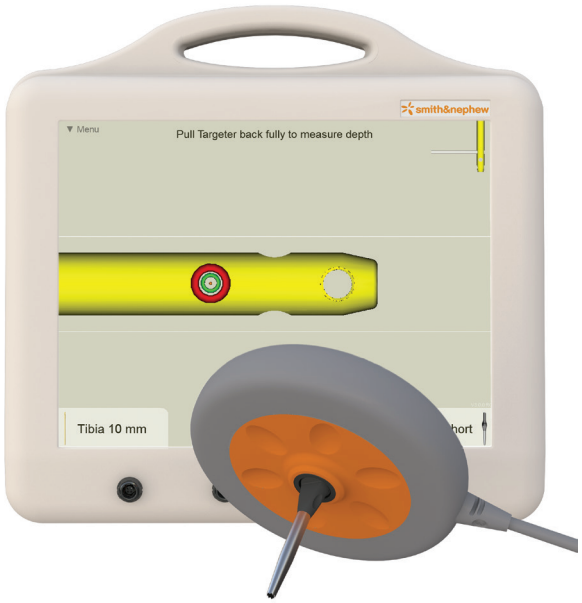
User Manual

smith&nephew

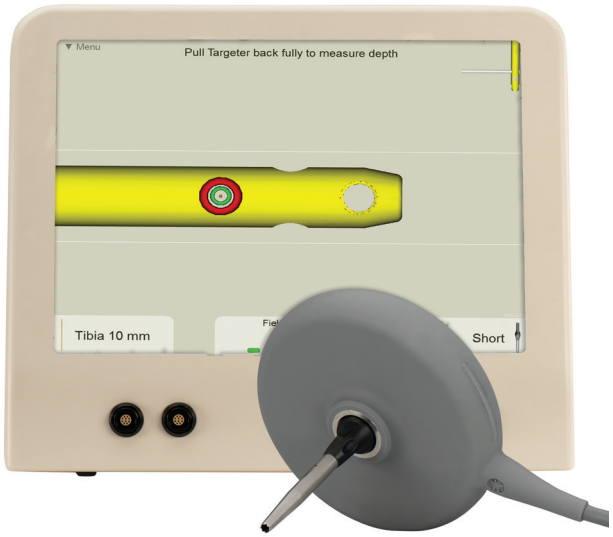
TRIGEN◇ SURESHOT◇ Distal Targeting System V4.0

CE 0086

81103554-0



TRIGEN® Trauma Interface and Targeter (1st Generation)

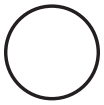


TRIGEN Trauma Interface and Targeter (2nd Generation)

Consult instructions for use

Equipment classification – Patient Isolation/Type BF Applied Part

Power ON (connection to the mains)



Power OFF (disconnection from the mains)

Catalog number

Humidity limit

Authorized representative in the European community

Serial number

Testing Lab certification

Fuse

CE Mark

Temperature range

EU Not for general waste

Manufacturer

Atmospheric pressue

Table of Contents

TRIGEN® SURESHOT®
Distal Targeting System

Device Description

The Smith & Nephew TRIGEN SURESHOT Distal Targeting System is a software-controlled electromagnetic tracking system. It assists the surgeon in locating and positioning screws in an intramedullary nail implant during orthopedic trauma surgery.

Indications for Use

The Smith & Nephew SURESHOT Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data.
The Smith & Nephew SURESHOT Targeting System is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Contraindications

The screw targeting software application for this system is contraindicated for all IM nails other than Smith & Nephew TRIGEN META-NAIL®, TRIGEN META-TAN®, TAN®, FAN, Humeral, Pediatric and Adolescent nails. Do not operate the TRIGEN SURESHOT Targeter within 200 mm of an installed pacemaker. The magnetic field produced by the Targeter may interfere with the operation of the pacemaker.

Training

Only trained operators are allowed to use the TRIGEN SURESHOT Distal Targeting System. The various operating instructions must be fully read and understood as part of the training. If any part of the instructions is not clear, please contact your local representative.

Plausibility Check

As with all technical equipment, malfunctions may occur due to improper use or, more rarely, technical failure. To reduce the risks involved with such technical malfunction the operation can be completed using manually controlled instruments, providing the malfunction is detected without delay.

It is, therefore, important to check the plausibility of the steps, as indicated by the system, and to carry out verification of the software targeting, particularly when using the system for the first time. Should there be any doubt regarding correct functioning, the targeting should be verified or a switch made to a traditional X-Ray technique.

℞ ONLY U.S. Federal law restricts this device to sale by or on the order of a physician.

⚠ Warnings and Cautions

⚠ WARNING: The maximum temperature of the Targeter body can reach 47° Celsius at ambient room temperatures above 30° C. The Targeter body should not remain in constant contact with a patient's exposed skin for more than one minute.

⚠ WARNING: Verify there are no other metal objects (including metal triangles) in the immediate targeting area. Metal interference will cause the system to be inaccurate.

Accessibility of documentation

Please ensure that all instructions are kept in an easily accessible place for operating personnel.

The operator checks and decides

All the information provided by the TRIGEN SURESHOT Distal Targeting System is to help the operator make decisions during the operation. The operator must check all the suggestions made by the system and is responsible for all decisions taken.

Responsibility of Smith & Nephew

In the event of improper use, Smith & Nephew accepts no responsibility or liability whatsoever for the functioning or utility of the TRIGEN SURESHOT Distal Targeting System when used in the operating theater.

Cleaning and sterilization

All instruments must be sterilized before use. Detailed information on the cleaning and sterilization of components is contained in the separate Cleaning and Sterilization Instructions Reference Instructions for care, maintenance, cleaning and sterilization of Smith & Nephew orthopaedic devices.

Repair or modifications to the system

The user is not permitted to modify or service the equipment. There are no serviceable parts inside the unit. Refer all service to authorized personnel.

Modifications/additions to the software

The user is not permitted to install or uninstall software. Any new software must be installed by the manufacturer or by authorized personnel.

It is only allowed to connect equipment to the interface and power supply connections of the TRIGEN® SURESHOT® Distal Targeting System which are IEC 60601-1 approved and which are approved by Smith & Nephew Orthopaedics. Do not modify this equipment without authorization of the manufacturer.

Electrical safety warning

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth (=ground).

Avoid spilling water or other liquids on electronic/electrical equipment. Use only Smith & Nephew disposables and accessories with the Smith & Nephew TRIGEN SURESHOT Distal Targeting System.

Maintenance

To verify accurate functionality, the device should be checked per the Maintenance section of this document. This accuracy check must be performed at least once every 12 months.

If this accuracy check is not performed as defined in the previous paragraph, all warranty claims expire and the device is operated at the user's own risk.

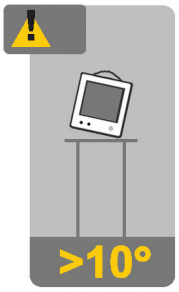
Recycling

Old electrical and electronic equipment must be disposed of separately and may not be included in the regular domestic waste. Alternatively, the unit can be handed over to Smith & Nephew Orthopaedics for correct recycling.

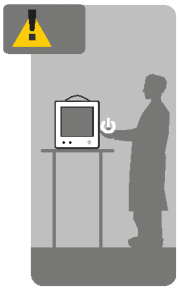
⚠WARNING: Do not unplug the power while the system is running!

⚠WARNING: Danger of damage and tipping over!

Note: Place the unit on a firm, level surface capable of holding at least 10 kg (22 lbs).



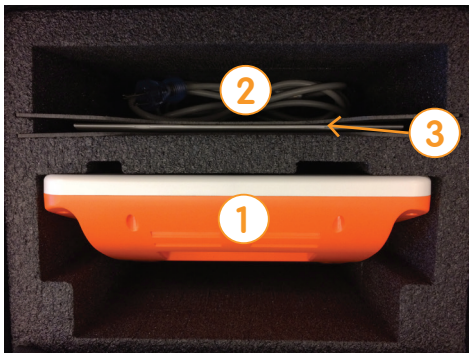
⚠WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



Quick Start Guide

Where to find the components

1. Trauma Interface
2. Power cord (country-specific)
3. User Manual slot



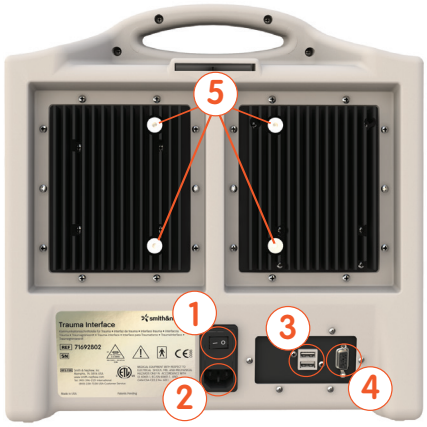
Front panel layout

(Same front panel layout on 1st and 2nd generation units.)

