

SwiftMR™

User Manual





Product Model

A20-CL

AIRS
MEDICAL

SwiftMR
User Manual, English
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AIRS Medical Inc. is a company devoted to developing products that exceed customer expectations as well as meet the relevant standards and legal requirements by aiming for world-class excellence in all tasks we perform.

This user manual provides instructions for using SwiftMR, including warnings and cautions to prevent hazardous situations. Please read this User Manual thoroughly before use.

Homepage

For more information about AIRS Medical and our products, please visit us at www.airsmc.com.

General Information

- 『SwiftMR』 is a registered trademark of AIRS Medical Inc.
- The content of this User Manual is protected by copyright. If the content of this User Manual is modified or distributed without the written consent of AIRS Medical Inc., you will be liable for legal responsibilities.
- AIRS Medical Inc. may change or modify the specifications of the product and the contents of the manual without prior notice.

Certified Use

Usage of SwiftMR is subject to local law and conditions of the regulations.

- USA/HSS (FDA): SwiftMR is an FDA 510(k) cleared medical device, Kxxxxxx (*To be updated upon clearance*). Rx only.

1. Introduction

1.1. Product Overview

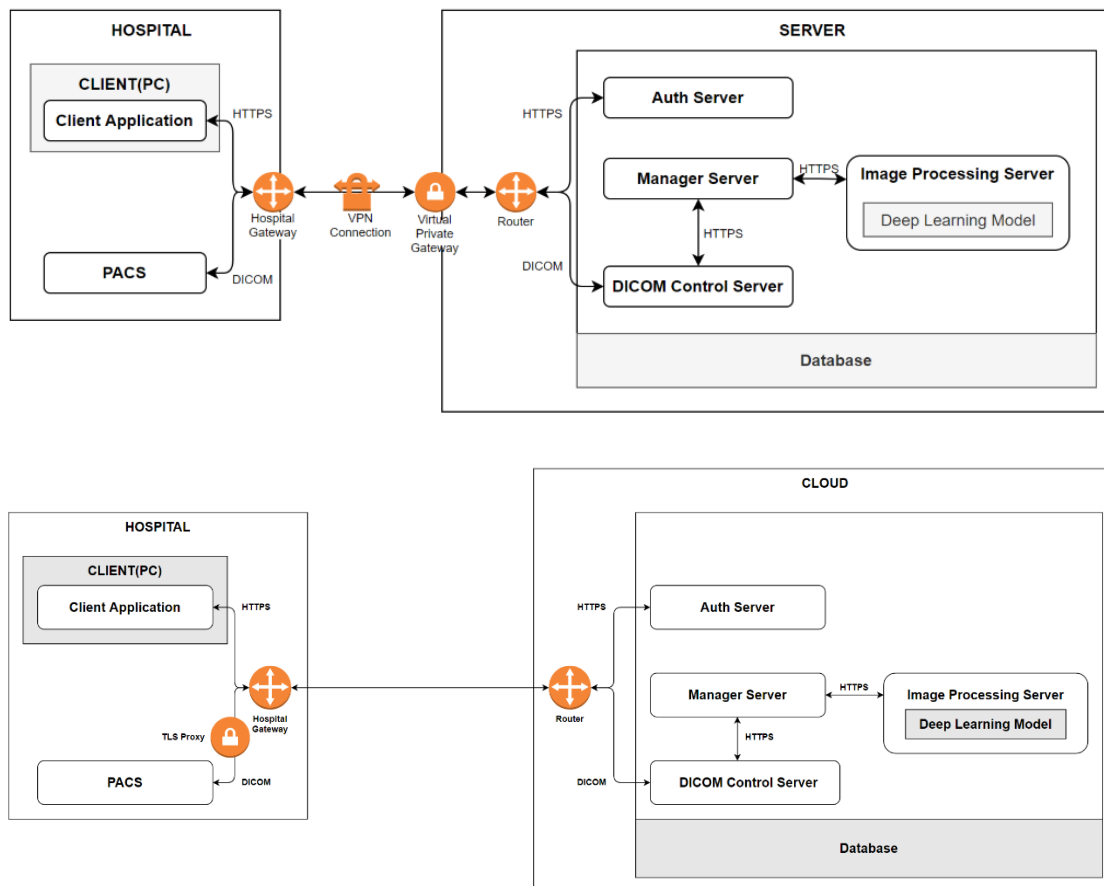
SwiftMR provides automated image quality enhancement for MR images acquired from various environments. This device is indicated for use only by trained radiology technologists.

SwiftMR automates below procedures:

- Upload MR images in DICOM format from PACS to the cloud server
- Enhance image quality using Deep Learning model on the cloud server
- Download enhanced MR images in DICOM format from the cloud server to PACS.

Integration of the institution's PACS with the manufacturer's cloud server is necessary at first to start using SwiftMR. After the integration, SwiftMR performs image processing in the background automatically and provides logged in users the authorization to use the functions or modify settings through Client Application. System admins can control the automated process and modify settings as required, while basic users can view image processing results in a worklist format.

The diagrams below depicts the two possible holistic system-level views of SwiftMR. Major modules, communication pathways, and protocols are shown.



1.2. Intended Use

SwiftMR is a stand-alone software solution intended to be used for acceptance, enhancement and transfer of brain MRI images in DICOM format. It can be used for noise reduction of MRI images and increasing image sharpness for non-contrast enhanced MRI images.

This device is indicated for use only by trained radiology technologists.

SwiftMR is not intended for use on mobile devices.

1.3. Limitations

SwiftMR is only available in certain countries.

This product meets the FDA requirements for medical device software.

1.4. Functionalities

- Worklist view
 - Search by Scan date
 - Search by Patient name and/or Patient ID
 - Search by Modality
 - Search by Body part
 - Search by Status of image processing
- Image processing
 - Import acquired MR images from PACS
 - Enhance image quality
 - Download to PACS the enhanced MR images








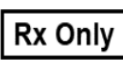
1.5. Minimum System Requirements for the Software

Minimum Specification	Client
OS	Microsoft Window 10 64 bit
Hardware	CPU: Intel i5 RAM: 4GB and above Storage: 2GB available Memory: 500MB available
Network	Intranet/internet network based on Ethernet
Monitor	1600X900 resolution with 16-bit color

1.6. Symbols Glossary

Symbols used in this user manual is as follows. Please familiarize yourself with the symbols in the table below.

Warnings, cautions and notes are for the correct and safe usage of the product. Please be advised of all the following for safety. AIRS Medical Inc. is not responsible for failures due to negligence of safety warnings and cautions.

Symbols	Meaning
Note	Indicates useful information about features of the software.
Caution 	Indicates potentially hazardous situations for the patient or user that could result in lost time, reduced image quality and/or re-examination of the patient.
Warning 	Indicates potentially hazardous situations that could result in direct or indirect patient injury, mainly in the form of misinterpretation or misdiagnosis.
	Manufacturer. The symbol is accompanied by the name and address of the manufacturer.
	e-IFU (electronic-Instructions for Use) The link that directs users to this user manual is alongside the symbol.
	Catalog number
	Lot number. Version number of the software.
	Unique Device Identifier
	Indicates that SwiftMR is a prescription device

1.7. Precautions



- **Warning**
 - SwiftMR is designed for trained radiology technologists.
 - Images that have already been quality-enhanced should not be processed again. This may cause damage to the image.



- **General Caution**
 - Installation, maintenance, and repair of SwiftMR must only be done by engineers qualified and certified by AIRS Medical Inc.
 - Operation and maintenance of SwiftMR strictly follow the user manual. Please keep this user manual.
 - System admin of SwiftMR must receive appropriate training from AIRS Medical Inc. The system admin must confirm that the user is fully familiar with the user manual and grant access rights.



- **Caution for Use**
 - Before use, check to see if Daily QC that the system conducts automatically or manually at a specified time and day of the week is completed successfully.
 - Do not turn off the power of the PC or programs during use.
 - After use, be sure to log out of the program.

1.8. Abbreviations

The following abbreviations are used in this User Manual.

DICOM	Digital Imaging and Communications in Medicine
MRI	Magnetic Resonance Imaging
PACS	Picture Archiving and Communication System

2. How to Install or Uninstall

2.1. How to Install SwiftMR Client App

Installation file for SwiftMR can be downloaded from a private link provided by the manufacturer. Once the installation file is downloaded, follow below installation process.

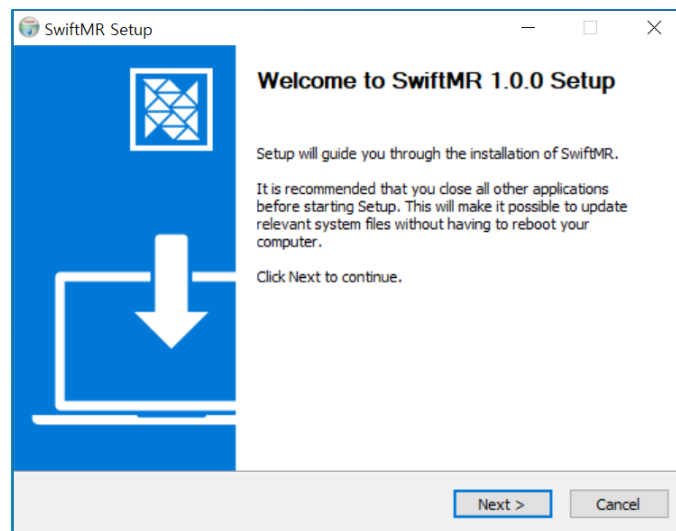


Caution: Prior to installing SwiftMR, use a reliable anti-virus program and spyware prevention program to inspect your PC.

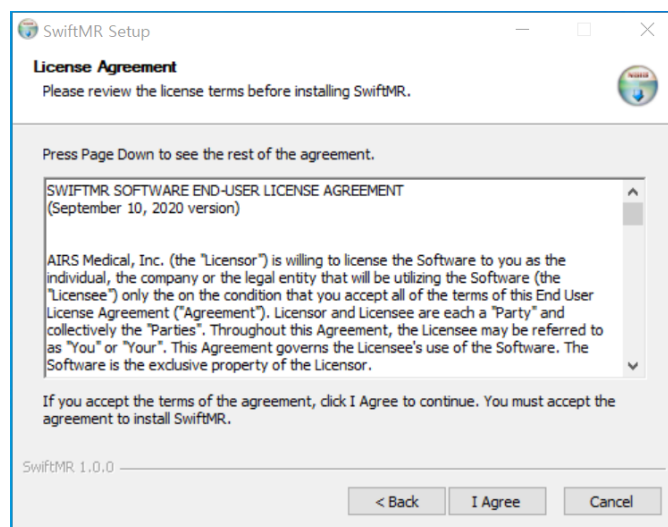


Caution: Prior to installing SwiftMR, check outgoing destination port 443 is allowed in your PC.

