Introduction

Legend

Important warnings appear in orange

Tips, tricks and important information appear in blue

Indications, contraindications, intended use and training
The Smith & Nephew TRIGEN® SURESHOT® Distal Targeting System is intended to be an intraoperative image-guided localization system. It is a computer-assisted orthopaedic 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 TRIGEN SURESHOT Targeting System V2.1 is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

An example of a surgical procedure includes but is not limited to locating and drilling the distal holes in an intramedullary nail.

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

Intended use
The TRIGEN SURESHOT Distal Targeting System is only designed for use with the indicated implants and instruments. Implants and instruments must be used in accordance with the instructions, as described in this manual and/or in the non-navigated surgical procedure.

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.
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

Serial number

Testing Lab certification

Fuse

CE Mark

Temperature range

Humidity limit

EU Not for general waste

European representative
Warnings and cautions

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 Orthopaedics
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 theatre.

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 (Smith & Nephew document 7138-1339).

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 IEC60601-1 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 (beginning on page 19). 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 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.
**Note** Do not unplug the power while the system is running!

**Note** Danger of damage and tipping over!

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

**Note** 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 (Cat. No. 7169-2802)
2. Power cord (country specific)

**Front panel layout**
1. Probe sensor ports
2. Targeter port
3. Touch screen interface

**Rear panel layout**
1. Power switch
2. Power connection
3. USB connections (service only)
4. VGA video output (1024 x 768 resolution)
5. VESA mounting posts (10-32 thread pitch, 100mm screw pattern)
Applied parts for targeting

**TRIGEN® SURESHOT® Targeter**
(Body Applied Part Type BF)

*Note* 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.

*Note* 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.

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

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

*Note* This device is provided non-sterile and must be cleaned and sterilized per *Cleaning and Sterilization* (Smith & Nephew document 7138-1339) prior to use.

**TRIGEN SURESHOT Probes**
(Body Applied Part Type BF)

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

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

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

*Note* This device is provided sterile by ethylene oxide gas and is single use.

*Note* In case the packaging is compromised, please replace with new sterile packaged probe.
Surgical procedure – OR preparation

**Note** 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 (7169-2802) in the desired non-sterile location and turn on the power switch.

![Trauma Interface](image)

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

**Note** 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.

When start-up screen disappears before the display prompts for tool connections, a warning screen will appear: Do not operate the TRIGEN SURESHOT Targeter within 200mm of an installed pacemaker.

The magnetic field produced by the Targeter may interfere with the operation of the pacemaker.

![Warning Screen](image)
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.

Note 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.

Note This step needs to be performed at least ten minutes prior to targeting in order to ensure proper accuracy.

Tip 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.

Tip 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.

Confirmation that the targeter tool has been connected when the center of the Targeter lights up orange.
Surgical procedure – After IM nail assembly to the drill guide

Probe selection and assembly
Assemble the appropriate probe and set stop for the TRIGEN® IM nail and drill guide that will be used.

*Note* 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)

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

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

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

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**Red probe**
Use only with META-NAIL Standard Drill Guide

**Blue probe**
Use only with META-NAIL Semi-extended Drill Guide

**Green probe**
Use only with Percutaneous TAN/FAN Drill Guide (7163-1021)

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

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

*For META-NAIL, notches should face anteriorly*

*For TAN/FAN, 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.

Tip 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.

Tip 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.

Confirm that the tool connection has been verified.

Drill sleeve selection
Select the length of the drill sleeve (7169-2804 or 7169-2805) that will be used.

Tip A different sleeve can be selected at any time during the procedure by choosing the drill sleeve option from the drop down menu after the implant has been selected. The selected sleeve will be noted on the navigation screen.

Note For Humeral Nails, there is only one option provided for the drill sleeve (7169-1154)
**Implant selection screen**
Select the TRIGEN™ IM nail and size that will be used.

Tip 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. The selected implant and diameter will be noted on the navigation screen.

Or

For TRIGEN Humeral Nail: Select the TRIGEN Humeral nail size that will be used.

