

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 48 dated 16/3/2023 Regarding NCMDR
FSN of Digital Diagnost C50 System from (mfr: Philips Healthcare).

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





Circular No. 48 / 2023

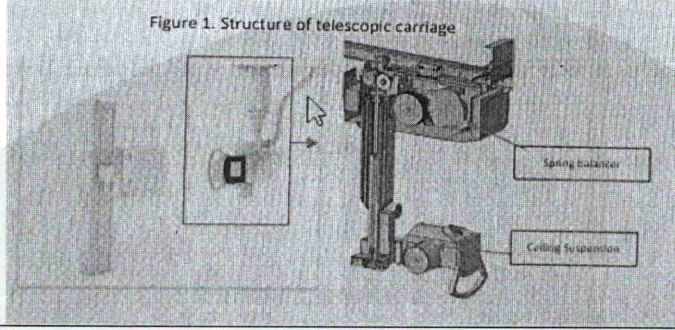
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16-03-2023

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رؤية عمان 2040
Vision Oman 2040

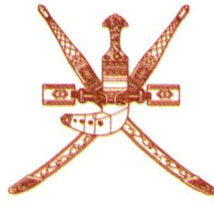
Field Safety Notice of Digital Diagnost C50 System from Philips Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18470
Product	Digital Diagnost C50 System.
Description	X-ray System.
Manufacturer	Philips Healthcare.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	DigitalDiagnost C50 1.1 (REF 712204) DigitalDiagnost C50 1.0 (REF 712201)
Reason	Telescopic Carriage Balance Issue.
Action	1. Follow the Planned Maintenance Program in the Addendum to the Instructions for Use in Appendix A of the attached FSN. 2. If the Ceiling Suspension is not able to be kept in its current position by itself and descends after the power to the system is off, contact your local Philips representative to perform the maintenance of the telescopic carriage. 3. Contact the local agent for remedial action.
Product Image	
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





URGENT Field Safety Notice

DigitalDiagnost C50 System
Telescopic Carriage Balance Issue
2040

27-Feb-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,

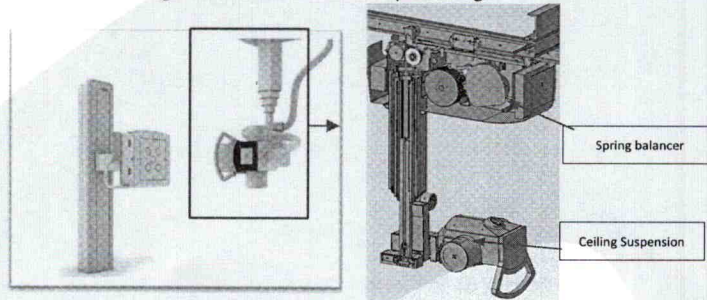
Philips has identified an issue with DigitalDiagnost C50 systems, that could pose a risk for patients and/or users. This *URGENT Field Safety Notice* is intended to inform you about:

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

Philips has identified an issue that may occur with the DigitalDiagnost C50 system if Planned Maintenance (PM) is not completed as prescribed in the Instructions for Use (IFU). If the PM for the telescopic carriage is not performed annually as defined in the Instructions for Use (IFU), the tension force of the spring balancer inside of the telescopic carriage will unavoidably decay through normal wear and tear; as a result there is a potential that the Ceiling Suspension of the DigitalDiagnost C50 system may descend inadvertently if power to the system is interrupted, which may result in injuries to patients and users (Refer to figure 1).

As of Dec-2022, there has been one (1) reported injury related to this issue.

Figure 1. Structure of telescopic carriage





2. Hazard/harm associated with the issue

If the Ceiling Suspension descends inadvertently, the patients or users may be hit by the Ceiling Suspension which may result in injuries to patients and users, such as fracture(s), concussion, hematoma, contusion, bruise, pain, etc.

3. Affected products and how to identify them

Intended Use:

The DigitalDiagnost C50 system is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Identification of Impacted Systems:

#	REF
DigitalDiagnost C50 1.1	712204
DigitalDiagnost C50 1.0	712201

See Appendix B for the list of affected models and serial numbers. To identify if your product is impacted, check the label on the system (See figures 2).

Figure 2: Example DigitalDiagnost model and serial numbers



4. Actions that should be taken by the customer/user in order to prevent risks for patients or users

- Follow the Planned Maintenance Program in the Addendum to the Instructions for Use in Appendix A of this notice for the safe use of your system(s).
- If the Ceiling Suspension is not able to be kept in its current position by itself and descends after the power to the system is off, contact your local Philips representative to perform the maintenance of the telescopic carriage.
- Place this **URGENT Field Safety Notice** with the documentation of your system(s).
- Complete the enclosed Customer Reply Form and send it back to confirm that users have reviewed and understood this **URGENT Field Safety Notice**.