1. Probe sensor ports
2. Targeter port
3. Touch screen interface

Rear panel layout

1. Power switch
2. Power connection (Appliance Inlet)
3. USB connections (service only)
4. VGA video output (1024 x 768 resolution)
   VGA video output (1280 x 800 resolution)*
5. VESA mounting posts (10-32 thread pitch, 100 mm screw pattern) (1st generation only)
6. HDMI video output (1280 x 800 resolution)* (2nd generation only)



* Trauma Interface (2nd Generation)

Note: External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 or IEC 62368-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated in the collateral standard IEC 60601-1-1 or the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents.

Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact a qualified medical technician or your local representative.

Applied Parts for Targeting

TRIGEN° SURESHOT° Targeter (Body Applied Part Type BF)

⚠WARNING: The maximum temperature of the Targeter body can reach 47° Celsius at ambient room temperatures above 30° C. The Targeter body should not remain in constant contact with a patient's exposed skin for more than one minute.

⚠WARNING: Verify that the Targeter housing is not damaged (holes, tears, cracks). If the housing or the connector is damaged, the Targeter is no longer safe to use.

⚠WARNING: This device is provided non-sterile and must be cleaned and sterilized per Cleaning and Sterilization Reference Instructions for care, maintenance, cleaning and sterilization of Smith & Nephew orthopaedic devices prior to use.

CAUTION: *The Targeter will be operated within the sterile field and may have contact with the skin of the patient. The drill sleeve inserts will be used in the incision and have direct bone contact.*

CAUTION: *If the Targeter is not recognized after its connection to the system, the Targeter is defective and must be exchanged. (See also instrument connection.)*

CAUTION: *Broken or damaged instruments must be exchanged immediately and sent back to Smith & Nephew, Inc.*

TRIGEN SURESHOT Probes (Body Applied Part Type BF)

TRIGEN SURESHOT META-NAIL° Standard Drill Guide Probe

The probe will be used as an intramedullary tool inside the nail placed in the patient's bone.

⚠WARNING: This device is provided sterile by ethylene oxide gas and is single use.

⚠WARNING: In case the packaging is compromised, please replace with new sterile packaged probe.

⚠WARNING: Do Not Resterilize SURESHOT Probes.

CAUTION: *If the probe is not recognized after its connection to the system, the probe is defective and must be exchanged. (See also instrument connection).*

CAUTION: *Broken or damaged instruments must be exchanged immediately and sent back to Smith & Nephew, Inc.*

Surgical Procedure – OR preparation

This procedure will cover only the specific steps of freehand targeting of intramedullary locking holes using the TRIGEN SURESHOT Distal Targeting System. For the full surgical procedure, please refer to the specific surgical technique for the TRIGEN IM Nail System being implanted.

Trauma Interface setup

After the sterile areas have been established, place the Trauma Interface in the desired non-sterile location and turn on the power switch.

CAUTION: *No other electrical devices should be placed near the Trauma Interface. See the "Guidance and Manufacturer's Declaration – Separation Distances" table at the end of this document.*

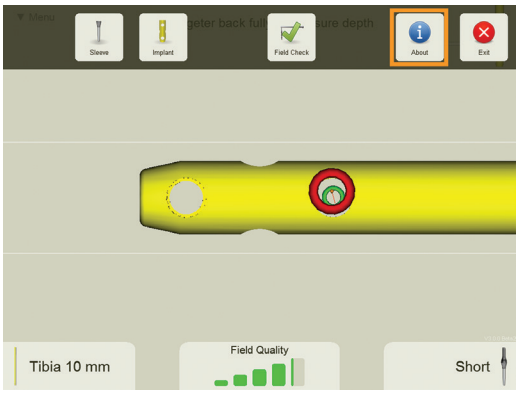
Note: If the Trauma Interface does not power on, make sure the switch is in the "on" position.

Note: The means for mains disconnection of power to the Trauma Interface is the appliance inlet located below the power switch. The Trauma Interface should not be positioned such that it is difficult to reach this location.

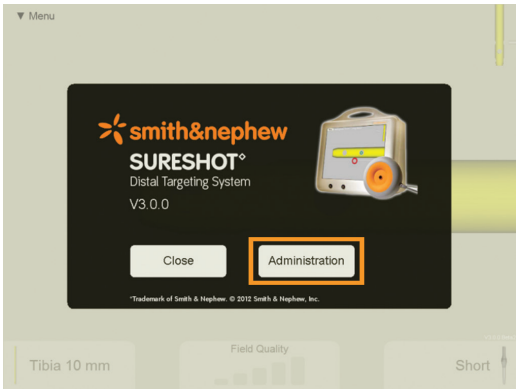
Software configuration

To enable or disable specific software features, use the following steps to make the desired changes. These software features could include, but are not limited to, TAN°/FAN nails, the Japan nail option, META-TAN° nails, the Drill Depth Measurement option, on screen nail rotation via the targeter, the Combo Drill Sleeve option, and shut down V2.

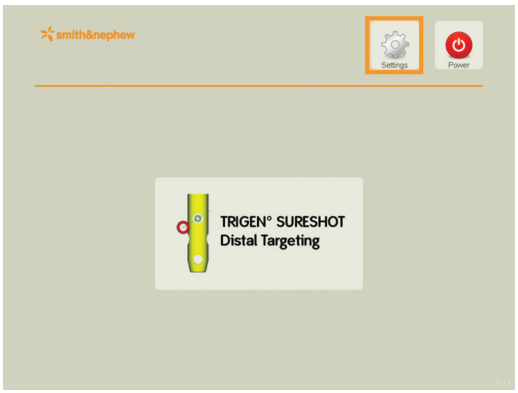
1. Press the “Menu” button.
2. Select the “About” button from the dropdown.



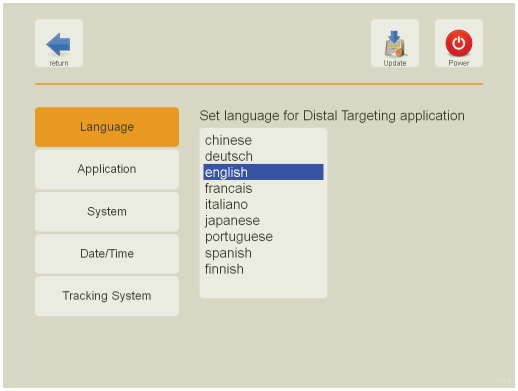
3. Select the “Administration” button.



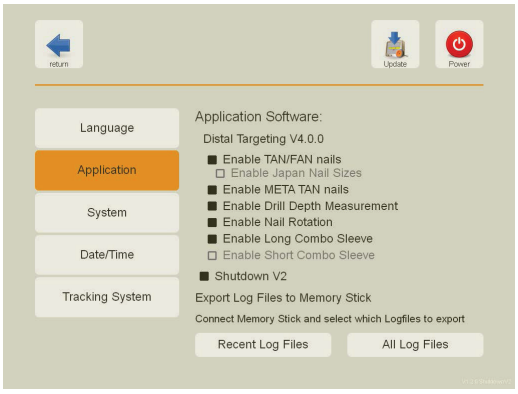
4. Press the “Settings” button in the upper right corner of the screen.



5. Select “Language” on the left to bring up the following screen:

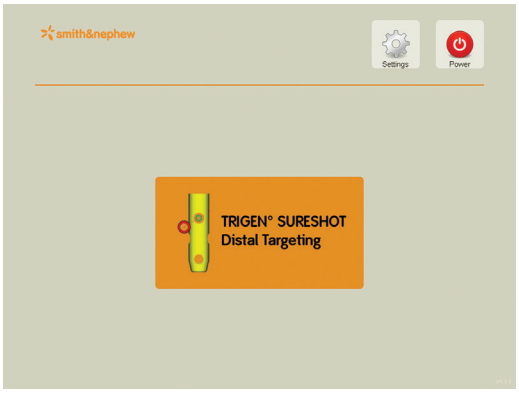


6. Select the desired language from the box on the right.
7. Select “Application” on the left to bring up the following screen:



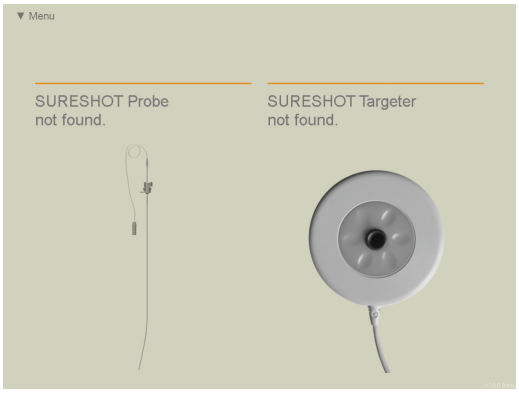
8. Press the feature to be changed to enable or disable that feature. Enabled features appear in black text with a filled check box; disabled features appear in gray text with an unfilled check box.

9. Press the “Return” button in the upper left corner when finished.
10. Press the “TRIGEN® SURESHOT® Distal Targeting” button in the center of the screen to return to the targeting application.

