appendix B.

Routine examination of the local wireless environment is recommended in order to select the best operating frequency for the CDTS system as in Appendix A. A utility program (inSSIDer) that can be used to monitor WiFi activity is available for download at this link:

http://www.noraxon.com/docs/default-source/Utility-Downloads/noraxon-inssider2-installer.zip?sfvrsn=0

The WiFi monitoring program must be installed on a PC that has WiFi capability. The utility program uses the computer's WiFi radio to detect and report on activity on the various WiFi channels. The inSSIDer display will appear as follows.



It can be readily seen that in the above circumstances, CDTS radio channels A1, D2, D3 and F4 are open or not being used by other radios identified in the immediate vicinity.

Battery Replacement

The Lithium Polymer battery used in the DTS sensors is rated for a minimum of 300 charge-discharge cycles. Typical usage is 500 charge-discharge cycles. As the number of charge-discharge cycles increases the battery capacity slowly declines thereby reducing run time despite being fully charged.

Brand new batteries can operate up to 8 hours when fully charged. If the run time of the sensors drops to 5-6 hours, battery replacement should be considered. The replacement battery is part #BP7. It comes with a short pigtail wire and connector. No soldering is required.

The DTS sensor battery packs should not be replaced by the user. Only qualified technical personnel may perform maintenance.

Section 12: Trouble Shooting, Fault Diagnosis

Troubleshooting Chart

Symptom: **Problem with the PC recognizing the Clinical DTS System**	
Possible Reason	**Remedial Action**
USB cable is disconnected or loose	Check USB cable connection at both receiver and computer
Symptom: **Problems with DTS Sensors communicating with the CDTS Receiver**	
Possible Reason	**Remedial Action**
Sensors were not assigned to receiver	Assign sensors (see section 6)
Receiver antenna is loose or not vertical	Hand tighten antenna and align vertically
Interference on wireless channel	Use another radio channel (see sections 6 and 12)
Symptom: **Problems with individual DTS Sensors**	
Possible Reason	**Remedial Action**
Sensor was not assigned to receiver	Assign sensor (see section 6)
Sensor battery is low (or sensor does not flash)	Retry after charging sensor for at least 15 minutes
Sensor shifts with very dynamic movements	Secure sensor with overlying elastic wrap
Symptom: **Problems with intermittent DTS Sensor signals**	
Possible Reason	**Remedial Action**
Electrode lead set is loose or disconnected	Check lead set connections at both the sensor and electrodes
Sensor reference pad is dirty or not in contact with bare skin	Clean reference pad if needed. Wipe and slightly abrade underlying skin if very dry
Sensor is too far from receiver	Move to within 30m (90 feet) of receiver
Sensor radio signal is partially blocked (absorbed) by subject's body (esp. at long distances)	Reposition sensor on subject to obtain a direct line-of-sight relationship between sensor and receiver

Website Link to FAQ

Answers to common questions can be found at Noraxon's Frequently Asked Questions (FAQ) website page at this link:

http://noraxon.com/faq

Other educational material is available at this link:

http://noraxon.com/educational-materials

Radio Considerations

The TeleMyo Clinical DTS radio system operates in the 2400 MHz ISM (Industrial, Scientific and Medical) radio band reserved for use in most countries of the world. The radio transfers data digitally using a proprietary wireless sensor protocol. Other devices operating in this frequency band include computer networks, microwave ovens, cordless phone sets and other WiFi enabled devices.

Despite all this competing radio activity the TeleMyo Clinical DTS System is able to discern its particular information from all the surrounding radio traffic. Reliable transmission depends on good signal quality. Signal quality will fall with extended distances between the Clinical DTS Receiver and the Clinical DTS EMG Sensors. Obstructions (walls, metal structures, trees, etc.) between the Clinical DTS Receiver and the Clinical DTS EMG Sensors will also lower the signal quality.

While the TeleMyo Clinical DTS is quite immune to interference, it does transmit a deliberate radio signal that could affect nearby sensitive equipment. Users should always be aware of this possibility. In a similar manner, although the energy level of the radio is considered harmless to human beings, it is still prudent to minimize exposure.

Finally, although available worldwide, each country places certain restrictions on the operation of radios in the 2400 MHz ISM band. These restrictions include allowable transmitter power levels and broadcast frequencies.

