SwiftMR™

User Manual

Product Model

A20-CL

Version v1.4.0.X

AIRS MEDICAL

SwiftMR
User Manual, English
A20-CL-UM-EU-EN Revision 7 (2022-12)

Contents

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.airsmed.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.
- User manuals for SwiftMR are provided in electronic forms (eIFU). Internet connection is essential to access the eIFU.
- Please contact Customer Support (support@airsmed.com) to request a paper copy of a user manual. Customers will receive a paper copy within seven business days upon receipt of the request.

Certified Use

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

- CE (European Union): SwiftMR is a CE-marked medical device that complies with the Regulation (EU) 2017/745 (MDR).

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.

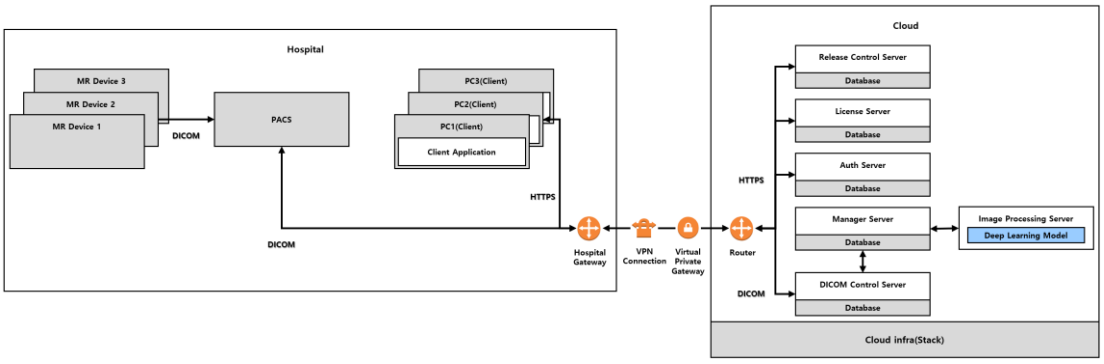
SwiftMR automates below procedures:

- Receive MR images that are in DICOM format from PACS or MR device and upload the images to the cloud server
- Enhance image quality using Deep Learning model and/or sharpening filter on the cloud server
- Download enhanced MR images in DICOM format from the cloud server to PACS.

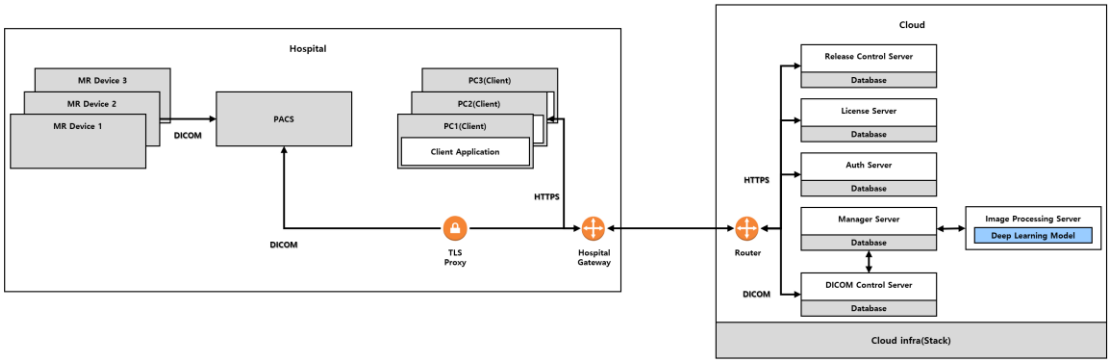
Integration of the institution's PACS with the manufacturer's DICOM control server is necessary at first to start using SwiftMR. After the integration, SwiftMR performs image processing in the background automatically and provides logged in users the authorization to use functions and view image processing results in a worklist format through Client Application.

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

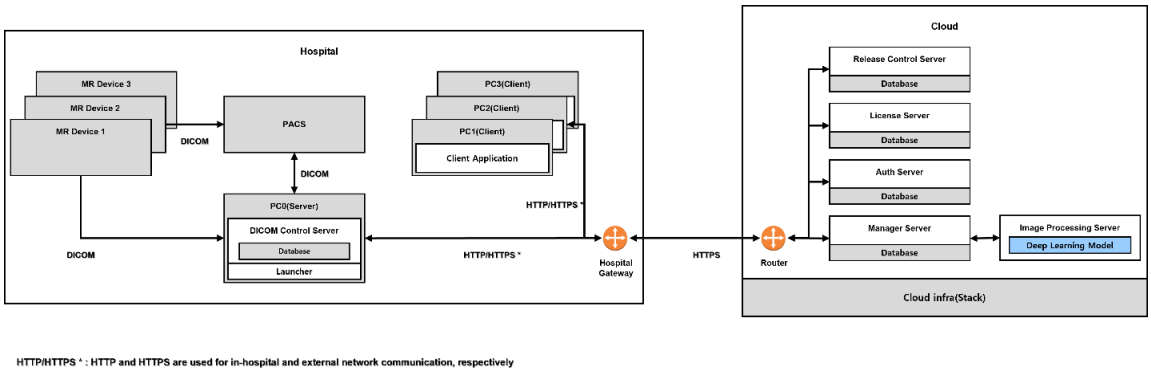
➢ **DICOM Control Server to run on the cloud (with VPN connection)**



➢ **DICOM Control Server to run on the cloud (with TLS Proxy)**



➢ **DICOM Control Server to run on the PC in the hospital**



HTTP/HTTPS * : HTTP and HTTPS are used for in-hospital and external network communication, respectively

1.2. Intended Use

SwiftMR is a stand-alone software solution intended to be used for acceptance, enhancement and transfer of **brain, spine, knee, ankle, shoulder and hip** MR images in DICOM format. It can be used for noise reduction and increasing image sharpness for MR images.
SwiftMR is not intended for use on mobile devices.