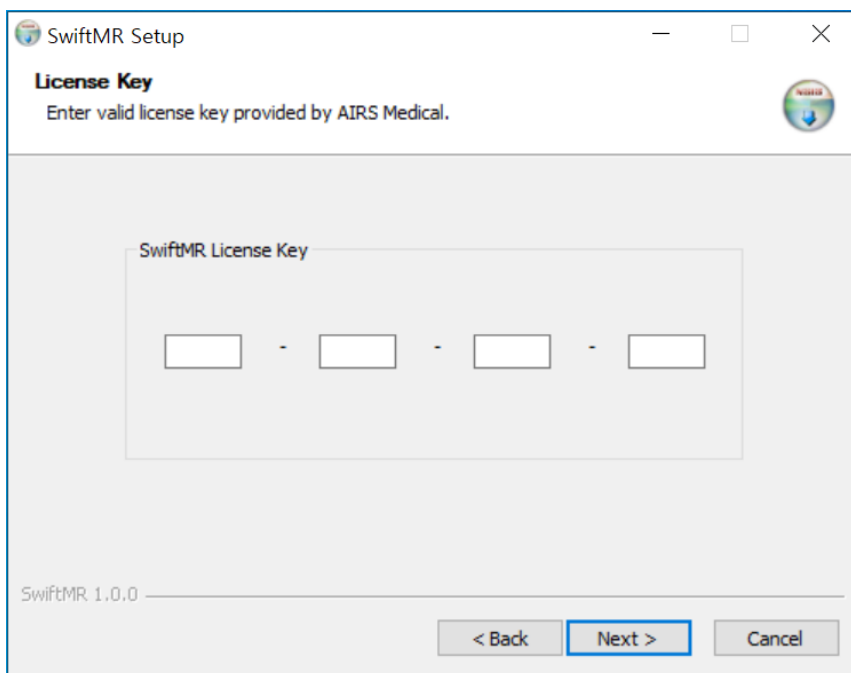
- (1) Double click and run “SwiftMR Setup (ver x.x.x).exe”. The latest version will be provided by the manufacturer. When the install wizard appears, click **Next**.



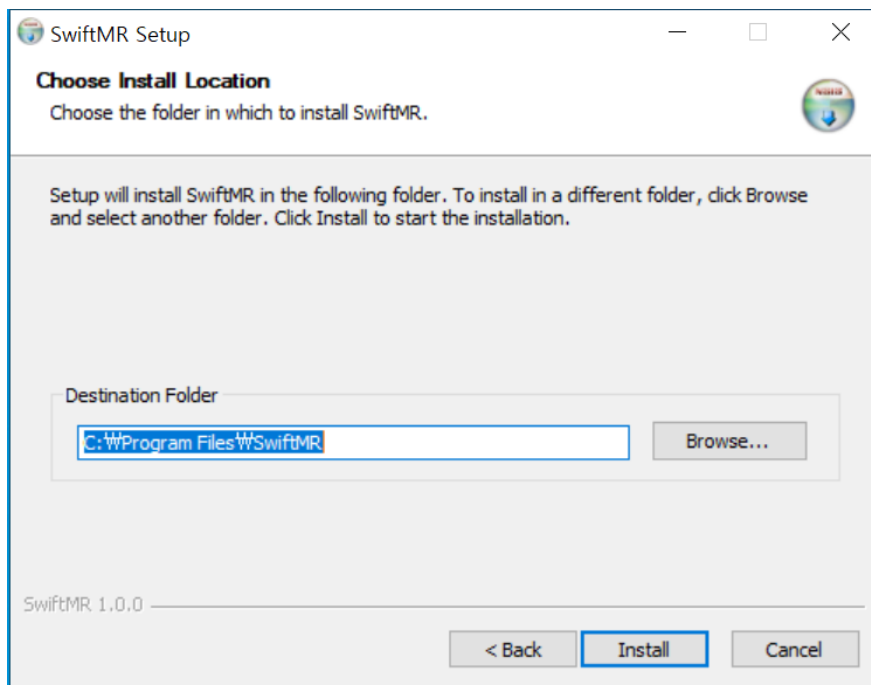
- (2) Check “I accept the terms of the License Agreement” and click **Next**.



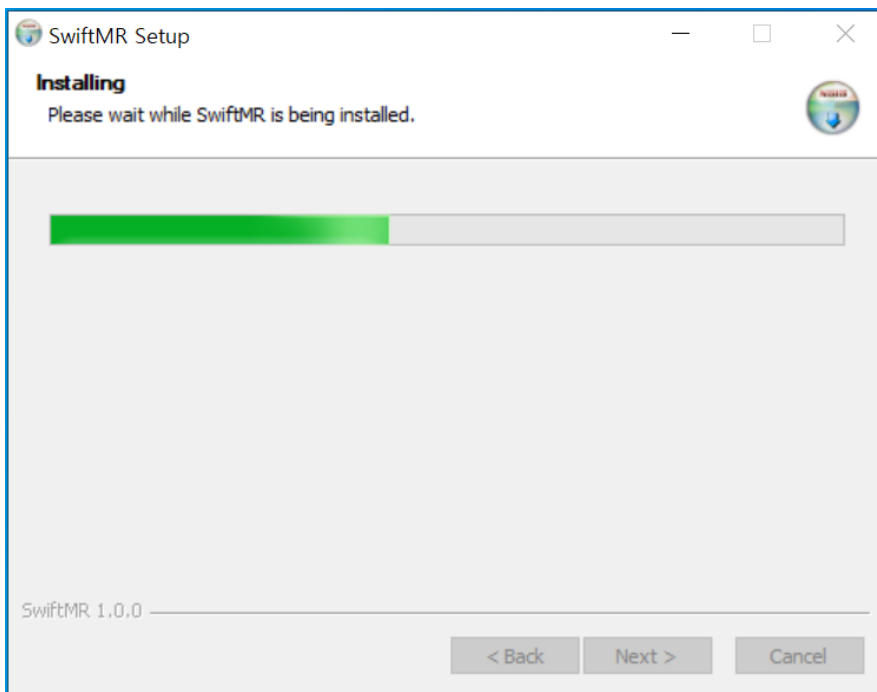
- (3) Enter the license key provided by the manufacturer and click **Next**. If the license key is invalid, installation will not proceed.



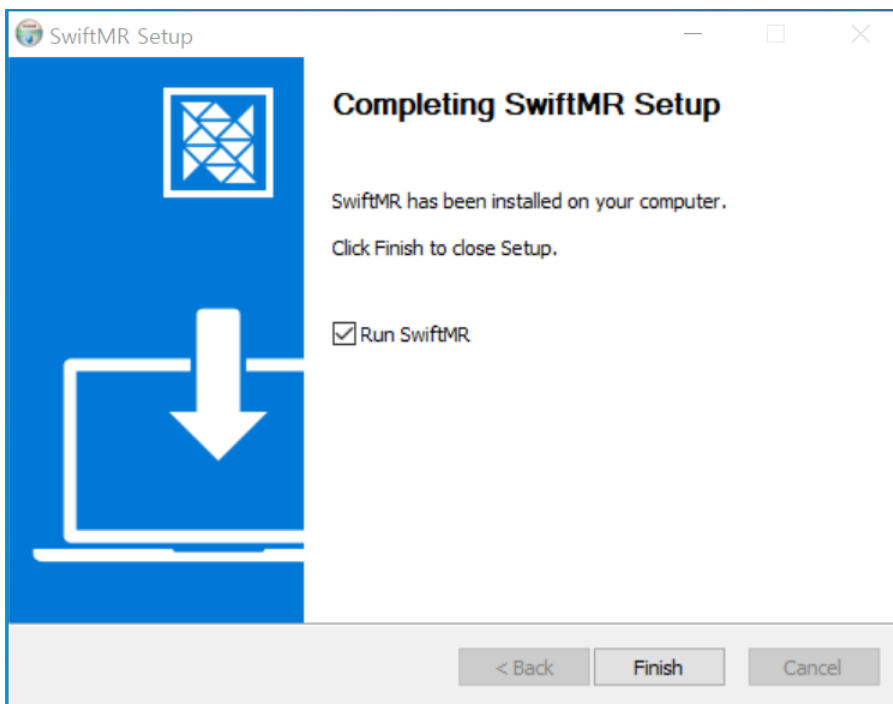
- (4) Select the destination folder to install SwiftMR and click **Install**.



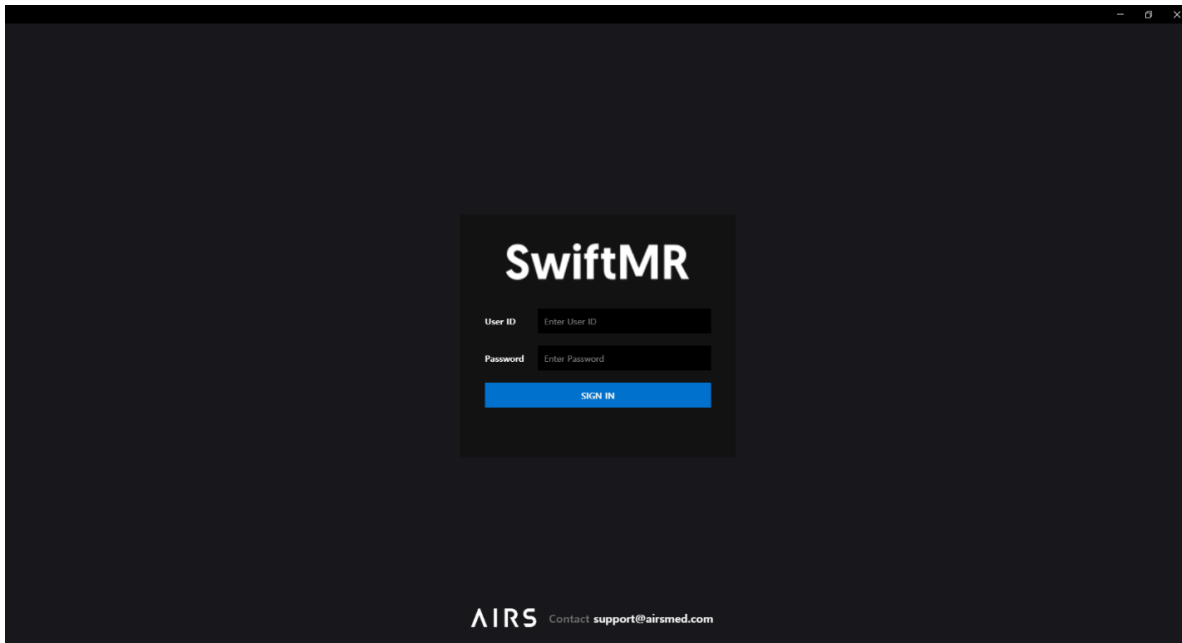
(5) Installation process runs. Once the installation is complete, click **Next**.



