Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 77 **dated** 19/4/2023 **Regarding NCMDR Field Safety Corrective Action of CombiDiagnost R90 and ProxiDiagnost N90 from (mfr: Philips Medical Systems).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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سلطنة عُمان
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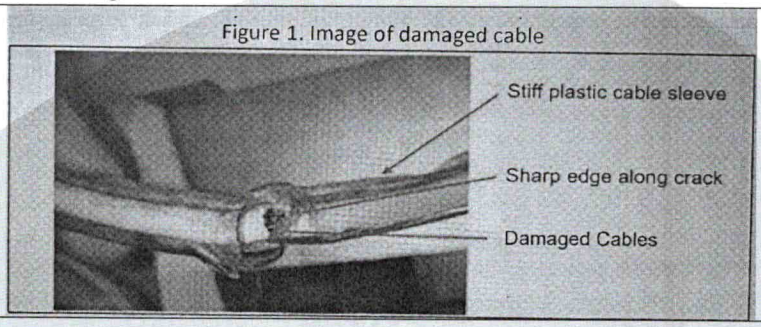
مسقط

Circular No. 77 / 2023

28 -09-1444 H

19 -04-2023

Field Safety Corrective Action of CombiDiagnost R90 and ProxiDiagnost N90 from Philips Medical Systems

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19490
Product	CombiDiagnost R90 and ProxiDiagnost N90.
Description	X-ray system.
Manufacturer	Philips Medical Systems.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Refer to "Appendix A" in the attached FSN.
Reason	Issues relating to potential component damage due to short circuit (CombiDiagnost R90, ProxiDiagnost N90) and potential table stop due to a broken tabletop cable (ProxiDiagnost N90 only) that could pose a risk for patients and/or users.
Action	1. Refer to "Actions that should be taken by the customer / user" in the attached FSN. 2. Contact the local agent for remedial action.
Product Image	Figure 1. Image of damaged cable 
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Field Safety Notice

Notification Update

CombiDiagnost R90 and ProxiDiagnost N90

Component damage due to short circuit & table stop due to broken tabletop cable

March 2023

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 this letter for your records.

Dear Customer,

Philips has previously notified you of issues relating to potential component damage due to short circuit (CombiDiagnost R90, ProxiDiagnost N90) and potential table stop due to a broken tabletop cable (ProxiDiagnost N90 only) that could pose a risk for patients and/or users. This updated Field Safety Notice supersedes the letter received previously and includes the following updates:

- Section 1 – The description of Issue 1 is updated to include the possibility of an electrical fire.
- Section 2 – The following hazards/harms are added under Issue 1: burns, asphyxia, delayed diagnosis, need to perform an additional scan, and/or repeat administration of intravenous contrast.
- Section 3 – Added Figure 3 to clearly indicate the label location on the system.
- Section 4 – Updated customer actions to include advice in case of an electrical fire.

1. What the problem is and under what circumstances it can occur

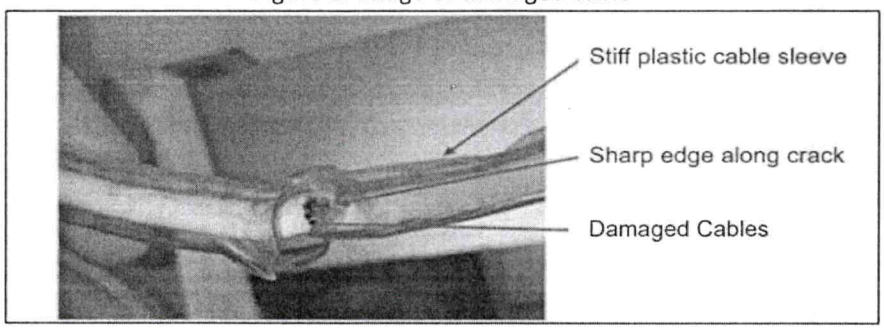
Issue 1: Component damage due to short circuit (CombiDiagnost R90 and ProxiDiagnost N90):
If the CombiDiagnost R90 or ProxiDiagnost N90 system experiences an overvoltage / power surge it can cause a short circuit condition within the Main-cabinet (M-Cabinet). The M-Cabinet is physically separated, but in or near the vicinity of the imaging suite. Philips has identified that the overvoltage impacts the Electromagnetic Interference (EMI) filter board which affects the System Power Distribution Unit (SPDU) contained within the M-Cabinet. If this issue occurs, the user may experience one or more of the following:

- Electrical fire within the M-cabinet
- See or smell smoke emitting from the M-cabinet
- Hear a popping sound coming from the M-cabinet

There have been no adverse events reported to Philips as of February 2023.