Tip A different TRIGEN Humeral Nail size can be selected at any time during the procedure by choosing the implant option from the drop down menu. The selected implant and diameter will be noted on the trauma interface screen.

**Drill sleeve attachment**
Tightly secure the selected drill sleeve to the Targeter.

Tip The drill sleeve (7169-2804 or 7169-2805) can be loosened from the Targeter using the slot in the TRIGEN Hammer (7167-4082).

Tip The 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.

Note 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).

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

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

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

Optional – Field accuracy check

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

Note This step should be performed at least once a year to ensure that the device is working properly.
Surgical procedure – Distal Targeting

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

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

**Probe and set stop insertion**
Following the removal of the Ball Tip Guide Rod, insert the probe and set stop into the IM nail as described in the locking hole accuracy check on the previous page.

**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.

**Targeting the locking hole**
With the appropriate length TRIGEN SURESHOT® 4.0mm 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.

**Tip** 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 4.0mm Drill Sleeve/Drill Bit to keep the IM nail from rotating.

**Critical** Verify there are no other metal objects (including metal triangles) in the field. Metal interference will cause the system to be inaccurate.
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.

Length measurement
Before drilling through the far cortex, measure the length using the calibrations on the TRIGEN SURESHOT 4.0mm Drill Bit or the TRIGEN SURESHOT Humeral AO Drill Bit (7169-1155).

Alternatively, the length measurement can be achieved using the standard Screw Length Gauge (7163-1189) through the Targeter after removing the drill sleeve.

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

Tip If the Targeter is placed too close to the bone, the image of the IM Nail on the display might disappear.

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

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

Note 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.
The depth of the screw can be verified by placing a 9.0mm Gold Drill Sleeve (7163-1152 or 7175-1128) down to bone over the hexdriver. The screw head will be flush with bone when the groove on the hexdriver is even with the end of the 9.0mm Gold Drill Sleeve.

The positioning of the screw may be verified using the C-arm.
Navigation screen operation

**Overview mode**
When the Targeter is greater than 5cm 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.

**Note** 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 AP or generally ML to orient the desired view.

**Drilling mode**
When the Targeter is moved within 5cm 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 2.5mm from the side of the IM nail for all IM nails 10mm and larger in diameter. These lines are located 2mm from the sides of 8.5mm IM nails.

**Drilling mode manual rotation**
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 flip the view**
Touch the “Menu” button and select “Toggle Back View.”

All changes made for a view are temporarily stored for that view until program exit.

**To reset the view**
The default view settings can be restored by touching the “Menu” button and selecting “Reset View” or double tapping the center of the screen.
Shutting down the system

- Shut down the Trauma Interface by selecting the “Shut Down” option from the on-screen “Menu” button.
- Switch off the main power switch on the rear of the unit.
- Unplug the power supply cable.

Note Shut down the Trauma Interface using the on-screen “Shut Down” option and wait for the system to power down before switching off power or unplugging from main power supply.

Caution Do not place any objects on top of the screen when the Trauma Interface is stored in the shipping container. Damage to the screen may occur.

Storage and transport

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

Note The internal fan of the Trauma Interface runs continuously whenever the rear power switch is in the ON position. Switch power off whenever the unit is not in use.
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.

Field accuracy check steps
1. Attach TRIGEN SURESHOT Field Accuracy Gauge (7169-2808) to 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, select “Field Check” option.
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.

**Cleaning and disinfection**

The TRIGEN SURESHOT Trauma Interface is used in the non-sterile area of the operating theatre 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.

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 (Smith & Nephew document 7138-1339).

- **Note** Observe the manufacturer’s instructions for dilution, exposure time, etc.
- **Note** DO NOT sterilize with ethylene oxide gas or steam sterilize the Trauma Interface.
- **Note** 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.

Note Disconnect the power cord before exchanging any fuse.
Note To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.

Technical information
Smith & Nephew Orthopaedics 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.