Setting the Sensor RF Channel

The Sensor RF Channel is the frequency used for communication between the Clinical DTS Receiver and the EMG Sensors. Typically, the default option of RF Channel “A1” (as set inside MyoResearch XP), works well. However, sometimes there is a lot of WiFi traffic in the area that may affect the data transmission between the Clinical DTS Receiver and the EMG Sensors.

If there is too much traffic on the selected RF Channel, significant data loss may occur. In order to avoid data loss, changing the RF Channel to another frequency may solve the problem.

If the RF Channel needs to be changed, select a different letter-number combination in MyoResearch XP Clinical DTS Settings and take another measurement to determine if the data loss problem is resolved.

If data loss is still a problem, please refer to Appendix A for instructions to select another RF Channel. Appendix B shows the actual frequency of each Sensor RF Channel. This information may be helpful in determining the best Sensor RF Channel.

Section 13: Service and Repair

Availability of Circuit Diagrams and Component Lists

Noraxon will make available on request circuit schematics, component parts lists and calibration instructions to assist qualified technical personnel in the service and maintenance of the TeleMyo Clinical DTS System.

Warranty Information

Noraxon equipment including optional items is guaranteed to be free from defects in material and workmanship for 1 year from the date of purchase. The warrant period begins on the date of product shipment from Scottsdale, Arizona.

Warranty coverage does not apply to damage incurred through accident, alteration, abuse or failure to follow instructions contained in this document.

An optional extended warranty is available. Please contact Noraxon USA for further details.

Submitting Service Requests

A Service Request can be submitted using the online form available at this link:

http://noraxon.com/service-request

Provide all information requested by the form including a **detailed** description of the problem being experienced and your telephone number or e-mail address.

Returning Equipment

Be sure to obtain an RMA Number (return material authorization) before returning any equipment. Completing the online service request form will assign an RMA Number. Otherwise contact Noraxon USA.

Send the equipment **postage prepaid** and **insured** to the address below. Include the RMA Number on the shipment label. Mark the package “Goods to be repaired – Made in USA” to avoid unnecessary customs charges. (Beware listing a Customs or Insurance value of $5,000.00 USD or more will result in a delay at United States Customs.)

Noraxon USA
15770 N. Greenway-Hayden Loop
Suite 100
Scottsdale, AZ
85260, USA

If you are shipping from outside the USA please use UPS, FedEx, DHL, or EMS (US Postal Service) and **not a freight-forwarder.** Using a freight-forwarder incurs additional brokerage fees. If a package is shipped to Noraxon via a carrier other than the ones listed above, it may be refused.

Section 14: Spare Parts and Consumables

Consumable Items

Part No.	Image	Description
272		Dual electrodes 8 per pouch or 200 per box
542C		Double sided tape for attaching DTS sensors, 504 per package

Replaceable Items

Part No.	Image	Description
542AP		EMG Lead set, 3 inches with pinch attachments
542AS		EMG Lead set, 3 inches with snap attachments
542AX		EMG Lead set, 7 inches with pinch attachments
BP7		Replacement battery for DTS Sensors
ES2		Elastic strap, 36 inches long (cut to length) for securing DTS sensors

Section 15: Taking Product out of Operation

Disposal of Equipment and Batteries

The Clinical DTS EMG Sensors contain Li-Polymer batteries, which may be hazardous if disposed of incorrectly. Please check with the governing authorities in your location before disposing of the TeleMyo Clinical DTS and its contents.

Section 16: Specifications of the Product

Expected Useful Lifetime

Both the TeleMyo Clinical DTS Receiver (584) and Clinical EMG Sensors (546) have a usable life of seven years.

The DTS EMG sensors (#546) operate with a rechargeable Lithium Ion battery, as do all DTS Sensors. The battery capacity will decline with ongoing use and require replacement after 300+ discharge/charge cycles to preserve the device's rated 8 hours of operating time.

Dimensions and Weight

- EMG Sensor Dimensions
  1.34" L x 0.95" W x 0.55" H (3.4 cm x 2.4 cm x 1.4 cm)
- EMG Sensor Weight: Less than 14 g.

- TeleMyo Clinical DTS Receiver Dimensions
  3.0" L x 4.0" W x 1.4" H (7.66 cm L x 10.18 cm W x 3.55 cm H)
- TeleMyo Clinical DTS Receiver Weight: Less than 120 g.

