Field Safety Notice
RadiForce RX360 and GX560 Abnormal image displayed

For Attention of: EIZO Valued Customers,

We regret to inform you that the RadiForce GX560 and RX360 may experience a phenomenon that causes the display of abnormal images.

Please see the attached Field Safety Notice that provides information on how to identify affected devices and instruction on actions to be taken. Please follow the "3.1 Action To Be Taken by the User" section of the notice.

A firmware update is now being prepared to solve this issue. The correction will consist of a software (firmware) upgrade and will be provided free of charge to all devices affected by this issue. Our representative will contact customers with affected devices to arrange for installation of the upgrade.

This issue has been reported to the appropriate regulatory agencies.

If you need any further information or support concerning this issue, please contact your local EIZO representative below.

Contact details of local representative (name, e-mail, telephone, address etc.)*
EIZO Austria GmbH, Pfarrgasse 87, 1230 Vienna, Austria, info.at@eizo.com, +43 1 6152886 10

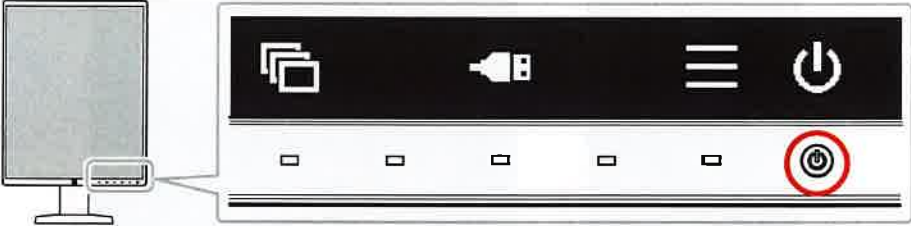We appreciate your understanding regarding this issue.

Sincerely yours,

EIZO Austria GmbH

Field Safety Notice (FSN)
RadiForce GX560 and RX360 Abnormal image displayed

1.	Information on Affected Devices*	
1.	1. Device Type(s)*	
	RadiForce GX560: 5MP 54.1cm (21.3") Monochrome LCD Monitor, Product page: https://www.eizoglobal.com/products/radiforce/gx560/index.html RadiForce RX360: 3MP 54.1cm (21.3") Color LCD Monitor Product page: https://www.eizoglobal.com/products/radiforce/rx360/index.html Front Rear Side 	
1.	2. Commercial name(s)	
	RadiForce GX560#, RadiForce RX360# (# represents any characters or blank)	
1.	3. Unique Device Identifier(s) (UDI-DI)	
	Please refer to the appendix 1.	
1.	4. Primary clinical purpose of device(s)*	

	RadiForce RX360:
	   This Product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography
	
	RadiForce GX560:
	   This product is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.	

1.	5. Device Model/Catalogue/Part number(s)*	
	Please refer to the appendix 1.	
1.	6. Firmware version	
	Please refer to the appendix 1.	
1.	7. Affected serial number range	
	Please refer to the appendix 1 or access our website below. *"RadiForce GX560 and RX360 Abnormal Image Display"* *https://www.eizoglobal.com/support/notice/gx560_rx360/index.html*	
1.	8. Associated devices	
	N/A	

2.	**Reason for Field Safety Corrective Action (FSCA)***	
2.	1.	Description of the product problem*

The following marble pattern fairly infrequently appears when one of the following conditions are met.

- Turning the power off and on by touching power switch in front of the monitor

- Returning from sleep mode of your computer or power save mode of the monitor
- Returning from power save mode by using Backlight Saver function of RadiCS/RadiCS LE

RadiForce GX560

Normal	Abnormal Display

RadiForce RX360

Normal	Abnormal display

2.	2.	Hazard giving rise to the FSCA*
		EIZO concluded there is no risk of misdiagnosis since it is easily recognized by user in case of an abnormal display.
2.	3.	Probability of problem arising
		Fairly infrequently
2.	4.	Predicted risk to patient/users
		It could be a cause of the delay of diagnosis at the very worst.
2.	5.	Further information to help characterise the problem
		N/A
2.	6.	Background on this issue
		Feedback from the market
2.	7.	Other information relevant to FSCA
		N/A

3.	**Type of Action to mitigate the risk***		
3.	**1.**	**Action To Be Taken by the User***	
		If you see abnormal display, please stop using your monitor and eliminate the phenomenon by turning the monitor's main power off and on again. Main Power Switch	
3.	2.	By when the action should be completed?	N/A
3.		Particular considerations for: Choose an item.	N/A
		Is follow-up of patients or review of patients' previous results recommended?	No
3.	3.	Is customer reply required? *	No
3.	4.	**Action Being Taken by the Manufacturer**	
		On-site device modification/inspection and Software upgrade A firmware update is now being prepared to solve this issue. The correction will consist of a software (firmware) upgrade and will be provided free of charge to all devices affected by this issue. An EIZO representative will contact customers with affected devices to arrange for installation of the upgrade.	
3	5.	By when should the action be completed?	31th December, 2020
3.	6.	Is the FSN required to be communicated to the patient /lay user?	Choose an item.No