(6) Click **Finish** to exit the installation process.



- (7) After installation, double-click on the SwiftMR shortcut icon in Desktop to run the software. If the installation is completed successfully, the following login screen should appear.



2.2. How to uninstall SwiftMR Client App

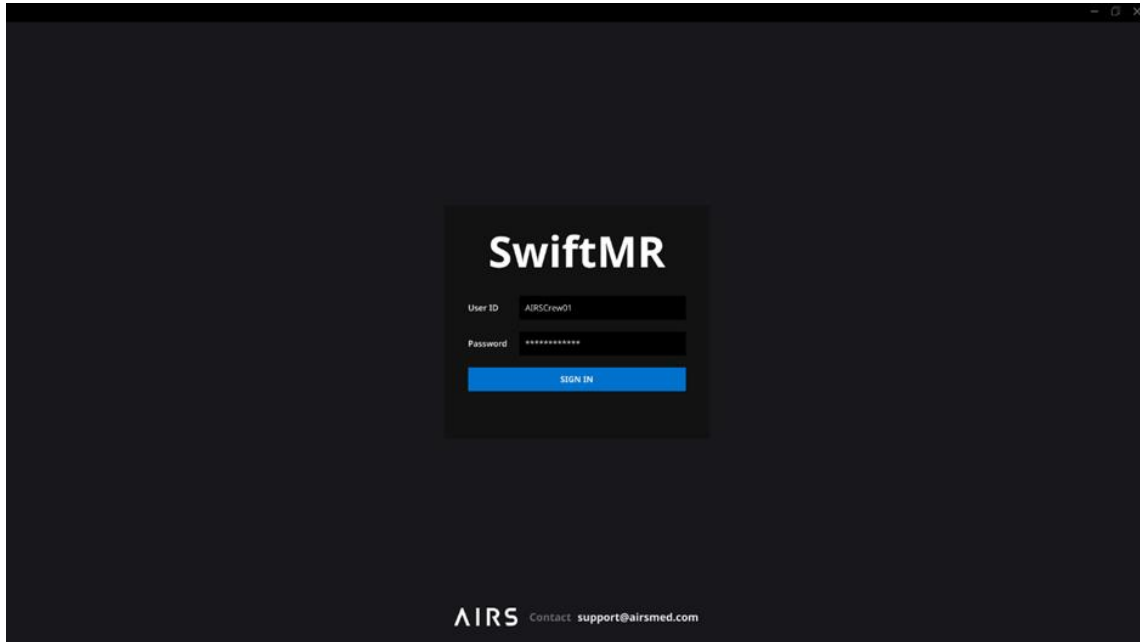
Choose one of the following methods to uninstall the program.


- (1) Go to **Control Panel** → **Apps** and delete SwiftMR.
- (2) Go to **Start** → **Shortcut to SwiftMR** and run “Uninstall”.
- (3) Open SwiftMR installation folder, double click and run “Uninstall SwiftMR.exe” file.

3. Functions

3.1. Login and Logout

To use main functions of SwiftMR, you need to login.



- **Login:** Enter ID and password provided by system admin and then click **SIGN IN**. When login succeeds, main page will appear.
- **Logout:** You can log out from SwiftMR to prevent unauthorized access by clicking **Logout** ( Logout). When logout succeeds, login page will appear again.

Note **Note:** User account is created by System admin. Upon first login, the user is required to reset the password to prevent unauthorized access.



Caution: When invalid ID or password is entered into the input field, login will fail and an error message will show up. If you forget your ID or password, contact the System admin or the IT manager.



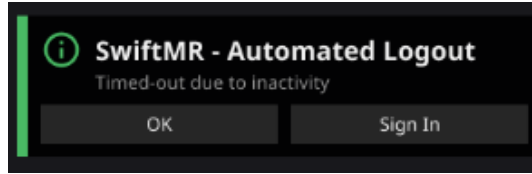
Caution: SwiftMR does not allow simultaneous logins of the same account. Users cannot access the software under the same account at the same time. If you try to login to an already logged-in account, the previous access will be terminated.



Caution: When the login attempt fails 10 times, you are not allowed to login for the next 5 minutes.

3.2. Automated Logout

Users inactive for a certain period will be automatically logged out from SwiftMR to prevent unauthorized access. Users can set the time for automated logout. In the event of an automated logout, a toast alarm will pop up and the main page will default back to the login page.



The toast alarm for automated logout disappears when clicking **OK** or after a certain period. Clicking **SIGN IN** will direct you to the login page.

3.3. Main Page

Main page of SwiftMR is constructed as follows:

- SwiftMR loads the list of acquired MR images from the connected PACS and display it in a worklist format.
- Users can view and easily search detailed information, processing status, and processing results of the listed MR images from the worklist that is updated periodically.
- Users can check image processing results of each MR image in Detailed Info section.

Study Table

Study Date	Patient ID	Patient Name	Sex	Age	Date of Birth	Requested Procedure	Study Description	Number of Series	Number of Instances	Accession Number	Status
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	ERROR
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Not Supported
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Paused
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed
2020-11-26 17:37:21	12341234	KIM HYEON JEONG	F	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed

Series Table

Series Number	Series Date	Series Description	Protocol Name	Number of Images	Status
1	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed
2	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed
3	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed
4	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed
5	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed
6	2020-11-26 17:37:21	AX_T2_Flair	AX_T2_Flair	24	Not Supported
7	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed
8	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed
9	2020-11-26 17:37:21	AX_T2_Flair_Swift	AX_T2_Flair_Swift	24	Completed







Detailed Info

Enhancement Result
 Status : Process paused
 Processing start time : 2020-12-31 15:00
 Processing end time :

Notification

- Daily QC Success 2020-11-06 06:30
- Completed - Patient ID 1234123412341 (243/243) 2020-11-06 06:30
- Error - Patient ID 1234123412341 2020-11-06 06:30
- Process Paused 2020-11-06 06:30
- Process Resumed 2020-11-06 06:30
- Completed - Patient ID 1234123412341 (243/243) 2020-11-06 06:30
- Completed - Patient ID 1234123412341 (243/243) 2020-11-06 06:30
- Completed - Patient ID 1234123412341 (243/243) 2020-11-06 06:30

Detailed functions on the main page are as follows.


No	Function	Item	Description
1	Status Bar		Network connectivity (Blue: Connected, Red: Disconnected)
		ABC Gwanak	Institution name
		AIRSAdmin01	Logged in User name
		MR 1	MRI devices selected by user
2	User Menu	 Profile	User Profile
		 Settings	Software settings
		 S/W Info	Software information (license, version), User manual download
		 Logout	Logout
3	Filter/Search	Date Range	Selects the study date range for MR Study to be displayed
		Patient ID	Text input field to search by patient ID
		Patient Name	Text input field to search by patient name
		Modality	Dropdown multi-select list for modality selection
		Body Part	Dropdown multi-select list for body part selection
		Status	Dropdown multi-select list for status selection <ul style="list-style-type: none"> • All • Completed • Error • In Progress • Not Supported
			Button to execute search by the selected conditions
4	MR Study Table	Study Date	Study scan date (YYYY-MM-DD hh:mm:ss)
		Patient ID	Patient ID
		Patient Name	Patient name
		Sex	Patient sex
		Age	Patient age
		Date of Birth	Patient date of birth (YYYY-MM-DD)
		Requested Procedure	Requested procedure
		Study Description	Name of study protocol
		Number of Series	Total number of series in a study
		Number of Total Images	Total number of images in a study
		Accession number	Unique identification number of each image
		Status	Image processing progress on MR study level <ul style="list-style-type: none"> • In Progress • Completed • Not Supported

			<ul style="list-style-type: none"> Error
5	MR Series Table	Series number	Order number of each series in a selected study
		Series Date	Scan date of each series (YYYY-MM-DD hh:mm:ss)
		Series Description	Series description of scanned sequence
		Protocol Name	Protocol name of scanned sequence
		Number of Images	Total number of images in a series
		Status	Image processing progress on MR series level <ul style="list-style-type: none"> In Progress Completed Not Supported Error
6	Detailed Info	SwiftMR Process ID	Unique task ID given by SwiftMR
		Enhancement Result	Enhancement result on MR series level <ul style="list-style-type: none"> Status: Completed, Not supported, Error Processing start time Processing end time
7	Notification	Notification	Notifications on image processing result (success/failure), image processing status (pause/resume), daily QC result (success/failure), etc.



Caution: The network connection status icon shows the connection between the institution's network (PACS) and the cloud server of SwiftMR. This icon is irrelevant to the local PC's internet connection, meaning that when the local PC with Client Application is disconnected from internet, this icon will not change but the software will force an automated logout.



Warning: When network connection status icon is marked as , it may cause problems regarding image processing. Contact IT manager or manufacturer as soon as possible.



Caution: Worklist displays only the acquired MR images from the selected MR devices. Therefore, when you cannot find the desired study in the worklist, check the registered MR device information.



Caution: SwiftMR supports worklist synchronization with PACS for studies within 7 days from the current date. Once a study becomes older than 7 days, it will be deleted from SwiftMR and its worklist, but will not impact the storage status in PACS.

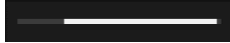
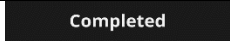


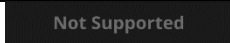


Caution: All personal information saved in SwiftMR will be anonymized 24 hours after registration. If you want to inquire patients' information about the MR studies processed by SwiftMR, please use the PACS viewer.

3.4. Status








- Status of image processing for a study is classified as follows.

Icon	Description
------	-------------

	In progress Image processing progress is indicated with a progress bar.
	Completed Image processing of all supported series in the study is successfully completed
	Error An error occurred while processing images in the study.
	Paused System admin has paused all the image processing for the institution.
	Not supported There is no SwiftMR supported MR series in the study.