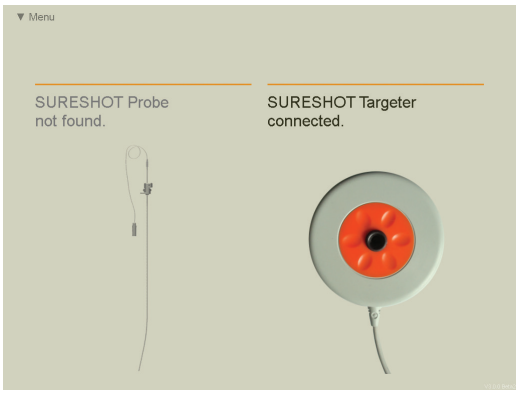


TRIGEN SURESHOT Targeter connection

When the display prompts for tool connections, connect the TRIGEN SURESHOT Targeter (7169-2801) to the Targeter port on the Trauma Interface.



The SURESHOT Targeter will change color to orange upon successful connection to the Trauma Interface.



CAUTION: *The Targeter body may have contact with the patient and must remain in the sterile field at all times. Only the cable and connector may be removed from the sterile field.*

CAUTION: *Connect the Targeter at least 10 minutes prior to targeting in order to ensure proper accuracy.*

Note: When oriented as shown, the connector should assemble easily. Do not force the connector into the port.

Note: If the Targeter is properly connected to the system and the application remains in this screen for more than 30 seconds, the Targeter may have been damaged during cleaning/sterilization. In this case another Targeter has to be used.

Note: It is possible at any time to disconnect and reconnect tools when the application is running. The display will show a screen reporting the missing instrument.

Surgical Procedure – After IM Nail Assembly to the Drill Guide

Probe selection and assembly

Assemble the appropriate probe and set the stop for the TRIGEN® IM Nail and Drill Guide that will be used.

CAUTION: *Proper orientation of the probes to the set stops as shown is required. Failure to do so may result in inaccurate targeting.*

TRIGEN SURESHOT®
META-NAIL®
Standard
Drill Guide Probe
(7169-2814)

Red probe
Use only with
META-NAIL
Standard Drill Guide
(7165-4502)

TRIGEN SURESHOT
META-NAIL
Semi-extended
Drill Guide Probe
(7169-2803)

Blue probe
Use only with
META-NAIL
Semi-extended Drill Guide
(7165-4524)

TRIGEN SURESHOT
Percutaneous
TAN®/FAN
Drill Guide Probe
(7169-2815)

Green probe
Use only with Percutaneous
TAN/FAN Drill Guide
(7163-1021)
and the META-TAN® Drill Guide
(7163-1451)

TRIGEN SURESHOT
Humeral Nail
Drill Guide Probe
(7169-1152)

Dark Green probe
Use only with
Humeral Drill Guide
(7175-1129)

Set the probe to the length of the TRIGEN IM Nail.

For META-NAIL,
notches should face anteriorly

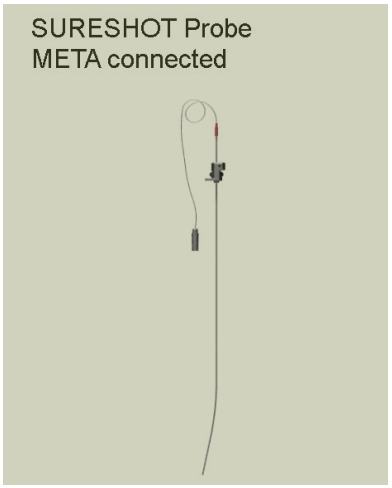
For TAN/FAN and META-TAN
notches should face medially

For Humeral,
notches should face laterally

Probe connection

Connect the probe to either of the probe sensor ports on the Trauma Interface.

Confirm that the tool connection has been verified.

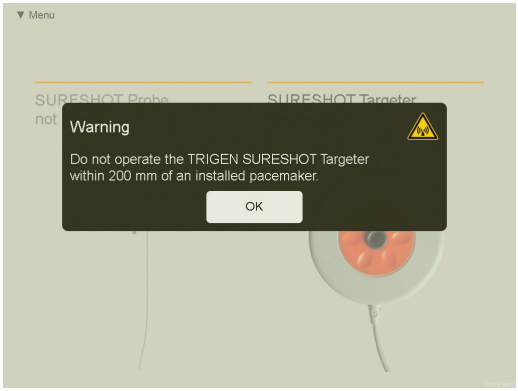


Note: When oriented as shown, the connector should assemble easily. Do not force the connector into the port. Simply try rotating the connector until the keys are oriented in the 12 o'clock position.

Note: If the probe is properly connected to the system and the application reports "Probe not found" for more than 10 seconds, the probe may be damaged or defective. In this case, the probe has to be exchanged.

Note: It is possible at any time to disconnect and reconnect tools when the application is running. The display will show a screen reporting the missing instrument.

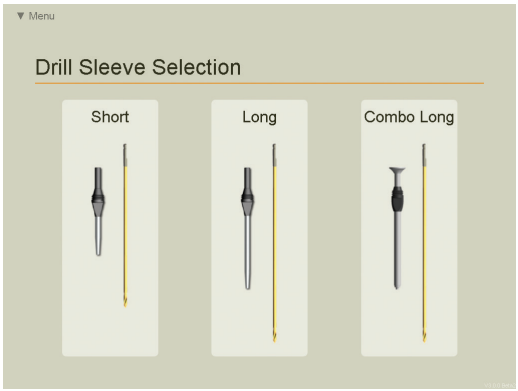
When a humeral probe is connected, the following warning message will appear:



⚠WARNING: Do not operate the TRIGEN® SURESHOT® Targeter within 200 mm of an installed pacemaker.

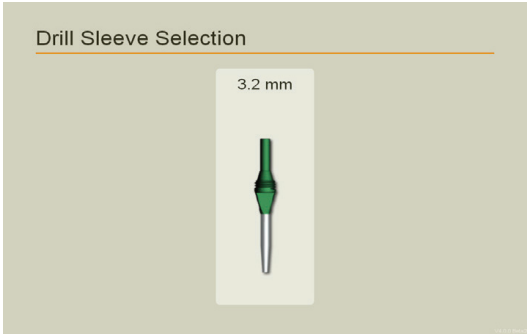
Drill sleeve selection

Select the length of the drill sleeve (7169-2804, 7169-2805, or 7169-1165 and 7169-1166) that will be used.



A different sleeve can be selected at any time during the procedure by choosing the drill sleeve option from the drop down menu OR by pressing the drill sleeve tab located in the lower right corner of the navigation screen.

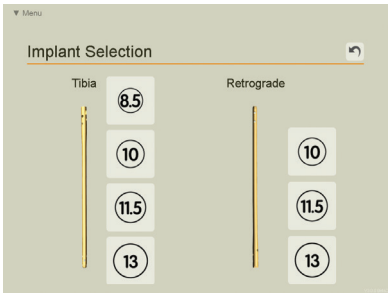
Note: For humeral nails, only one drill sleeve option will appear (7169-1154).



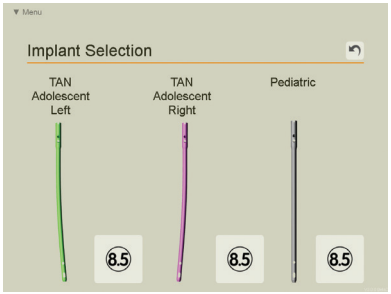
Implant selection screen

Select the TRIGEN® IM Nail and size that will be used.

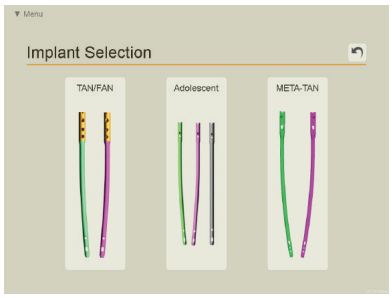
META-NAIL®



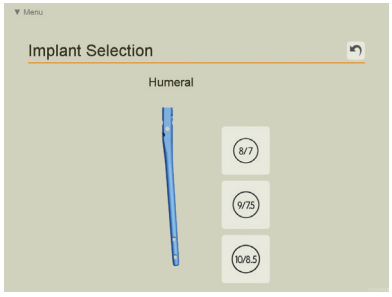
TAN®/FAN



META-TAN®



Humeral Nail



Note: A different TRIGEN IM Nail and/or size can be selected at any time during the procedure by choosing the Implant option from the drop down menu OR by pressing the implant tab located in the lower left corner of the navigation screen.

Drill sleeve attachment

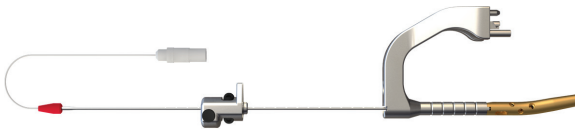
Tightly secure the selected drill sleeve to the Targeter.

Note: The short, long, and long combo drill sleeves (7169-2805, 7169-2804, and 7169-1166) can be loosened from the Targeter using the slot in the TRIGEN® Hammer (7167-4082).

Note: The Humeral Drill Sleeve (7169-1154) can be loosened from the targeter using the slot in the TRIGEN Slotted Hammer (7175-1135).

Locking hole accuracy check in the operative field

Insert the probe with the assembled set stop through the drill guide and cannulation of the TRIGEN IM Nail.



Attach the set stop to the drill guide, ensure that the probe is oriented correctly and that the set stop position and IM nail length match.