4.	**General Information***		
4.	1.	FSN Type*	New
4.	2.	For updated FSN, reference number and date of previous FSN	N/A
4.	**3.**	For updated FSN, key new information as follows:	N/A
4.	4.	Further advice or information already expected in follow-up FSN? *	N/A
4.	5.	If follow-up FSN expected, what is the further advice expected to relate to:	N/A
4.	6.	Anticipated timescale for follow-up FSN	N/A
4.	**7.**	Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
		a. Company Name	EIZO Corporation
		b. Address	153 Shimokashiwano, Hakusan, Ishikawa, JAPAN 924-8566
		c. Website address	https://www.eizoglobal.com/
4.	8.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9.	List of attachments/appendices:	N/A
4.	10. Name/Signature		(Print name and title) Alexander Artner General Manager
			(Signature)

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Appendix 1

1. **Details on Affected device** [1]

Commercial name	Device Model	P/N	UDI-DI	F/W Version	S/N
RadiForce GX560-BK	GX560	0FTD2339	04995047053194	1.0000, 1.0001, 1.0002, 1.0003	20001xxx ~22874xxx
RadiForce GX560-ARBK			04995047053231		
RadiForce GX560-BK-MD		0FTD2347	04995047053217		
RadiForce GX560-ARBK-MD			04995047053255		
RadiForce GX560-BK-P		0FTD2379	04995047054108		
RadiForce RX360-BK	RX360	0FTD2346	04995047053279	1.0000, 1.0001	20001xxx ~28451xxx
RadiForce RX360-ARBK			04995047053293		

[1] Monitor with a black dot mark on the nameplate are unaffected by this issue (see below)

Black Dot Mark

2. **How to Find the Model Name, Product Code, UDI-DI, Firmware version and Serial Number (Use either of the following ways)**

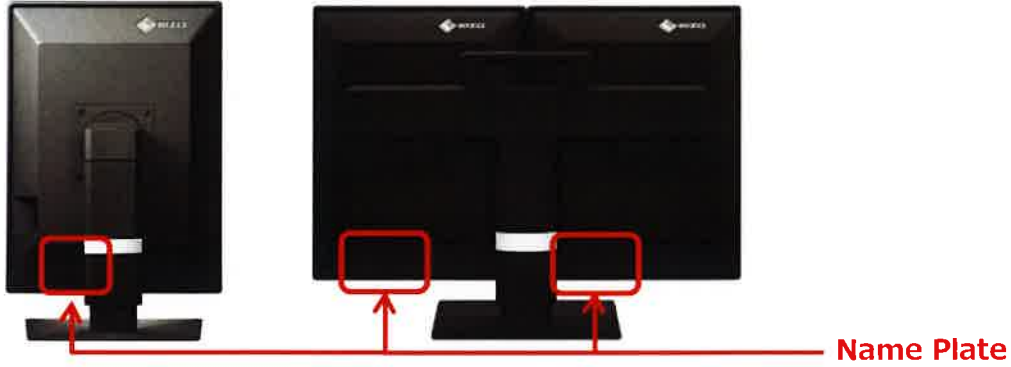A) Referring to the name plate located on the back of the monitor.

RadiForce GX560 Name Plate Sample
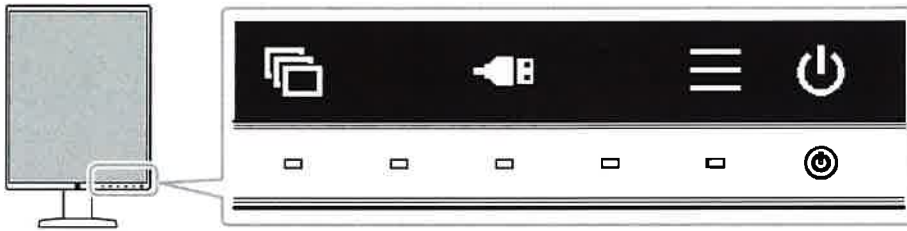

RadiForce RX360 Name Plate Sample

(Location of Name Plate)

Name Plate

B) Referring to the information in the monitor's Setting menu

i. Touch any switch (except ⏻). The Operation guide appears on the screen.

ii. Select ☰ from the Operation guide. The Setting menu appears.

Model Name → ***** S/N: 12345678 ← Serial Number

CAL Switch Mode
RadiCS SelfQC
Preferences
Languages
Information

iii. Select "Information" from the Setting menu, then select ☑.
Model name, serial number and firmware version are displayed.

Information

RadiForce *****   S/N: 00000001 ← Serial Number
Version   1UUUU-1C0000-10000 Firmware Version
         Model Name
Usage Time (h)   Product: 4294967295
                         Backlight: 4294967295

Asset Tag Number   ************
Input Signal   DisplayPort 1
                         1600 X 1200
                         fH: 75.05 kHz
                         fV: 60.09 Hz
                         fD: 162.1 MHz