Issue 2: Table stop due to a broken tabletop cable (ProxiDiagnost N90 only):
On the ProxiDiagnost N90 table there is a cable located under the tabletop that is covered by a plastic sleeve which can crack and damage the cable (see Figure 1). If the tabletop cable is damaged or breaks, the user may not be able to initiate table tilting movements. However, if the cable breaks, the braking mechanism is released, but the system is counterbalanced in all directions which prevents movement of the table. The table can still be brought back to 0° position using the Tilting Switch and the patient can be safely moved off the table.

Figure 1. Image of damaged cable



There have been no adverse events reported to Philips as of February 2023.

Note: Issue 2 is not correlated with Issue 1.

2. **Hazard/harm associated with the issue**

Issue 1: Component damage due to short circuit (CombiDiagnost R90 and ProxiDiagnost N90):
If fire or smoke is emitted due to components overheating, the risk to patients or operators may include:

- Burns
- Smoke inhalation
- Asphyxia

Additionally, components overheating may impact system functionality resulting in:

- Delayed diagnosis
- The need to perform an additional scan
- Repeat administration of intravenous contrast

This issue could also lead to property damage.

Issue 2: Table stop due to a broken tabletop cable (ProxiDiagnost N90 only):
If this issue occurs, there is a potential for delayed diagnosis or a need to perform an additional scan.

3. **Affected products and how to identify them**

Intended Use:
The CombiDiagnost R90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

The ProxiDiagnost N90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

Identification of Impacted Systems:
The model name, model number (REF), and serial number (SN) of impacted systems are listed in Appendix A. The model name, model number (REF), and serial number (SN) can be found on the system label, as indicated in Figure 2. The location of the label is described in Figure 3.

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Figure 2. Example System Label

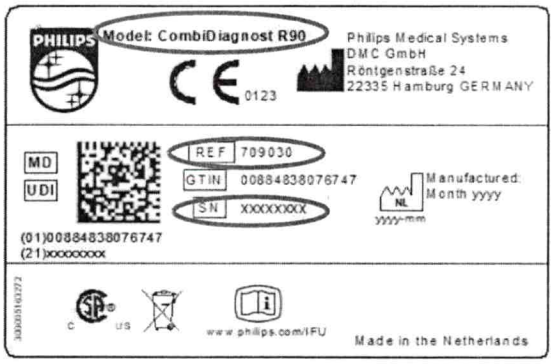
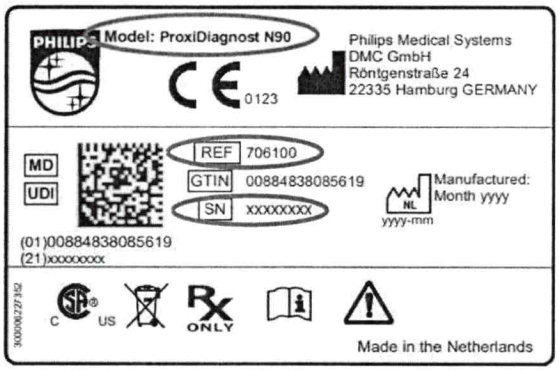
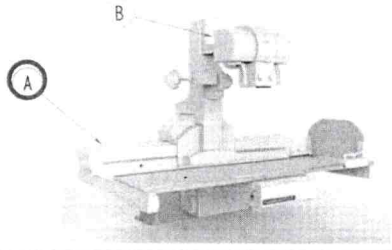
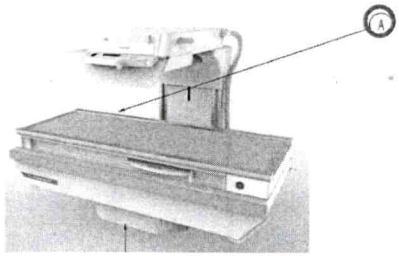
System Label	Model Name	Model Number (REF)
	CombiDiagnost R90	709030 709031
	ProxiDiagnost N90	706100 706110