1.3. Intended Patient Population

Adults over 21 years of age

1.4. Intended Users

Health care professionals (trained radiology technologists)

- User should have experience with operating a S/W User Interface based on PC (including MRI and PACS)
- User should be able to understand terminology in the user manual and GUI in English

1.5. Contraindication

None.

1.6. Intended Use Environment

This product is to be used in the following care area:

• MRI room

1.7. Storage Condition

SwiftMR is stored on a cloud server.

1.8. Medical Indication

Patients with clinical conditions that need MR imaging of brain, spine, knee, ankle, shoulder, or hip.

1.9. Clinical Benefit

SwiftMR provides diagnosis support.
Outcome parameters:

• Diagnostic quality

• SNR

• Image sharpness.

1.10. Supported MR and PACS devices

The scope of MR devices supported by SwiftMR is as follows:

• Manufacturers: Siemens / GE / Philips

• Field Strength: 1.5T / 3.0T

• MR device models: All 1.5T / 3.0T models of the above 3 companies are supported.

The scope of PACS devices supported by SwiftMR is as follows:

• All DICOM-compliant PACS devices can communicate

1.11. Processing/Protection of Sensitive Information

1) Processing/Protection of User information (from user account)

User information such as name, ID, e-mail, and description are acquired during the SwiftMR user account creation process. These contents are stored in the AWS Cloud DB, where all information is encrypted

2) Processing/Protection of patient sensitive Information

The DICOM images that were sent to SwiftMR for image processing are encrypted and stored in the DICOM Control Server's storage only for 6 hours from the time they are uploaded to the storage, while the images that failed are encrypted and stored for 7 days.

In order to display the study information that is being processed in the client application, the DICOM Control Server acquires the patient's name, ID, age, gender, and date of birth from the DICOM file that derived from the patient's scan. All information is encrypted and stored in the DICOM Control Server's DB.

In addition to this, when 24 hours have passed from the time of registration, the patient's name information is deleted from the DICOM Control Server's DB, while the Patient ID gets stored by applying a hash algorithm.

When DICOM Control Server and the Cloud exchange DIOCM files containing sensitive information, the information is anonymized, and TLS security communication is applied. The cloud does not store any sensitive information.

1.12. Limitations

SwiftMR is only available in certain countries.
This product meets the EU MDR for medical device software.

1.13. 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 or MR Device
  - Enhance image quality
  - Download to PACS the enhanced MR images

1.14. 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

1.15. 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, address of the manufacturer, and date of manufacture
	Consult electronic instructions for use (eIFU) The link that directs users to this user manual is alongside the symbol.
	Catalog number
	Lot number. Version number of the software.
	Indicates the product is a medical device.
	Unique Device Identifier
	Authorized representative in the European Community/European Union
	CE Mark Notified Body: DNV Product Assurance AS(2460)

1.16. Precautions

Caution for Use

- Before use, check to see if Daily QC that the system conducts automatically 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.
- Images that have already been quality-enhanced should not be processed again. This may cause damage to the image.

Note **Important Notes**

- SwiftMR is designed for trained radiology technologists.
- 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.
- Contact Customer Support (support@airsmed.com) to modify Daily QC time settings.

