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JTECH Medical DUALER IQ Pro<sup>™</sup> Manual <u>Publication Information</u>

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## Manufacturer

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## EC REP

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## **Graphic Symbol Definitions**

Symbol		Meaning	
<b>P</b>	An ISO 7010-M002 symbol	Consult Instructions	
Ţ	An ISO 15223 symbol	Keep dry, do not immerse in water or other liquids	
0		Information symbol	
IPXN	An IEC 60529 symbol	IPXN, N=0 no protection against ingress of water.	
	An IEC 60878 symbol	General Warning	
*	An IEC 60417-5840 symbol	Indicates type of protection against electric shock: Type B applied part	
NON	An ISO 15223 symbol	Warning: devices are non sterile	
F©	FCC Logo		
	An IEC 60878 symbol	Indicating degree of protection against electric shock: Class 2 electrical equipment	
	An ISO 15223 symbol	Indicating upper and lower temperature limits	
<u>(</u>	An ISO 15223 symbol	Indicating upper and lower humidity limits	
<b>.</b>	An ISO 15223 symbol	Indicating upper and lower atmospheric pressure limits	
CE	"Conformité Européenne" ("European Conformity")	Dualer IQ Pro instrument meets the provisions of the Council Directive 93/42/EEC	
	An EN 980 symbol	Identifying the Manufacturer	
EC REP	An EN 980 symbol	Identifying the Authorized Representative for European Communities	
$\sim$	An IEC 60878 symbol	Signifying Alternating Current	
	An IEC 60878 symbol	Signifying Direct Current	

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## **Conventions Used Throughout This Manual**

The following conventions will be used throughout this manual to describe the Dualer IQ Pro Primary and Secondary Inclinometer and their operation:

- Calibration The process of using a known angle to adjust the instrument parameters so that any arbitrary angle input can be accurately determined.
- Select Button The center button on the Dualer IQ Pro Primary Inclinometer, which can be used in connection with the Up/Down Buttons in order to operate the device.
- Enter Button The singular button on the top of the Dualer IQ Pro Primary Inclinometer, which can be used to enter the test zero and repitition values.
- Device This refers to a singular JTECH Medical testing device, i.e. only the Dualer IQ Pro Primary Inclinometer or only the Dualer IQ Pro Secondary Inclinometer.
- Exam This term is used to refer to a group of tests performed on a single subject.
- Hold Indicates that a button should be pressed and held.
- Instrument Refers to both the Dualer IQ Pro Primary Inclinometer and the Dualer IQ Pro Secondary Inclinometer when used singularly as the Primary only, or together (Primary and Secondary) to record test data.
- Repetition A repeated portion of a test.
- ROM Range of Motion.

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- Side Either left or right, noted as A and B, respectively.
- Test Used to refer to a group of repetitions performed for one or more sides with a given instrument.
- Up/Down Buttons The buttons to either side of the center select button used to navigate the menus and change options.
- Zero or Set Zero The process of determining the instrument parameters when no angle is applied to the instrument

## Conventions Used Throughout The Menus

The following additional conventions are used throughout the menus:

- Clear Tests A global function that deletes all test data.
- Info Abbreviation on the Primary Inclinometer screen for Information.
- Press any key Indication to press any button.
- Press Enter Indication to press the top Enter Button down.
- Reps See Manual convention Repetition.
- SN Serial Number also referred to as device ID#.

Primary Inclinometer LED states	Explanation
All LEDs off	Normal operation or charging
Blue LED solid	Enter the device zero by pressing "Enter"
Blue LED slowly blinking 1 time per second (1 Hz, 50%) • •	Enter motion A for the current repetition by pressing "enter"
Blue LED rapidly blinking 4 times per second (4 Hz, 50%) • • • •	End the current repetition by pressing "enter"
Orange LED slowly blinks on 1 time per second (1 Hz, 10%)	The battery is low (less than 30 minutes remaining)
Orange LED quickly blinks off 3 times per second (3 Hz, 90%) — — — —	The battery is critically low (less than five minutes remaining)
Orange LED rapidly blinks 5 times per second (5 Hz, 50%) when device is turned on	The battery is dead.

Secondary Inclinometer LED states	Explanation
LED off	Device is off or sleeping
h LED solid	Device is actively communicating, with Primary inclinometer.

## **Errors and Messages**

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A number of errors and messages exist that will be displayed on the LCD when certain conditions are met. Each message is displayed with a message number as described below.

Message #	Message	Description
2:	Check Connection To Secondary	This message is displayed when the Primary inclinometer is expecting to be able to communicate with the Secondary inclinometer but cannot.
3:	Primary Calibration Is Corrupt	This message is displayed if a data error is detected when loading the Primary inclinometer calibration data from memory.
4:	Secondary Calibration Is Corrupt	This message is displayed if a data error is detected when loading the Secondary inclinometer calibration data from memory.
5:	Primary Sensor Error	This message is displayed when the Primary inclinometer experiences a failure of its main sensor.
6:	Test Data Read Error	This message is displayed when there is a problem reading the saved test data from memory in the review mode.
7:	Test Not Saved	This message is displayed if a data error is detected when saving test data to memory.
8:	Test Not Loaded	This message is displayed if a data error is detected when loading saved test data from memory in testing mode.
50:	There Are No Empty Tests	This message is displayed if there are no free tests in the available testing range and the start of a new test is being attempted.
51:	There Are No Saved Tests	This message is displayed when attempting to enter the review mode and no saved tests exist in memory

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## **Warnings and Notifications**