For META-NAIL®, notches should face anteriorly

Use only with the META Standard (7165-4502) or Semi-extended Drill Guide (7165-4524)

For TAN®/FAN and META-TAN® notches should face medially

Use only with the Percutaneous TAN/FAN Drill Guide (7163-1021) and the META-TAN Drill Guide (7163-1451)

For Humeral, notches should face laterally

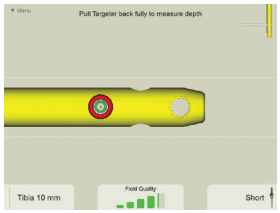
Use only with the Humeral Drill Guide (7175-1129)

CAUTION: *The TRIGEN SURESHOT® Distal Targeting System cannot be used with the META-NAIL Extension Drill Guide (7165-4503) or the Standard TRIGEN Drill Guide (7163-1134).*

CAUTION: *All tool cables should be uncoiled completely and any excess cables should be kept out of the Targeter measurement volume.*

CAUTION: *To guarantee system accuracy, the accuracy check has to be performed directly in the operative field.*

Place the IM nail with inserted probe directly beside the patient's limb. Position the Targeter over the locking holes and verify the accuracy on the Trauma Interface.



Optional – Field accuracy check

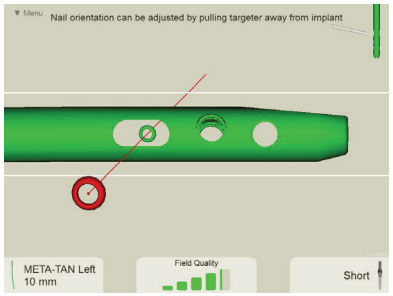
An optional field accuracy check can be performed at this point using the instructions in the Maintenance section.

On-screen Nail Rotation

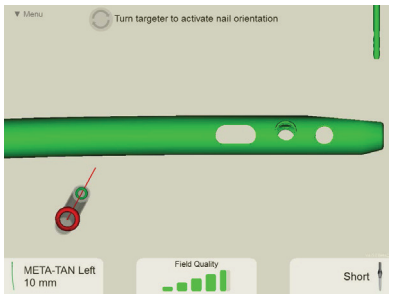
Rotation using Targeter

One of the new features to version 4.0 software is the surgeon's ability to manipulate nail rotation by rotating the Targeter in hand as opposed to having to touch the Interface monitor.

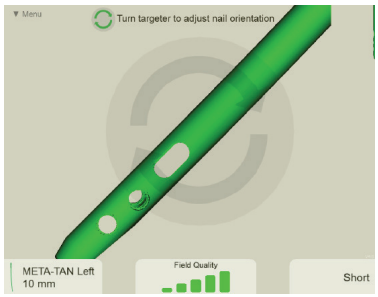
1. To activate the on-screen nail rotation feature, pull Targeter away from the implant.



2. Once the Targeter is pulled back, the on-screen message will appear, instructing the operator to rotate Targeter to trigger nail rotation.



3. Now that the nail rotation feature is activated, the operator can rotate the Targeter to position the implant to appropriate patient orientation.

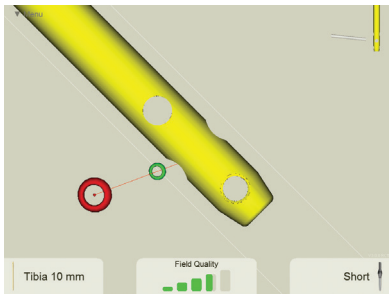


Note: The Targeter should remain constant. Moving the Targeter toward the implant while performing implant rotation will deactivate the nail rotation feature.

Note: This feature can be disabled in the Settings menu of the Software as described in the software configuration section of this manual.

Rotation using Monitor

Each IM nail has several predefined views that are automatically selected depending on the position of the Targeter to the IM nail. Depending on the operating environment, these predefined views might not be appropriate and can be manually adjusted.



To rotate the view

Touch the screen near the outside and "drag" the view in a clockwise or counterclockwise direction.

To reset the view

The default view settings can be restored by touching the center

Surgical Procedure – Distal Targeting

⚠ WARNING: Verify there are no other metal objects (including metal triangles) in the immediate targeting area. Metal interference will cause the system to be inaccurate.

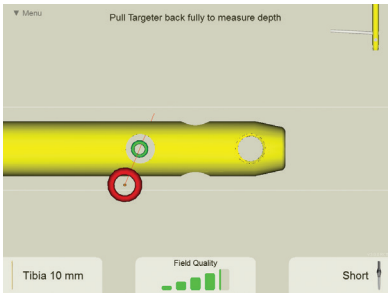
Probe and set stop insertion

Insert the probe and set stop into the IM nail as described in the locking hole accuracy check on the previous page.

Note: Reference the cautions in the "Locking hole accuracy check" section.

Skin incision

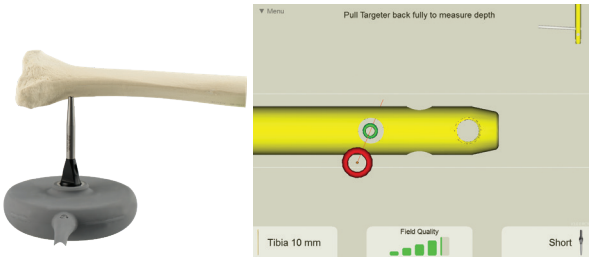
Position the serrated tip of the drill sleeve (represented by the green circle) over the desired locking hole and make the initial incision.



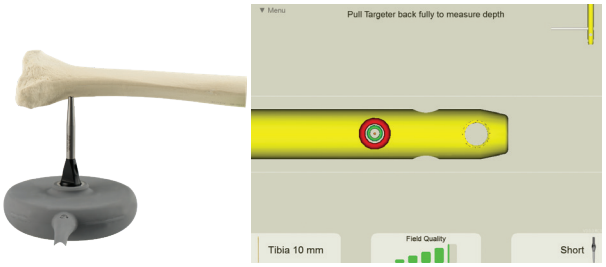
Note: If performing this procedure using any of the TRIGEN® femoral antegrade nails (TAN®/FAN/Pediatric/Adolescent), the Anteversion Locking Guide (7169-2816) should be used along with a 4.0 mm Drill Sleeve/Drill Bit to keep the IM nail from rotating.

Targeting the locking hole

With the appropriate length TRIGEN SURESHOT® 4.0 mm Drill Bit (7169-2810 or 7169-2811) or the TRIGEN SURESHOT Humeral AO Drill Bit (7169-1155) inserted into the Targeter, insert the tip of the drill sleeve (represented by the green circle) through the incision and down to bone.



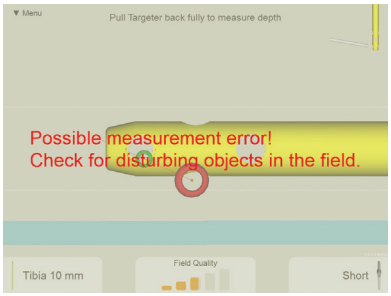
Adjust the trajectory of the Targeter (represented by the red circle) until both the green and red circles are concentric and drill through to the far cortex.



⚠ WARNING: The standard TRIGEN Drill Bits are made from magnetic stainless steel that will cause interference with the system and cannot be used. Be sure to use the gold non-magnetic TRIGEN SURESHOT Drill Bit or long gold non-magnetic drill bit.

Note: The green ring must be fully within the hole of the IM nail displayed on the navigation screen to ensure accurate drilling.

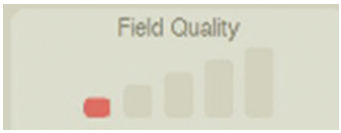
When the Targeter is out of the preferred range or there is metal or electrical interference, the green and red Targeter circles on the navigation screen may become unstable and/or a warning message will be displayed. If the interference is excessive, the IM nail image on the navigation screen will disappear.



A Field Quality meter is located at the bottom of the screen. There are three field quality states: OK, Warning, and Error.

OK: Field Quality is adequate for proper function.

Warning: Possible measurement error due to metal or electrical interference.



Error: Interference is excessive. IM nail tracking not possible.

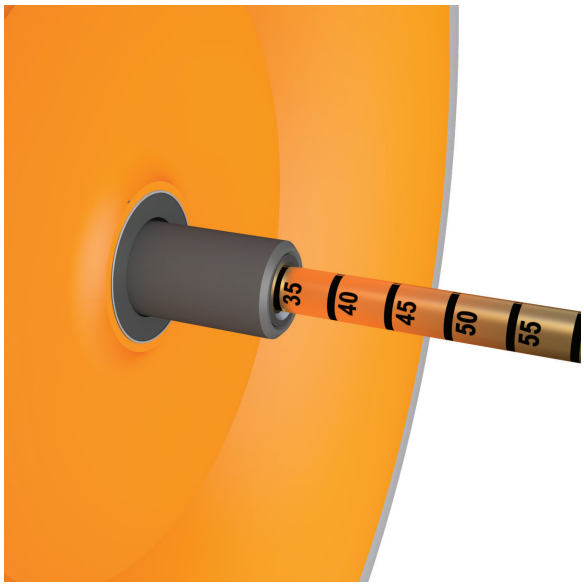
If interference cannot be avoided, a standard X-Ray technique must be used.