Performance Characteristics

Output & Transmission Frequency (Depending on country)

- Up to 2.5 mW (depending on country allowance)
- DSSS 2403-2472 MHz on (up to) 20 selectable radio channels
- TeleMyo Clinical DTS sensor transmission range: 10m (typical)

EMG Sensor Data Acquisition System

- 16-bit resolution
- Initial Sample Rate 3000Hz
- 100ms RMS filter before wireless transmission
- Wireless update rate 100Hz

EMG Sensors

- No notch (50/60 Hz) filters are used
- 1st order high-pass filters set to 10 Hz +/- 10% cutoff
- Baseline noise < 1 uV RMS
- Input impedance > 100 Mohm
- CMR > 100 dB
- Input range: +/- 6.3 mV
- Electronic Gain: 200
- Overall Gain: 500
- Sensor operation up to 8 hours on a fully charged battery (recharge time 3 hours)
- Snap-style or Pinch-style terminal electrode connections
- Measurement Function Accuracy: +/- 2uV_{RMS} (EMG)

Energy Consumption, Condition of Use

- Receiver is powered by 5V USB host

Environmental Conditions for Storage and Transport

- Ambient Temperature: -40C to +70C
- Relative Humidity: 10% to 100%
- Atmospheric Pressure: 500hPa to 1060hPa

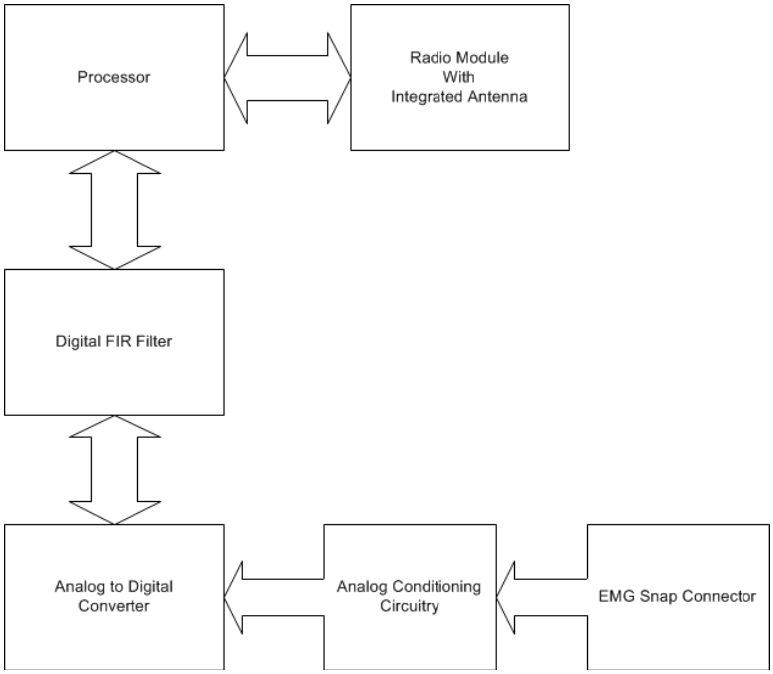
IP (Ingress Protection) Rating

The TeleMyo DTS device enclosures have a low ingress protection rating (IP20). The TeleMyo Clinical DTS Receiver, and in particular the various DTS Sensors are not waterproof. Care must be taken to avoid exposure to all liquids. Heavy perspiration may present problems if the DTS Sensors are secured to bare skin with an over wrap of tape or elastic belting. In such cases it is advisable to first add adsorptive material or cloth over the DTS Sensor before covering the sensor with tape or elastic bands.