Ĵ	Protection against ingress of liquids: Not protected against ingress of liquids. Keep dry, do not immerse in water or autoclave any portion of Dualer IQ Pro Primary or Secondary Device or accessories.		
Ŕ	Type of protection against electric shock: Type B applied part.		
NON STERILE	Warning: Devices are not sterile.		
$\triangle$	Warning: Dualer IQ Pro should only be used by trained professionals.		
Â	Contraindications Warning: This device should not be used in the following circumstances: <ul> <li>On or near the eye</li> <li>On or near bone fractures</li> <li>On or near open wounds</li> <li>On or near burned tissue</li> <li>With patients suffering with severe osteoporosis</li> <li>For any purpose other than indicated</li> </ul>		
Â	<b>Warning:</b> No modification of equipment is allowed. Do not open the Dualer IQ Pro devices or power supply housings. Opening of housings by anyone other than an authorized JTECH service representative will void your warranty.		
Â	<b>Warning:</b> Changes, or modifications, not expressly approved by JTECH Medical could void the user's authority to operate the equipment.		
	<b>Warning:</b> Use only a factory-supplied charger. Use of another charger may result in electrical shock or equipment damage.		
Ŵ	<b>Warning:</b> Dualer IQ Pro devices are not intended for use while attached to the charger. Never attempt to operate the instrument while it is connected to the charger as electrical shock or damage to the instrument may occur.		
$\triangle$	Warning: Dualer IQ Pro devices have no user serviceable parts.		
$\triangle$	Warning: This device is not suitable for use in the presence of flammable anesthetic mixture with air, or with oxygen or nitrous oxide		
$\triangle$	<b>Warning:</b> Follow all directions as specified by the Caviwipe product being used. Allow device to dry before use.		
0	<b>Notice:</b> Dualer IQ Pro is a precision medical device and should be treated with care. Avoid dropping, banging, or other impacts to the instrument.		
0	Notice: Use only within designated operating parameters, i.e. temperature and humidity limits.		
$\triangle$	Warning: Discontinue use of any product if skin irritation develops.		
Waste Dispo	osal		
$\triangle$	<b>Warning:</b> The Dualer IQ Pro contains Lithium Polymer batteries. Do not dispose of any Dualer IQ Pro device in fire.		
0	<b>Disposal Instructions: The</b> Dualer IQ Pro devices are not known to contain any hazardous materials. Consult your local waste management facility on proper disposal of solid waste. Recycling should be used where available.		

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## **EMC Notice**

For more information on EMC see appendix "EMC Guidance" on page 32.

<b>WARNING:</b> Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Carefully read the information contained in this section.
<b>WARNING:</b> The use of portable and mobile RF equipment can affect the normal operation of medical electrical equipment.
<b>WARNING:</b> Making any modifications or using any accessories not specifically approved by JTECH Medical may reduce immunity to electromagnetic interference or increase electromagnetic emissions.
<b>WARNING:</b> The Dualer IQ Pro instrument should not be used while stacked on, or adjacent to, other electrical or medical electrical equipment. If stacked or adjacent use is necessary, all electrical equipment should be observed to verify normal operation.

## Part 15 Declaration

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (i) this device may not cause harmful interference and (ii) this device must accept any interference received, including interference that may cause undesired operation.

## **Declaration of Conformity**

Dualer IQ Pro instrument is a Class I medical device per Annex IX of Council Directive 93/42/EEC and CFR Title 21 Part 888 Subpart B. The Dualer IQ Pro Instrument also meets the following technical standards, to which conformity is declared:

## ISO 9001:2008

ISO 13485:2003 with Canadian Medical Devices Conformity Assessment System (CMDCAS) Safety and EMC requirements for medical electrical systems (based on the IEC 60601-1 and IEC 60601-1-2 standards)

JTECH Medical and its manufacturing facility are certified to the following technical standards. ISO 9001:2008

ISO 13485:2003 with Canadian Medical Devices Conformity Assessment System (CMDCAS)

#### Intended Use and Indications for Use

The Dualer IQ Pro instrument is used to indicate a value of no direct relevance to patient safety regarding range of motion abilities. The Dualer IQ Pro should only be used by trained professionals.



## Dualer IQ Pro (CM102)

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Used to convey functional abilities concerning Range of Motion (ROM).



- 1. If using the alignment rails accessory, attach the alignment rail to the inclinometer by setting the "Feet" of the inclinometer on top of one alignment rail. Repeat for other inclinometer. To remove the alignment rail, grasp the alignment rail and inclinometer in opposite hands and pull to separate.
- 2. If using VELCRO<sup>®</sup> straps, attach the VELCRO<sup>®</sup> strap to the subject and then attach the back of the inclinometer to the VELCRO<sup>®</sup> strap using a slight twisting motion. To remove the inclinometer from the VELCRO<sup>®</sup> strap, peel the inclinometer from the VELCRO<sup>®</sup> strap and then remove the strap from the subject.
- 3. Push the "On" button on the inclinometer to enable communication with the Dualer IQ Pro Primary Inclinometer . If necessary, repeat this procedure for the other inclinometer.



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For instructions on operating the Dualer IQ Pro, please refer to the Operating Section of the manual. "Using the Dualer IQ Pro" on page 10

For instructions on performing specific tests, please refer to the optional Multimedia Help System.

For troubleshooting information, please see page 19

For technical specifications, please see page 27

Accessories



Alignment Rail (8MH068) – The Alignment Rail magnetically attaches to the Inclinometers for easy visual confirmation of alignment.



VELCRO<sup>®</sup> Strap (47) – The 28 inch VELCRO<sup>®</sup> strap can be used for dynamic range of motion inclinometry testing.



Wrist Lanyard (7AC006) – The Wrist Lanyard is used to help prevent dropping devices when carrying, or when performing some tests.



Connection Cable (7WR020) – The Connection Cable is used to connect the Primary and Secondary inclinometers for dual inclinometry use.

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## System Setup

## Initial Battery Charge

Performing the required initial charge for your new device batteries is essential before attempting to use them. After initial charging is complete, you can begin testing immediately.

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	Warning: Dualer IQ Pro should not be used for testing while connected to the charger.	
	Warning: Use only a factory-supplied charger. Use of another charger may result in electrical shock or equipment damage.	
0	<b>Notice:</b> Device batteries must be fully charged before attempting to use them with your Dualer IQ Pro. Device must charge for at least four (4) continuous hours before its first use.	
0	<b>Notice:</b> Be careful not to drop instrument while connected to the charger as it may cause damage to the instrument.	