CAUTION: *All tool cables should be uncoiled completely and any excess cables should be kept out of the Targeter measurement volume.*

Surgical Procedure – Drill Depth Measurement

Option 1: Measure off Drill Bit Calibrations

Begin drilling the hole at the near cortex. Before drilling through the far cortex, measure the length using the calibrations on the TRIGEN® SURESHOT® 4.0 mm Drill Bit (7169-2810 or 7169-2811), or the TRIGEN SURESHOT Humeral AO Drill Bit (7169-1155).



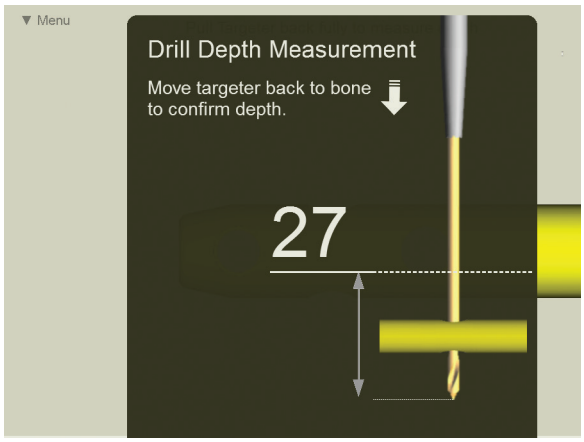
After measuring the length on the drill bit prior to drilling the far cortex, add the appropriate screw length in order to account for the thickness of the far cortex. Ensure the Targeter and the sleeve are pushed against the bone.

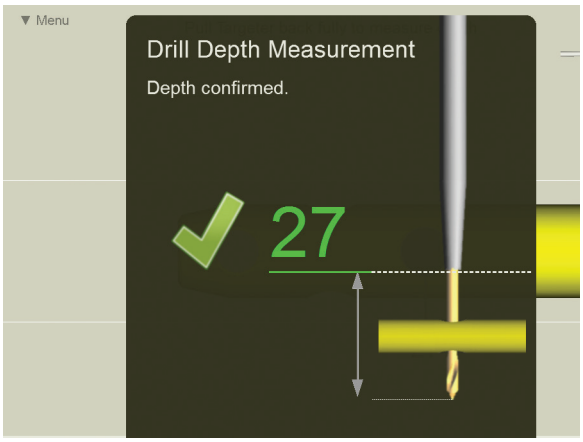
Option 2: Measure Using Drill Depth Software

When software is enabled for performing drill depth measurements, the following message will be displayed at the top of the screen, “Pull Targeter back fully to measure depth.”

Begin drilling the hole at the near cortex. Before drilling through the far cortex, pull the Targeter back to the drill connection while keeping the drill bit in place. This action will trigger the software to display the Drill Depth Measurement window.

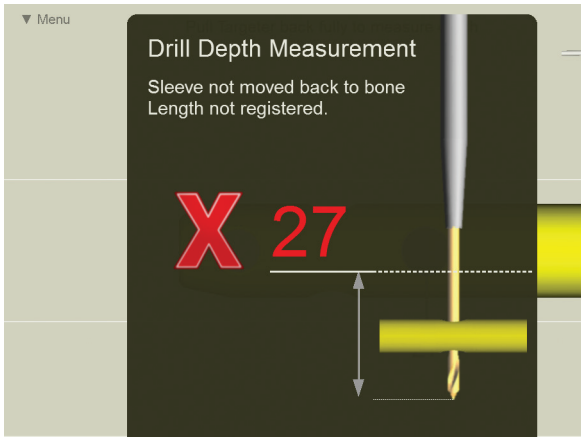
Surgical Procedure – Drill Depth Measurement





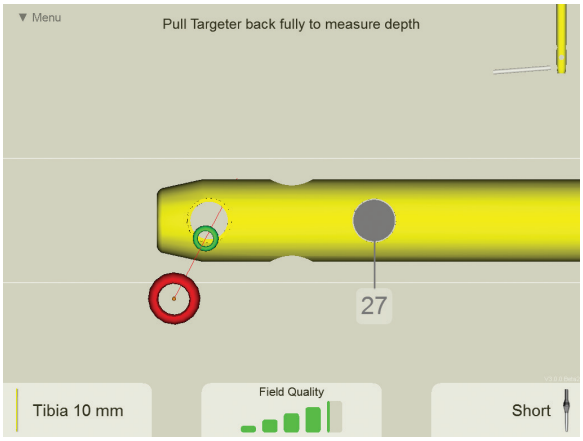
Note: Do not excessively rotate the Targeter while sliding it along the drill bit as this movement is used to cancel the Drill Depth Measurement software feature.

If the Targeter distance pulled back does not match the distance pushed back to bone then a warning message is displayed.



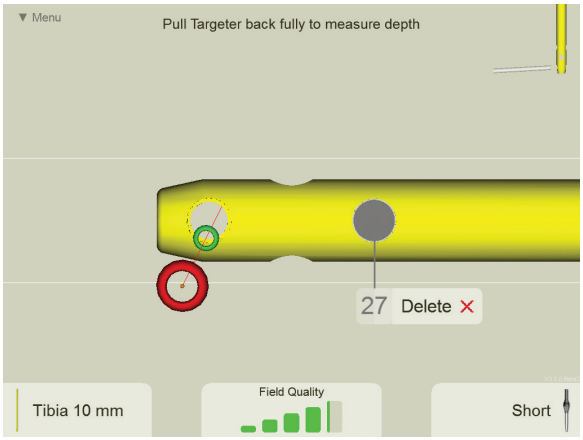
Push the Targeter drill sleeve forward to the bone to verify the length measured. This action verifies the drill bit did not change position during the Targeter movement. If the distance the Targeter was pulled back equals the distance pushed back to bone a confirmation message indicating an accurate measurement is displayed.

Note: After measuring the length on the drill bit prior to drilling the far cortex, add the appropriate screw length in order to account for the thickness of the far cortex.



Note: The Drill Depth Measurement software feature can be cancelled at any time by rotating the Targeter about the drill bit axis.

After a successful Drill Depth Measurement is performed the software will display the measured length at the drilled location.



Note: A Drill Depth Measurement software operation can be repeated on a drilled hole at any time. The newest measurement will be displayed at that location.

The user can delete a measurement at any time by tapping the measurement number on the touchscreen. A button will appear allowing the user to delete the measurement.

Screw insertion

Using the TRIGEN® SURESHOT® Hexdriver (7169-2809 or 7169-1153), the screw may be inserted using the Targeter.

⚠ **WARNING: The standard TRIGEN Hexdrivers are made from magnetic stainless steel that will cause interference with the system and cannot be used.**

Using the Combo Drill Sleeve

TRIGEN SURESHOT Inner Drill Sleeve-Long (7169-1165)

TRIGEN SURESHOT Outer Screw Sleeve-Long (7169-1166)

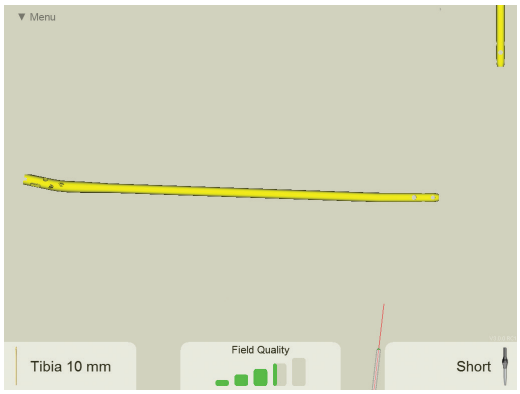
1. While holding the Targeter to bone, remove the SURESHOT Inner Drill Sleeve-Long (7169-1165) from the SURESHOT Outer Screw Sleeve-Long (7169-1166).
2. Use the TRIGEN SURESHOT Hexdriver (7169-2809 or 7169-1153) to insert the appropriate length screw through the SURESHOT Outer Screw Sleeve-Long.
3. When screw insertion is complete, remove the probe from the IM nail.

Navigation Screen Operation

Overview mode

When the Targeter is greater than 5 cm from the interlocking holes, the navigation screen will display the IM nail in the overview mode. This provides the user with a larger field of view in order to help find the general location of the interlocking holes.