Note Service can only be performed by authorized Smith & Nephew personnel.
**TRIGEN® SURESHOT® Distal Targeting System service philosophy**

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 your 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. Your Smith & Nephew customer service representative will provide additional instructions for shipment.

**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 related policy relating to obsolete electronic equipment.

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**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.
## Troubleshooting

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<th>Possible cause</th>
<th>Suggested action</th>
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</thead>
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<td>Trauma Interface unit is without power</td>
<td>Mains power plug is not inserted (properly) or there is no mains power</td>
<td>Insert mains power plug into reliable power supply</td>
</tr>
<tr>
<td></td>
<td>No power on the wall outlet</td>
<td>Try other power outlet</td>
</tr>
<tr>
<td></td>
<td>One or both mains power fuses are blown</td>
<td>Replace mains fuses</td>
</tr>
<tr>
<td>Buttons or items are difficult to select on the touchscreen</td>
<td>Touchscreen is de-calibrated</td>
<td>Access calibration software by selecting “Maintenance” from the “About” option under the “Menu” options (password required)</td>
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<tr>
<td>VGA video out not functioning</td>
<td>VGA port not activated on Trauma Interface</td>
<td>Connect VGA cable to both Trauma Interface and video monitor before powering on Trauma Interface</td>
</tr>
<tr>
<td></td>
<td>Damaged VGA cable</td>
<td>Replace VGA cable</td>
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<tr>
<td></td>
<td>Video monitor not on correct input</td>
<td>Select proper input on video monitor</td>
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<tr>
<td>TRIGEN® SURESHOT® Targeter not recognized</td>
<td>Error reading data from Targeter</td>
<td>Unplug Targeter, wait 10 seconds, plug back in</td>
</tr>
<tr>
<td></td>
<td>Damaged Targeter</td>
<td>Replace Targeter with new unit</td>
</tr>
<tr>
<td>Probe not recognized</td>
<td>Error reading data from probe</td>
<td>Unplug probe, wait 10 seconds, plug back in</td>
</tr>
<tr>
<td></td>
<td>Damaged probe</td>
<td>Replace probe with new unit</td>
</tr>
<tr>
<td>Probe will not insert to the proper depth in the nail</td>
<td>Obstruction within the nail cannulation</td>
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<tr>
<td>Nail not visible on the screen</td>
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<td>Remove any metal objects from the targeting field</td>
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<tr>
<td></td>
<td>TRIGEN SURESHOT Targeter and probe not within range of each other</td>
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</tr>
<tr>
<td>Drill bit too short</td>
<td>Short drill bit being used and long drill sleeve option selected within software</td>
<td>Press “Menu”, “Drill Sleeve” and select the short drill sleeve option and use the short drill bit</td>
</tr>
<tr>
<td>Drill bit too long</td>
<td>Long drill bit being used and short drill sleeve option selected within software</td>
<td>Press “Menu”, “Drill Sleeve” and select the long drill sleeve option and use the long drill bit</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible cause</td>
<td>Suggested action</td>
</tr>
<tr>
<td>---------</td>
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</tr>
<tr>
<td>Red and Green targeting circles representing the drill sleeve appear incorrect</td>
<td>Incorrect drill sleeve length selected</td>
<td>Verify the correct drill sleeve length is selected from the software menu</td>
</tr>
<tr>
<td></td>
<td>Metal interference within the TRIGEN® SURESHOT® electromagnetic field</td>
<td>Remove any metal objects from the targeting field</td>
</tr>
<tr>
<td></td>
<td>Probe not inserted correctly within set stop</td>
<td>Verify probe is oriented and seated correctly in the notches of the set stop</td>
</tr>
<tr>
<td></td>
<td>Damaged probe</td>
<td>Verify probe accuracy with Field Accuracy Gauge</td>
</tr>
<tr>
<td>Targeting missed the intended hole</td>
<td>Metal interference within the TRIGEN SURESHOT electromagnetic field</td>
<td>Remove any metal objects from the targeting field</td>
</tr>
<tr>
<td></td>
<td>Probe not inserted correctly within set stop</td>
<td>Verify probe is oriented and seated correctly in the notches of the set stop</td>
</tr>
<tr>
<td></td>
<td>Damaged probe</td>
<td>Verify probe accuracy with Field Accuracy Gauge</td>
</tr>
<tr>
<td>Drill sleeve cannot be removed from TRIGEN SURESHOT Targeter</td>
<td>Over-tightening of drill sleeve</td>
<td>Use the Slotted Hammer from the instrument tray as a wrench to unscrew the drill sleeve counter-clockwise from the Targeter</td>
</tr>
<tr>
<td>The 4.7mm/4.0mm step drill will not fit through the drill sleeve</td>
<td>Not compatible with the TRIGEN SURESHOT Distal Targeting System</td>
<td>Only use the long (7169-2811) and short (7169-2810) drills designated for use with the TRIGEN SURESHOT Distal Targeting System</td>
</tr>
<tr>
<td>Field accuracy check fails</td>
<td>Metal interference within the TRIGEN SURESHOT electromagnetic field</td>
<td>Remove any metal objects from the targeting field</td>
</tr>
<tr>
<td></td>
<td>Field Accuracy Gauge improperly installed on Targeter</td>
<td>Verify Field Accuracy Gauge is fully seated within Targeter port and knob is hand tightened to Targeter</td>
</tr>
<tr>
<td></td>
<td>META Set Stop improperly installed on Field Accuracy Gauge</td>
<td>Verify META Set Stop is correctly oriented and tightened securely to Field Accuracy Gauge</td>
</tr>
<tr>
<td></td>
<td>Probe is incorrectly inserted within META Set Stop</td>
<td>Verify probe is oriented properly and inserted to the “REF” notches on probe body</td>
</tr>
<tr>
<td></td>
<td>Probe is damaged</td>
<td>Replace probe with a new probe</td>
</tr>
<tr>
<td></td>
<td>Targeter is damaged</td>
<td>Replace Targeter with a new Targeter and return old one for service</td>
</tr>
</tbody>
</table>
Trauma Interface label