1.17. Abbreviations

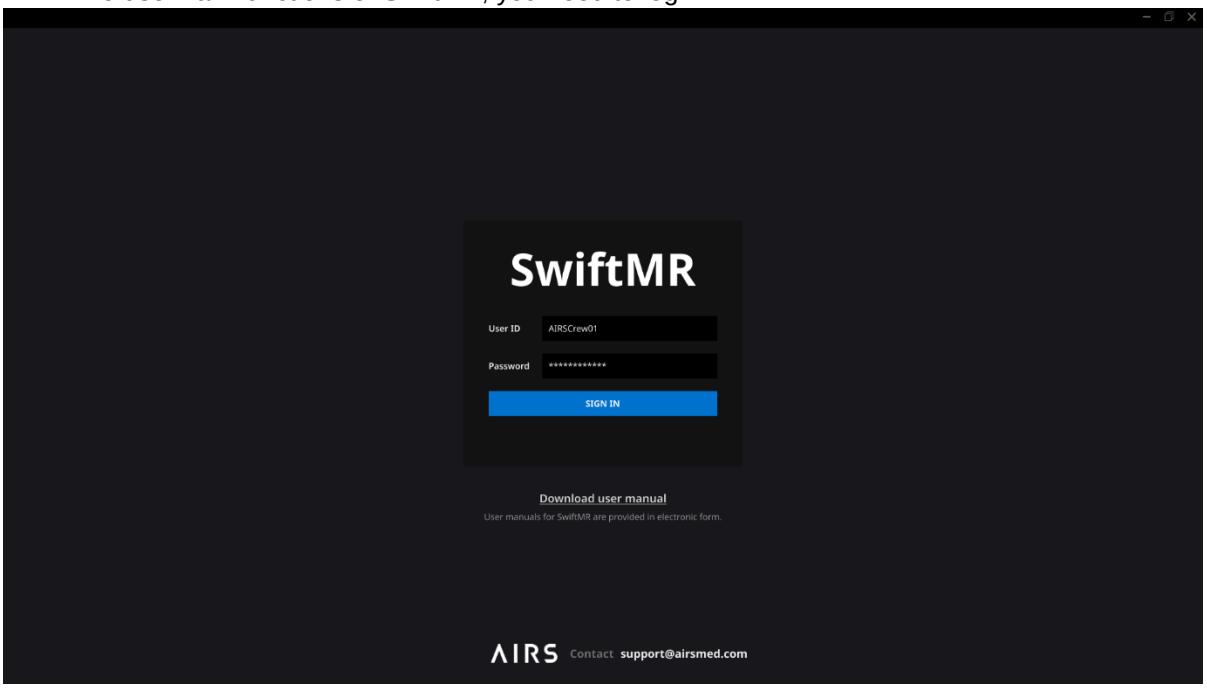
The following abbreviations are used in this User Manual.

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

2. Functions

2.1. Login and Logout

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

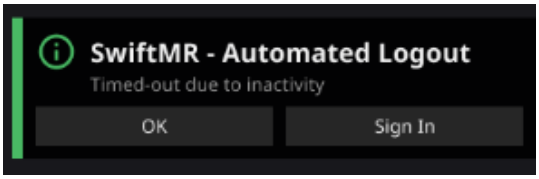


- **Login:** Enter ID and password provided by AIRS Medical and then click **SIGN IN**. When login succeeds, main page will appear.
- **Logout:** You can log out from SwiftMR to prevent unauthorized access by clicking the Logout button (Logout). When logout succeeds, login page will appear again.
- **User Manual:** You can access the e-IFU download page of AIRS Medical by clicking on the “Download user manual” button (Download user manual).

Note	**Note:** User account is created by **AIRS Medical**. Upon first login, the user is required to reset the password to prevent unauthorized access.
Note	**Note:** 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 Customer Support.
Note	**Note:** When the login attempt fails 10 times, you are not allowed to login for the next 5 minutes.
Note	**Note:** 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.

2.2. 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 Message will pop up and the main page will default back to the login page.



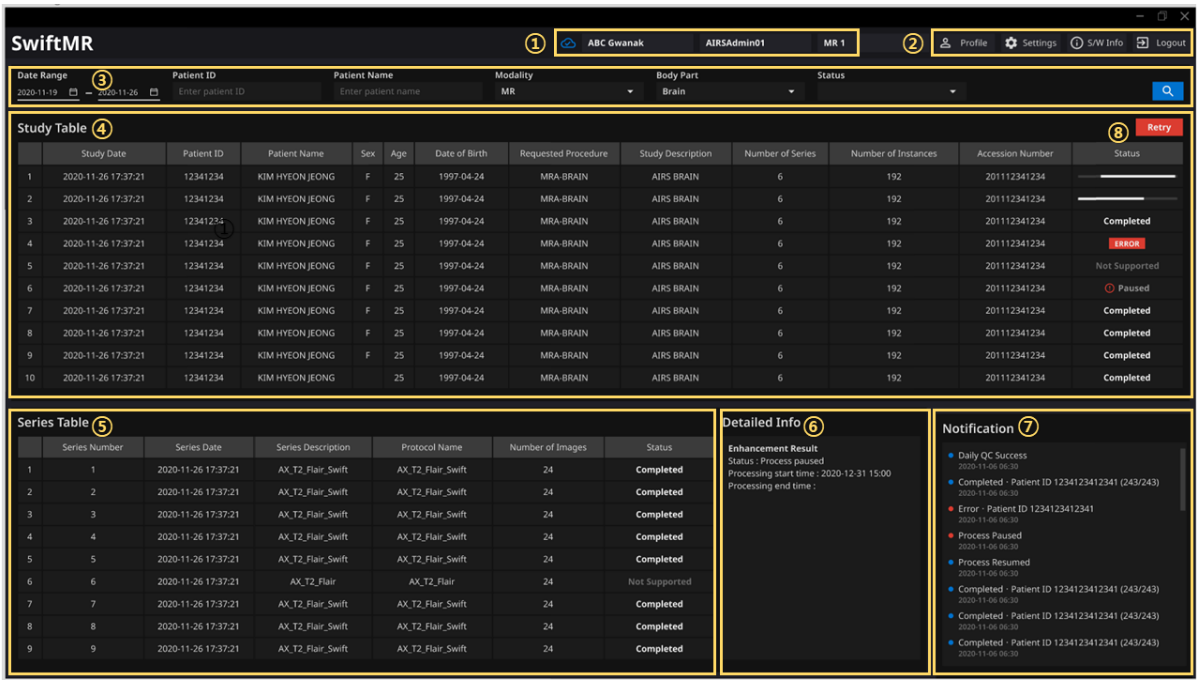
The Toast Message for automated logout disappears when clicking **OK** or after a certain period. Clicking **SIGN IN** will direct you to the login page.