5. Actions planned by Philips to correct the problem

Philips is informing customers through this *URGENT Field Safety Notice* and providing the Addendum to the Instructions for Use of the Digital Diagnost C50 system.

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.
met.quality@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Li Xin
Quality Leader
Philips Precision Diagnostics (PD) China





Appendix A Addendum to the Instructions for Use

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About this Addendum

This addendum is intended to provide additional information to the Instructions for Use and shall be used in conjunction with the Instructions for Use.

This addendum replaces the Planned Maintenance Program section captured in section "Maintenance, Cleaning and Disposal/Maintenance/Planned Maintenance".

Planned Maintenance Program

To ensure that maintenance is performed at the required intervals, the responsible organization (The owner of the equipment) should raise a request to the maintenance organization for maintenance to be carried out in accordance with the planned maintenance program described in this section.

Planned maintenance may only be carried out by qualified and authorized personnel, and is comprehensively described in the service documentation.

Philips Medical Systems provides a full planned maintenance and repair service on both call and contract basis. Full details are available from your local Philips representative.

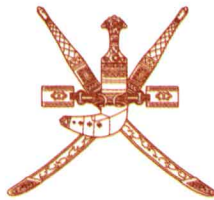
Task	Frequency
Visually inspect the system and all sub-components	Every year
Visually inspect the covers, handles, grips and accessories	Every year
Check all system functional movements	Every year
Check all system interface cable connections and the cable hoses	Every year
Check the emergency switch, X-ray door lamp and door switch	Every year
Visually inspect the labels	Every year
Check HV cables, thermal cable and rotor cable connections	Every year
Check the X-ray Tube assembly	Every year
Check the Rails and Carriages	Every year
Check the Telescopic Carriage	Every year
Check the Ceiling Rails	Every year
Check the Longitudinal Carriage	Every year
Check the Ball Bearings	Every year
Check the Vertical Column and the Tracking unit	Every year
Check the Vertical Switch	Every year





Task	Frequency
Check the Wire Ropes	Every year
Check Supporting Bracket for the X-ray Tube and Control Panel	Every year
Check the Collimator	Every year
Check the Safety Circuit	Every year
Check the Detector battery health	Every year
Check ethernet and backup cable	Every year
Check the Shock Sensor	Every year
Check the Anti-Scatter Grids and Handle	Every year
Check fixations of Wallstand	Every year
Check Tube calibration and function tests of generator	Every year
Ensure that all earthing wires are connected	Every year
Check the SSD ¹ /hard disk	Every year
Perform AWS/RAM cleaning	Every year
Check latest Service Packs are installed	Every year
Check DAP ² (Option)	Every year
Perform functional test for UPS(Option)	Every year
Check Battery status of UPS (Option)	Every year
Perform UPS cleaning (Option)	Every year
Perform Image Quality test	Every year
Check the electrical safety	Every year
Perform Wallstand Functional test	Every alternate years
Check Vertical Chain, guide rails and castors	Every alternate years
Perform Vertical collision Check	Every alternate years
Check Tilting function(Option)	Every alternate years
Check Tilting Safety switches (Option)	Every alternate years
Perform Table(TF/TH) Functional test	Every alternate years
Check Table Brakes	Every alternate years
Check fixations of Table Fixed	Every alternate years
Perform Bucky Brake Functional test	Every alternate years





Task	Frequency
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Check Collimator Component Integrity

- 1) Solid State Drives
- 2) Dose Area Product

Integrity
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Every three years

You should ensure that the planned maintenance program is fully up to date before using the product with a patient.

Philips Medical Systems will make the required information available that assists technical support personnel to repair those parts of the equipment that are designated by Philips Medical Systems as repairable by qualified and authorized technical support personnel.

If you require further information, please contact your local Philips representative.

The following important information is a supplement to Mechanical Safety section captured in Section "Safety and Requirements" of the Instructions for Use.

WARNING



The planned maintenance for the Telescopic Carriage must be performed routinely every year, which is essential to keep sufficient counterbalance of CS (Ceiling Suspension). Insufficient counterbalance of CS could cause unexpected movement of CS, which may expose the patient to the hazardous situation of "Person trapped/squeezed between CS and other equipment", and may result in patient injuries, such as fracture(s), concussion, hematoma, contusion, bruise, pain, etc.