Trauma Interface label

Trauma Interface case label

Trauma Interface case label
## Technical specifications

<table>
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<th>System power supply</th>
<th>Voltage</th>
<th>100–240 VAC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>50–60 Hz</td>
</tr>
<tr>
<td></td>
<td>Connected load</td>
<td>≤ 2.2 Amps</td>
</tr>
<tr>
<td>Fuses</td>
<td>Type</td>
<td>T3.15A L 250V</td>
</tr>
<tr>
<td></td>
<td>Quantity</td>
<td>2</td>
</tr>
<tr>
<td>Classification</td>
<td>Protection class</td>
<td>Class I (with protective earth [=ground])</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IPX0, continuous operation</td>
</tr>
<tr>
<td></td>
<td>Type</td>
<td>BF (with hand-held FG, targeting probe)</td>
</tr>
<tr>
<td></td>
<td>Humidity</td>
<td>No protection</td>
</tr>
<tr>
<td></td>
<td>Explosion</td>
<td>No protection</td>
</tr>
<tr>
<td>Ambient conditions</td>
<td>Temperature</td>
<td>10–40°C</td>
</tr>
<tr>
<td></td>
<td>Humidity</td>
<td>30–75% RH (non-condensing)</td>
</tr>
<tr>
<td></td>
<td>Air pressure</td>
<td>700–1060 HPa</td>
</tr>
<tr>
<td>Storage and transport</td>
<td>Temperature</td>
<td>-20–50°C (in original packaging)</td>
</tr>
<tr>
<td></td>
<td>Humidity</td>
<td>10–90% RH (non-condensing)</td>
</tr>
<tr>
<td></td>
<td>Air pressure</td>
<td>700–1060 HPa</td>
</tr>
<tr>
<td>System</td>
<td>Dimensions (DxWxH)</td>
<td>40cm x 38cm x 20cm</td>
</tr>
<tr>
<td></td>
<td>Weight</td>
<td>9kg</td>
</tr>
<tr>
<td>Transportation case</td>
<td>Dimensions (DxWxH)</td>
<td>63cm x 50cm x 35cm</td>
</tr>
<tr>
<td>System + case + accessories</td>
<td>Weight</td>
<td>≈ 20kg</td>
</tr>
<tr>
<td>Complies with standards</td>
<td></td>
<td>USA, Canada, Europe</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IEC 60601-1 (2nd edition)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IEC 60601-1-2:2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CSA C22.2#601-1 (2nd edition)</td>
</tr>
</tbody>
</table>