Note	**Note:** Even if the Client Application becomes inactive, image processing will remain functional in the Server.

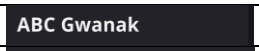
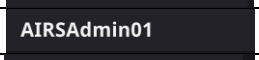
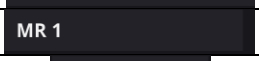
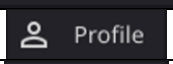
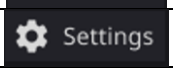
2.3. Main Page

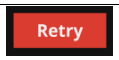
Main page of SwiftMR is constructed as follows:

- 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.



Detailed functions on the main page are as follows.

No	Function	Item	Description
1	Status Bar		Network connectivity (Blue: Connected, Red: Disconnected)
			Institution name
			Logged in Username
			MR devices selected by user
2	User Menu		User Profile
			Software settings
			Software information (license, version), User manual download
			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 • 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)
		MR Device Name	Name of the MR device that created the study (based on SwiftMR registration)
		Requested Procedure	Requested procedure
		Study Description	Name of study protocol
		Number of Series	Total number of series in a study

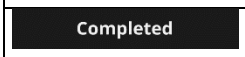
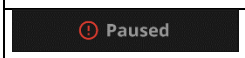
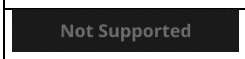
		Number of Instances	Total number of images in a study
		Accession number	Unique identification number of each image
		Status	Image processing progress on MR study level • In Progress • Completed • Not Supported • Error
5	MR Series Table	Series number	Order number of each series in a selected study
		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 • In Progress • Completed • Not Supported • Error
6	Detailed Info	Enhancement Result	Enhancement result on MR series level • 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.
8	Force Retry		This button is activated when user select a row from the study table that is not in the 'In-progress' status. When the retry button is pressed, a confirmation window will open, and image processing will be performed on the selected study upon confirmation. The applicable images will be taken from PACS and be processed.

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

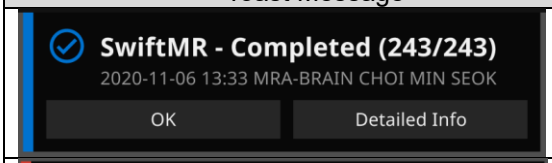
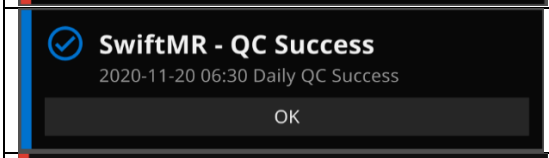
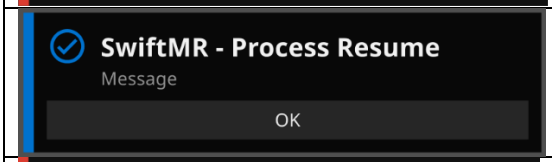
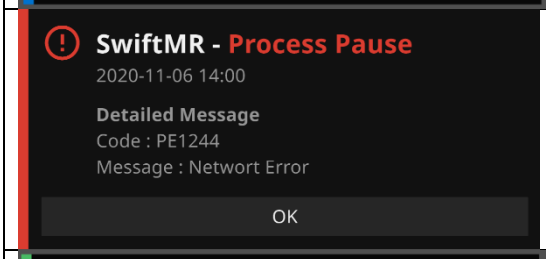
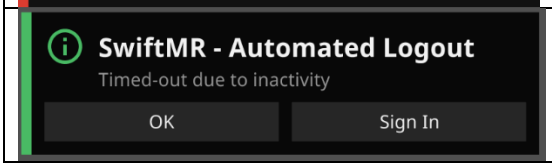
2.4. Status

- 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** AIRS Medical has paused all the image processing for the institution.
	**Not supported** There is no SwiftMR supported MR series in the study.

2.5. Toast Message

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

Toast Message	Description
	Image processing complete.
	Image processing failed.
	Daily QC succeeded.
	Daily QC failed.
	Image processing resumed.
	Image processing paused.
	Automated logout.