3.5. Alarm

Users are notified of significant processing results with a toast alarm and through the Notification section. Toast alarms for each situation are as follows:

Toast Alarm	Description
 SwiftMR - Completed (243/243) 2020-11-06 13:33 MRA-BRAIN CHOI MIN SEOK OK Detailed Info	Image processing complete.
 SwiftMR - Process Error 2020-11-06 13:33 MRA-BRAIN CHOI MIN SEOK Error Detail Code : NE4944 Message : Networt Error Ignore Detailed Info Retry	Image processing failed.
 SwiftMR - QC Success 2020-11-20 06:30 Daily QC Success OK	Daily QC succeeded.
 SwiftMR - QC Error 2020-11-20 06:30 Detailed Message Code : QE2844 Message : Networt Error OK	Daily QC failed.
 SwiftMR - Process Resume Message OK	Image processing resumed.
 SwiftMR - Process Pause 2020-11-06 14:00 Detailed Message Code : PE1244 Message : Networt Error OK	Image processing paused.
 SwiftMR - Automated Logout Timed-out due to inactivity OK Sign In	Automated logout.



Caution: When image processing fails, you can retry the processing by clicking **Retry** directly from the toast alarm. If you accidentally close the toast alarm, you can take alternative actions from the Detailed Info section on the worklist.

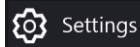


Caution: Toast alarm for image processing and image processing history in Notification section is only shown for the connected MR device. Therefore, if alarm for a desired study does not show up, check the device setting in Settings → Device.



Caution: When QC process fails, you can retry the process manually by clicking the button in Settings→QC. If the error repeats, please contact the manufacturer.

3.6. User Settings



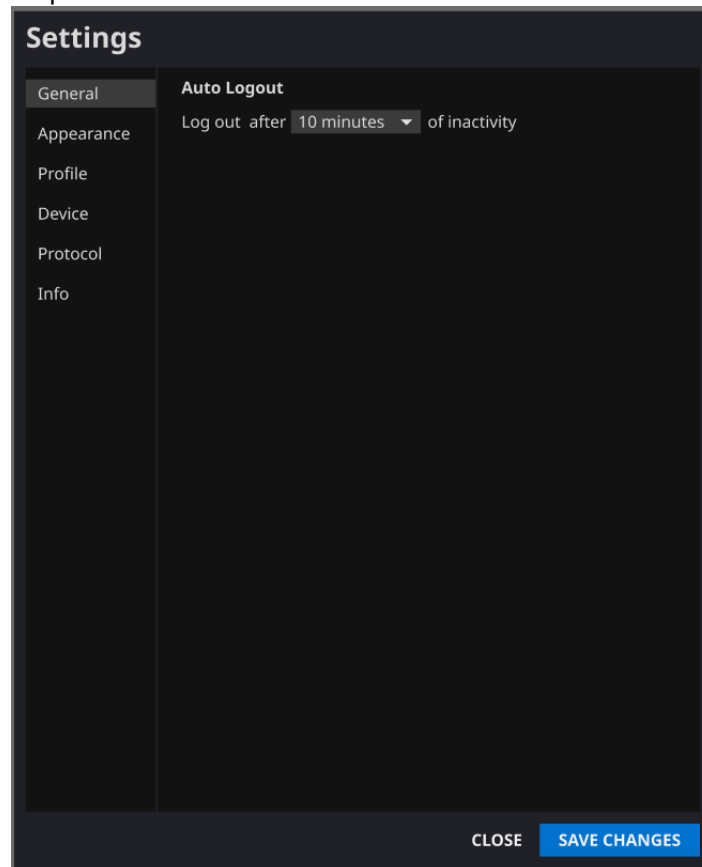
Users can set up the software configuration by clicking **Settings** button. When you login as user mode, software settings window consists of General, Appearance, Profile, Device, Protocol, and Info tabs.



Caution: User configurations are saved locally in the application's app data directory in an AES-256 encrypted format. Using this configuration file, SwiftMR makes a backup and restores the configurations when needed.

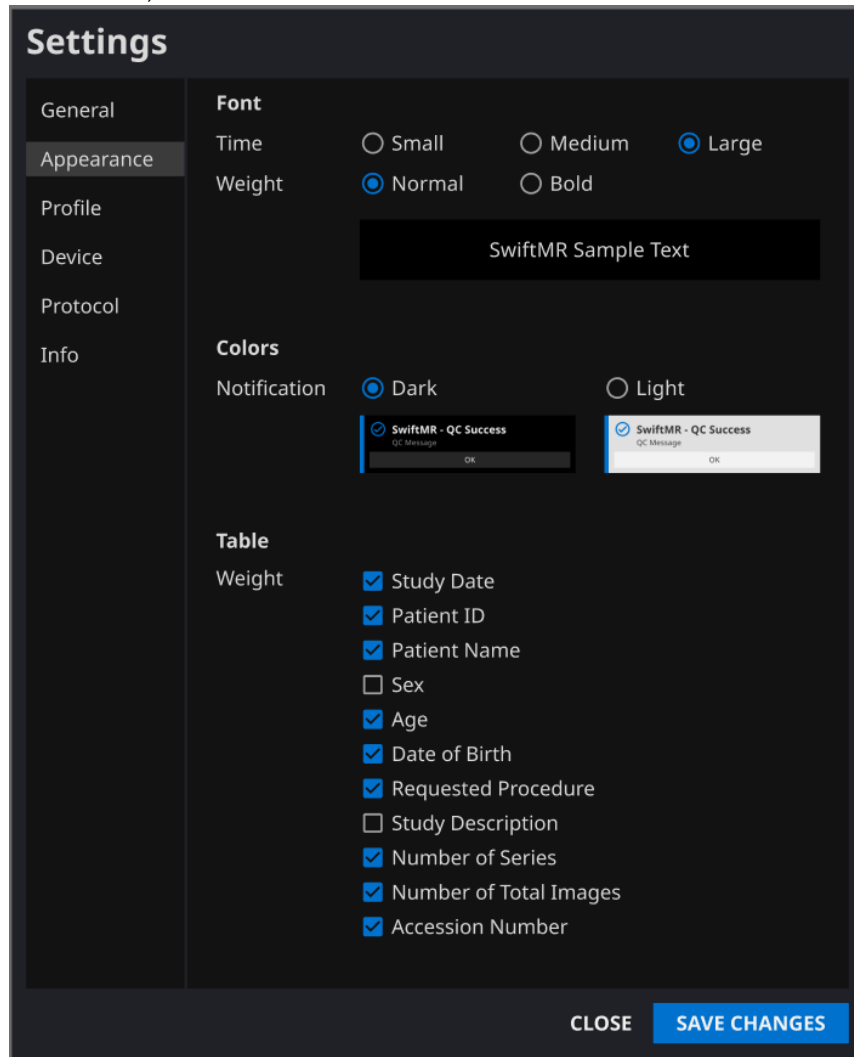
3.6.1. General Settings

- **Auto logout time setting:** The inactive period after which automated logout will occur can be set from General tab of Settings. Choose the desired time from the drop-down menu and click **SAVE CHANGES**.



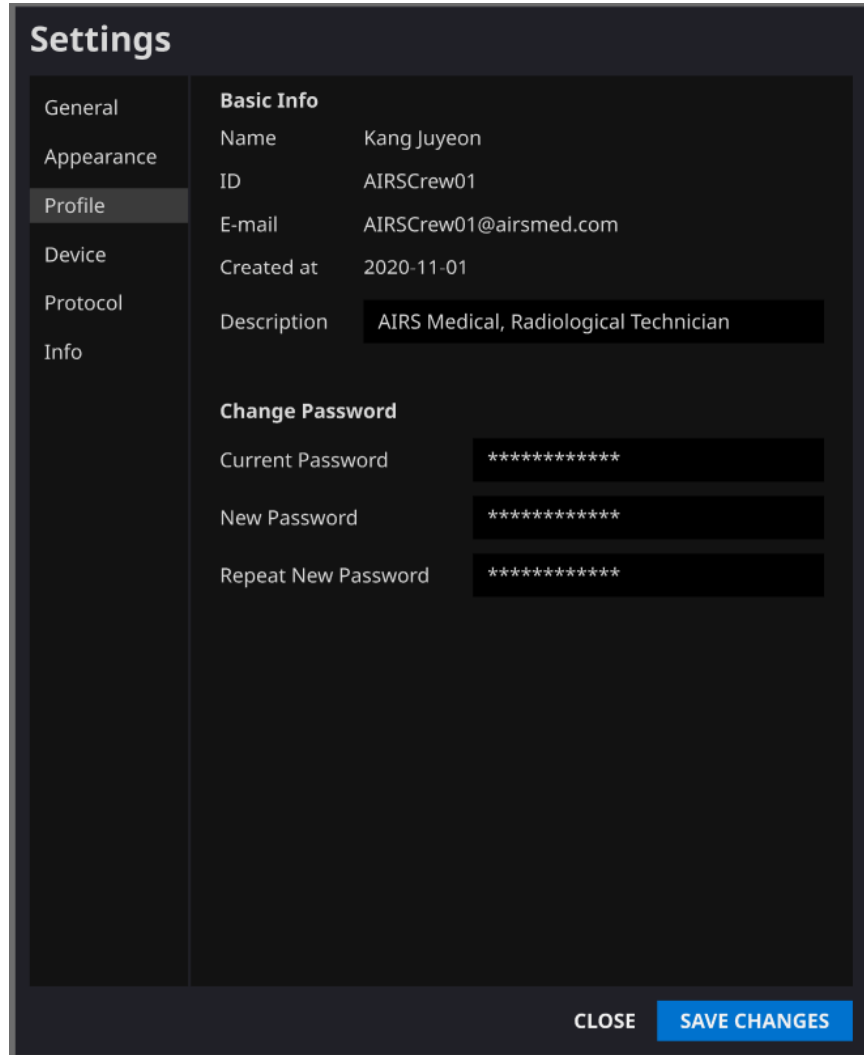
3.6.2. Appearance Settings

- The look of the main page can be set from Appearance tab of Settings.
 - Font:**
 - Time(Size) – Choose one from Small, Medium, and Large
 - Weight – Choose between Normal and Bold
 - Colors:** Set the toast alarm color by choosing between Dark and Light.
 - Table:** Select the columns to be shown in Study Table.
- When done, click **SAVE CHANGES**.