## **Charging Instrument Batteries**

- 1. Plug USB daisy chain plug into the Primary inclinometer USB charging jack.
- 2. Plug the battery charger into the USB daisy chain.
- 3. Place the instrument on a flat level surface or back in the box while it charges.
- 4. Plug the battery charger into a properly rated wall outlet (mains supply).
- 5. Allow the Primary inclinometer to charge until the display indicates that charging is complete. This will typically take four (4) continuous hours each time you charge.
- 6. Once the Primary inclinometer is charged, disconnect it from the USB daisy chain.

During normal operation (when the device is not charging) a low battery is indicated by a blinking orange LED. For more information see "Primary Inclinometer LED states" on page 5

## **Battery Life**

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The Dualer IQ Pro primary inclinometer has a rechargeable Lithium Polymer battery. The Dualer IQ Pro is able to operate for approximately ten (10) hours of continual use. In order to conserve battery life, the Primary Inclinometer has an automatic shut-off, which will trigger after 5 minutes of inactivity in any mode except the testing mode. (Note: test data and defaults will not be affected by the instrument turning off). Disconnect the inclinometer from the charger after charge is complete to avoid damage to the battery.

**①** Note: The Secondary inclinometer does not contain a battery. It is powered by the Primary inclinometer.

## **Displaying Battery Voltage**

- 1. Select "Settings" from the main menu.
- 2. Highlight "System," and press the Select Button.
- 3. Press Up/Down until "Info" is displayed, and press the Select Button.
- 4. The LCD screen will show the firmware revision, battery voltage, and calibration information.



## Turning Dualer IQ Pro On and Off

## **Turn On the Primary Inclinometer**

To turn on the Primary inclinometer press the Select Button.

## **Turn Off the Primary Inclinometer**

To turn off the Primary inclinometer press and hold the Select Button while in the main menu. **① Important Note:** When test data is stored in the Dualer IQ Pro memory, turning the power off does not erase that data from the memory. See "Reviewing and Deleting a Test" on page 14 for information about clearing the memory.

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## **Settings**

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To change the Dualer IQ Pro settings, enter the settings screen from the main menu. While in the settings screen, press up and down to change the highlighted settings. Press select to either change or enter the highlighted setting. For more information see "Global System Settings" on page 14

## **Connecting Primary and Secondary Inclinometers**

**O** Note: The Primary inclinometer must be in testing mode before connecting the secondary to ensure proper communications between the devices.

The Primary and Secondary inclinometer are only connected when used for dual inclinometer measurements, such as spine ROM. The inclinometer's do not need to be turned off when making the connection.

- 1. Insert an end of the connecting cable into the port on top of the Primary inclinometer. Make sure the cable is fully inserted.
- 2. Insert the other end of the connecting cable into the port on the Secondary inclinometer, also making sure it is fully inserted.

**()** Note: The Primary inclinometer functions as a stand-alone instrument for single inclinometry procedures, while the Secondary device only functions when attached to the Primary inclinometer.

#### **Disconnecting Cables**

- 1. Pull the connecting cable end out of the Primary Inclinometer.
- 2. Pull the connecting cable end out of the Secondary Inclinometer.

#### Main Menu

When the Dualer IQ Pro Primary Inclinometer is powered on, the main menu will always be the starting screen. From the main menu, you can select the following options:

Test - Select this option to begin performing tests.

Review - Select this option to review any completed test data, or delete specific tests.

Settings - Select this option to set test defaults, for more information see "Settings" above or "Global System Settings" on page 14.

For menu structure see "Menu Tree" on the next page

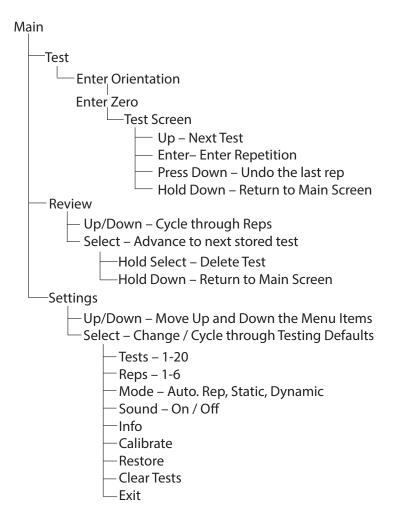
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## Menu Tree



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## Performing an Exam

#### **General Inclinometry Testing**

Prior to beginning a test, ensure that the test defaults are set as desired (i.e. unit of measurement, number of tests, number of repetitions, etc.). Once test defaults are set (see "Global System Settings" on page 14), choose the "Test" option from the main menu, and follow these steps:

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To test using dual inclinometry, simply plug the Secondary inclinometer into the Primary inclinometer at the beginning of a test (before entering the zero). If the Secondary inclinometer becomes unplugged (or otherwise experiences a hardware issue) during a dual inclinometer test, the test will be paused until the issue is resolved.

## **Dualer IQ Pro Orientation During Use**

The Dualer IQ Pro uses gravity (or the floor) as the reference point when measuring range of motion. There are several different orientations which can be used for measurement. At the start of a test the orientation can be selected and an icon on the LCD displays the current orientation for the current test.

• To change the plan of motion, press select at the beginning of a test (before entering the zero).

While in the test mode, the controls are as follows:

- 1. Press down to be prompted to redo the last rep. This does not work in auto-rep mode.
- 2. Press up to skip to the next test.
- 3. Hold down to exit the test mode.
- 4. Press select to cycle through the planes of motion prior to beginning a test.

**1** Note: The Dualer IQ Pro does not require a full calibration of the Inclinometers prior to starting each exam.

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## **Static Testing Mode**

Each individual repetition is zeroed by pressing the Enter Button at the beginning of the repetition and ended by pressing the Enter Button at the end of the repetition.

Static testing can be performed using either single or dual inclinometry protocols. Static testing means the patient's range of motion is measured in a static position. In Static Testing Mode, ROM is also only measured for a single joint movement, such as single inclinometry elbow flexion or dual inclinometry thoracic kyphosis. To perform static tests you must change into Static Testing Mode.