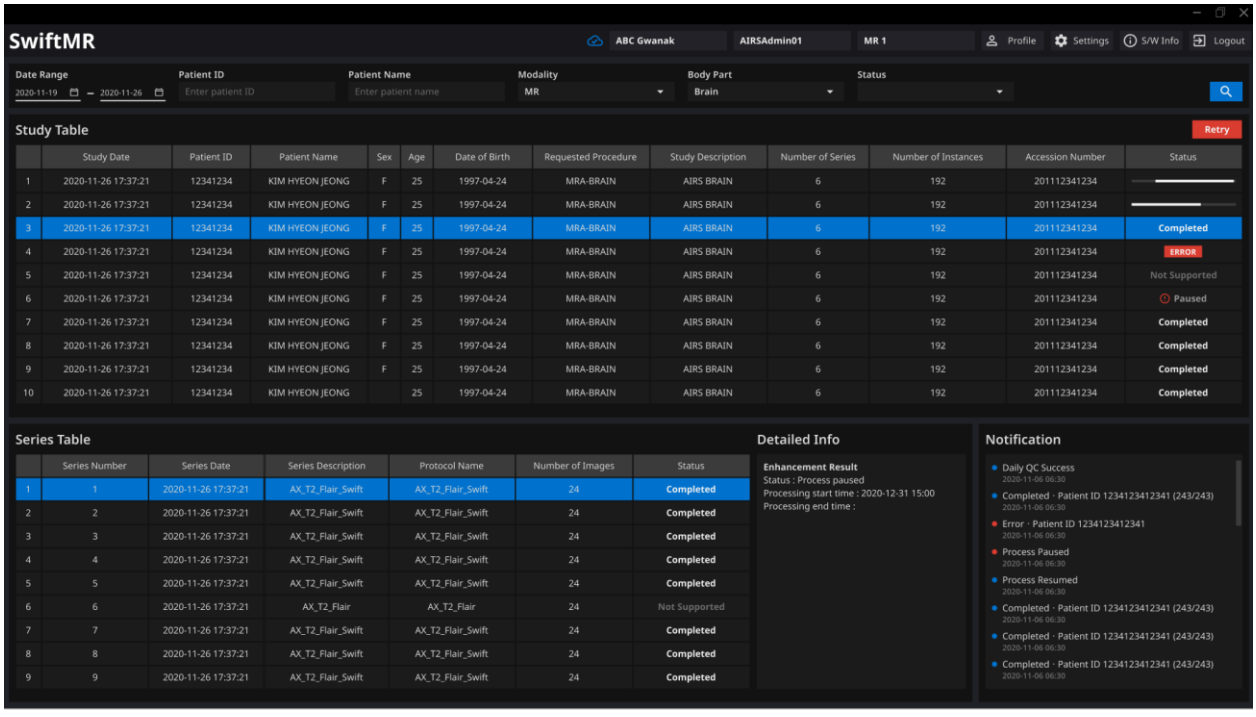
Note	**Note:** When image processing fails, you can retry the processing by clicking **Retry** directly from the toast message. If you accidentally close the toast message, you can take alternative actions from the Detailed Info section on the worklist.

Note	**Note**: Toast message for image processing and image processing history in Notification section is only shown for the connected MR device. Therefore, if toast message for a desired study does not show up, check the device setting in Settings → Device.
Note	**Note**: When QC process fails, you can retry the process manually by clicking the manual QC execution button in Setting->QC. If the error repeats, please contact the manufacturer.

2.6. MR Study Retry

If an error occurred during image processing or if reprocessing is necessary by sending an additional image even if processing was successful, you can use the Retry button.

- Select the MR study you want to reprocess from the study table, that is not in the 'In progress' status.
- The Retry button at the top right of the study table should become activated.
- If you click the button, a confirmation window appears. Click the OK button to proceed.
- When reprocessing is entered, the status of the study changes back to in-progress, and when the processing is complete, a notification appears as in the previous processing.
- In order to differentiate between the original series and the reprocessed ones, 20,000 is added to the original series number for the series that have been reprocessed via this retry function.



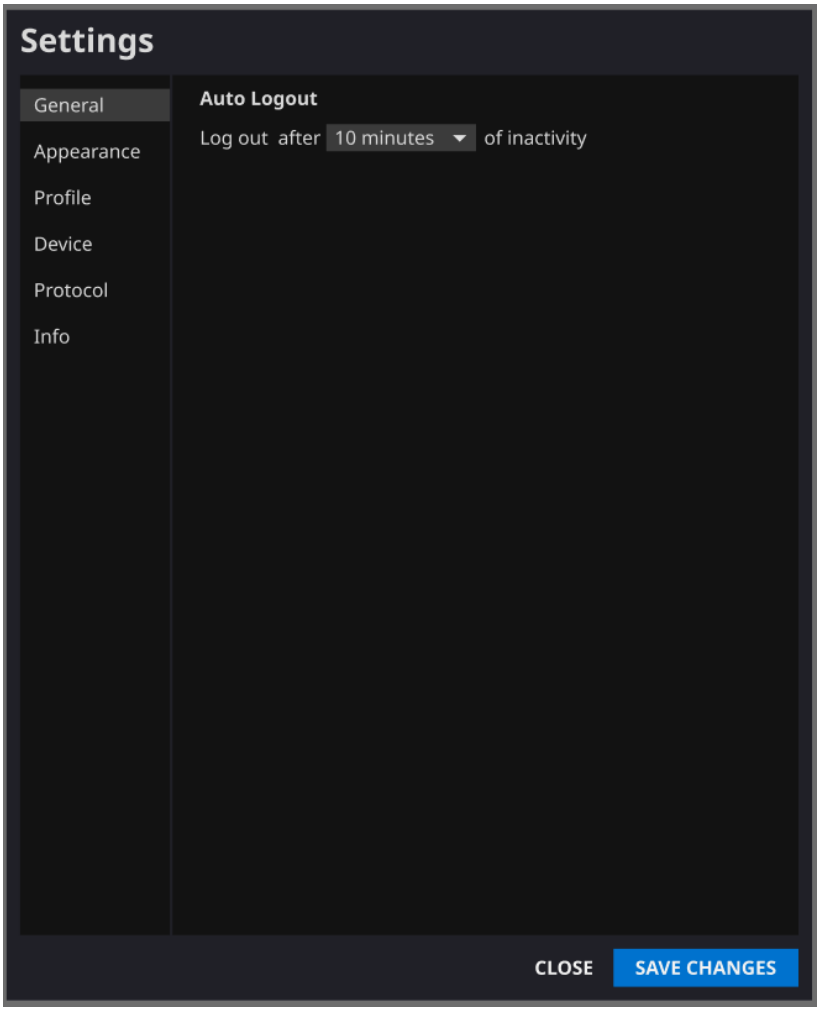
2.7. User Settings 

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.