3.6.3. Profile Settings

- Users can retrieve his/her own profile and modify it by clicking Profile or from Profile tab of Settings.
- Users can change his/her password by entering the previous password and new password.
- When done, click **SAVE CHANGES**.



Settings

Category	Field	Value
Basic Info	Name	Kang Juyeon
	ID	AIRSCrew01
	E-mail	AIRSCrew01@airsmmed.com
	Created at	2020-11-01
Description	Description	AIRS Medical, Radiological Technician
Change Password		
Current Password	*****	
New Password	*****	
Repeat New Password	*****	

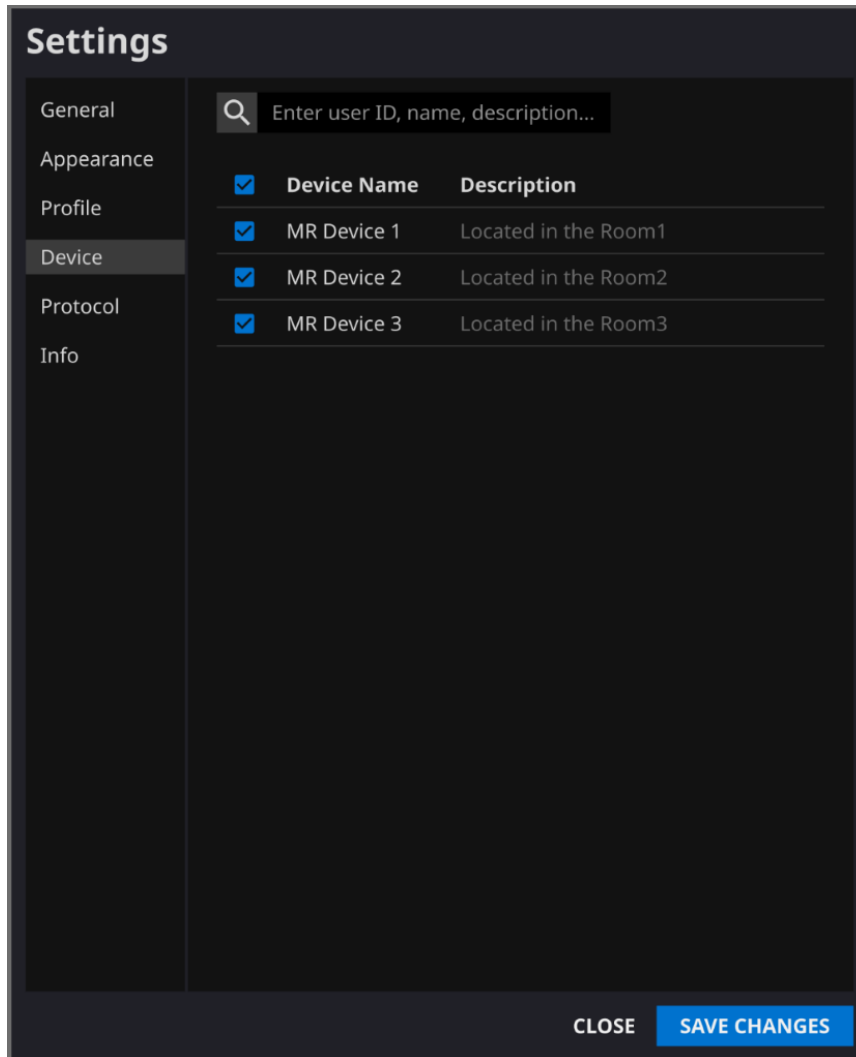
CLOSE **SAVE CHANGES**

Note: Only English is supported in the Description field.

Note: Password must satisfy the string rule of at least 8 characters including 1 letter, 1 number, and 1 special symbol.

3.6.4. Device Settings

- Users can select the MR devices to receive notifications for image processing results among the comprehensive list of registered MR devices for the institution from Device tab of Settings.
- All registered MR devices are selected by default.
- **Unselect:** Uncheck the device and click **SAVE CHANGES**.
- **Select:** Check the device and click **SAVE CHANGES**.
- When done, click **SAVE CHANGES**.



Note: Each user can select multiple MR devices to receive notification for. For example, a radiological technician in charge of MR Device 1 and 2 can select the two devices to receive notifications only for those two devices.

3.6.5. Protocol Settings

- Users can view the protocol settings for SwiftMR processing from Protocol tab of Settings. Modifications in SwiftMR can only be done by System Admin (see Section 3.7.6)
- SwiftMR takes the Protocol Name of an MR image to decide whether to process it. When processing is required, the enhancement will follow the Swift Model predefined in the Protocol setting.

The screenshot shows the 'Settings' application with the 'Protocol' tab selected. A search bar at the top right contains the text 'Enter protocol name or swift m...'. Below the search bar is a table with two columns: 'Protocol Name' and 'Swift Model'. The table lists five protocols, all with 'GENERAL' as the Swift Model.

Protocol Name	Swift Model
AX_T2_FLAIR_FS_TIR_SWIFT	GENERAL
AX_T2_tse_SWIFT	GENERAL
AX_T1_se_SWIFT	GENERAL
AX_T1_FLAIR_tir_Swift	GENERAL
AX_DWI_epse_SWIFT	GENERAL

A 'CLOSE' button is located at the bottom right of the settings window.



Caution: Users should scan images with supported scanner model, pulse sequences, and scan parameters. Otherwise, image processing performance cannot be guaranteed. For supported acquisition conditions, see 3.7.5 and 3.7.6 of the user manual.

3.6.6. Software Information

Users can check necessary software information including license, software version, and manufacturer by clicking **S/W Info** or from Info tab of Settings.



Settings

- General
- Appearance
- Profile
- Device
- Protocol
- Info**

SwiftMR

Software
Version 1.1.0

License info
Belongs to AIRS Clinic ABC Gwanak

Manufactured by
Full Name AIRS Medical Inc.
E-mail support@airsmc.com

SwiftMR
Picture archiving and communications system,
software (GMDN: 41670)

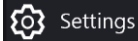
REF A20-CL **LOT** 1.1.0 **Rx Only**

UDI (01)08801234123457 (10)1.1.0

 Name : AIRS Medical Inc.
Address : 8-9F, CS Tower, 1838, Nambusunhwan-ro,
Gwanak-gu, Seoul, 08788 Korea

CLOSE

3.7. System Admin Settings



System admin can configure advanced settings by clicking Settings. When you login as System admin mode, software settings window consists of General, QC, Appearance, Profile, User Management, PACS, Device, Protocol, and Info tabs.

Note: The contents from 3.7.1 General Settings to 3.7.6 Protocol Settings are additional functions provided only when logged in as System admin. All other setting functions not described in this section are the same with user mode.




Caution: When System admin enters invalid ID or password into the input field, login fails and error message appears. If System admin forgets his/her ID or password, contact the manufacturer.



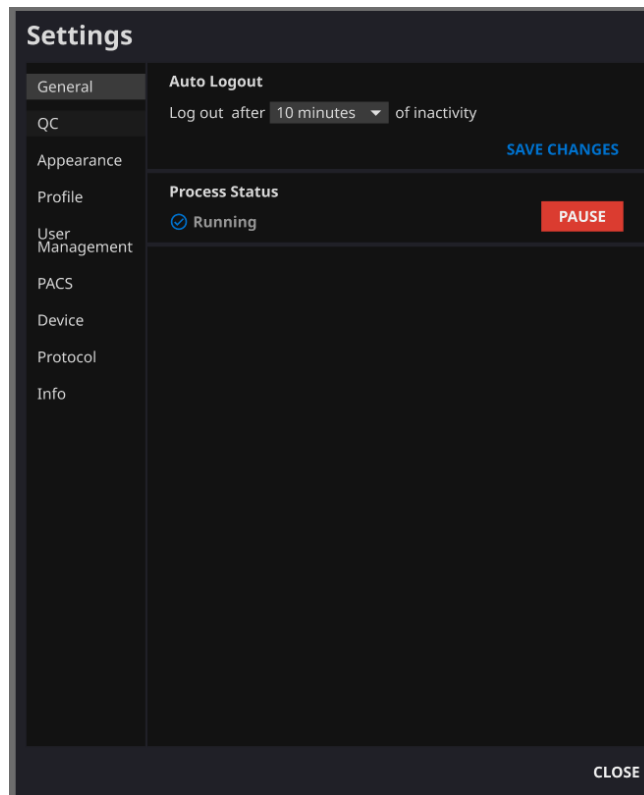
Caution: Configuration set by System admin is stored in the cloud server and affects users of SwiftMR in the same institution. Once the configuration is set by System admin, it is applied every time SwiftMR is executed.

3.7.1. General Settings


- **Auto logout time setting:** Same with User (See 3.6.1)
- **Pause/Resume image processing:**

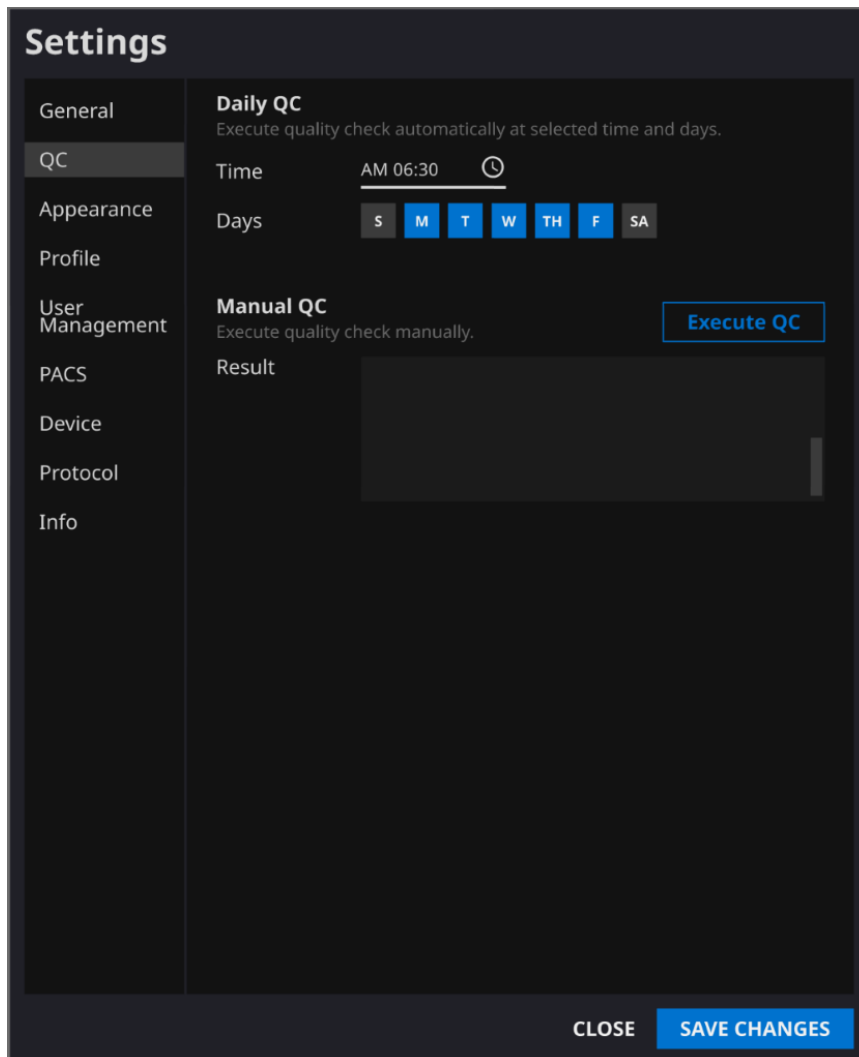
To stop image processing by SwiftMR on the institution level, click pause ().