## **Dynamic Testing Mode**

Each test is zeroed on the first repetition. After being zeroed on the first repetition, each repetition is ended by pressing the Enter Button again. This is similar to Static Testing Mode except that there is only one zero (at the beginning of repetition 1).

Using dual inclinometry in Dynamic Testing Mode is the preferred method for measuring most spine ranges of motion. Dynamic Testing Mode measures movement pairs, such as cervical flexion/extension, or left and right cervical lateral flexion. To perform dynamic tests you must change into Dynamic Testing Mode.

Dynamic tests can be performed using dual or single inclinometry. For dual inclinometry, the display provides three measurements: movement of both devices and Total Range of Motion. For single inclinometry, the display only shows the Primary device's movement. Dynamic testing for dual or single inclinometry is essentially the same.

#### Auto-Rep Mode:

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Each test is zeroed on the first repetition. After being zeroed on the first repetition, the inclinometer moves to some max angle (greater than 10 degrees from zero), and then returns to within 10 degrees of the zero position. The maximum angle will automatically be stored and the next repetition will start.

#### **Extremity Protocols**

Dual or single inclinometer methods can be used for measuring range of motion of each joint. Choose the method most comfortable for you to use. Dual or single inclinometer methods can be used with the protocols for measuring ankylosed joints. For instructions on performing specific tests, please refer to the optional Multimedia Help System CD.

#### **Simulated Goniometer**

The Inclinometers can be used to simulate a goniometer, both in dual and single inclinometry modes, when measuring extremity ranges of motion. While the individual angles of the Primary and Secondary units are displayed for dual inclinometry, only the Total Range of Motion value is typically required for extremity range of motion. The Dual Inclinometers are very accurate for measuring extremity ranges of motion because it effectively eliminates goniometer alignment errors and substantially increases inter- and intra-rater repeatability. For instructions on performing specific tests, please refer to the optional Multimedia Help System CD.

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## **Viewing and Changing Testing Defaults**

The Dualer IQ Pro has several global settings, which will change the defaults used by the Dualer IQ Pro Primary and Secondary Inclinometers.

## **Reviewing and Deleting a Test**

- 1. To review saved tests, enter the review mode from the main menu.
- 2. While in the review mode, the controls are as follows:
  - Press up to view the next repetition
  - Press down to view the previous repetition
  - Press select to skip to the next test
  - Hold select to be prompted to delete the current test
  - Hold down to return to the main menu

## **Global System Settings**

- Tests This is the maximum number of tests to use in test mode. This can be set from 1-20.
- Reps This is the number of repetitions to use for each test. This can be set form 1-6.
- Mode This is the testing mode to use. This can be static, dynamic, or auto-rep.
  - Static: In static mode, each repetition is started by pressing enter to zero the devices, and then pressing enter a second time to record the measurement and end the rep.
  - Dynamic: In dynamic mode, each test is zeroed at the beginning of the first rep only, and then motion A is recorded by pressing select, followed by motion B. After motion B is recorded the next rep begins (or the test ends upon completion of the last rep)
  - Auto-rep: In auto-rep mode, each test is zeroed at the beginning of the first rep only. The repetitions
    then automatically progress by moving the inclinometers through the range of motion. The Dualer
    IQ Pro will keep track of the maximum angle reached for each motion (motion A and motion B) and
    automatically advance to the next motion or rep when the inclinometers near the zero point. In this
    mode, passing 10 degrees from the zero point will start the motion, dropping 10 degrees from the
    maximum point in the motion will capture the measurement, and dropping below 7 degrees from the
    zero point will end the current motion.
- Sound On/Sound Off This toggles the sound on and off.
- Info This displays the firmware revision, battery voltage, and user calibration information.
- Calibrate This puts the Dualer IQ Pro into user calibration mode.
- Restore This overwrites user calibration data with factory calibration data.
- Clear Tests This deletes all saved test data.

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## Calibration Settings

## **Restoring Factory Calibration**

Each instrument has been factory calibrated to ensure accuracy. It is possible that the user calibration may be different from these pre-set parameters, which may lead to invalid force/angle reading. Prior to performing a full calibration, attempt to restore the factory calibration stored on each instrument. If this does not correct the problem a full calibration may be required.

Follow these steps to restore the factory calibration:

- 1. Select "Settings" from the main menu.
- 2. Use the Up or Down buttons until you highlight "Restore."
- 3. Press the Select Button to select restore.
- 4. The LCD screen will display "RESTORE CALIBRATION."
  - i. Select, "No" to return to the Settings menu.
  - ii. Select "Yes" to restore the factory calibration settings.

**()** Note: Restoring the factory calibration only overwrites the user calibration data with the factory calibration data stored on the instrument.

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**()** Note: For information on recommended annual factory recalibration, contact JTECH Customer Service at 1-800-985-8324, ext. 4 or service@jtechmedical.com

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**Performing a Full Calibration on the Inclinometers** Follow These Steps to Perform a Full Calibration:

**①** Note: The angles for a full calibration on the inclinometers must be exact for the calibration to be valid. It is recommended to use a T-Square or other tools that have exact right angles. You should also always use the same surface on the inclinometer for reference; the feet and the back of the inclinometer are the recommended reference surfaces on the inclinometer

- 1. Begin with the Secondary inclinometer disconnected from the Primary inclinometer
- 2. Select "Settings" from the main menu.
- 3. Use the Up or Down buttons until you highlight "Calibration."
- 4. Press the Select Button to begin calibration.
- 5. Set the inclinometer in the upright position.
- 6. Press the Select Button to save this position.
- 7. Rotate the inclinometer 90 degrees to the left.
- 8. Press the Select Button to save this position.
- 9. Rotate the inclinometer 90 degrees more to the left, so it is 180 degrees from the starting position.
- 10. Press the Select Button to save this position.
- 11. Rotate the inclinometer an additional 90 degrees to the left, so it is 270 degrees from the starting position.
- 12. Press the Select Button to save this position.