Note	**Note:** 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.

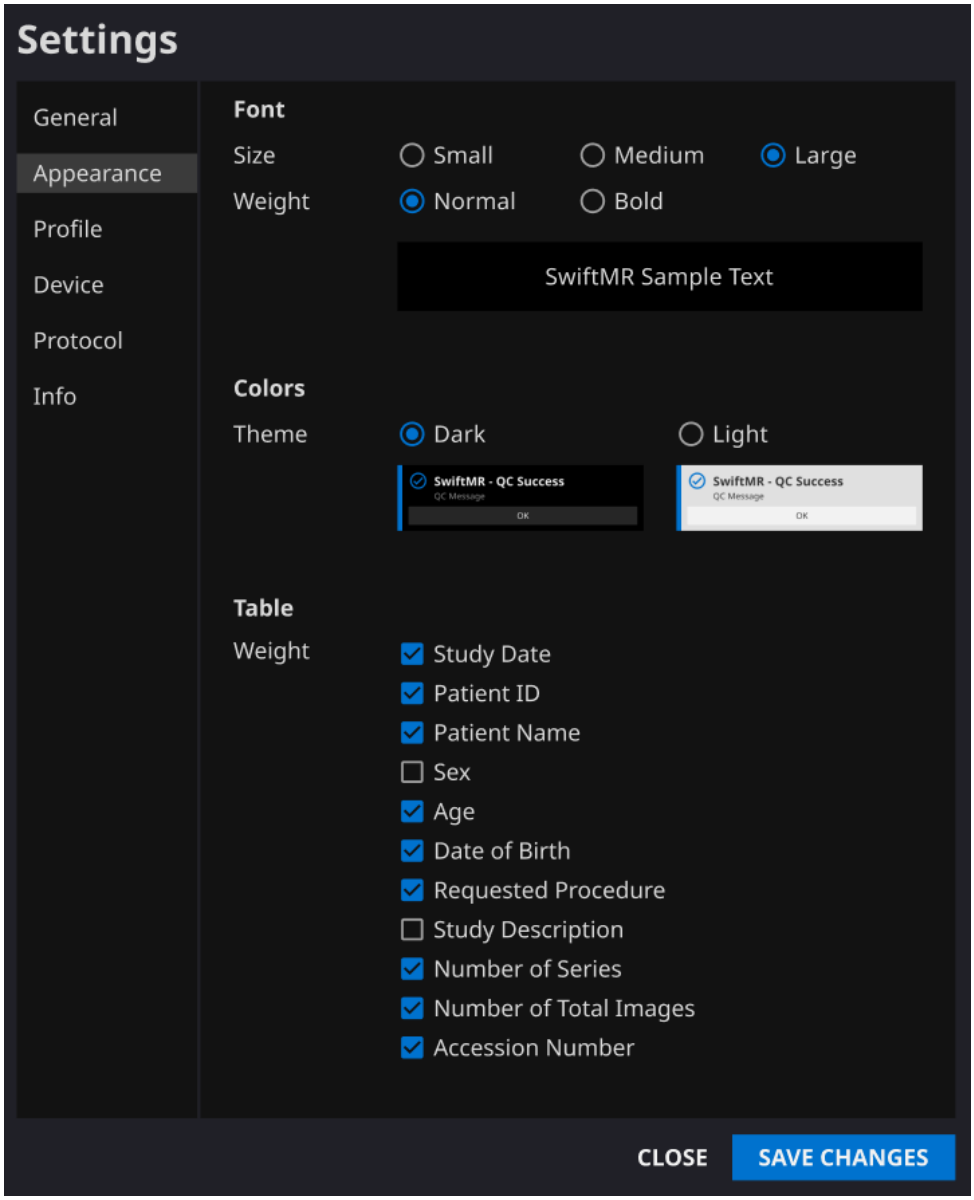
2.7.1. General Settings

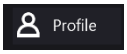
- **Auto logout time setting:** The inactive period after which automated logout will occur can be set from General tab of Settings. Choose the desired time from the drop-down menu and click **SAVE CHANGES**.