To resume image processing by SwiftMR, click resume ().






3.7.2. QC Settings

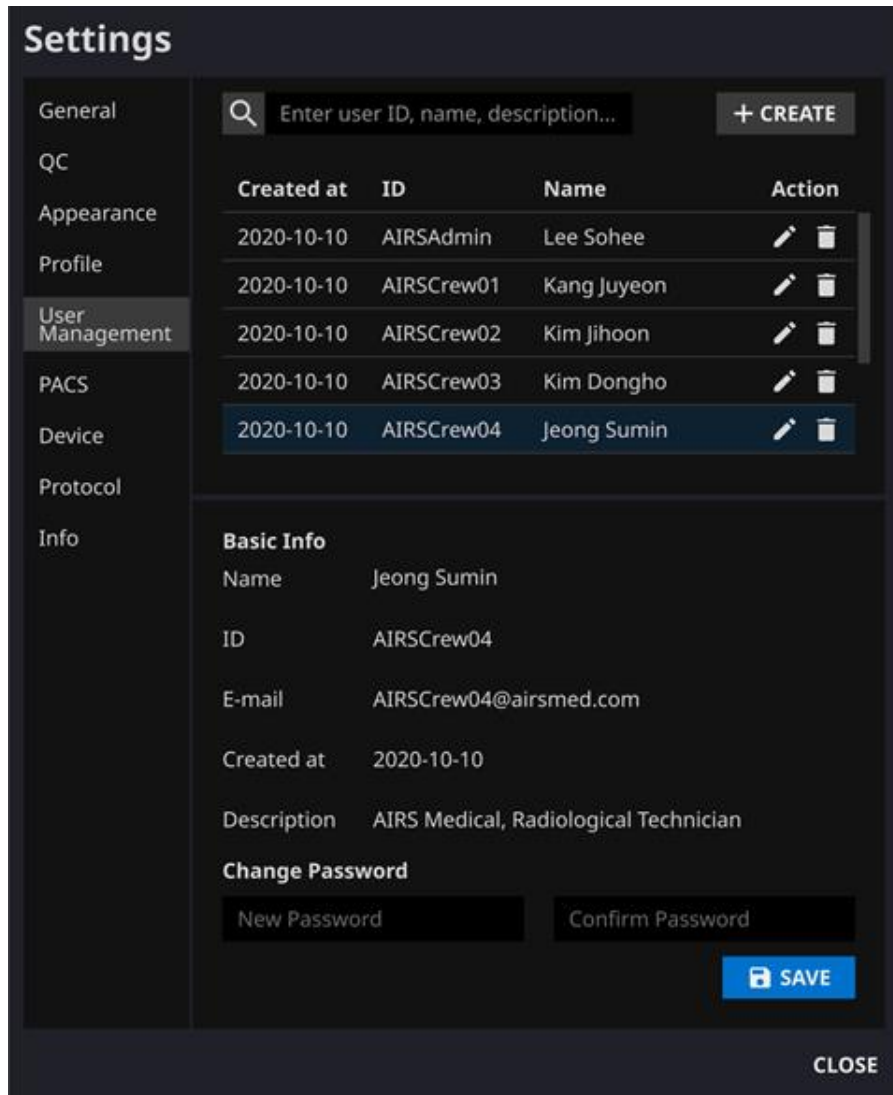
- SwiftMR provides a QC (Quality Check) function where the software confirms that the operation of image processing module is error-free and that PACS-cloud server connectivity is normal.
- **Daily QC:** System admin can set the days of the week and time for Daily QC execution. The system will conduct QC routine automatically on the set days and time of the week. It is recommended to set the days of the week and time for Daily QC so that the check can be done before using MR devices to scan.
- **Manual QC:** If necessary, System admin can execute the QC routine manually and check the results by clicking on Execute QC ()
- When done, click **SAVE CHANGES**.



The screenshot shows the 'Settings' window with a sidebar on the left containing menu items: General, QC, Appearance, Profile, User Management, PACS, Device, Protocol, and Info. The 'QC' menu item is selected and highlighted. The main content area is titled 'Daily QC' and includes the instruction 'Execute quality check automatically at selected time and days.' Below this, there are two sections: 'Time' set to 'AM 06:30' with a clock icon, and 'Days' with a row of seven buttons labeled 'S', 'M', 'T', 'W', 'TH', 'F', and 'SA'. The 'M', 'T', 'W', 'TH', and 'F' buttons are highlighted in blue. Below the 'Daily QC' section is the 'Manual QC' section with the instruction 'Execute quality check manually.' and an 'Execute QC' button. A 'Result' label is followed by a large, empty text area. At the bottom right of the settings window, there are two buttons: 'CLOSE' and 'SAVE CHANGES'.

3.7.3. User Management

- System admin can create user accounts in SwiftMR and manage existing users. Users can login to the software only after System admin has created an account.
- **Create user:** Click  **CREATE**. Enter user information including ID, password, name and e-mail.
- **Modify user:** Click  on the righthand side of the user. Modify user information or change user password as needed.
- **Delete user:** Find the user from the list and click  on the right hand side of the user.
- When done, click **SAVE CHANGES**.



Settings

General **+ CREATE**

QC

Appearance

Profile











User Management

PACS

Device

Protocol

Info

Created at	ID	Name	Action
2020-10-10	AIRSAdmin	Lee Sohee	 
2020-10-10	AIRSCrew01	Kang Juyeon	 
2020-10-10	AIRSCrew02	Kim Jihoon	 
2020-10-10	AIRSCrew03	Kim Dongho	 
2020-10-10	AIRSCrew04	Jeong Sumin	 

Basic Info

Name Jeong Sumin

ID AIRSCrew04

E-mail AIRSCrew04@airsmed.com

Created at 2020-10-10

Description AIRS Medical, Radiological Technician

Change Password




New Password

Confirm Password

SAVE

CLOSE



3.7.4. PACS Settings

- System admin can create new PACS connections with SwiftMR or manage the existing PACS connections. System admin needs to setup PACS connections for users to be able to view MR images from PACS in SwiftMR's worklist.
- **Create PACS:** Click  **CREATE**. Enter PACS information to connect to SwiftMR including AE Title, IP address, and port.
- **Modify PACS:** Click  on the righthand side of the PACS to modify and modify PACS information.
- **Delete PACS:** Click  on the righthand side of the PACS to delete.
- When done, click **SAVE CHANGES**.

Settings

- General
- QC
- Appearance
- Profile
- User Management
- PACS
- Device
- Protocol
- Info

+ CREATE

Alias	IP Address	Description	Action
PACS1	255.255.255.255	aaa	 

Application Entity

Alias

IP Address

Query

AE Title

Port

Store SCP

AE Title

Port

Store SCU




AE Title

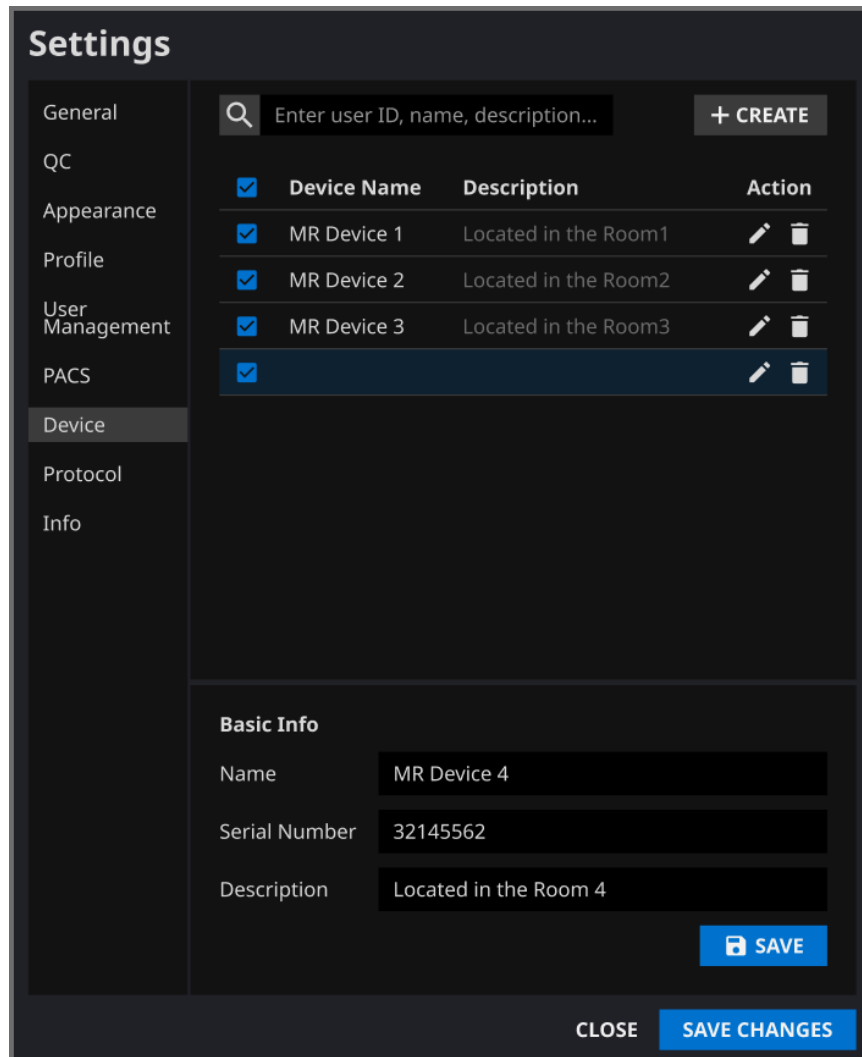
Description

SAVE









CLOSE

3.7.5. Device Settings

- System admin can register new MR devices and manage the registered devices.
- The scope of scanner models supported by SwiftMR is as follows.
 - Scanner manufacturers: Siemens / GE / Philips
 - Field Strength: 1.5T / 3.0T
 - Scanner models: All 1.5T / 3.0T models of the above 3 companies are supported.
- **Register device:** Click . Enter information of the MR device to register including device serial number.
- **Modify device information:** Click  on the righthand side of the device to modify, and modify the information.
- **Delete device:** Click  on the righthand side of the device to delete.
- When done, click **SAVE CHANGES**.