Appendix B – Affected Serial Numbers

Serial Numbers for: DigitalDiagnost C50 1.1 (Model Number: 712204)								
200005	200006	200011	200014	200015	200031	200040	200041	200046
200047	200048	200050	200058	200063	200064	200067	200068	210001
210003	210007	210008	210009	210010	210011	210016	200001	200002
200007	200009	200010	200012	200013	200017	200018	200019	200022
200023	200024	200026	200027	200028	200029	200030	200032	200033
200034	200035	200036	200037	200042	200044	200045	200049	200051
200052	200053	200055	200056	210002	210004	210005	210006	210012
210017	210018	210019	210020	210021	210022	210023	210024	210025
210026	210027	210028	210029	210030	210031	210032	210033	210035
210036	210037	210038	210039	210056	210057	210058	210059	210060
210061	210063	210064	210065	210066	210067	210068	210070	210071
210072	210073	210074	210075	220139	210077	210078	210079	210081
210082	210083	210086	210087	210089	210090	210092	210096	210098
210100	210101	210103	210104	210105	210106	210108	210109	210111
210112	210118	210119	210121	210128	210129	210132	220137	210134
210135	210136	210138	210139	210140	210141	210145	210146	210148
210149	210150	210151	210152	210154	210155	210156	210157	210158
210159	210167	210168	210169	210171	210172	210173	210174	210175
210179	210180	210181	210186	210189	210191	210192	210194	210196
210197	210198	210206	210208	210210	210211	210213	210214	210215
210216	210219	210220	210221	210222	210223	210224	210225	210226
210227	210228	210229	210230	210231	210235	210236	210237	210240
210241	210246	220001	220003	220134	220133	220015	220017	220018
220019	220021	220132	220023	220024	220025	220026	220027	220033
220034	220036	220037	220038	220039	220040	220041	220042	220043
220044	220045	220046	220047	220048	220049	220050	220051	220052
220053	220054	220055	220056	220057	220058	220059	220061	220062
220064	220066	220067	220068	220069	220070	220073	220074	220075
220131	220078	220095	220096	220097	220099	220100	220101	220102
220103	220104	220105	220106	220107	220108	220130	220113	220114
220115	220116	220117	220129	220122	220123	220126	220127	220128





Serial Numbers for: DigitalDiagnost C50 1.0 (Model Number: 712201)								
200005	200006	200011	200014	200015	200031	200039	200040	200041
200046	200047	200048	200050	200058	200063	200064	200067	200068
210001	210003	210007	210008	210009	210010	210011	210016	200004
200043	200054	200059	200060	200061	200062	200065	200069	200070
200073	200074	200075	200077	200078	200079	200080	200081	200082
200083	200085	200087	200089	200090	200091	200092	200093	200095
200096	200098	200099	200100	200101	200102	200103	200104	200105
200106	200107	200108	200109	200110	200112	200113	200114	200115
200116	200117	200118	200119	200120	200121	200122	200123	200124
200125	200130	200133	200134	200135	200138	200141	200144	200146
200147	210013	210014	SN160004	SN160005	SN160006	SN160007	SN160008	SN160009
SN160011	SN160012	SN160013	SN160014	SN160015	SN160016	SN170001	SN170002	SN170003
SN170004	SN170005	SN170007	SN170008	SN170009	SN170010	SN170014	SN170015	SN170016
SN170017	SN170018	SN170019	SN170020	SN170021	SN170022	SN170023	SN170024	SN170025
SN170028	SN200053	SN170030	SN170031	SN170032	SN170033	SN170034	SN170035	SN170036
SN170037	SN170038	SN170039	SN170040	SN170041	SN170042	SN170043	SN170044	SN170045
SN170046	SN170048	SN170049	SN170050	SN170052	SN170054	SN170055	SN170056	SN170057
SN170058	SN170060	SN170061	SN170062	SN170063	SN170066	SN170067	SN170068	SN170069
SN170070	SN170071	SN170072	SN170073	SN170075	SN170076	SN170078	SN170081	SN170082
SN170083	SN170084	SN170085	SN170086	SN170087	SN170088	SN170091	SN170093	SN170097
SN170104	SN170106	SN170109	SN170111	SN170112	SN170114	SN170116	SN170118	SN170128
SN170131	SN170132	SN180006	SN180007	SN180008	SN180009	SN180010	SN180011	SN180012
SN180014	SN180015	SN180016	SN180017	SN180018	SN180019	SN180020	SN180021	SN180022
SN180023	SN180024	SN180025	SN180028	SN180029	SN180030	SN180031	SN180032	SN180033
SN180034	SN180035	SN180036	SN180038	SN180039	SN180040	SN180041	SN180043	SN180044
SN180045	SN180046	SN180047	SN180048	SN180049	SN180050	SN180051	SN180052	SN180053
SN180054	SN180055	SN180056	SN180057	SN180058	SN180059	SN180060	SN180061	SN180062
SN180063	SN180064	SN180065	SN180066	SN180067	SN180068	SN180069	SN180070	SN180071
SN180072	SN180073	SN180075	SN180076	SN180077	SN180078	SN180079	SN180080	SN180081
SN180082	SN180083	SN180085	SN180086	SN180087	SN180088	SN180089	SN180090	SN180091
SN180092	SN180093	SN180094	SN180095	SN180096	SN180097	SN180098	SN180099	SN180100
SN180101	SN180102	SN180103	SN180104	SN180105	SN180106	SN180107	SN180108	SN180112
SN180113	SN180114	SN180115	SN180116	SN180117	SN180118	SN180119	SN180120	SN180121
SN180122	SN180123	SN180124	SN180125	SN180126	SN180130	SN180131	SN180133	SN180134
SN180135	SN180136	SN180137	SN180138	SN180139	SN180140	SN180141	SN180142	SN180144
SN180145	SN180146	SN180147	SN180148	SN180150	SN180151	SN180152	SN180153	SN180154
SN180156	SN180157	SN180158	SN180159	SN180160	SN180161	SN180162	SN180164	SN180165
SN180166	SN180167	SN180168	SN180169	SN180170	SN180171	SN180172	SN180173	SN180174
SN180175	SN180176	SN180177	SN180178	SN180179	SN180180	SN180184	SN180185	SN180186
SN180187	SN180188	SN180189	SN180190	SN180191	SN180195	SN180196	SN180197	SN180198
SN180199	SN180200	SN180201	SN180202	SN180203	SN180204	SN180207	SN180208	SN180210
SN180214	SN190001	SN190002	SN190003	SN190004	SN190005	SN190006	SN190007	SN190008





