URGENT – Medical Device Correction
GEMINI TF 16 and GEMINI TF 64 PET/CT Systems
Software Versions 3.5.1 and 3.5.1.1
Auto Delete Update

Dear Customer,

This letter is to inform you that a software update for the Auto Delete Function is available and will be installed onto your GEMINI TF PET/CT System. This Customer Letter is intended to inform you about:

- what the software update consists of
- the actions that should be taken by the customer
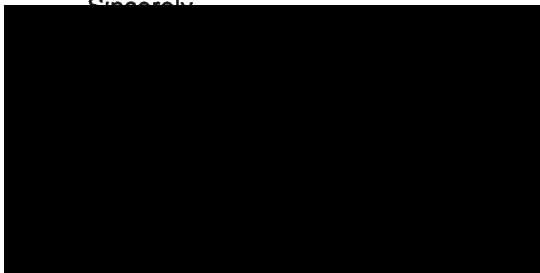- the actions planned by Philips to correct the problem

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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.

If you need any further information or support concerning this issue, please contact your local Philips representative. In the United States and Canada, please contact the Philips Healthcare Customer Care Solutions Center at 1-800-722-9377 and follow the recorded menu options to reach a Customer Solutions Engineer; in all other countries please dial your local Philips Healthcare office.

Sincerely,

CNT-073105-03
29-Jun-2011

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AFFECTED PRODUCTS	GEMINI TF 16 PET/CT Systems currently running software version 3.5.1 GEMINI TF 64 PET/CT Systems currently running software version 3.5.1 GEMINI TF 16 PET/CT Systems currently running software version 3.5.1.1 GEMINI TF 64 PET/CT Systems currently running software version 3.5.1.1 The affected systems serial numbers are listed in appendix A.
PROBLEM DESCRIPTION	The Auto Delete function on your GEMINI TF PET/CT System that automatically removes old data from the PET Reconstruction Server (PRS) may not be functioning as expected.
HAZARD INVOLVED	Prior to the Auto Delete Update being installed on your system, the Auto Delete Function could have deleted raw data prior to the images being reconstructed which could have resulted in a rescan and/or reinjection of a patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	To identify the affected units, the serial number label is visible on the top of the Gantry Seperation Unit (GSU) when in the closed position. Refer to Appendix B for a diagram.
ACTION TO BE TAKEN BY CUSTOMER / USER	The following are recommended actions regarding this software update relating to the Auto Delete Function: • Please ask your local Philips Service Engineer to ensure that the Auto Delete function is configured to run automatically. • Please share this information with all Philips GEMINI TF System operators at your site. • Retain this document with your system's Instructions for Use Manual.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected customers and the Field Service Engineer will be installing this software update free of charge.
FURTHER INFORMATION AND SUPPORT	For further information or support concerning this issue, please contact your local Philips representative. In the United States and Canada, please contact the Philips Healthcare Customer Care Solutions Center at 1-800-722-9377 and follow the recorded menu options to reach a Customer Solutions Engineer; in all other countries please dial your local Philips Healthcare office.

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Appendix A
Affected System Serial Numbers

7002	7027	7058	7084	7114	7143	7173	7199
7003	7028	7059	7085	7115	7144	7174	7200
7004	7029	7060	7086	7116	7145	7175	7201
7005	7030	7061	7087	7117	7146	7176	7202
7006	7031	7062	7088	7118	7147	7177	7203
7007	7032	7063	7089	7119	7148	7178	7204
7008	7034	7064	7091	7120	7149	7179	7205
7009	7035	7065	7092	7121	7152	7180	7206
7010	7036	7066	7093	7122	7153	7181	7207
7011	7038	7067	7094	7123	7154	7182	7208
7012	7039	7068	7095	7125	7156	7183	7209
7013	7041	7069	7096	7126	7158	7184	7210
7014	7042	7071	7097	7128	7159	7185	7211
7015	7043	7072	7098	7129	7160	7186	7212
7016	7044	7073	7099	7131	7161	7187	7213
7017	7045	7074	7102	7132	7163	7188	7214
7018	7047	7075	7103	7133	7164	7189	7215
7019	7049	7076	7104	7135	7165	7190	7216
7020	7050	7077	7105	7136	7166	7192	7217
7021	7051	7078	7106	7137	7167	7193	7218
7022	7052	7079	7107	7138	7168	7194	7219
7023	7053	7080	7108	7139	7169	7195	7220
7024	7054	7081	7109	7140	7170	7196	7221
7025	7055	7082	7110	7141	7171	7197	7223
7026	7057	7083	7112	7142	7172	7198	7224

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Appendix B
Serial Number Location