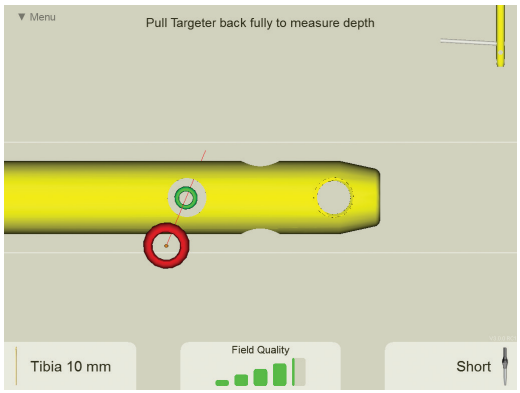
CAUTION: *If the desired hole in the nail is not oriented to be viewed on the screen, then the orientation of the Targeter is not aligned closely enough to that specific hole. Try holding the Targeter generally anterior-posterior (AP) or generally mediolateral (ML) to orient the desired view.*



Drilling mode

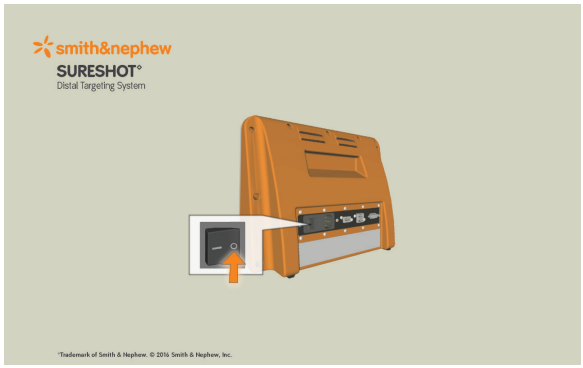
When the Targeter is moved within 5 cm of the interlocking holes, the navigation screen will display the IM nail in the drilling mode. This provides the user with a smaller field of view that automatically zooms in to the interlocking holes.

The white lines displayed on either side of the IM nail can be used for targeting blocking screws. These lines are located 2.5 mm from the side of the IM nail for all IM nails 10 mm or larger in diameter. These lines are located 2 mm from the sides of 8.5 mm IM nails.



Shutting Down the System, Storage, and Transport

Shutting down the system

1. Shut down the Trauma Interface by selecting the “Exit” option from the on-screen “Menu” button. Wait for the system to display the following screen:
2. 

3. Switch off the main power switch on the rear of the unit.
4. Unplug the power supply cable.

***CAUTION**: The system MUST fully shutdown (as shown above) before switching the power off.*

***CAUTION:** The internal fan of the Trauma Interface runscontinuously whenever the rear power switch is in the ONposition. Switch power off whenever the unit is not in use.*

Storage and transport

- Coil the power cord and store in the transportation case.
- Consider the temperature and humidity range for storage and transportation on the transportation case.
- Place the Trauma Interface (screen up) in the transportation case.

- Place the Trauma Interface 2nd Generation (screen facing inwards) in the transportation case.

***CAUTION:** Do not place any objects on top of the screen or system when the Trauma Interface is stored in the shipping container. Damage to the screen or system may occur.*

Maintenance

Field accuracy check

A field accuracy check procedure should be performed at least once a year or whenever the accuracy of a TRIGEN® SURESHOT® Probe or TRIGEN SURESHOT Targeter needs to be verified. This procedure can also be performed during surgery to verify all components are working correctly prior to their use on a patient.

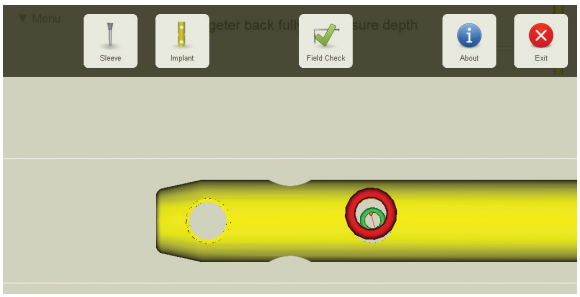
CAUTION: *This step should be performed at least once a year to ensure that the device is working properly.*

Field accuracy check steps

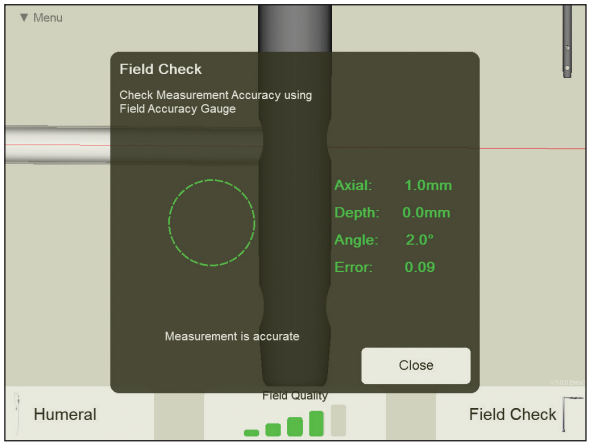
1. Attach TRIGEN® SURESHOT® Field Accuracy Gauge (7169-2808) to the TRIGEN SURESHOT Targeter. The knob on the Field Accuracy Gauge should be hand-tightened only.

2. Attach the META Set Stop (7169-2806) to the end of the Field Accuracy Gauge, insert a TRIGEN SURESHOT probe into the set stop, and set the depth to the "REF" mark on the probe body.

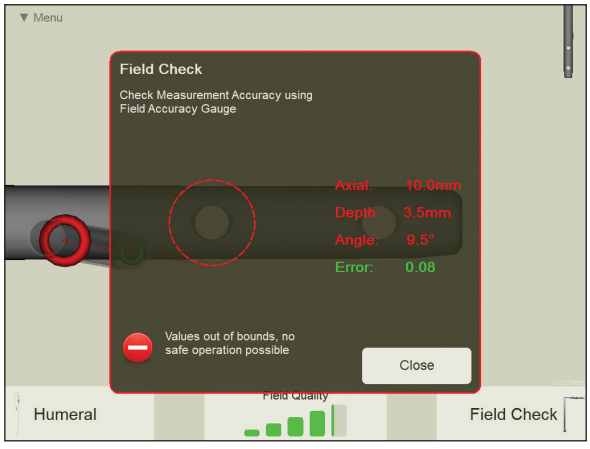
3. From the software "Menu" button located in the upper left corner of the screen, select the "Field Check" option.



4. A software window will appear informing the user if the TRIGEN SURESHOT Targeter and Probe combination is within the predefined accuracy parameters ("Pass" or "Fail" message).



If the field accuracy check fails, check the "Troubleshooting" section of this document for possible solutions.



Software upgrades

Software upgrades are performed using a Smith & Nephew, Inc. - supplied USB memory stick and a Work Instruction document. The Work Instruction document should be filled out and returned to Smith & Nephew Customer Service upon completion of the upgrade.

Cleaning and disinfection

The TRIGEN SURESHOT Trauma Interface is used in the non-sterile area of the operating theater and is cleaned and disinfected using commercial cleaning and disinfectant products such as a mild detergent and water, or a bactericidal cleaning solution such as 70% isopropyl alcohol.

CAUTION: *Care must be taken not to allow any liquid to pass into any electrical connections or the interior of the unit. Let the surfaces dry thoroughly before plugging in the unit. DO NOT steam sterilize the system. DO NOT submerge the system for any reason.*

All other reusable instruments shall be cleaned and sterilized according to the Cleaning and Sterilization Instructions.

⚠WARNING: Observe the manufacturer's instructions for dilution, exposure time, etc.

⚠WARNING: DO NOT sterilize with ethylene oxide gas or steam sterilize the Trauma Interface.

⚠WARNING: Probes are NOT reusable.

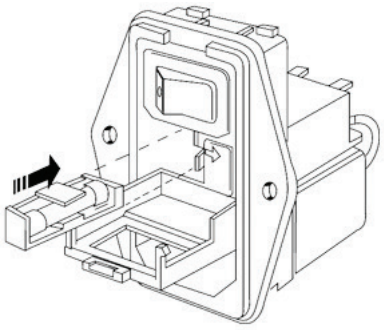
Replacing fuses

See the "Technical Specifications" section for replacement fuse type.

1. Disconnect main power cord.
2. Use a screwdriver to open the fuse compartment door on the AC receptacle.

3. Pull out fuse carriers to exchange fuses.

4. Reinsert fuse carriers using the arrows on the inside of the fuse compartment door as a guide.



5. Snap the fuse compartment door closed.

⚠WARNING: To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.

CAUTION: *Disconnect the power cord before exchanging any fuse.*

Technical information

Smith & Nephew will make available on request a list of all repairable exterior parts with descriptions. Interior schematics and circuit diagrams will be made available to qualified personnel only.

CAUTION: *Service can only be performed by authorized Smith & Nephew personnel.*

Service

TRIGEN® SURESHOT®
Distal Targeting System

There are no user-serviceable components inside the TRIGEN SURESHOT Trauma Interface. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers.

If service becomes necessary, call an authorized Smith & Nephew customer service representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available service replacement and repair programs.

The device should be packaged in its original transportation case and returned postage paid. A Smith & Nephew customer service representative will provide additional instructions for shipment.

Note: Product returned that is found to have been serviced by an unauthorized third-party repair facility and/or sterilized with a sterilization method other than one approved by Smith & Nephew will incur additional costs, regardless of warranty status.

Electrical interference

This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment, it may be corrected by one or more of the following measures:

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

Environmental protection

This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment, it should be disposed of in accordance with any applicable national or institutional policy relating to obsolete electronic equipment.