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- 13. Place the back of inclinometer on a flat surface with the LCD face up.
- 14. Press the Select Button to save this position.
- 15. Place the front of the inclinometer on a flat surface with the LCD facing down.
- 16. Press the Enter Button to save this position.
- 17. Connect the Secondary inclinometer and repeat the process

**①** Note: For information on recommended annual factory recalibration, contact JTECH Customer Service at 1-800-985-8324, ext. 4 or service@jtechmedical.com



## Features and Benefits

- The Dualer IQ Pro is a battery powered ROM testing system, which allows for unprecedented mobility.
- Easy-to-read 2.5" diagonal backlit Liquid Crystal Display (LCD).
- Straightforward and easy to navigate menus and testing screens.
- Test settings can be changed to accommodate many different testing goals.
- Test data for up to 20 tests with up to 6 repetitions per test are stored on the Dualer IQ Pro until deleted, which allows for the freedom of testing now, and reviewing the tests at a later time.
- Impact resistant Polyvinyl Chloride (PVC) plastic housings.
- Ergonomic designs.
- Functions in Dual or Single inclinometry modes.
- Designed to meet testing criteria for published research.
- Solid-state accelerometer sensors for increased reliability and accuracy.
- Long life rechargeable Lithium Polymer battery, no replacement batteries needed.
- Auto-rep, Dynamic and Static measurement modes.
  - Static: Calculates anatomic angles based on two stationary landmarks
  - Dynamic: Examiner measures functional ROM through opposing joint motions using a common neutral zero point
  - Auto-rep: Automatically detects ROM end points after examiner establishes neutral zero
  - Testing displays Total ROM, Primary value, Secondary value, Test number, Repetition, Mode
- Magnetic rail attachments for easier alignment with anatomical landmarks.

## **Available Upgrades**

The following upgrade products are available:

EasyDocs<sup>™</sup> Software - Enter Dualer IQ Pro test data into your PC with this keyboard entry software. EasyDocs Software maintains your test data, with the option to print computerized reports in both narrative and data formats. With EasyDocs you can quickly and easily create cutting-edge data and narrative reports.

For easier impairment rating, Easy Docs has an optional AMA licensed Impairment Module. The Impairment Module automatically calculates test validity and impairments to the whole-person level based on your test data.

For more information on upgrades, contact your JTECH sales representative or call JTECH at 1-800-985-8324 or 1-385-695-5000.



## **General Information**

The following section is provided to help you with questions about your Dualer IQ Pro

How do I know when the instrument's battery is low?

The LED on the instrument will begin rapidly blinking Orange instead of Blue (see the instrument LED codes on page 5). If the LED is slowly blinking Orange, this indicates that less than 20 minutes of battery power remains.

How long does the DualerIQ Pro continue to operate after the low power signal?

The total amount of operational time varies, normal use is approximately 10 hours of continual use before the low power signal is displayed. Like a cell phone, the instrument uses more power when active and recording data than when in the off power state. Our recommendation is to place the instrument on the charger as quickly as possible after the low power signal comes on.

Can I use the instrument without fully charging it?

*Yes. The instrument will function without a full charge, but the operational time will be significantly reduced. You should place the instrument back on the charger to completely charge the battery as soon as possible.* 



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Warning: Dualer IQ Pro is not intended for use while attached to the charger. Never attempt to operate the instrument while it is connected to the charger as electrical shock or damage to the instrument may occur.



**Warning:** Use only a factory-supplied charger. Use of another charger may result in electrical shock or equipment damage.

## How long do the batteries take to charge?

The initial charge takes four (4) continuous hours of charging to complete. The first charge is important as it can affect the amount of power the battery will hold. Subsequent charges should also be completed in four hours, or until the device indicates that charging is complete.

## What happens if I leave the instrument on the charger too long?

We have designed special circuitry to protect the instrument's electronic components. The instrument automatically turns off after four (4) to six (6) hours, or when charging is complete. Devices should be left to charge until they indicate that they are done. As with any Lithium Polymer battery, leaving instrument connected to the charger for extended periods (e.g. weeks) can reduce the overall life of the battery. Leaving instrument connected over the weekend should not affect the life of the batteries.

What happens if my instrument does not recharge?

Because of the sensitive electronics inside, the Dualer IQ Pro is not designed for battery replacement in the field. If an instrument fails to hold a charge, contact JTECH Medical Customer Service for repair or replacement options.

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What are the current travel restrictions for Dualer IQ Pro?

Current regulations do not prohibit carrying on Dualer IQ Pro or checking them in baggage. Since the batteries are already installed safely in the devices, there are no FAA, TSA or DOT restrictions on checking Dualer IQ Pro. If the devices are checked, they should be secured properly in the hard case to guard against the device being turned on during transport.

More information and Frequently Asked Questions are available for your JTECH Medical Dualer IQ Pro and instrument by visiting our customer portal at http://portals.jtechmedical.com

Problem	Probable Cause	Possible Solution
Does not appear to respond to the charger. The colored LED does not light.	Bad Connection or Inoperable Battery.	Check the USB daisy chain connection to the charger and the connection to the wall outlet. If the LED does not light up after 60 minutes, contact JTECH Customer Service for repair options.
A button will no longer click when pressed.	Possible damaged button.	Please contact JTECH Support for repair options.
LED blinks rapid orange and does not stop.	Dead battery indicator.	Charge for one complete cycle (up to 4 hours) and attempt to use it again.
The Primary inclinometer will not turn on	The software has locked up or the battery charge is fully depleted.	<ol> <li>Use a paper clip to press the miniature reset switch located on the bottom of the inclinometer. Try to turn the device on.</li> <li>Connect the Primary inclinometer to the charger and wait one hour. If the battery is deeply discharged it may take this long for the inclinometer to respond when plugged into the charger.</li> <li>Otherwise contact JTECH support for repair options.</li> </ol>
The angles being displayed in the test mode do not correspond with the movement of the device		<ol> <li>Ensure the device is being moved in the same plane as what is selected in the test screen.</li> <li>Ensure the device has proper calibration.</li> </ol>
The Secondary inclinometer will not connect to the Primary inclinometer		<ol> <li>Ensure the cable is fully inserted in both devices.</li> <li>Ensure that the Secondary inclinometer is connected prior to entering the first zero for a test.</li> <li>Ensure the Primary inclinometer does not have a critically low battery.</li> </ol>

Troubleshooting Your Dualer IQ Pro

Additional troubleshooting information can be found by visiting our customer portal at http://portals.jtechmedical.com

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## **Storage and Cleaning of Instrument**

**O** Notice: The Dualer IQ Pro is a sensitive electronic device, and should be handled with care. If handled and cared for properly, the devices have all been designed and manufactured to provide years of accurate and reliable use. Avoid dropping, banging, or other impacts to the instrument. Use only within designated operating temperatures.

