

SERVICE INFORMATION

SI. No. : FCO-CT-22-0010

Classification : Corrective Action without recall

Date : *Sep. 12. 2022*

• FPR Information

FPR from () FPR No. : _____
 None

• Risk assessment Information

Risk assessment document No. : RC0739-2(Rev.558), P-RC0307, CT-RC0489 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 V3.22

SUBJECT :

Up to system software V3.22 SP V1.01

PURPOSE :

For reliability improvement at the time of the use of System.

Prepared by :

Shuichi Okamoto

Checked by :

Akira Sasaki

Approved by :

Tetsuya Hayashi

Checked by :
 (QA Section Manager)

O. Shiono

Checked by :
 (QA Manager)

G. Crown

Checked by :
 (PM Manager)

N.A.

Checked by :
 (Division Manager, QA)

N.A.

OUTLINE OF THE CORRECTIVE ACTION :

Installation of system software V3.22SP V1.01

DETAILS OF THE CORRECTIVE ACTION :

Refer to the attached "Installation procedure of Supria System Software V3.22SP V1.01"

SPECIAL TOOLS :

Prepare a backup new media (DVD-R).

PARTS TO BE SUPPLIED :

Supria System Software V3.22SP V1.01 (install disc)

CHECK PROCEDURE AFTER THE WORK :

Refer to the attached "Installation procedure of Supria System Software V3.22SP V1.01"

CHANGE OF SYSTEM REVISION :

System software V3.22 → V3.22SP V1.01

STANDARD WORKING TIME :

1.0h/person

ADVISORY NOTICE :

Provide the following document to the customer for explanation.

"FIELD 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 V3.22SP V1.01

1. Outline

This document describes the installation procedure for Supria V3.22SP V1.01 software. The applicable system version is below:

System Software Version: V3.22

All changes of V3.22SP V1.01 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 V1.01 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: V1.01" 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 new media.

2.1.4. System Maintenance mode ON

- 1) Restart to System Maintenance Mode.

2.1.5. Confirming that the backup media has been successfully created

- 1) Create a folder named "temp" on the desktop.
- 2) Double-click the temp folder to open an Explorer window and open the media drive.
- 3) Select all files and folders in the media drive and copy them to the temp folder on the desktop.
- 4) Delete the temp folder.

* If the file copy performed in step 3) completes without problems, the backup media has been successfully created. If file copying stops in the middle and does not complete successfully, the backup media has failed to be created. Since a failure of the device's media drive or poor media quality is suspected, please perform steps 2.1.3 and 2.1.5 again with new media.

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.
※When restoring data, a shutdown request message will be displayed but you don't have to restart.

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 V1.01 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: V1.01" 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.