The screenshot shows the 'Settings' interface with a sidebar on the left containing menu items: General, QC, Appearance, Profile, User Management, PACS, Device (selected), Protocol, and Info. The main content area features a search bar with the placeholder text 'Enter user ID, name, description...' and a '+ CREATE' button. Below the search bar is a table with the following data:

<input checked="" type="checkbox"/>	Device Name	Description	Action
<input checked="" type="checkbox"/>	MR Device 1	Located in the Room1	 
<input checked="" type="checkbox"/>	MR Device 2	Located in the Room2	 
<input checked="" type="checkbox"/>	MR Device 3	Located in the Room3	 
<input checked="" type="checkbox"/>			 

Below the table is a 'Basic Info' section with the following fields:

- Name: MR Device 4
- Serial Number: 32145562
- Description: Located in the Room 4




At the bottom right of the 'Basic Info' section is a blue 'SAVE' button. At the bottom of the entire settings panel are 'CLOSE' and 'SAVE CHANGES' buttons.

3.7.6. Protocol Settings

- System admin can set the rules for image processing by SwiftMR from Protocol tab of Settings.
- The range of pulse sequences and scan parameters supported by SwiftMR is as follows.

Vendor	Field Strength	Number of Coils	Sequence	Scan Parameters					
				Acceleration Factor*	TR (ms)	TE (ms)	Resolution (mm)	Slice Thickness (mm)	Matrix Size
GE	1.5T	~8	Axial T1	1~2	333.3~800.0	8.0~21.0	0.43~0.94	5.0~5.0	256x256~512x512
			Axial T2	1~1	3000.0~7883.3	92.2~123.9	0.43~0.47	5.0~5.0	512x512~512x512
			Axial FLAIR	1~1	8002.0~10002.0	120.4~150.3	0.43~0.94	3.0~5.0	256x256~512x512
			Axial GRE	1~1	667.0~667.0	15.0~15.0	0.47~0.47	5.0~5.0	512x512~512x512
			Sagittal T1	1~1	316.7~1844.5	9.0~27.6	0.43~1.02	4.0~6.5	256x256~512x512
GE	3.0T	~32	Axial T1	1~2	700~1763.9	9.0~22.2	0.43~0.86	5.0~5.0	256x267~512x512
			Axial T2	1~3	700.0~6433.0	15.0~114.7	0.43~0.86	5.0~5.0	256x256~512x512
			Axial FLAIR	1~2	8800.0~11002.0	85.6~155.6	0.43~0.94	5.0~5.0	256x256~512x512
			Axial GRE	1~1	375.0~445.0	4.3~7.0	0.47~0.47	5.0~5.0	512x512~512x512
			Sagittal T1	1~2	416.7~3152.5	6.1~17.0	0.43~0.51	4.0~7.0	512x512~512x512
			Coronal T2	1~2	5035.5~6800.0	99.9~109.0	0.47~0.47	3.0~3.0	512x512~512x512
			Axial TOF	2~2	20.0~20.0	3.4~3.4	0.41~0.45	1.2~1.2	512x512~512x512
PHILIPS	1.5T	~20	Axial T1	1~1	400.0~613.0	10.0~12.0	0.45~0.92	5.0~5.0	256x256~512x512
			Axial T2	1~1	2268.8~5400.0	100.0~110.0	0.22~0.94	5.0~5.0	256x256~1024x1024
			Axial FLAIR	1~1	6000.0~11000.0	120.0~142.0	0.43~0.96	5.0~5.0	240x240~560x560d
			Sagittal T1	1~1	450.0~812.8	12.0~18.0	0.45~0.86	5.0~5.0	256x256~512x512
PHILIPS	3.0T	~32	Axial T1	1~1	400.0~719.0	10.0~10.8	0.43~0.76	4.0~5.0	288x288~512x512
			Axial T2	1~1	3000.0~3831.7	80.0~110.0	0.43~0.45	5.0~5.0	512x512~560x560
			Axial FLAIR	1~1	9000.0~11000.0	110.0~125.0	0.43~0.69	5.0~5.0	320x320~512x512
			Sagittal T1	1~1	350.0~500.0	6.6~10.0	0.43~0.94	4.0~5.0	256x256~560x560
			Axial TOF	1~1	20.0~20.0	3.5~3.5	0.21~0.41	1.2~1.2	512x512~1024x1024
SIEMENS	1.5T	~20	Axial T1	1~1	406.0~642.0	8.7~17.0	0.45~0.94	5.0~6.0	256x192~512x416
			Axial T2	1~1	3720.0~6470.0	85.0~113.0	0.26~0.75	5.0~5.0	320x320~896x812
			Axial FLAIR	1~1	8000.0~10000.0	73.0~130.0	0.38~0.90	5.0~5.0	256x204~640x560
			Sagittal T1	1~1	450.0~650.0	9.4~17.0	0.72~0.94	5.0~6.0	256x256~320x320
			Sagittal MPRAGE	1~1	2530.0~2530.0	3.1~3.1	1.00~1.05	1.3~1.3	256x256~256x256
			Axial TOF	2~2	25.0~30.0	7.0~7.2	0.27~0.62	0.5~0.5	384x288~768x616
SIEMENS	3.0T	~64	Axial T1	1~3	500.0~1800.0	9.0~9.8	0.57~0.69	4.0~5.0	320x270~384x348
			Axial T2	1~2	2690.0~10070.0	86.0~100.0	0.21~0.34	4.0~5.0	640x540~1024x928
			Axial FLAIR	1~2	8000.0~9000.0	97.0~105.0	0.29~0.57	4.0~5.0	384x348~768x696

		Sagittal T1	1~1	450.0~550.0	6.9~9.8	0.29~0.62	5.0~5.0	384x384~768x768
		Axial SWI	2~2	28.0~29.0	20.0~20.0	0.46~0.57	2.5~2.5	384x300~480x434
		Axial TOF	2~2	22.0~25.0	3.7~4.2	0.43~0.54	0.5~0.6	448x348~512x416

- SwiftMR takes the Protocol Name of an MR image to decide whether to process it. When the description matches a series in the Protocol Settings page, processing is carried out whereby the enhancement method will follow the Swift Model predefined in the Protocol setting.
- There are two types of selectable Swift Model: GENERAL and TOF. Supported pulse sequences that correspond to each Swift Model are as follows.
 - GENERAL: Axial T1, Axial T2, Axial FLAIR, Axial GRE, Sagittal T1, Coronal T2, Sagittal MPRAGE, Axial SWI
 - TOF: Axial TOF
- Before use, be sure to check the protocol for image processing.
 - If the existing protocol in the MR device is to be used, SwiftMR Protocol Name needs to be updated to match the MR device protocol.
 - If a new protocol is to be created in the MR device, it is recommended to use the Protocol Name shown as default in Protocol tab of Settings.
- **Create protocol:** Click  **CREATE**. Enter new Protocol Names to register and select the Swift Model that corresponds to the Protocol Name.
 - In the case of A20-CL, Swift Model “Brain Routine” is recommended.
- **Modify protocol:** Click  on the righthand side of the protocol and modify as needed.
- **Delete protocol:** Click  on the righthand side of the protocol.
- When done, click **SAVE CHANGES**.

Settings

General + CREATE

QC

Appearance

Profile

User Management

PACS

Device

Protocol

Info

Protocol Name	Swift Model	Action
AX_T2_tse_Swift	GENERAL	
AX_T1_se_Swift	GENERAL	
AX_T1_FLAIR_tir_Swift	GENERAL	
COR_T1_se_Swift	GENERAL	
COR_T2_tse_Swift	GENERAL	
SAG_T1_se_Swift	GENERAL	

Rule Settings

Protocol Name

Swift Model

SAVE

CLOSE



Caution: Users should scan images with supported scanner model, pulse sequences, and scan parameters. Otherwise, image processing performance cannot be guaranteed. For supported acquisition conditions, see 3.7.5 and 3.7.6 of the user manual.



Caution: When performing image processing on MR images with our product, make sure to set the protocol with the values provided by us on the MR device. After applying the correct settings, it is recommended to attach a suffix to the protocol name such as **_swift** to distinguish them.



Caution: MR images of protocol name registered in protocol settings are processed in SwiftMR cloud. Therefore, if you want to process with SwiftMR, be sure to check whether the protocol name is registered in the settings before conducting an MRI scan.