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## **Storage**

When your Dualer IQ Pro is not in use, store it in the protective carrying case which came with your device.

- 1. If instrument are stored for periods longer than 30 days, recharge batteries before using.
- 2. Store in an area with a controlled temperature within the recommended temperature range. (see temperature and humidity limits in "Technical Specifications" on page 26)

**1 Important Notice:** Never store Dualer IQ Pro instrument in an automobile, except when transporting them, regardless of the season.

## Cleaning, Disinfection, and Sterilization.



Warning: Keep dry, do not immerse any part of any Dualer IQ Pro instrument, or accessories in water or any other fluid.



Dualer IQ Pro, instrument and accessories are non-sterile devices and are not compatible with sterilization techniques, such as autoclave.

- Do not autoclave the Dualer IQ Pro or accessories.
- Do not clean with abrasive materials.
- Do not clean with solvents, or disinfectant not approved by JTECH Medical.

## **Recommended Cleaning of Dualer IQ Pro and Accessories**

• Wipe surfaces with a soft, dry cloth.

## Recommended Alternative Method for Cleaning Dualer IQ Pro and Accessories.

- CaviWipes disinfecting Towlette
  - Use only as directed, following all instructions and warnings on the CaviWipes packaging.

**Warning:** Follow all directions as specified by the CaviWipe product being used. Allow devices to dry before use.

## **Preventative Inspection**

Dualer IQ Pro devices have no associated methods of preventative inspection.

## Maintenance

Dualer IQ Pro is not user serviceable and does not include a service manual. For any service including maintenance, repair, and calibration, contact JTECH Medical Customer Support at 1-800-985-8324 or 1-385-695-5000

## Calibration of Instrument

## **Full Calibration**

Your Dualer IQ Pro has been factory calibrated. Factory calibration information is stored directly on the instrument itself. Should the Dualer IQ Pro ever begin to display erroneous information, the factory calibration can be restored from within the Dualer IQ Pro menus, see "Restoring Factory Calibration" on page 15 for more information. If necessary, a full calibration can also be performed. Refer to "Full Calibration" on page 21 for further information on this process.

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## **Factory Calibration**

**()** Note: For information on recommended annual factory recalibration, contact JTECH Customer Service at 1-800-985-8324, ext. 4 or service@jtechmedical.com

## **Product Registration**

Please register your Dualer IQ Pro as soon as possible. Your registration ensures that you have easy access to JTECH Medical Customer Service and Support.

To register your system, contact JTECH Medical Customer Service at (800) 985-8324 or (385) 695-5000.

## **Repair Policy**

**1** Important Notice: JTECH will not accept any products without a JTECH issued RMA number.

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Warning: Dualer IQ Pro has no user serviceable parts.

## To have your Dualer IQ Pro repaired

Although the Dualer IQ Pro is manufactured with great care, and tested thoroughly prior to shipment, it is possible that your Dualer IQ Pro may require repair. If this unlikely event arises, please follow these instructions in order to ensure accurate and prompt servicing of your instrument.

- 1. Contact JTECH Medical Customer Support at 1-800-985-8324 ext. 4 to obtain a Return Material Authorization (RMA) number.
- Carefully package the instrument and all accessories, mark the RMA# on the outside of the package, and ship the instrument using a service that offers both insurance and tracking of your package (Note: JTECH Medical is not responsible for any damages or loss that may occur during shipment).

**()** Notice: JTECH reserves the right to refuse or to return-collect any merchandise sent for repair without prior authorization from our Customer Service Department. Please refer to the customer support section of this manual for requesting an RMA.

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Authorized repairs must be shipped to:

JTECH Medical 7633 S Main St. Midvale, UT 84047 ATTN.: RMA# (insert number)

Return the Dualer IQ Pro (including all accessories) postage paid and insured to JTECH Medical. **(f)** Notice: JTECH Medical is not responsible for loss or damage during shipping.

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## **Customer Support**

JTECH Medical provides customer support for all products we sell.

You may register up to three individuals from your office to serve as eligible customer support contacts (this can be done anytime during your support agreement). The three contacts are registered for the life of your support agreement. Please note that support will only be available to the registered individuals from your office.

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## Support Policies

## Hardware

Your hardware is shipped with a limited warranty (Please refer to warranty section). You will be charged for any hardware issues (repair, replacement, shipping, etc.), after the initial warranty time period. You can buy extended warranties for your Dualer IQ Pro hardware.

Please contact JTECH Medical Customer Service for more information on JTECH Guardian Hardware Maintenance plans.

## Before Calling for Support

- 1. Refer to the Instrument User's Guide in this manual first.
- This User's Guide was written to acquaint you with the instrument. The guide explains how to use the instrument and how to review the data. Please read through this documentation carefully.



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- 2. Refer to the Troubleshooting section in your documentation. Many hardware issues can be resolved by referring to this section. Additional troubleshooting
  - information can be found by visiting our customer portal at http://portals.jtechmedical.com
- 3. If you are unable to solve your problem using the included documentation, please have a registered support contact call JTECH Medical Customer Support at 1-800-985-8324 or 1-385-695-5000.