Figure 3. System Label Location

Label Location	Model Name	Model Number (REF)
	CombiDiagnost R90	709030 709031
	ProxiDiagnost N90	706100 706110

4. **Actions that should be taken by the customer / user in order to prevent risks for patients or users**
   A. Circulate this notice to all users of the device so that they are aware of the issue.

   B. Attach the notice as an addendum to the CombiDiagnost R90 IFU (User Manual) and/or ProxiDiagnost N90 IFU (User Manual) for ease of reference.

   C. **Issue 1 – Component damage due to short circuit:**
   If a user observes fire in the M-cabinet, sees or smells smoke, or hears a popping noise coming from the M-cabinet:
      1. Immediately remove power to the room using the main circuit breaker and remove the patient.
      2. Immediately stop using the system for further examinations.
      3. Follow local fire regulations (e.g. evacuation, inform firefighters)
      4. Immediately contact your local Philips representative and reference FCO70900054 (CombiDiagnost R90), FCO70600105 (ProxiDiagnost N90 1.0), or FCO70600108 (ProxiDiagnost N90 1.1) to arrange for a Philips Field Service Engineer to visit your site.

   Issue 2 – Table stop due to a broken tabletop cable:
   If the table is not tilting or braking as expected:
      1. Bring the table back to 0° position using the Tilting Switch.
      2. Remove the patient off the table.
      3. Immediately stop using the system for further examinations.
      4. Immediately contact your local Philips representative and reference FCO70600105 (ProxiDiagnost N90 1.0) or FCO70600108 (ProxiDiagnost N90 1.1) to arrange for a Philips Field Service Engineer to visit your site to inspect and fix the cable.

   D. Complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Please note, even if you have provided a completed response form for the previous communication, you are still required to complete the response form attached to this notice.

5. **Actions planned by Philips to correct the problem**
   Issue 1 – Component damage due to short circuit (CombiDiagnost R90 and ProxiDiagnost N90):
   A Philips Field Service Engineer (FSE) will visit impacted customer sites to update the system with a hardware component to prevent the issue from occurring.

   Issue 2 – Potential table stop due to a broken tabletop cable (only impacts ProxiDiagnost N90):
   A Philips Field Service Engineer (FSE) will visit impacted customer sites to replace the tabletop cable to prevent the issue from occurring.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Karmen Gruenert
Head of Diagnostic X-Ray (DXR) Quality and Regulatory

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Appendix A – Impacted System Serial Numbers