Caution: Users should select Swift Model between GENERAL or TOF according to the protocol to be registered

3.8. Image Processing

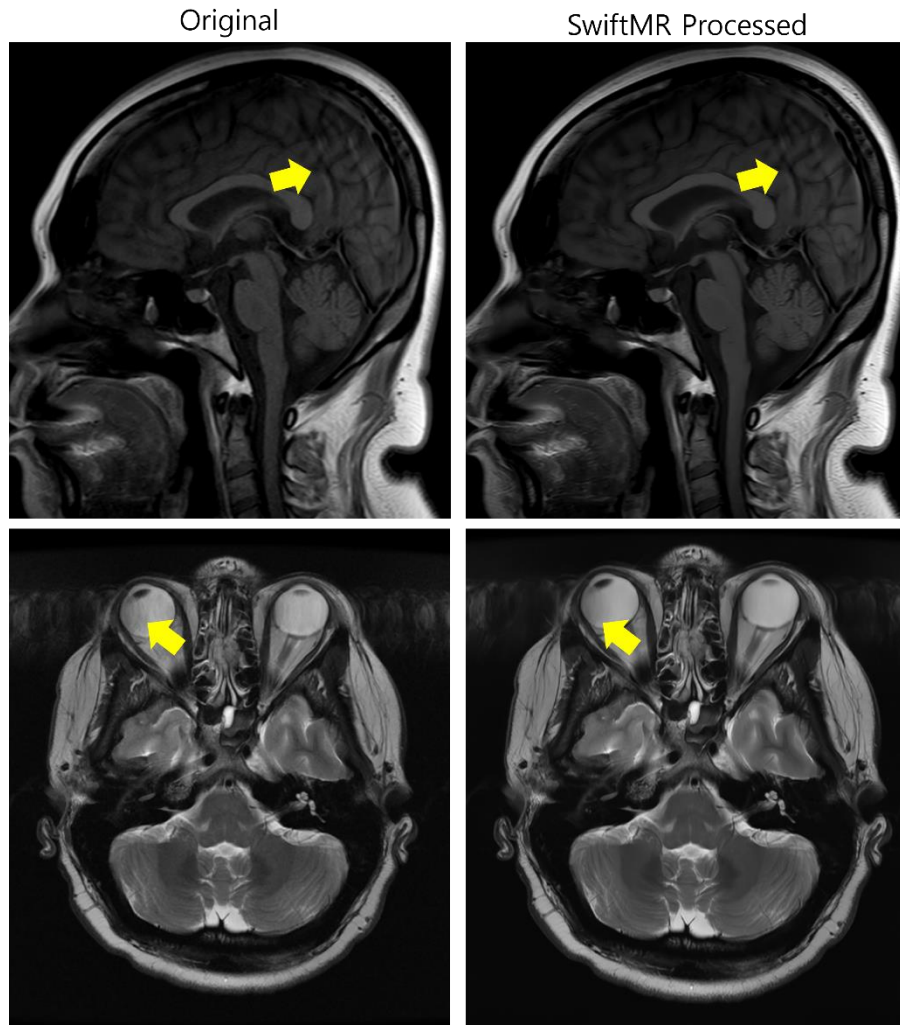
3.8.1. General Information

- The intended patient population is adults (greater than 21 years of age) only.
- SwiftMR simultaneously performs noise reduction and increasing sharpness functions on processed images. User cannot choose between the two functions.
- Image enhancement process is fully automatic. When the DICOM images captured by the MRI equipment are stored in PACS, SwiftMR cloud server automatically imports them to enhance the image quality and saves them in PACS again.
- There is no configuration setting for de-noising and sharpening functionalities. There is only one level of enhancement for de-noising and sharpening functionalities.
- After image processing, both the original image and the enhanced image are stored in PACS. For enhanced Image, the phrase '**_recon**' is added at the end of the protocol name and series description of the DICOM tag. Users can distinguish between original images and enhanced images by looking at the DICOM tag and depending on whether there is '**_recon**'.
- The performance of SwiftMR both for noise reduction and sharpness increase was validated for the supported acquisition conditions described in 3.7.5 and 3.7.6. As a result of the test, it was demonstrated that SwiftMR increases the SNR of original image by 40% or greater than that on average, and sharpness was increased in original images for at least 90% of the dataset, with an average FWHM decrease rate of 2.3% or more.

3.8.2. Warning – Image Artifacts



If image artifacts or processing errors are found in the SwiftMR processed image, user has the option to use the original image.



When image artifacts including motion artifacts, aliasing, noise, or ghosting exist in the original image, SwiftMR handles them in the same way as normal images. Due to the denoising / sharpening function of the SwiftMR process, there is a possibility that the artifacts of the original image may be reduced or, conversely, become more distinct.

Accordingly, if an image artifact is identified in the SwiftMR processed image, the user can use the original image. Original image and processed image can be distinguished through DICOM tag, see 3.8.1 for details.



3.8.3. Warning-TOF pulse sequence

For TOF pulse sequence slice images, it may seem that the vessel detail is not completely preserved after SwiftMR processing, but this is because the resolution is improved so that the cross section of the vessel spread out in the original image is seen narrower and more clearly in the processed image (Fig. (a), (b)). According to our validation results, vessel detail does not disappear due to SwiftMR processing, and users can check this by comparing MIP images before and after processing (Fig. (c), (d)).

However, user has the option to use the original image at any time, see 3.8.1 for details.

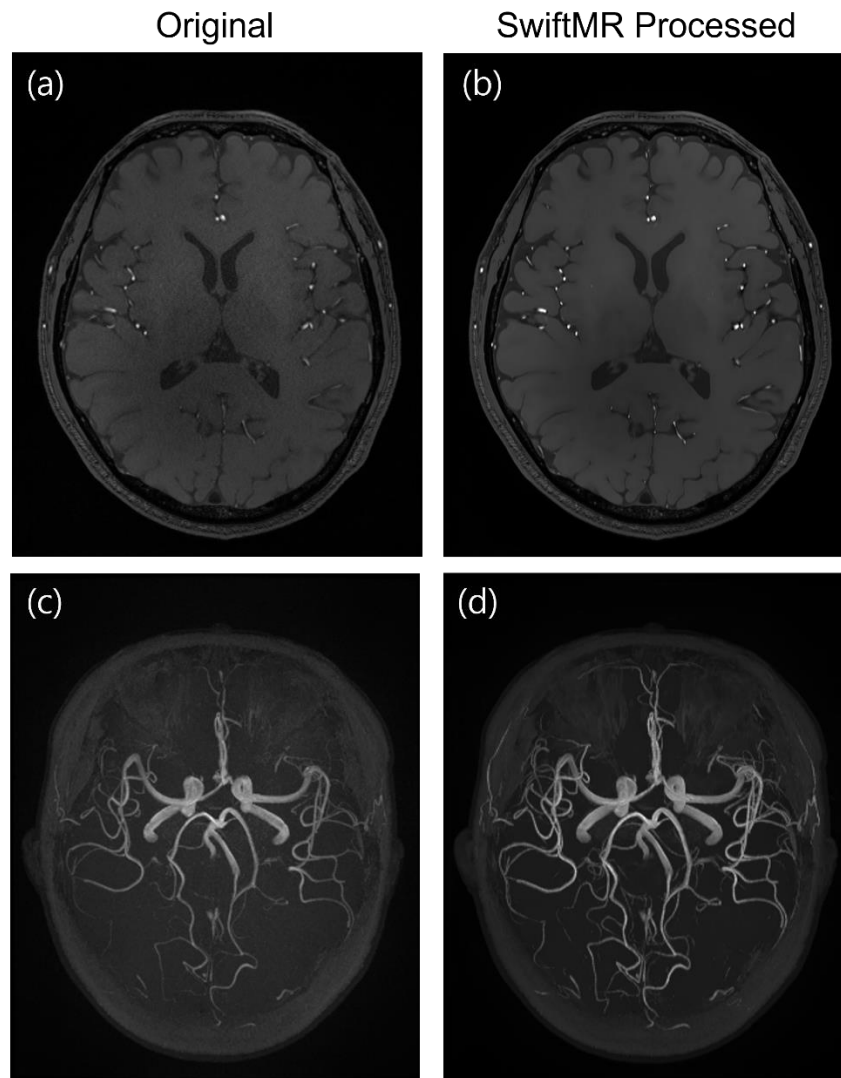


Figure. (a), (b): Slice image before and after SwiftMR processing. (c), (d): MIP image before and after SwiftMR processing

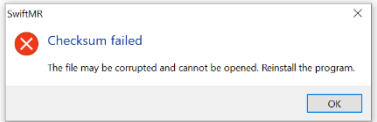

4. Cybersecurity

Before installing and running SwiftMR, cybersecurity procedures must be performed according to the following guideline. The following guideline will help you protect this software from cybersecurity threats such as virus or breaches.

- Prior to installing and running SwiftMR, run a reliable anti-virus program to prevent data corruption from viruses.
- Keep your anti-virus software up-to-date.
- Confirm that the latest security updates are applied to your OS.
- Activate your PC's firewall. Windows 10 or above is equipped with a built-in firewall.
- When there is a new update, System admin can choose whether to perform the update or not.
- When a forced update is required due to security issues or critical bugs, software update is mandatory. If not updated in a timely manner, the software may not function properly.
- When the software's cybersecurity has been compromised, System admin can disconnect the VPN to protect critical functionalities and data.
- AIRS Medical is not responsible for accidents caused by not complying with the above instructions.
- If you have any concerns or issues related to cybersecurity, use the phone number and email address listed below to contact our customer service center.

5. Troubleshooting

The following are frequently asked questions. If you have the same problem with any below, take the listed steps.

Category	Symptom	Cause & Measure
File verification	 <p>File verification failed.</p>	The installed files may be corrupted or missing. Reinstall the program. If that fails, contact the manufacturer.
Network	<p>Network connection status</p> 	The icon indicates disconnection between institution's network and cloud server of SwiftMR. Because it may cause a problem regarding image processing, contact IT manager or manufacturer.
	<p>Automated logout even when the set time for automatic logout has not elapsed.</p>	When the local PC where client application is installed is disconnected from internet, software forces automatic logout. Check your PC internet connection.
Worklist Synchronization	<p>SwiftMR worklist not showing synchronized studies with PACS.</p>	This problem may occur if the registered MR device information is incorrect or may be caused by selecting a different MR device.

For issues that go beyond this User Manual, please contact Customer Support (support@airsmed.com).



Caution: All activity and system logs of SwiftMR are stored and archived. When anomalies are detected from the log files, AIRS Medical will try to solve the issue immediately and contact you if necessary.

6. Maintenance

Before using SwiftMR, please check to see if Daily QC has been completed successfully. When a problem is detected, the system will utilize latest QC logs to investigate root causes.

To fix bugs and update image processing algorithms, it is recommended to upgrade the product (Client App) at least once a year, or when prompted by the software.

7. Quality Assurance

AIRS Medical Inc. warrants against defects in the design and production process during the warranty period of 1 year from the date of receipt of the product by the customer. In the event of a dispute, it will be proceeded in accordance with the Fair Trade Commission's settlements of consumer disputes.

AIRS Medical Inc. does not guarantee the following items:

- Damage caused by external factors such as accidents, misuse, fire, earthquake, etc.
- Modified products without the written consent of AIRS Medical Inc.
- Damage caused by service performed by an engineer or service provider not authorized by AIRS Medical Inc.

Before requesting warranty service, please refer to the contents of this user manual first, and then contact us through customer support.

- Customer Support: support@airsmc.com

SwiftMR

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