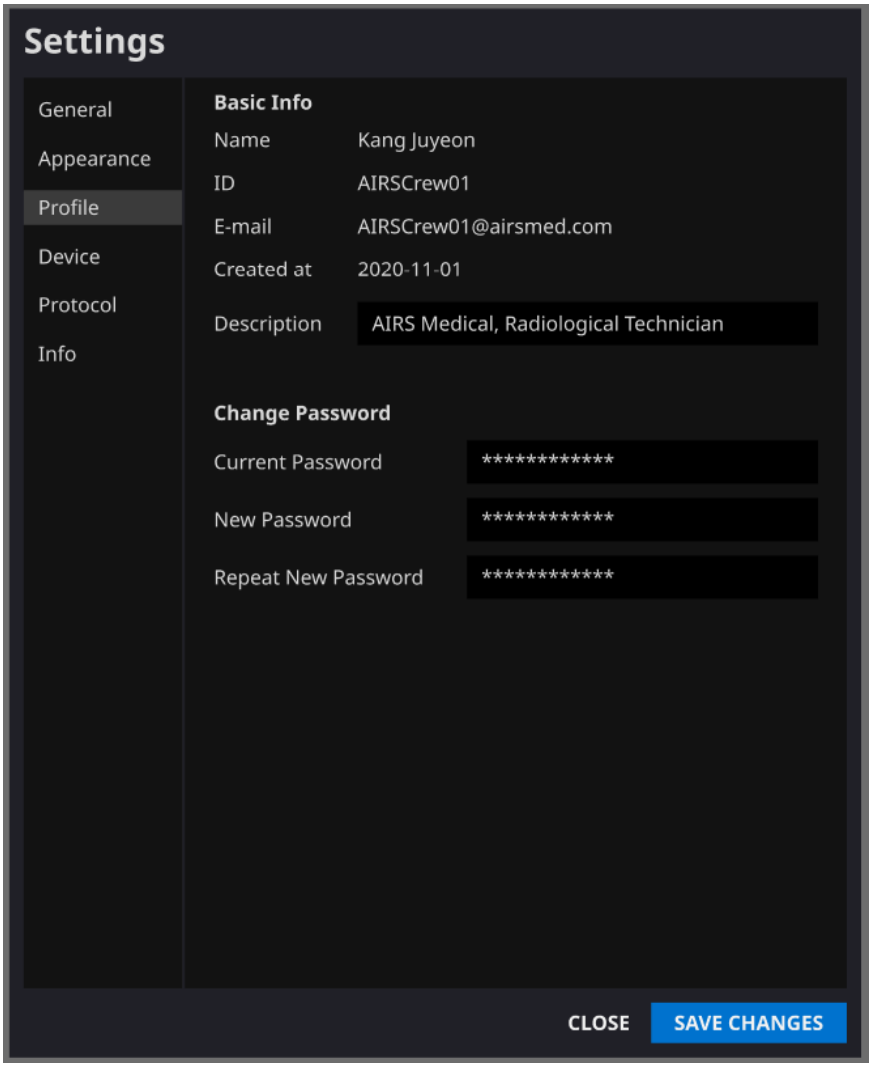
2.7.2. Appearance Settings

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



2.7.3. Profile Settings 

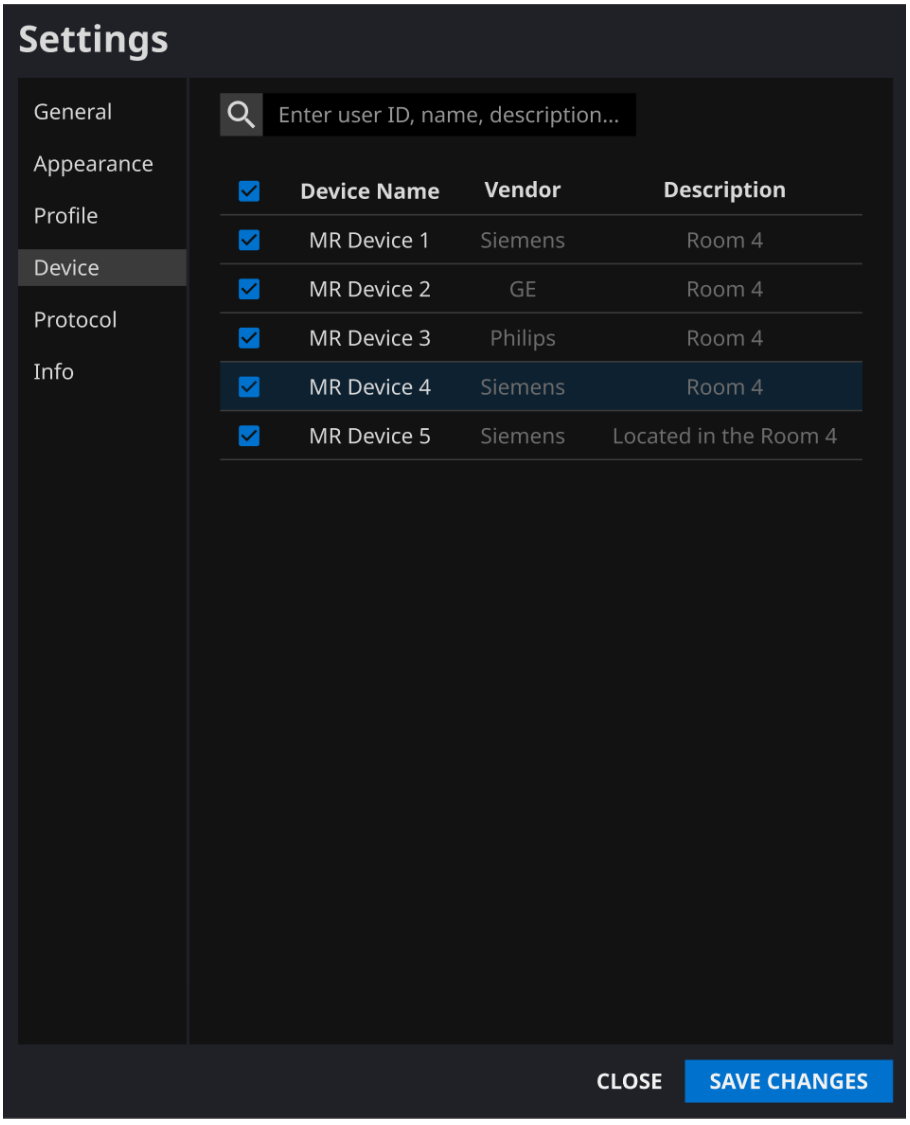
- Users can retrieve his/her own profile and modify it by clicking Profile or from Profile tab of Settings.
- Users can change his/her password by entering the previous password and new password.
- When done, click **SAVE CHANGES**.