Serial Numbers for: DigitalDiagnost C50 1.0 (Model Number: 712201)								
SN190009	SN190013	SN190017	SN190019	SN190020	SN190022	SN190023	SN190024	SN190025
SN190026	SN190027	SN190028	SN190029	SN190030	SN190032	SN190033	SN190034	SN190035
SN190036	SN190037	SN190039	SN190040	SN190041	SN190042	SN190043	SN190044	SN190045
SN190046	SN190047	SN190048	SN190049	SN190050	SN190051	SN190052	SN190053	SN190054
SN190055	SN190056	SN190057	SN190058	SN190059	SN190060	SN190061	SN190063	SN190064
SN190066	SN190067	SN190068	SN190070	SN190071	SN190072	SN190073	SN190074	SN190075
SN190076	SN190077	SN190078	SN190079	SN190080	SN190081	SN190082	SN190083	SN190084
SN190085	SN190086	SN190087	SN190088	SN190089	SN190090	SN190093	SN190094	SN190095
SN190096	SN190097	SN190098	SN190099	SN190100	SN190101	SN190102	SN190103	SN190104
SN190105	SN190106	SN190107	SN190108	SN190109	SN190110	SN190111	SN190114	SN190118
SN190121	SN190122	SN190124	SN190125	SN190126	SN190127	SN190128	SN190129	SN190130
SN190131	SN190134	SN190136	SN190137	SN190138	SN190139	SN190140	SN190141	SN190142
SN190143	SN190144	SN190145	SN190146	SN190147	SN190148	SN190149	SN190150	SN190151
SN190154	SN190155	SN190156	SN190157	SN190158	SN190159	SN190160	SN190161	SN190163
SN190164	SN190165	SN190166	SN190167	SN190168	SN190169	SN190170	SN190174	SN190175
SN190176	SN190177	SN190178	SN190179	SN190180	SN190181	SN190183	SN190184	SN190185
SN190186	SN190187	SN190191	SN190193	SN190197	SN190198	SN190199	SN190200	SN190201
SN190202	SN190203	SN190205	SN190206	SN190207	SN190208	SN190209	SN190210	SN190211
SN190212	SN190213	SN190214	SN190216	SN190220	SN200008	SN200009	SN200010	SN200013
SN200016	SN200018	SN200020	SN200022	SN200023	SN200024	SN200025	SN200026	SN200027
SN200028	SN200029	SN200032	SN200034	SN200035	SN200037	SN200038	SN200044	SN200045
SN200049	SN200052	220004	220005	220076	210076			





URGENT Field Safety Notice Response Form

Reference: Telescopic Carriage Balance Issue on Digital Diagnost C50 System (Reference C&R 2022-PD-DXR-106)

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 Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Follow the Planned Maintenance Program in the Addendum to the Instructions for Use in Appendix A of this notice for the safe use of your system(s).
- If the Ceiling Suspension couldn't be kept in its current position by itself and descends after the power to the system is off, contact your local Philips representative to perform the maintenance of the telescopic carriage.
- Place this *URGENT Field Safety Notice* with the documentation of your system(s).
- Complete the enclosed Customer Reply Form and send it back to confirm that users have reviewed and understood this *URGENT Field Safety Notice*.

We acknowledge receipt and understanding of the accompanying *Urgent Field Safety Notice* and confirm that the information from this Letter 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 form to Philips at met.quality@philips.com.