Model Name: CombiDiagnost R90									
Model Number (REF): 709030									
10000000	10000001	10000002	10000003	10000004	10000006	10000007	10000010	10000011	10000012
10000013	10000014	10000015	10000016	10000019	10000020	10000021	10000022	10000023	10000024
10000025	10000026	10000027	10000029	10000030	10000031	10000032	10000034	10000035	10000036
10000037	10000038	10000040	10000041	10000042	10000043	10000044	10000045	10000046	10000047
10000048	10000049	10000050	10000051	10000052	10000053	10000054	10000055	10000056	10000057
10000058	10000060	10000061	10000063	10000064	10000065	10000066	10000067	10000068	10000069
10000070	10000071	10000072	10000073	10000075	10000076	10000078	10000079	10000080	10000081
10000082	10000083	10000087	10000089	10000090	10000092	10000093	10000094	10000095	10000096
10000097	10000099	10000100	10000102	10000103	10000104	10000107	10000108	10000109	10000111
10000112	10000114	10000115	10000116	10000117	10000118	10000119	10000121	10000122	10000124
10000125	10000126	10000127	10000130	10000131	10000133	10000134	10000135	10000136	10000137
10000138	10000139	10000140	10000144	10000145	10000149	10000151	10000152	10000156	10000165
10000166	10000168	10000169	10000170	10000171	10000174	10000176	10000178	10000179	10000180
10000184	10000185	10000186	10000187	10000188	10000189	10000190	10000191	10000194	10000198
10000199	10000202	10001000	10001001	10001010	10001070	10001071	10001072	10001074	10001076
10001080	10001081	10001082	10001083	10001084	10001085	10001086	10001087	10001088	10001089
10001090	10001091	10001092	10001093	10001094	10001095	10001096	10001097	10001098	10001099
10001100	10001216	10001218	17000018	17000164	18000069	11201-10	24233-03	24592-122	28
7175_04	7896_04	SN16000001	SN16000002	SN16000003	SN16000004	SN16000006	SN16000007	SN16000008	SN16000009
SN17000001	SN17000002	SN17000003	SN17000004	SN17000006	SN17000007	SN17000008	SN17000009	SN17000010	SN17000011
SN17000012	SN17000013	SN17000014	SN17000015	SN17000016	SN17000017	SN17000018	SN17000019	SN17000020	SN17000021
SN17000022	SN17000023	SN17000024	SN17000101	SN17000102	SN17000103	SN17000104	SN17000105	SN17000106	SN17000107
SN17000108	SN17000109	SN17000110	SN17000111	SN17000112	SN17000113	SN17000114	SN17000115	SN17000116	SN17000117
SN17000118	SN17000119	SN17000120	SN17000121	SN17000122	SN17000123	SN17000124	SN17000126	SN17000127	SN17000128
SN17000129	SN17000130	SN17000131	SN17000132	SN17000133	SN17000134	SN17000135	SN17000136	SN17000137	SN17000138
SN17000139	SN17000140	SN17000141	SN17000142	SN17000143	SN17000144	SN17000145	SN17000146	SN17000147	SN17000148
SN17000149	SN17000150	SN17000151	SN17000152	SN17000153	SN17000154	SN17000155	SN17000156	SN17000157	SN17000158
SN17000159	SN17000160	SN17000161	SN17000162	SN17000163	SN17000164	SN17000165	SN17000166	SN17000167	SN17000168
SN17000169	SN17000170	SN17000171	SN17000227	SN18000001	SN18000002	SN18000003	SN18000004	SN18000005	SN18000006
SN18000007	SN18000008	SN18000009	SN18000010	SN18000011	SN18000012	SN18000013	SN18000014	SN18000015	SN18000016
SN18000017	SN18000018	SN18000019	SN18000020	SN18000021	SN18000022	SN18000023	SN18000024	SN18000025	SN18000026
SN18000027	SN18000028	SN18000029	SN18000030	SN18000031	SN18000032	SN18000033	SN18000034	SN18000035	SN18000036
SN18000037	SN18000038	SN18000039	SN18000041	SN18000044	SN18000045	SN18000046	SN18000047	SN18000048	SN18000049
SN18000050	SN18000051	SN18000052	SN18000053	SN18000054	SN18000055	SN18000056	SN18000057	SN18000058	SN18000060
SN18000061	SN18000062	SN18000063	SN18000064	SN18000065	SN18000066	SN18000067	SN18000068	SN18000069	SN18000070
SN18000071	SN18000072	SN18000073	SN18000074	SN18000075	SN18000076	SN18000077	SN18000078	SN18000079	SN19000001
SN19000002	SN19000003	SN19000004	SN19000005	SN19000006	SN19000007	SN19000008	SN19000009	SN19000010	SN19000011
SN19000012	SN19000013	SN19000014	SN19000015	SN19000016	SN19000017	SN19000018	SN19000019	SN19000020	SN19000021
SN19000022	SN19000023	SN19000024	SN19000025	SN19000026	SN19000027	SN19000028	SN19000029	SN19000030	SN19000031
SN19000032	SN19000033	SN19000034	SN19000035	SN19000036	SN19000037	SN19000038	SN19000039	SN19000040	SN19000041
SN19000042									