### Electrical safety

The system meets IEC standards (eg IEC 60601). All configurations comply with standard IEC 60601-1-1. 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.

**Note** 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.

**Note** 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.

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

**Note** 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.
<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7169-1151</td>
<td>TRIGEN® SURESHOT® Humeral Set Stop</td>
</tr>
<tr>
<td>7169-1153</td>
<td>TRIGEN SURESHOT Humeral 3.5mm Hexdriver</td>
</tr>
<tr>
<td>7169-1154</td>
<td>TRIGEN SURESHOT Humeral 3.2mm Drill Sleeve</td>
</tr>
<tr>
<td>7169-1156</td>
<td>TRIGEN SURESHOT Humeral Instrument Caddy</td>
</tr>
<tr>
<td>7169-1152</td>
<td>TRIGEN SURESHOT Humeral Drill Guide Probe</td>
</tr>
<tr>
<td>7169-1155</td>
<td>TRIGEN SURESHOT Humeral 3.2mm AO Drill</td>
</tr>
<tr>
<td>7169-2801</td>
<td>TRIGEN SURESHOT Targeter</td>
</tr>
<tr>
<td>7169-2802</td>
<td>Trauma Interface</td>
</tr>
<tr>
<td>7169-2803</td>
<td>TRIGEN SURESHOT META-NAIL® Semi-extended Drill Guide Probe</td>
</tr>
<tr>
<td>7169-2804</td>
<td>TRIGEN SURESHOT Long Drill Sleeve</td>
</tr>
<tr>
<td>7169-2805</td>
<td>TRIGEN SURESHOT Short Drill Sleeve</td>
</tr>
<tr>
<td>7169-2806</td>
<td>TRIGEN SURESHOT META Set Stop</td>
</tr>
<tr>
<td>7169-2807</td>
<td>TRIGEN SURESHOT Percutaneous TAN/FAN Set Stop</td>
</tr>
<tr>
<td>7169-2808</td>
<td>TRIGEN SURESHOT Field Accuracy Gauge</td>
</tr>
<tr>
<td>7169-2809</td>
<td>TRIGEN SURESHOT Hexdriver</td>
</tr>
<tr>
<td>7169-2810</td>
<td>TRIGEN SURESHOT Short AO Drill</td>
</tr>
<tr>
<td>7169-2811</td>
<td>TRIGEN SURESHOT Long AO Drill</td>
</tr>
<tr>
<td>7169-2814</td>
<td>TRIGEN SURESHOT META-NAIL® Standard Drill Guide Probe</td>
</tr>
<tr>
<td>7169-2815</td>
<td>TRIGEN SURESHOT Percutaneous TAN/FAN Drill Guide Probe</td>
</tr>
<tr>
<td>7169-2816</td>
<td>TRIGEN SURESHOT TAN Anteversion Locking Guide</td>
</tr>
<tr>
<td>7169-2817</td>
<td>Trauma Interface Case</td>
</tr>
<tr>
<td>7169-2819</td>
<td>TRIGEN SURESHOT TAN Set Stop Bolt</td>
</tr>
<tr>
<td>7169-2830</td>
<td>TRIGEN SURESHOT Distal Targeting Instrument Tray</td>
</tr>
<tr>
<td>7169-2831</td>
<td>TRIGEN SURESHOT Distal Targeting Instrument Tray Lid</td>
</tr>
<tr>
<td>6680-0193</td>
<td>Power Cord, 125 Volt 10 AMP, North America (Hospital Grade)</td>
</tr>
<tr>
<td>6680-0291</td>
<td>Power Cord, 250 Volt 10 AMP, Continental Europe</td>
</tr>
<tr>
<td>6680-0213</td>
<td>Power Cord, 250 Volt, 10 AMP, UK</td>
</tr>
<tr>
<td>6680-0303</td>
<td>Power Cord, 250 Volt, 10 AMP, Australia/New Zealand</td>
</tr>
<tr>
<td>6680-0302</td>
<td>Power Cord, 250 Volt, 10 AMP, South Africa/India</td>
</tr>
</tbody>
</table>