## To receive more accurate and efficient support

Please be ready with the following:

- 1. Name of clinic and support contact
- 2. Customer number
- 3. Date of purchase
- 4. Product name or type and Product serial number(s)
- 5. Description of the problem

## **Product Return Policy**

• New hardware may only be returned for credit within 15 days of receipt. No cash refunds will be issued.

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• No returns of used or purchased demonstration inventory will be accepted.

Hardware items returned for credit within 15 days will be subject to a 20% restocking fee, provided the items are in new condition and in the original packaging. If items require refurbishing or repair, the cost of service or repair will be deducted from the amount of credit. A Return Material Authorization (RMA) number must be obtained from JTECH Customer Service prior to returning any merchandise. When phoning or writing for an authorization number to return merchandise, please provide the Customer Service Department with:

- 1. Your name or customer number as it appears on the invoice or packing slip.
- 2. Your telephone number and person to contact.
- 3. Your P.O. number if applicable.
- 4. The part or catalog number(s) and description.
- 5. The reason for the return.

JTECH reserves the right to refuse or to return-collect any merchandise sent back without prior authorization from our Customer Service Department. Authorized returns must be shipped to:

JTECH Medical 7633 S Main St. Midvale, UT 84047 United States of America ATTN.: RMA# (insert number)

When returning merchandise, please include a copy of your original invoice or packing slip to ensure prompt issuing of credit. Return the Dualer IQ Pro (including all accessories) postage paid and insured to JTECH Medical.

O Notice: JTECH Medical is not responsible for loss or damage during shipping.
 O Important Notice: JTECH will not accept any products without a JTECH issued RMA number.

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## **Hardware Limited Warranty**

Dualer IQ Pro is designed to perform reliably, meet manufacture's specification, and provide long lasting service. In spite of diligence in manufacturing, eliminating malfunctions resulting from random component failure is impossible. Should the product fail to work properly within the designated warranty period, JTECH will, at its option, repair or replace the product with a new or reconditioned instrument at no charge. Warranty begins at the date of purchase. New hardware includes a standard one year limited warranty.

In view of the varied conditions in which the equipment will be used, it is sold "as is" and JTECH's responsibility does not go beyond the terms set forth above. JTECH will not be responsible for medical expenses or any direct, incidental, or consequential damages arising from the use of this product. JTECH shall in no way be liable for the loss of revenue or profits resulting from, or alleged to result from, use of this product.

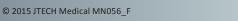
THIS WARRANTY IS MADE EXPRESSLY IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING AN IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. UNDER NO CIRCUMSTANCES SHALL JTECH BE LIABLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. THE REMEDIES SET FORTH IN THIS WARRANTY SHALL BE THE ONLY REMEDIES AVAILABLE, EXCEPT AS SPECIFICALLY PROVIDED BY STATE LAW. NO PERSON HAS ANY AUTHORITY TO BIND JTECH TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

**①** For Government Use: Please refer to the hardware warranty on the installation media you received.

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## **Technical Specifications**



## Dualer IQ Pro Primary Inclinometer (CM113)

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Used to convey functional abilities concerning Range of Motion (ROM).

## **Technical Specifications**

Dimensions	5.84 cm x 7.37 cm x 2.49 cm (2.3 in x 2.9 in x 0.98 in)
Weight	0.15 kg (0.33 lb)
Accuracy	±2°
Memory Capacity	20 Tests with up to 6 repetitions per test
Operating Temperature, Humidity, and Atmospheric Pressure	+10°C +50°F +50°F 10 % -50 kPa
Transportation and Storage Conditions	-40° <u>C</u> -40° <u>F</u> -40°F
Internal Power Source	Non-User serviceable, Lithium Polymer battery
Recharge time	Four(4) - six(6) continuous hours of charging following initial charge
Operating time per charge	10 hours minimum
Specified Power Supply, (Battery Charger)	Powertek Model PMP15M-10-B1 JTECH PN: PW006
Maximum Input Voltage/Current	5 V / 3 A
Type of Operation	Continuous
Type of Protection against electric shock	Internally powered equipment
Degree of protection against electric shock	Type B equipment
Protection against harmful ingress of water	IPX0 - ordinary equipment
Degree of Safety of Application in the presence of flammable mixtures	This device is not suitable for use in the presence of flammable anesthetic mixture with air, or with oxygen or nitrous oxide
Symbols	PX0 T IPX0

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## Dualer IQ Pro Secondary Inclinometer (9CM114)

Used with the Primary inclinometer to enable the collection of dual inclinometry data for conveying functional abilities concerning Range of Motion (ROM).

## **Technical Specifications**

Dimensions	6.6 cm x 7.1 cm x 2.5 cm (2.6 in x 2.8 in x 0.98 in)
Weight	0.09 kg (0.20 lb)
Accuracy	±2°
Operating Temperature, Humidity, and Atmospheric Pressure	+10°C +50°F +50°F +50°F +50°F +50°F +50°F +50°F +50°F +50°F +50°F +10°C +50°F +10°C +10 +10°C +1
Transportation and Storage Conditions	-40° <u>C</u> -40°F
Internal Power Source	None
Maximum Input Voltage/Current	5 V / 3 A
Type of Operation	Continuous
Type of Protection against electric shock	Internally powered equipment
Degree of protection against electric shock	Type B equipment
Protection against harmful ingress of water	IPX0 - ordinary equipment
Degree of Safety of Application in the presence of flammable mixtures	This device is not suitable for use in the presence of flammable anesthetic mixture with air, or with oxygen or nitrous oxide
Symbols	🌮 TPX0 🛧 🖳 🧲

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## Specified Power Supply (Battery Charger PW006\*)

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The Specified Power Supply (Battery Charger) is used with the Daisy Chain, for charging your Dualer IQ Pro.

