

via Certified Mail - Return Receipt Requested

IMPORTANT ACTION NECESSARY FOR YOUR PHILIPS/ATL HDI 4000 ULTRASOUND IMAGING SYSTEM.
PLEASE FORWARD TO THE MANAGER RESPONSIBLE FOR THESE SYSTEMS AT YOUR FACILITY.

May 6, 2005

RE: Philips HDI 4000 Ultrasound System, Acoustic Output Display Accuracy Issue
Information and Instructions for Use: 453561219731

Dear Ultrasound System User,

Philips Medical Systems has recently identified an acoustic output display accuracy issue with the HDI 4000 system. The acoustic display of MI (Mechanical Index) and TI (Thermal Index) on the HDI 4000 is inaccurate and should not be relied upon to gauge acoustic exposure. To help you gauge acoustic exposure, please follow the attached instructions to create new low power presets. Use these new presets when initiating new exams and, except as noted below, adjust the acoustic power until a satisfactory image is obtained.

We have additionally identified two transducers that may exceed limits for acoustic intensity (Ispta) and MI, depending on their mode of operation. The P4-2 (Cardiac transducer) may exceed the acoustic intensity limit, and the L7-4 (Vascular transducer) may exceed the MI limit.

To use the P4-2 and L7-4 transducers, follow the attached instructions to create new low power presets and do not adjust the acoustic power to improve image quality. Instead, adjust image quality using 2D or color gain. Further, do not use the P4-2 transducer in PW mode or combined PW modes (Triple mode or Simultaneous mode).

To remedy this situation, Philips is releasing software to resolve both the acoustic display inaccuracies as well as the intensity and MI limit issues. This software modification will be available on or before November 2005 and will be installed in your system at no cost to you. Our local service organization will contact you to arrange for this installation. We expect to complete modifications to all affected systems no later than the end of June 2006. Until you have received the software upgrade, please follow the instructions in this letter and insert this letter in your HDI 4000 Operator's Manual.

We apologize for any inconvenience this may represent and appreciate your forwarding this information to the appropriate individuals within your organization. Please contact your Philips Service Representative if you have any questions regarding this upgrade.

Sincerely,



Lee Ann Rogus
Director, Quality and Regulatory, Philips Ultrasound

Enc: 453561219731: Instructions for creating system presets

To create new, lower output pre-sets for the HDI 4000 following these steps:

1. Select the transducer and application, as you normally would start an exam.
2. Adjust TGC slide pots to the center of their range and obtain a 2D image
3. Using the power knob located on the upper right corner of the control panel reduce the output power by rotating the knob counter-clockwise while watching the display numbers shown in the upper right image window (see figure 1) until the reading is P50.
4. Increase the overall 2D gain using the 2D knob located on the control panel above the trackball until the 2D image is again bright.
5. Now press the UTILITY key located on the upper left of the control panel
6. Using the menu knob highlight the Pre-set control and press the Select key
7. Use the menu knob again to highlight the SETTING control and press the Select key
8. Use the menu knob to select USER 1
9. Now use the menu knob to select the SAVE control and press the SELECT key to save the new Pre-set
10. The Save Success message will flash in the lower left of the image window

To name the newly saved Pre-set follow these steps:

1. Press the scanhead key located on the upper left control panel
2. Make certain the currently active transducer and application are highlighted
3. The USER 1 name should be highlighted indicating this is the newly created Pre-set
4. Move the cursor to the icon located within the text box in lower right corner.
5. Press the set key. This will highlight the name within the text box.
6. Type the new name and select OK. (see figure 2)



Fig. 1

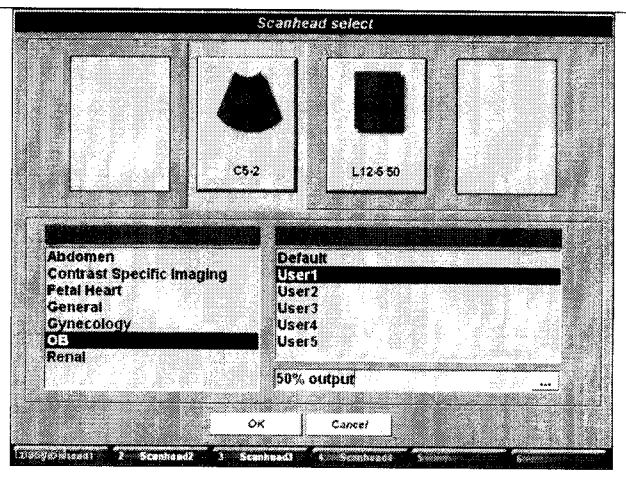


Fig. 2