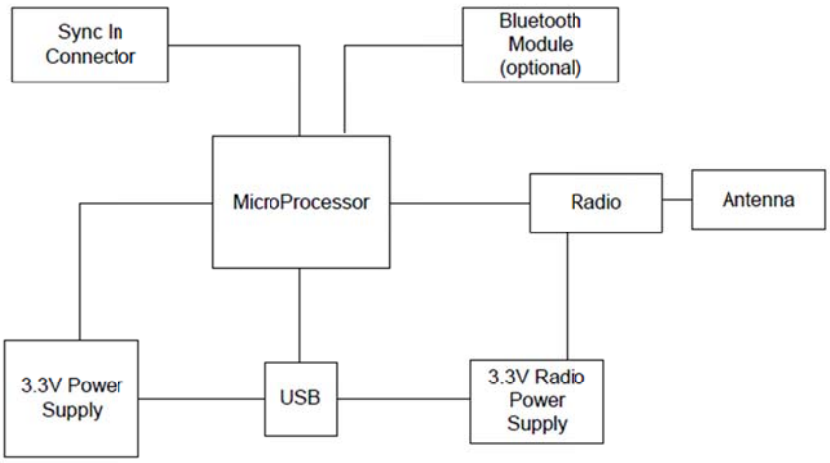
Section 17: Technical Information

Block Diagram

Model 546 Clinical DTS EMG



Model 584 Clinical DTS Receiver



Theory of Operation

The Clinical DTS wireless system is based on a pre-certified transceiver module: UGWG4USHN33 by Unigen. This radio module operates in the 2.4 GHz bands with an output power level of 1 mW and is based on a Wireless USB product by Cypress Semiconductor.

Part 546 Clinical DTS Transmitter (EMG Sensor)

Each Clinical DTS transmitter module (part # 546) incorporates one Unigen transceiver module together with an EMG preamplifier / data acquisition motherboard. The 546 is powered by one 382030 battery (190maH). Each transmitter module is identified by a unique serial number.

The #546 EMG module has 3 patient contact points (applied parts). Two points are standard snap receptacles for attachment to disposable EKG style electrodes. The snap wires are removable. The third patient contact point is a metal disk on the bottom of the EMG sensor enclosure. This disk is intended to be in contact with bare skin. Double-sided tape secures the sensor to the patient.

The opposite end of the transmitter has two recessed contact pads for recharging its battery. To recharge the battery the #546 module is placed inside a charging station. The EMG sensor cannot be applied to the patient and charged at the same time.

Part 543 DTS Charging Station

The charging station (part #543) is configured to hold up to eight (8) #546 EMG Sensor modules. All battery-charging controls are inside the sensor modules. The charging station merely supplies a 5VDC source of power through a set of spring-loaded pins. The spring-loaded pins make contact with the recessed charging pads of the EMG sensors. The 5VDC supply is a medical grade external power supply by Globtek (model GTM41060).

Part 584 Clinical DTS Receiver

The Clinical DTS receiver (part #584) consists of a main motherboard, a Unigen transceiver module and an optional Blueradios Bluetooth module. The receiver has **no applied parts**.

The receiver interfaces to a PC via a USB port. The Clinical DTS Receiver is also powered via the USB connection to the PC.

The Unigen transceiver in the #584 Clinical DTS receiver can communicate with up to four (4) #546 DTS EMG Sensors.

Electro-Magnetic Compatibility Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The TeleMyo DTS is intended for use in electromagnetic environment specified below. The customer or the user of the TeleMyo DTS should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The TeleMyo DTS must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The TeleMyo DTS is suitable for use in all establishments other than domestic establishments 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The TeleMyo DTS is intended for use in electromagnetic environment specified below. The customer or the user of the TeleMyo DTS 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 64000-4-2	±6 kV contact ± 8 kV air	±6 kV contact ±6 kV air	Device user should avoid touching subject and sensor probes while a measurement is active.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines Not applicable	For battery charging mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	For battery charging 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 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) For 25 cycles <5 % U_T (>95 % dip in U_T) For 5 sec	Not applicable to operation Not applicable to operation Not applicable to operation Not applicable to operation	For battery charging mains power quality should be that of a typical commercial or hospital environment.
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 U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The TeleMyo DTS is intended for use in electromagnetic environment specified below. The customer or the user of the TeleMyo DTS should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 (Charging System)	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the TeleMyo DTS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz 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 metres (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 a 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 TeleMyo DTS is used exceeds the applicable RF compliance level above, the TeleMyo DTS should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the TeleMyo DTS.

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

Recommended separation distances between portable and mobile RF communications equipment and the TeleMyo DTS

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
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 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.