\*Power supply connection may vary according to the country shipped to

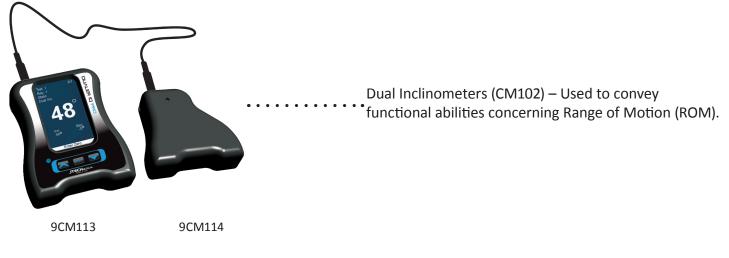
Dimensions	7.8 cm x 5.2 cm x 3.5 cm (3.1 in x 2.0 in x 1.4 in)		
Weight	0.21 kg (0.38 lb)		
Operating Temperature, Humidity, and Atmospheric Pressure	+10° <u>C</u> +50°F		
Transportation and Storage Conditions	-40° <u>C</u> -40° <u>F</u> -40°F		
Type of Operation	Continuous		
Input Voltage	100-240 VAC		
Input Frequency	50-60 Hz		
Input Current	0.5 A (rms) for 115 VAC 0.3 A (rms) for 240 VAC		
Enclosure Leakage Current	100 uA max. @ 264 VAC, 63 Hz		
Maximum Output Voltage/Current	5 V / 3 A		
Maximum Output Power	15 W		
Type of Protection against electric shock	Class II		
Manufacture, Model	Powertek, PMP15M-10-B6		
Protection against harmful ingress of water	IPXO - ordinary equipment		
Degree of Safety of Application in the presence of flammable mixtures	This device is not suitable for use in the presence of flammable anesthetic mixture with air, or with oxygen or nitrous oxide		
Symbols			

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# <u>Appendix</u>

**Dualer IQ Pro Devices** 



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**Accessories and Detachable Parts** 



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... Alignment Rail (8MH068) – The Alignment Rail magnetically attaches to the Inclinometers for easy visual confirmation of alignment.

VELCRO<sup>®</sup> Strap (47) – The 28 inch VELCRO<sup>®</sup> strap can be used for dynamic ••• range of motion inclinometry testing.





Accessories and Detachable Parts (continued)



Specified Power Supply (Battery Charger) (PW006) – The Specified Power
Supply (Battery Charger) is with the Daisy Chain, for charging your Dualer IQ Pro devices.



USB Daisy Chain (8WR009) – The USB Daisy Chain is used with the specified power supply to charge the Dualer IQ Pro device.



... Wrist Lanyard (7AC006) – The Wrist Lanyard is used to help prevent dropping devices when carrying or while performing some tests.



Connection Cable (7WR020) – The Connection Cable is used to connect the Primary and Secondary inclinometers for dual inclinometry use.



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## **EMC Guidance**

	WARNING:
<u> </u>	installed and
	read the info
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**WARNING:** Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Carefully read the information contained in this section.

**/ARNING:** The use of portable and mobile RF equipment can affect the normal operation of redical electrical equipment.

**WARNING:** Making any modifications or using any accessories not specifically approved by JTECH Medical may reduce immunity to electromagnetic interference or increase electromagnetic emissions.

## Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The Dualer IQ Pro must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A and D	The Dualer IQ Pro is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	network that supplies buildings used for domestic purposes.

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**WARNING:** The Dualer IQ Pro instrument should not be used while stacked on, or adjacent to, other electrical or medical electrical equipment. If stacked or adjacent use is necessary, all electrical equipment should be observed to verify normal operation.

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Guidance	and Manufacture	r's Declaration - Ele	ctromagnetic Immunity	
			gnetic environment specified	
such an environr		e Dualer IQ Pro shol	uld assure that it is used in	
Immunity test	IEC 60601 test	Compliance level	Electromagnetic	
-	level	-	environment - guidance	
Electrostatic discharge (ESD) IEC-61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The Dualer IQ Pro must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.	
Electrical fast transient/burst	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical	
IEC 61000-4-4	± 1 kV for input/ output lines	± 1 kV for input/ output lines	commercial or hospital environment.	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical	
	± 2 kV line(s) to earth	± 2 kV line(s) to earth	commercial or hospital environment.	
Voltage dips, short interruptions	<5 % <i>U</i> <sub>T</sub> (>95 % dip in <i>U</i> <sub>T</sub> ) for 0,5 cycle	<5 % UT (>95 % dip in UT) for 10ms		
and voltage variations on power supply input lines	40 % <i>U</i> <sub>τ</sub> (60 % dip in <i>U</i> <sub>τ</sub> ) for 5 cycles	40 % UT (60 % dip in UT) for 100ms	Mains power quality should be that of a typical	
IEC 61000-4-11	70 % <i>U</i> <sub>τ</sub> (30 % dip in <i>U</i> <sub>τ</sub> ) for 25 cycles	70 % UT (30 % dip in UT) for 500ms	commercial or hospital environment.	
	<5 % U <sub>T</sub> (>95 % dip in U <sub>T</sub> ) for 5 s			
Power frequency			Power frequency magnetic fields should be at levels characteristic of a typical	
(50/60 Hz) magnetic field	3 A/m	3 A/m	location in a typical commercial or hospital	
IEC 61000-4-8			environment.	
NOTE $U_{\rm T}$ is the a	.c. mains voltage p	rior to application of	of the test level.	

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			s Declaration – Electromagnetic Immunity
			ctromagnetic environment specified below. The customer or t is used in such an environment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Dualer IQ Pro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms	3 Vrms	Recommended separation distance
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	
			d=1.2VP
Radiated RF	3 V/m	3 V/m	d=1.2√P 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	d=2.3√P 800 MHz to 2.3 GHz
			where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>
			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.

<sup>a</sup> 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 Dualer IQ Pro is used exceeds the applicable RF compliance level above, the Dualer IQ Pro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Dualer IQ Pro.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

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## Recommended separation distances between portable and mobile RF communications equipment and the Dualer IQ Pro

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

Rated maximum output	Separation distance according to frequency of transmitter m			
power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
W	d=1.2√P	d=1.2√P	d=2.3√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.

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