

URGENT - Medical Device Correction
Field Generator Stand
for the Philips or Traxtal PercuNav™ System
Potential Tipping Hazard

Dear Customer,

A potential problem has been detected in the Philips Field Generator Stand that, if it were to occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- actions that should be taken by the customer / user in order to prevent risks for patients or users
- actions planned by Philips to correct the problem

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Philips Healthcare has discovered a problem that could result in the Field Generator Stand tipping over during set up, during use, or during transport. Tipping could occur when the Field Generator is attached to the Mounting Arm of the Field Generator Stand and has been positioned further than 40 in (100 cm) from the back of the clamp on the stand's central pole.

All Field Generator Stands provided as a component of PercuNav Systems could be affected by this issue. Systems were distributed under the Philips or Traxtal name (Traxtal, Inc. is now part of Philips Healthcare). Models affected are the PercuNav TX and TX2-120 carts, and the iU22 Ultrasound with integrated PercuNav functionality.

You are being contacted because our records indicate a Field Generator Stand has been distributed to your facility.

To immediately avoid the potential tipping hazard, customers should ensure the articulating Mounting Arm is positioned so the Field Generator is not further than 40 in (100 cm) from the back of the clamp on the stand's central pole during set up or during use. Additionally, customers are reminded to use caution when moving the Field Generator Stand up or down a ramp or over any obstructions on the floor (such as power cords or elevator thresholds), not to park the stand on any incline or to push or lean on the stand or Mounting Arm with excessive force. Customers are also reminded to follow the guidance in the Instructions for Use prior to using the Field Generator Stand.

For transport, customers should remove the Field Generator from the Mounting Arm and place the Field Generator in the storage compartment on the system cart. The Mounting Arm should then be collapsed and folded into a 90 degree angle.



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Please refer to Appendix A for diagrams of the recommended Mounting Arm and Field Generator positioning. Please forward this letter including pages 3-5, to appropriate staff members of your facility. Include a copy with each Field Generator Stand's Instruction for Use in your facility.

Please find included with this letter an additional safety label. The symbol on this new label warns of a potential for tipping due to excessive force. Please immediately apply two (2) of these labels to each Field Generator Stand in your facility. Place the two (2) labels on the clamp of the Mounting Arm attached to the stand's central pole as shown in Appendix B. To apply the labels, first clean the surface of the clamp with alcohol and allow the surface to dry. Remove the paper backing from the labels and place one (1) label on the back of the clamp and one (1) label on the flat side of the clamp, making sure to orient the labels with the human figure right side up. Press the labels firmly onto the clamp to ensure complete adhesion.

Philips plans to take further action to improve the stability of the Field Generator Stand, so that the restriction on the extension of the Mounting Arm will no longer be necessary. Once upgrade kits are available, a Philips Healthcare representative will contact your facility to modify your Field Generator Stand by installing an additional weight to the base of the stand. Philips will perform this modification to your stand free of charge.

Please complete the reply card in Appendix C confirming your receipt and understanding of this important Field Safety Notice and return it to Philips Healthcare through one of the listed options.

If you need any further information or support concerning this issue, please call Philips Customer Service at 866 767-7822.

This notice has been reported to the appropriate regulatory authorities.

Philips apologizes for any inconvenience caused by this problem.

Sincerely,



Senior Director, Quality & Regulatory
Philips Healthcare - Ultrasound



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AFFECTED PRODUCTS	All Field Generator Stands distributed with Philips or Traxtal PercuNav systems, (i.e. PercuNav TX and TX2-120 carts, and the iU22 Ultrasound with integrated PercuNav functionality).
PROBLEM	The Field Generator Stand could tip over during set up, during use or during transport.
HAZARD INVOLVED	Patients or users may receive minor injuries as a result of contact with a tipping Field Generator Stand. Additionally, if the Field Generator Stand were to tip over during a procedure, the patient may be injured if the Field Generator were to impact the instrument in use, such as a needle or biopsy gun.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Field Generator Stands are affected by this issue.
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Customers should ensure the articulating Mounting Arm is positioned so the Field Generator is not further than 40 in (100 cm) from the back of the clamp on the stand's central pole during set up or during use. Additionally, customers are reminded to use caution when moving the Field Generator Stand up or down a ramp or over any obstructions on the floor (such as power cords or elevator thresholds), not to park the stand on any incline or to push or lean on the stand or Mounting Arm with excessive force. Customers are also reminded to follow the guidance in the Instructions for Use prior to using the Field Generator Stand.</p> <p>For transport, customers should remove the Field Generator from the Mounting Arm and place the Field Generator in the storage compartment on the system cart. The Mounting Arm should then be collapsed and folded into a 90 degree angle.</p> <p>Customers should apply the included warning labels to the Field Generator Stand as advised.</p>
ACTIONS PLANNED BY PHILIPS	Philips plans to take further action to improve the stability of the Field Generator Stand, so that the restriction on the extension of the Mounting Arm will no longer be necessary. Once upgrade kits are available, a Philips Healthcare representative will contact your facility to modify your Field Generator Stand by installing an additional weight to the base of the stand. Philips will perform this modification to your stand free of charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please call Philips Customer Service at 866 767-7822.



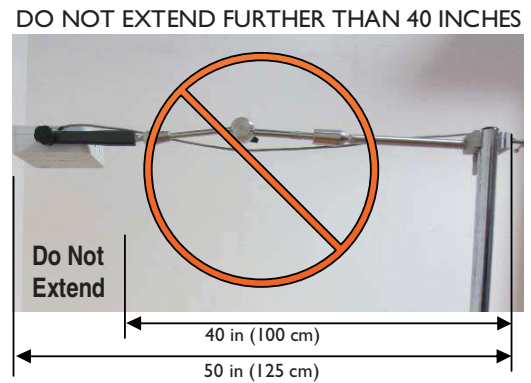
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Appendix A:

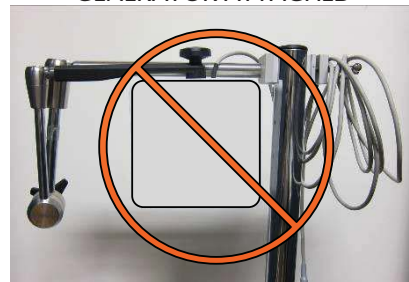
Positioning the Field Generator for Use:



Preparing the Field Generator Stand for Transport:



DO NOT TRANSPORT WITH THE FIELD GENERATOR ATTACHED



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Appendix B:

Symbol Definition:



“Pushing Prohibited”. Informs the user of a potential for tipping due to excessive force

NOTE: For transport, customers should remove the Field Generator from the Mounting Arm and place the Field Generator in the storage compartment on the system cart. The Mounting Arm should then be collapsed and folded into a 90 degree angle (as shown in Appendix A).

Correct Label Positioning:

Position 1



Position 2



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Appendix C:

Field Safety Notice – Reply Card

Please complete the below table and return to Philips Healthcare. By completing this reply card you are confirming that you have received and understood this Field Safety Notice and that the information has been appropriately disseminated within your facility.

Facility Name	
Contact Name	
Title	
Contact Telephone	
Signature	
Date	

Promptly returned reply cards will ensure your facility does not receive repeat notices.

Completed reply cards may be returned to Philips Healthcare by:

FAX: 978-683-6337 (A cover page is not required)