SECTION 18: APPENDICES

Appendix A – Interference Between WiFi and DTS Radio Frequency Channels

Because any neighboring WiFi radios and the Clinical DTS System share the 2.4GHz frequency spectrum there is the possibility that the RF channels may overlap and interfere with each other resulting in lost data. To avoid interference, use the chart below to identify Clinical DTS System RF and WiFi channels that do not interfere with each other. For example, Clinical DTS System RF Channels starting with the letter “A” do not interfere with WiFi Channels 4-11. Clinical DTS System RF Channel Set D does not interfere with WiFi channels 1-4 and 11.

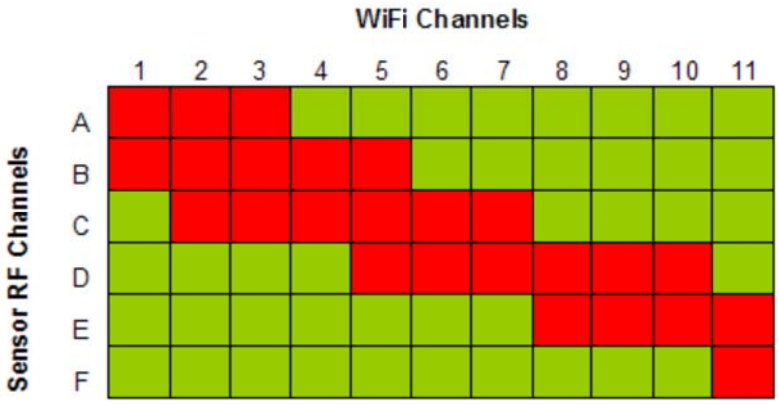
If you are aware of WiFi activity in the vicinity of the DTS system, it is helpful to identify which combinations of the eleven WiFi channels are being used. Once this is determined, use the chart below to select a DTS channel set (A-F) that avoids, as much as possible, WiFi channels that share the same radio frequencies.

Instructions to change the RF channel:

Use a network sniffer program to determine which WiFi RF channels are being used in your area. InSSIDer” is a network sniffer with a graphical display that is available as a free download from the Noraxon website at:

http://www.noraxon.com/docs/default-source/Utility-Downloads/noraxon-inssider2-installer.zip?sfvrsn=0

This network sniffer is compatible with Windows XP, Vista and 7 (32 and 64-bit). You can use most 802.11 a/b/g wireless adapters, e.g. PC internal WiFi, PCMCIA card Wireless network adapter and USB Wireless network adapter, to scan the networks in the area. Once the busy WiFi channels are identified, change the DTS Sensor RF Channel to avoid those WiFi channels.



Appendix B – Sensor RF Channel Frequencies

The EMG Sensors and Biomechanical Sensors operate on a RF channel. The RF Channels (A1-F4) are assigned to the RF frequencies according to the table below.

RF Channel	Frequency (GHz)
A1	2.400
A2	2.403
A3	2.406
A4	2.409
B1	2.415
B2	2.418
B3	2.421
B4	2.424
C1	2.427
C2	2.430
C3	2.433
C4	2.436
D1	2.439
D2	2.442
D3	2.445
D4	2.448
E1	2.451
E2	2.454
E3	2.457
E4	2.460
F1	2.463
F2	2.466
F3	2.469
F4	2.472

Appendix C – Use of Disposable Electrodes

While the TeleMyo Clinical DTS can operate with reusable electrodes, it is typically used with disposable surface electrodes. Any good quality silver/silver chloride electrode is acceptable. Noraxon provides several types of quality disposable electrodes for a wide variety of Surface EMG applications. Other electrodes may be used, but it is recommended that any electrodes used with the TeleMyo Clinical DTS satisfy the requirements for standard ANSI/AAMI EC12-1991 Disposable ECG electrodes.

- Because disposable electrodes have a shelf life, it is important not to use expired parts.
- Bulk disposable electrodes come packaged in a sealed container or bag.
- The expiration date can be found printed on the package container.
- After the sealed bulk container is opened, the remaining electrodes should be used before their gel begins to dry out.
- Always keep the remaining electrodes in their bulk package until they are used.
- If the electrode package does not seal itself, closing the package with tape or using a zippered plastic bag is recommended.
- Do not store the electrode package in the direct sun, as this will accelerate drying.
- Avoid using electrodes that are randomly found lying outside of their bulk packaging as their expiration date is uncertain and their gel has been exposed to accelerated drying.