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Model Name: CombiDiagnost R90									
Model Number: 709031									
10001004	10001005	10001006	10001008	10001009	10001010	10001011	10001012	10001013	10001018
10001020	10001024	10001026	10001027	10001028	10001029	10001030	10001031	10001032	10001035
10001036	10001043	10001044	10001045	10001046	10001047	10001048	10001049	10001050	10001051
10001052	10001053	10001054	10001055	10001056	10001057	10001058	10001059	10001060	10001061
10001062	10001063	10001064	10001065	10001066	10001067	10001068	10001069	10001070	10001071
10001072	10001074	10001075	10001076	10001077	10001078	10001079	10001080	10001081	10001083
10001084	10001085	10001087	10001090	10001091	10001093	10001094	10001095	10001096	10001097
10001098	10001099	10001100	10001101	10001102	10001103	10001104	10001105	10001106	10001107
10001108	10001109	10001110	10001111	10001112	10001113	10001114	10001115	10001116	10001117
10001118	10001119	10001120	10001121	10001122					

Model Name: ProxiDiagnost N90									
Model Number: 706100									
597241	10000000	10000001	10000004	10000005	10000006	10000008	10000009	10000010	10000011
10000012	10000013	10000014	10000015	10000016	10000017	10000018	10000019	10000020	10000021
10000022	10000023	10000024	10000025	10000026	10000027	10000028	10000030	10000031	10000032
10000033	10000034	10000035	10000036	10000037	10000039	10000040	10000041	10000042	10000043
10000044	10000045	10000046	10000047	10000048	10000049	10000050	10000051	10000052	10000053
10000054	10000055	10001013	10001014	10001015	10001017	10001018	10001019	10001020	10001021
10001022	10001023	10001025	10001026	10001028	10001029	10001030	10001033	10001035	10001037
10001039	10001040	10001041	10001042	10001043	10001044	10001048	10001049	10001050	10001051
10001053	10001054	10001059	18000001	20000022	20000026	20000034	20000044	20000045	20000046
20000051	20000052	20000054	20000055	20000061	20000062	20000063	20000064	20000065	20000066
20000067	20000068	20000069	20000070	20000071	20000072	20000073	20000074	20000077	20000078
20000079	20000081	20000082	20000083	20000085	20000086	20000089	721815121706	SN10001000	SN10001001
SN10001002	SN10001003	SN10001004	SN10001005	SN10001006	SN10001007	SN10001008	SN10001009	SN10001010	SN10001011
SN10001012	SN18000001	SN18000002	SN18000003	SN18000004	SN18000005	SN18000006	SN18000007	SN18000008	SN18000009
SN18000011	SN18000012	SN18000013	SN18000014	SN18000015	SN18000016	SN18000017	SN18000018	SN18000019	SN18000020
SN18000021	SN18000022	SN18000023	SN18000024	SN18000152	SN18000249	SN19000001	SN19000002	SN19000003	SN19000004
SN19000005	SN19000006	SN19000007	SN19000008	SN19000009	SN19000010	SN19000011	SN19000012	SN19000013	SN19000014
SN19000015	SN19000016	SN19000017	SN19000018						

Model Name: ProxiDiagnost N90									
Model Number: 706110									
10001045	10001052	10001055	10001057	10001058	10001059	10001060	10001061	10001062	10001063
10001064	10001065	10001066	10001067	10001068	10001069	10001070	10001071	10001072	10001073
10001074	10001075	10001076	10001077	10001078	10001079	10001080	10001082	10001083	10001084
10001085	10001086	10001087	10001088	10001089	10001090	10001091	10001092	10001093	10001094
10001095	10001096	10001098	10001099	10001100	10001101	10001102	10001103	10001104	10001105
10001106	10001107	10001108	10001109	10001110	10001111	10001112	10001113	10001116	10001118

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Field Safety Notice Response Form

Reference: CombiDiagnost R90 and ProxiDiagnost N90 - Potential component damage due to short circuit & Potential table stop due to a broken tabletop cable

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

A. Circulate this notice to all users of the device so that they are aware of the issue.

B. Attach the notice as an addendum to the CombiDiagnost R90 IFU (User Manual) and/or ProxiDiagnost N90 IFU (User Manual) for ease of reference.

C. Until Philips has completed the system corrections, follow the instructions provided in Section 4 of this letter.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this notice has been properly distributed to all users that handle the system.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete and return the attached acknowledgment form to Philips via email to: met.quality@philips.com