

RECALL

SERVICE INFORMATION

Classification : Corrective Action with recall

SI. No. : FCO-CT-22-0007Z

Date : *Aug .15 2022*

• FPR Information

FPR from (HCUS) FPR No. : FPR 2022-13744 (V5027), 2022-14429 (V5048), 2022-14244 (V5050)

None

• Risk assessment Information

Risk assessment document No. : P-RC0308 RC0739-2(Rev.552) Item No. : _____

None

PRIORITY : Top Urgent (Recall) () As Soon As Possible ()
 Next Time Visit () When the Symptom Again ()

APPLIES TO :

System : Supria/Supria 64
 Subsystem : System software V3.11
 System software V3.22

SUBJECT :

Fixing the issue that when patient information contains specific words, the error occurs.

PURPOSE :

To apply the countermeasure software for the problem that when patient information contains specific words, the error occurs.

Prepared by :

shuichi Okamoto

Checked by :

J. Kato

Approved by :

T. Hayashi

Checked by :
 (QA Section Manager)

O. Shiono

Checked by :
 (QA Manager)

Y. Arai

Checked by :
 (PM Manager)

y. Ohamoto

Checked by :
 (Division Manager, QA)

Y. Yamazaki

OUTLINE OF THE CORRECTIVE ACTION :

Implement according to the target system.

- Installation of system software V3.11SP V1.04
- Installation of system software V3.22SP V1.00

DETAILS OF THE CORRECTIVE ACTION :

Refer to the attached below according to target system.

- "Installation procedure of Supria System Software V3.11SP V1.04"
- "Installation procedure of Supria System Software V3.22SP V1.00"

SPECIAL TOOLS :

Prepare a backup media (DVD-R).

PARTS TO BE SUPPLIED :

Following install disk according to the target system

- Supria System Software V3.11SP V1.04 (install disc)
- Supria System Software V3.22SP V1.00 (install disc)

CHECK PROCEDURE AFTER THE WORK :

Refer to the attached below according to target system.

- "Installation procedure of Supria System Software V3.11SP V1.04"
- "Installation procedure of Supria System Software V3.22SP V1.00"

CHANGE OF SYSTEM REVISION :

Implement according to the target system.

- System software V3.11 → V3.11SP V1.04
- System software V3.22 → V3.22SP V1.00

STANDARD WORKING TIME :

1.0h/person

ADVISORY NOTICE :

Provide the following document to the customer for explanation.

"URGENT FIELD SAFETY NOTICE - Information about Whole Body X-ray CT Scanner System Supria / Supria 64"

JUSTIFICATION RECORDS OF NEW510(k) OR DOCUMENTATION No. :

N.A.

Installation procedure of Supria System Software V3.11 SP V1.04

1. Outline

This document describes the installation procedure for Supria V3.11 SP V1.04 software.
The applicable system version is below:

System Software Version: V3.11

All changes of V3.11 SP V1.04 will be applied by this work.

1.1. Contents of Installation procedure

No.	Contents
1	Procedure before installing software
2	Installation
3	Procedure after installing software
4	Checking of operation
5	End processing

1.2. Installation software

- Supria System Software V3.11 SP V1.04 Install Disc

2. Detail of the Operation

2.1. Procedure before installing software

2.1.1. Checking the version information

- 1) Display the Version Information.

Confirm that display "System Software Version: V3.11".

*** If "Service pack: V1.04" or later is displayed on the SP area, do not perform this work.**

2.1.2. Maintenance mode ON

- 1) Switch to the Maintenance Mode.

2.1.3. Backup data

- 1) Start Service Backup.
- 2) Save user data, service data and reinstallation data to the media.

2.1.4. System Maintenance mode ON

- 1) Restart to System Maintenance Mode.

2.2. Installation

2.2.1. Software installation

- 1) Double-click the [Install Application] icon on the desktop.
- 2) Insert the SP install disc into the media drive.
- 3) Click the [Yes] button on the dialog.
- 4) Confirmation of the backup is displayed. Confirm that 2.1.3 is performed, enter Y and press ENTER.
- 5) When the dialog for complete the installation is shown, click [OK] button and remove the SP Install disc.

2.3. Procedure after installing software

2.3.1. Restoring data

- 1) Double-click the [Service Backup] icon on the desktop.
- 2) Restore all user data, service data and reinstallation data that were backed up at 2.1.3.
※A shutdown request message may appear after the restore, but there is no need to reboot the system.

2.3.2. Start CT System

- 1) Double-click the [Start CT System] icon on the desktop to shut down the CT System.

Then, turn on the power of the CT System.

2.4. Checking if V3.11 SP V1.04 is applied

2.4.1. Checking the version information

- 1) Display the Version Information.

Confirm that display "System Software Version: V3.11".

Confirm that display "Service Pack: V1.04" on the SP area.