**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.
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.

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

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

**Note** 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.

**Note** 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.

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7169-1152</td>
<td>Sensor</td>
<td>Humeral Drill Guide Probe</td>
</tr>
<tr>
<td>7169-2801</td>
<td>Field Generator</td>
<td>TRIGEN® SURESHOT® Targeter</td>
</tr>
<tr>
<td>7169-2814</td>
<td>Sensor</td>
<td>META-NAIL® Standard Drill Guide Probe</td>
</tr>
<tr>
<td>7169-2815</td>
<td>Sensor</td>
<td>Percutaneous TAN®/FAN Drill Guide Probe</td>
</tr>
<tr>
<td>7169-2803</td>
<td>Sensor</td>
<td>META-NAIL Semi-extended Drill Guide Probe</td>
</tr>
</tbody>
</table>
The TRIGEN SURESHOT Distal Targeting System is intended for use in the electromagnetic environment specified below. The customer or the user of PiGalileo should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
### 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 PiGalileo should assure that they are used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact&lt;br&gt;±8 kV air</td>
<td>±6 kV contact&lt;br&gt;±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>Electrical fast transient / burst</td>
<td>±2 kV for power supply lines&lt;br&gt;±1 kV for input/output lines</td>
<td>±2 kV for power supply lines&lt;br&gt;±1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV line(s) to line(s)&lt;br&gt;±2 kV line(s) to earth</td>
<td>±1 kV differential mode&lt;br&gt;±2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply lines</td>
<td>&lt;5 % $U_T$&lt;br&gt;(&gt;95% dip in $U_T$) for 0.5 cycle&lt;br&gt;40% $U_T$&lt;br&gt;(60% dip in $U_T$) for 5 cycles&lt;br&gt;70% $U_T$&lt;br&gt;(30% dip in $U_T$) for 25 cycles&lt;br&gt;&lt;5 % $U_T$&lt;br&gt;(&gt;95% dip in $U_T$) for 5s</td>
<td>&lt;5 % $U_T$&lt;br&gt;(&gt;95% dip in $U_T$) for 0.5 cycle&lt;br&gt;40% $U_T$&lt;br&gt;(60% dip in $U_T$) for 5 cycles&lt;br&gt;70% $U_T$&lt;br&gt;(30% dip in $U_T$) for 25 cycles&lt;br&gt;&lt;5 % $U_T$&lt;br&gt;(&gt;95% dip in $U_T$) for 5s</td>
<td>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.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>not tested</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2,5 GHz</td>
<td>3 V/m</td>
</tr>
</tbody>
</table>

**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.
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.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>W</td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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 materials and workmanship for the warranty period for a particular product, beginning from the 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 and 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

The Smith & Nephew TRIGEN® SURESHOT® Trauma Interface replacement unit assumes the remainder of the original unit’s warranty (if applicable). If the replacement unit is new to the customer or replacing a unit with less than 90 days remaining on the original warranty, this unit is warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.
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 repackaged, marked with the return Authorization (RA) number, and returned postage-paid to the appropriate Smith & Nephew Customer Service Center. Smith & Nephew Customer Service or your local authorized representative can provide shipping information.

Smith & Nephew
Orthopaedics GmbH
Tuttlingen, Germany