

Philips Healthcare

Ultrasound

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FSN79500115

June 2008

URGENT- Medical Device Correction

Biopsy Guide Starter Kits used with Philips Model HD3 Ultrasound Systems

Dear Philips Ultrasound System User:

Philips Ultrasound recently identified an omission in Biopsy Guide Starter Kit models C7-3, C5-2 and L9-5.

Model C7-3 kits that were distributed between November 29, 2005 and April 3, 2008 contained only the mounting bracket and reusable needle guides. The user manual and all other components were inadvertently omitted from this kit. Philips developed a new model C7-3 kit to correct this omission. All model C7-3 kits distributed after April 3, 2008 contain the correct components and include the user manual which provides instructions for cleaning, disinfecting and sterilization of reusable parts.

Customers who previously purchased and received a model C7-3 Biopsy Guide Starter Kit between November 29, 2005 and April 3, 2008 will receive a new kit at no charge, to replace the incomplete C7-3 kit previously purchased. New C7-3 kits will be distributed to affected customers by June 30, 2008. Please discard immediately the old C7-3 Biopsy Guide Kit.

The user manuals for Biopsy Guide Starter Kit models C5-2 and L9-5 incorrectly reference the HD3 system user manual for instructions on cleaning, disinfecting and sterilization of reusable parts contained in the biopsy kit. The HD3 Getting Started Guide does not contain instructions for cleaning, disinfecting and sterilization of reusable biopsy guide kit components. Philips has corrected this by developing new user manuals for models C5-2 and L9-5, which now include instructions for cleaning, disinfecting and sterilization of reusable parts.

Customers who received a model C5-2 kit between December 09, 2005 and November 27, 2007 with a serial number within the sequential range of SN123 through SN269 are affected. Model C5-2 kits distributed after November 27, 2007 have the corrected manual.

Customers who received a model L9-5 kit between December 09, 2005 and November 27, 2007 with a serial number within the sequential range of SN133 through SN264 are affected. Model L9-5 kits distributed after November 27, 2007 have the corrected manual.

Serial numbers of model C5-2 and L9-5 Biopsy Guide Starter Kits can be found in the upper right hand corner of the manufacturer's label located on the exterior of the packaging

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Customers who previously purchased and received model C5-2 and / or model L9-5 will find the respective new user manual enclosed with this letter. Please discard any old user manuals for models C5-2 and L9-5. The old C5-2 and L9-5 user manual is identified by part number 1-041-7385-02 and 1-041-7587-02 respectively. The part number is located in the lower left hand margin of the single page document.

You are receiving this letter because our records indicate your facility received at least one of the affected biopsy guide starter kits. We apologize for any inconvenience that this situation may present. Please complete the enclosed Medical Device Correction Confirmation form, and fax it back to the number listed on the top of the page. Please forward this information to the appropriate individuals within your organization. If you have any questions, please contact your local field service representative.

Sincerely,


Director, Quality & Regulatory
Philips Ultrasound