2.4.2. Checking of scanning operation

- 1) Register the patient.
- 2) Scan under any scanning conditions.
At that time, be sure to any scan the phantom.
- 3) Check the images scanned on the Image Viewer.

•Confirm that scanning is completed without error.

•Confirm that performed scanned images are displayed on the Image Viewer.

2.5. End processing

2.5.1. Deletion of checking operation data

- 1) Start Patient List and delete images and RawData created by checking of operation.

2.5.2. Shut down the CT System

- 1) Shut down the CT System.

Installation procedure of Supria System Software V3.22SP V1.00

1. Outline

This document describes the installation procedure for Supria V3.22SP V1.00 software.
The applicable system version is below:

System Software Version: V3.22

All changes of V3.22SP V1.00 will be applied by this work.

1.1. Contents of Installation procedure

No.	Contents
1	Procedure before installing software
2	Installation
3	Procedure after installing software
4	Checking of operation
5	End processing

1.2. Installation software

- Supria System Software V3.22SP V1.00 Install Disc

2. Detail of the Operation

2.1. Procedure before installing software

2.1.1. Checking the version information

- 1) Display the Version Information.

Confirm that display "System Software Version: V3.22".

*** If "Service pack: V1.00" or later is displayed on the SP area, do not perform this work.**

2.1.2. Maintenance mode ON

- 1) Switch to the Maintenance Mode.

2.1.3. Backup data

- 1) Start Service Backup.
- 2) Save user data, service data and reinstallation data to the media.

2.1.4. System Maintenance mode ON

- 1) Restart to System Maintenance Mode.

2.2. Installation

2.2.1. Software installation

- 1) Double-click the [Install Application] icon on the desktop.
- 2) Insert the SP install disc into the media drive.
- 3) Click the [Yes] button on the dialog.
- 4) When the dialog for complete the installation is shown, click [OK] button and remove the SP Install disc.

2.3. Procedure after installing software

2.3.1. Restoring data

- 1) Double-click the [Service Backup] icon on the desktop.
- 2) Restore all user data, service data and reinstallation data that were backed up at 2.1.3.
※A shutdown request message may appear after the restore, but there is no need to reboot the system.

2.3.2. Start CT System

- 1) Double-click the [Start CT System] icon on the desktop to shut down the CT System.
Then, turn on the power of the CT System.

2.4. Checking if V3.22SP V1.00 is applied

2.4.1. Checking the version information

- 1) Display the Version Information.
Confirm that display "System Software Version: V3.22".
Confirm that display "Service Pack: V1.00" on the SP area.

2.4.2. Checking of scanning operation

- 1) Register the patient.
- 2) Scan under any scanning conditions.
At that time, be sure to any scan the phantom.
- 3) Check the images scanned on the Image Viewer.

- Confirm that scanning is completed without error.
- Confirm that performed scanned images are displayed on the Image Viewer.

2.5. End processing

2.5.1. Deletion of checking operation data

- 1) Start Patient List and delete images and RawData created by checking of operation.

2.5.2. Shut down the CT System

- 1) Shut down the CT System.

To Whom It May Concern:

This notice is intended to be sent to the person who is responsible for compliance with applicable medical device regulations in your Business Area. When you receive the SIB (Service Information Bulletin) with Z, please fill in the SIB number, receipt date and your name, etc. on this page and return it to the person shown in the bottom of the page **within 3 business days** by facsimile or e-mail. If you have any questions, please contact 'Contact person' listed at the end of this document.

SIB Number	
Receipt date	
Checked and written by	
Department	
Facsimiles or E-mail	
Company Name	

For the SIB is indicated by "RECALL" and its affix is "Z", FUJIFILM Healthcare Corporation. (herein after called "FHC") considers that the contents indicated by this SIB needs to be reported as RECALL to the competent authority based on Japanese medical device regulations for recall reporting.

In the light of your local medical device regulations for recall reporting(if any) and actual operations, if you agree with our suggestion, please draft a recall report for the corrective action indicated by the SIB and send the draft report to FHC's contact person before you submit the report to the competent authority. **Please reply to FHC within 2 weeks at the latest.** If you have any questions when you draft the recall report, please contact our contact person.

In addition, on the occasion of the sending of the draft report, please send it with the PDF file which can extract the text data or a Microsoft Word file etc. We thereby perform contents confirmation.

After FHC agrees to the draft report, please send the report to the competent authority and also send us the copy of the submitted report. You make a PDF file from the report which the signature that the competent authorities received was filled in with, and, please send it to us. Because a report system is electronic means, when receipt confirmation on the competent authority side is not provided, please send the copy of a report screen or

the E-mail you sent.

If you judge that a reporting to the competent authority is unnecessary, please send us your response with evidence which made such a judgment.

< Point >

***Report case**

- 1. Send the draft report to contact FHC person before you submit it.**
- 2. Send the report to FHC person the copy of submitted report after competent authority accepted it.**

***Unnecessary case**

- 1. Send FHC person your response with evidence which made such a judgment.**