Be aware that when disposable electrodes are removed, some individuals may notice a faint red skin discoloration over the site previously occupied by the electrode. This skin discoloration is typically benign and temporary and may be due to a mild allergic reaction to the adhesive or simply be a slight abrasion caused by peeling away the tape. It will usually disappear within 24 hours**.**

Noraxon discourages any attempt to reuse a disposable electrode, even if it is simply pulled off to slightly reposition the electrode's muscle placement. Some of the electrode gel may remain on the original site and the EMG signal may be affected. Also, sometimes the electrode adhesive may not adhere to the skin as well when it is reapplied. Noraxon strongly recommends against the use of dried out electrodes that are re-wetted with electrode gel.

Electrode Application Guidelines and Facts

1. If the subject has a fair amount of hair at the electrode application site, the hair should be clipped. Shaving is not necessary and may irritate the skin.
2. The electrode application site should be clean and dry. The preferred method of cleaning is with soap and water plus drying the skin with a dry cloth. Dry skin contributes to good electrode adhesion and good trace quality.
3. Cleaning with isopropyl alcohol should be limited to situations where electrode adhesion is an issue (diaphoresis, excessively oily or lotion covered skin), since it may dehydrate the skin thereby causing skin impedance to increase. If alcohol is used, allow it to dry prior to electrode application.
4. Noraxon recommends attaching the lead wire to the electrode prior to placing the electrode on the skin. This will eliminate the potential for discomfort if snap lead wires are pressed onto the electrode after the electrode has been applied. It will also prevent the electrode gel from seeping out. Additionally, this method will prevent unattached leads from coming into accidental contact with other conductive objects.
5. Electrode application sites may need to be abraded to lower the skin impedance. Fine sand paper or electrode prep gel, e.g. NuPrep, can be used to abrade the skin.

6. Electrodes are the weak link in the EMG measurement chain. Lack of proper attention to electrode quality or site preparation is by far the most common cause of inferior recordings.
7. It may take up to 5 minutes for disposable electrodes to fully stabilize electrically once applied to the skin. If extremely critical or precise measurements are intended, the electrodes should be applied several minutes in advance of the recording.

Appendix D – Radiation Exposure Information Regarding Use of DTS Sensors

Each DTS sensor contains a radio frequency transmitter. The radiated power emitted from each individual DTS sensor is very low. To put this in perspective, at full power each DTS sensor transmits at less than 0.1% of the power of a typical active cell phone. Radiation exposure from a single DTS sensor is thus extremely low.

The DTS sensors are designed to operate at two different power levels in order to keep the already very low levels of radiation exposure to an absolute minimum. The DTS sensors activate their higher power level only during periods of actual data collection. During idle times (at setup and in between actual measurements) the DTS sensors reduce their radiated power to an even lower level (less than 0.01% of the power of a typical active cell phone).

The effects of non-ionizing radiation on biological tissue are still being studied and published 'safe levels' of exposure are subject to review. Today, cell phone usage is widespread and declared 'safe,' although the long-term cumulative effect of cell phone usage has yet to be determined. In contrast, the DTS sensors operate at power levels 1000 to 10,000 lower than typical cell phones while limiting exposure to a single episode over a brief time interval.

Because there can be multiple DTS sensors applied in intimate contact with the body, their sum total collective radiation effect may be questioned. Based on comparative power levels, a full complement of 4 DTS sensors emit a combined (distributed) radiation level still several orders of magnitude lower than that of a typical cell phone, which radiates all of its energy from one focal point (next to the person's head).

At present, Noraxon identifies no restrictions on use and placement of the DTS sensors on any portion of the human body. The DTS sensors operate at radio frequencies known to effect older style pacemakers. Because the effects are not known at this time, Noraxon advises against using the DTS system on anyone with an implanted pacemaker.

In summary it is prudent to keep in mind that due to biological diversity, certain individuals may have higher sensitivity to radiated emissions. Although it has never been known to occur, the use of the DTS system should be stopped if the person being monitored reports any unusual sensations.

Appendix E – Radio Regulatory Statements

FCC Statement

This device 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. Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device contains modules with FCC ID: R8KUGWG4USHN33A.

Industry Canada Statement

This product contains Unigen Wireless USB module Canadian Cert No IC: 5125A-UGWG4US