Troubleshooting

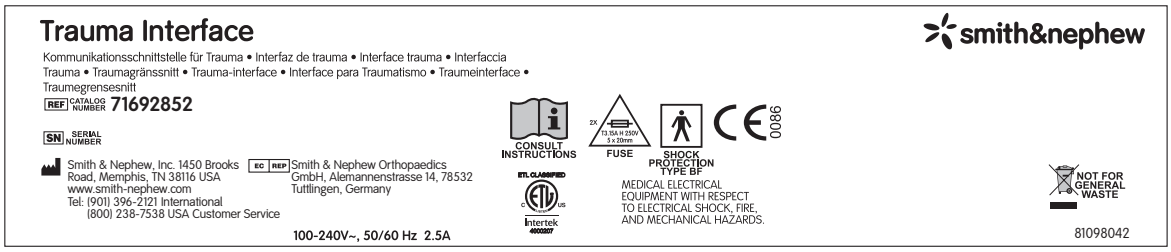
Problem	Possible cause	Suggested action
Trauma Interface unit is without power	Mains power plug is not inserted (properly) or there is no mains power No power on the wall outlet One or both mains power fuses are blown	Insert mains power plug into reliable power supply Try another power outlet Replace mains fuses
Buttons or items are difficult to select on the touchscreen	Touchscreen is not calibrated	Access calibration software by selecting "Administration" from the "About" option under the "Menu" button. From the "Administration" screen, select the "Settings" button, then select the "Calibrate touch screen..." button
VGA video out not functioning	VGA port not activated on Trauma Interface Damaged VGA cable Video monitor not on correct input HDMI cable also connected	Connect VGA cable to both Trauma Interface and video monitor before powering on Trauma Interface Replace VGA cable Select proper input on video monitor Disconnect HDMI cable. Only one video output is possible at a time from the Trauma Interface
HDMI video out not functioning	HDMI port not activated on trauma Interface Damaged HDMI cable Video monitor not on correct input VGA cable also connected	Connect HDMI cable to both Trauma Interface Replace HDMI cable Select proper input on video monitor Disconnect VGA cable. Only one video output is possible at a time from the Trauma Interface
TRIGEN® SURESHOT® Targeter not recognized (error message)	Error reading data from Targeter Connection issue with Targeter Damaged Targeter	Unplug Targeter, wait 10 seconds, and plug back in Power off Trauma Interface. Securely connect Targeter to unit then power on Trauma Interface Replace Targeter with new unit
Probe not recognized	Error reading data from probe Connection issue with probe Damaged probe	Unplug probe, wait 10 seconds, and plug back in Try other port on front of unit Power off Trauma Interface. Securely connect probe to unit then power on Trauma Interface Replace probe with new unit
Probe will not insert to the proper depth in the nail	Obstruction within the nail cannulation	Re-insert the ball tip guide rod into the nail cannulation to clear any obstruction
Nail not visible on the screen	Metal interference within the TRIGEN SURESHOT electromagnetic field TRIGEN SURESHOT Targeter and probe not within range of each other	Remove any metal objects from the targeting field Move the TRIGEN SURESHOT Targeter closer to the sensor end of the probe

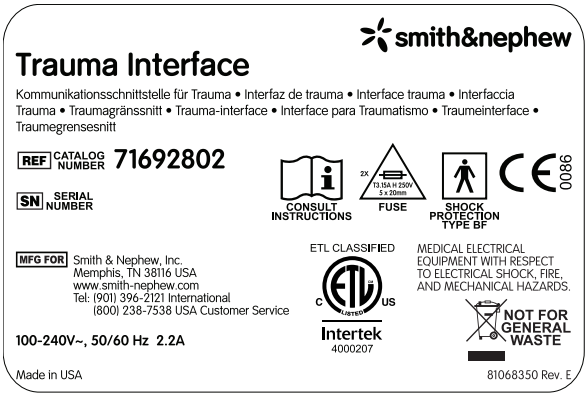
Problem	Possible cause	Suggested action
Drill bit too short	Short drill bit being used and long drill sleeve option selected within software	Press “Menu”, “Drill Sleeve” and select the short drill sleeve option to use the short drill bit
Drill bit too long	Long drill bit being used and short drill sleeve option selected within software	Press “Menu”, “Drill Sleeve” and select the long drill sleeve option to use the long drill bit
Red and Green targeting circles representing the drill sleeve appear incorrect	Incorrect drill sleeve length selected Metal interference within the TRIGEN® SURESHOT® electromagnetic field Probe not inserted correctly within set stop Damaged probe	Verify the correct drill sleeve length is selected from the software menu Remove any metal objects from the targeting field Verify probe is oriented and seated correctly in the notches of the set stop Verify probe accuracy with Field Accuracy Gauge
Targeting missed the intended hole	Metal interference within the TRIGEN SURESHOT electromagnetic field Probe not inserted correctly within set stop Damaged probe	Remove any metal objects from the targeting field Verify probe is oriented and seated correctly in the notches of the set stop Verify probe accuracy with Field Accuracy Gauge
Drill sleeve cannot be removed from TRIGEN SURESHOT Targeter	Over-tightening of drill sleeve	Use the Slotted Hammer from the instrument tray as a wrench to unscrew the drill sleeve counter-clockwise from the Targeter
The 4.7 mm/4.0 mm step drill will not fit through the drill sleeve	Drill not compatible with the TRIGEN SURESHOT Distal Targeting System	Only use the long (7169-2811) and short (7169-2810) drills designed for use with the TRIGEN SURESHOT Distal Targeting System
Field accuracy check fails	Metal interference within the TRIGEN SURESHOT electromagnetic field Field Accuracy Gauge improperly installed on Targeter META Set Stop improperly installed on Field Accuracy Gauge Probe is incorrectly inserted within META Set Stop Probe is damaged Targeter is damaged	Remove any metal objects from the targeting field DO NOT perform test with Targeter still in the autoclave tray! Metal interference will occur Verify Field Accuracy Gauge is fully seated within Targeter port and knob is hand-tightened to Targeter Verify META Set Stop is correctly oriented and tightened securely to Field Accuracy Gauge Verify probe is oriented properly and inserted to the “REF” notches on probe body Replace probe with a new probe Replace Targeter with a new Targeter and return old one for service

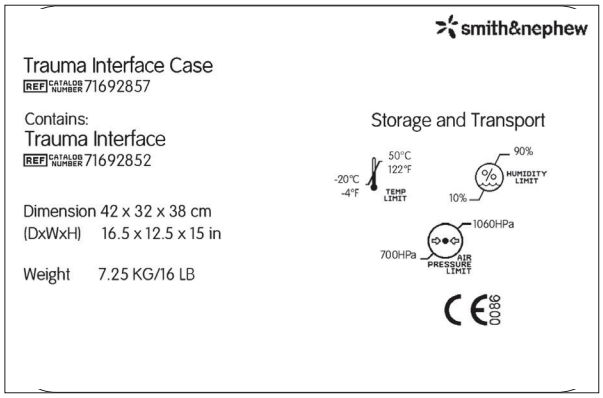
Troubleshooting

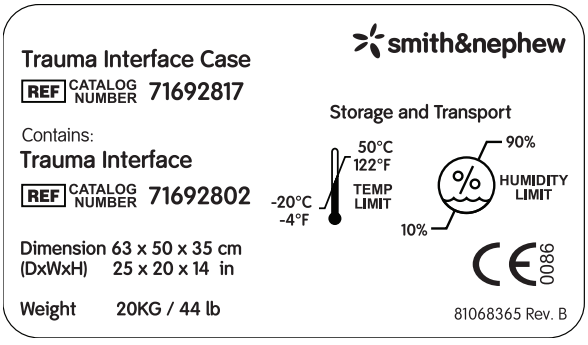
Problem	Possible cause	Suggested action
Drill Depth Measurement will not trigger	Drill Depth Measurement Software is not enabled Operator may be trying to drill in a location that interferes with implant	Follow the instructions in the manual to enable the Drill Depth Measurement software Software will only allow Drill Depth Measurement activation to occur in areas that are safe to drill
Drill Depth Measurement triggers but cancels	Targeter is being rotated during action The angle to the nail hole is greater than 15 degrees	Do not rotate Targeter while performing Drill Depth Measurement feature Rotation is used to reset the Drill Depth Measurement Maintain alignment when targeting circles
Combo Drill Sleeve selection button is not available on the drill sleeve selection screen	Combo sleeve software feature is not enabled in the Administration menu	Follow the instructions under “Software configuration” in this User Manual to enable the Combo sleeve feature.
META-TAN® nail selection button is not available on the implant selection screen	META-TAN nail software feature is not enabled in the Administration menu	Follow the instructions under “Software configuration” in this User Manual to enable the META-TAN Nail feature
On-screen Nail Rotation feature via the Targeter does not work	Nail Rotation software feature is not enabled in the Administration menu	Follow the instructions under “Software configuration” in this User Manual to enable the Nail Rotation feature
Unit does not display pictorial image of power switch when pressing the “power off” on-screen button. The screen simply turns black but the fan continues to run.	The “Shutdown V2” option has been disabled in the Administration menu	Follow the instructions under “Software configuration” in this User Manual to enable the “Shutdown V2” option Power off the unit via the rear power switch
All on-screen text is in a foreign language	A different language has been selected in the Administration menu	Follow the instructions under “Software configuration” in this User Manual to select the appropriate language from the available options

Product Label and Transportation Case Label









Technical Specifications

		71692802	71692852
System power supply	Voltage Frequency Connected load	100–240 VAC 50–60 Hz ≤ 2.2 Amps	100–240 VAC 50–60 Hz ≤ 2.2 Amps
Fuses	Type Quantity	T3.15A H 250V 2	T3.15A H 250V 2
Classification	Protection class	Class I (with protective earth [=ground]) IPX0, continuous operation	Class I (with protective earth [=ground]) IPX0, continuous operation
	Type	BF (with hand-held FG, targeting probe)	BF (with hand-held FG, targeting probe)
	Humidity	No protection	No protection
	Explosion	No protection	No protection
Ambient conditions	Temperature	10–35°C	10–35°C
	Humidity	30–75% RH (non-condensing)	30–75% RH (non-condensing)
	Air pressure	700–1060 HPa	700–1060 HPa
Storage and transport	Temperature	-20–50°C (in original packaging)	-20–50°C (in original packaging)
	Humidity	10–90% RH (non-condensing)	10–90% RH (non-condensing)
	Air pressure	700–1060 HPa	700–1060 HPa
System	Dimensions (DxWxH)	40 cm x 38 cm x 20 cm	31 cm x 26 cm x 13 cm
	Weight	9 kg	3.5 kg
Transportation case	Dimensions (DxWxH)	63 cm x 50 cm x 35 cm	42 cm x 32 cm x 38 cm
System + case + accessories	Weight	≈ 20 kg	≈ 7 kg
Complies with standards		USA, Canada, Europe IEC 60601-1 (3rd edition) IEC 60601-1-2:2007 CSA C22.2#601-1 (2nd edition)	USA, Canada, Europe IEC 60601-1 (IEC 60601-1:2005 Ed.3 + A1;C1:2014) IEC 60601-1-2 Ed.3.0 (2007-03) CSA C22.2#60601-1:2014 Ed.3

Electrical safety

The system meets IEC standards (e.g. IEC 60601). All configurations comply with standard IEC 60601-1. Any person connecting equipment to the system is responsible for the configuration and must ensure that it complies with system standard 60601-1-1 or equivalent national standards. Please contact your customer service representative in the event of any queries.

⚠WARNING: This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

CAUTION: *The system may reboot after a power line surge greater than 1KV. This is considered a normal condition and the system will automatically reboot to the software application.*

CAUTION: *Only use 110V/60Hz AC connection when powering the Trauma Interface within the United States. The Trauma Interface is not certified for 220V/60Hz operation within the United States.*

CAUTION: *To ensure proper operation, no other electrical components should be located near the TRIGEN® SURESHOT® Distal Targeting unit.*

Smith & Nephew reserves the right to make any technical changes.

Parts and Accessories List

Catalog No.	Description
7169-1151	TRIGEN® SURESHOT® Humeral Set Stop
7169-1153	TRIGEN SURESHOT Humeral 3.5 mm Hexdriver
7169-1154	TRIGEN SURESHOT Humeral 3.2 mm Drill Sleeve
7169-1156	TRIGEN SURESHOT Humeral Instrument Caddy
7169-1152	TRIGEN SURESHOT Humeral Drill Guide Probe
7169-1155	TRIGEN SURESHOT Humeral 3.2 mm AO Drill
7169-1165	TRIGEN SURESHOT Inner Drill Sleeve-Long
7169-1166	TRIGEN SURESHOT Outer Screw Sleeve-Long
7169-2801	TRIGEN SURESHOT Targeter
7169-2851	TRIGEN SURESHOT Targeter 2nd Generation
7169-2802	Trauma Interface
7169-2803	TRIGEN SURESHOT META-NAIL® Semi-extended Drill Guide Probe
7169-2804	TRIGEN SURESHOT Long Drill Sleeve
7169-2805	TRIGEN SURESHOT Short Drill Sleeve
7169-2806	TRIGEN SURESHOT META Set Stop
7169-2807	TRIGEN SURESHOT Percutaneous TAN®/FAN Set Stop
7169-2808	TRIGEN SURESHOT Field Accuracy Gauge
7169-2809	TRIGEN SURESHOT Hexdriver
7169-2810	TRIGEN SURESHOT Short AO Drill
7169-2811	TRIGEN SURESHOT Long AO Drill
7169-2814	TRIGEN SURESHOT META-NAIL Standard Drill Guide Probe
7169-2815	TRIGEN SURESHOT Percutaneous TAN/FAN Drill Guide Probe
7169-2816	TRIGEN SURESHOT TAN Anteversion Locking Guide
7169-2817	Trauma Interface Case
7169-2819	TRIGEN SURESHOT TAN Set Stop Bolt
7169-2830	TRIGEN SURESHOT Distal Targeting Instrument Tray
7169-2831	TRIGEN SURESHOT Distal Targeting Instrument Tray Lid
7169-1540	TRIGEN SURESHOT Distal Targeting System V4.0 User Manual
7169-2852	Trauma Interface 2nd Generation
7169-2857	Trauma Interface Case 2nd Generation
6680-0193	Power Cord, 125 Volt, 10 AMP, North America (Hospital Grade)
6680-0291	Power Cord, 250 Volt, 10 AMP, Continental Europe
6680-0213	Power Cord, 250 Volt, 10 AMP, UK
6680-0303	Power Cord, 250 Volt, 10 AMP, Australia/New Zealand
6680-0302	Power Cord, 250 Volt, 10 AMP, South Africa/India

CAUTION: *Inspect all components regularly for wear.*

CAUTION: *Use only Smith & Nephew disposables and accessories with the Smith & Nephew TRIGEN SURESHOT Distal Targeting System.*

CAUTION: *The TRIGEN SURESHOT probes are defined as single use items. The risk of reuse includes, but is not limited to, cross contamination between patients, probe malfunction and probe breakage. After use, the probe should be discarded per hospital policy/ procedures for biohazard material disposal.*

Guidance and Manufacturer's Declaration

Electromagnetic emissions, immunity and separation distances

Changes or modifications to this system not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the equipment or system and could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

CAUTION: *Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.*

CAUTION: *The presence of certain metal objects within the electromagnetic tracking volume system may cause unexpected or adverse operation.*

CAUTION: *The equipment or system shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system shall be tested to verify normal operation in the configuration in which it is being used.*

CAUTION: *The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.*

Compliant cables and accessories

The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.

Note: Any supplied accessories that do not affect EMC compliance are not listed.

Part No.	Type	Description
7169-2801	Field Generator	TRIGEN® SURESHOT® Targeter
7169-2851	Field Generator	TRIGEN SURESHOT Targeter 2nd Generation
7169-2814	Sensor	META-NAIL® Standard Drill Guide Probe
7169-2815	Sensor	Percutaneous TAN®/FAN Drill Guide Probe
7169-2803	Sensor	META-NAIL Semi-extended Drill Guide Probe
7169-1152	Sensor	Humeral Drill Guide Probe

Guidance and manufacturer's declaration – electromagnetic emissions

The TRIGEN® SURESHOT® Distal Targeting System is intended for use in the electromagnetic environment specified below. The customer or the user of the TRIGEN SURESHOT Distal Targeting System should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The TRIGEN SURESHOT Distal Targeting System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The TRIGEN SURESHOT Distal Targeting System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The TRIGEN SURESHOT Distal Targeting System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supplylines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/outputlines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply 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% UT (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<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 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the table requires continued operation during power mains interruptions, it is recommended that the TRIGEN SURESHOT Distal Targeting System is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	If image distortion occurs, it may be necessary to position the TRIGEN SURESHOT Distal Targeting System further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended location to assure that it is sufficiently low.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The TRIGEN SURESHOT Distal Targeting System is intended for use in the electromagnetic environment specified below. The customer or the user of the tables should assure that they are used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the TRIGEN SURESHOT Distal Targeting System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 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). b 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

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

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

b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the TRIGEN SURESHOT Distal Targeting System

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

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter m**		
W	**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 metres (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 80MHz and 800MHz, 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.

Warranty

Smith & Nephew products are guaranteed to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

This limited warranty is restricted to repair or replacement by Smith & Nephew, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Smith & Nephew be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

Service Replacement Units Warranty

Smith & Nephew service replacement units are warranted to be free from defects in material workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

Service Replacement Program

Smith & Nephew offers a 24-hour Service Replacement Program for its products to minimize downtime in the operating room. Our goal is to ship a service replacement unit within 24 hours** of a call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service at +1 800 238 7538 in the U.S., or contact an authorized representative.

** 24-hour shipment is not offered in all countries.

Repair Service Program

For devices no longer under warranty, repairs can be made by Smith & Nephew or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully disinfected, repackaged, marked with the Return Authorization (RA) number, and returned postpaid to the appropriate Smith & Nephew Service Center. Smith & Nephew Customer Service or a local authorized representative can provide shipping information.

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

www.smith-nephew.com

+1 901 396 2121
+1 800 238 7538 U.S. Customer Service
+1 901 396 2121 International Customer Service

EC REP

European Representative
Smith & Nephew Orthopaedics GmbH
Alemannenstrasse 14
78532 Tuttlingen, Germany
Tel: 07462/208-0
Fax: 07462/208-135

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