Note	**Note:** Only English is supported in the Description field.
Note	**Note:** Password must satisfy the string rule of at least 8 characters including 1 letter, 1 number, and 1 special symbol.

2.7.4. Device Settings

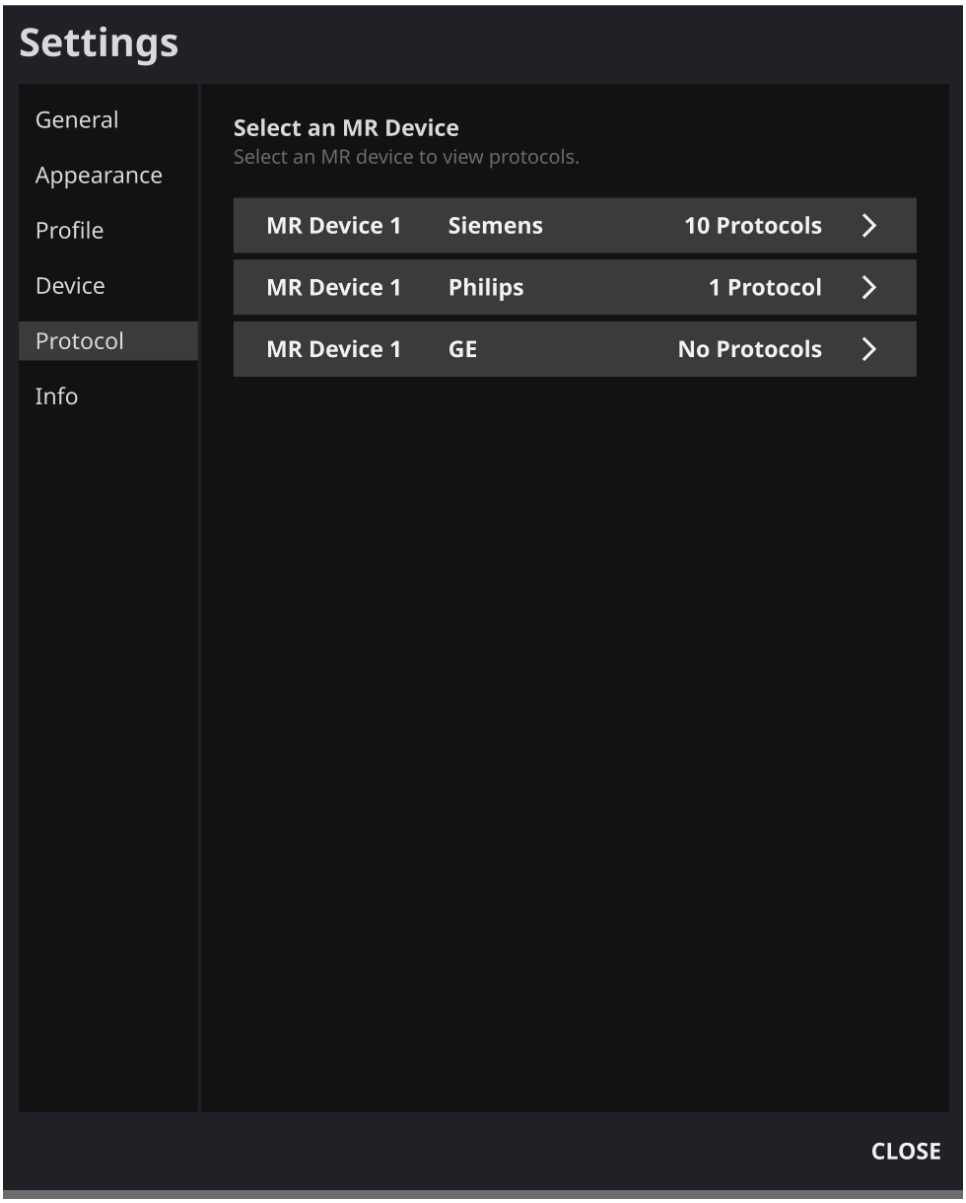
- Users can select the MR devices to receive notifications for image processing results among the comprehensive list of registered MR devices for the institution from Device tab of Settings.
- All registered MR devices are selected by default.
- **Unselect**: Uncheck the device and click **SAVE CHANGES**.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

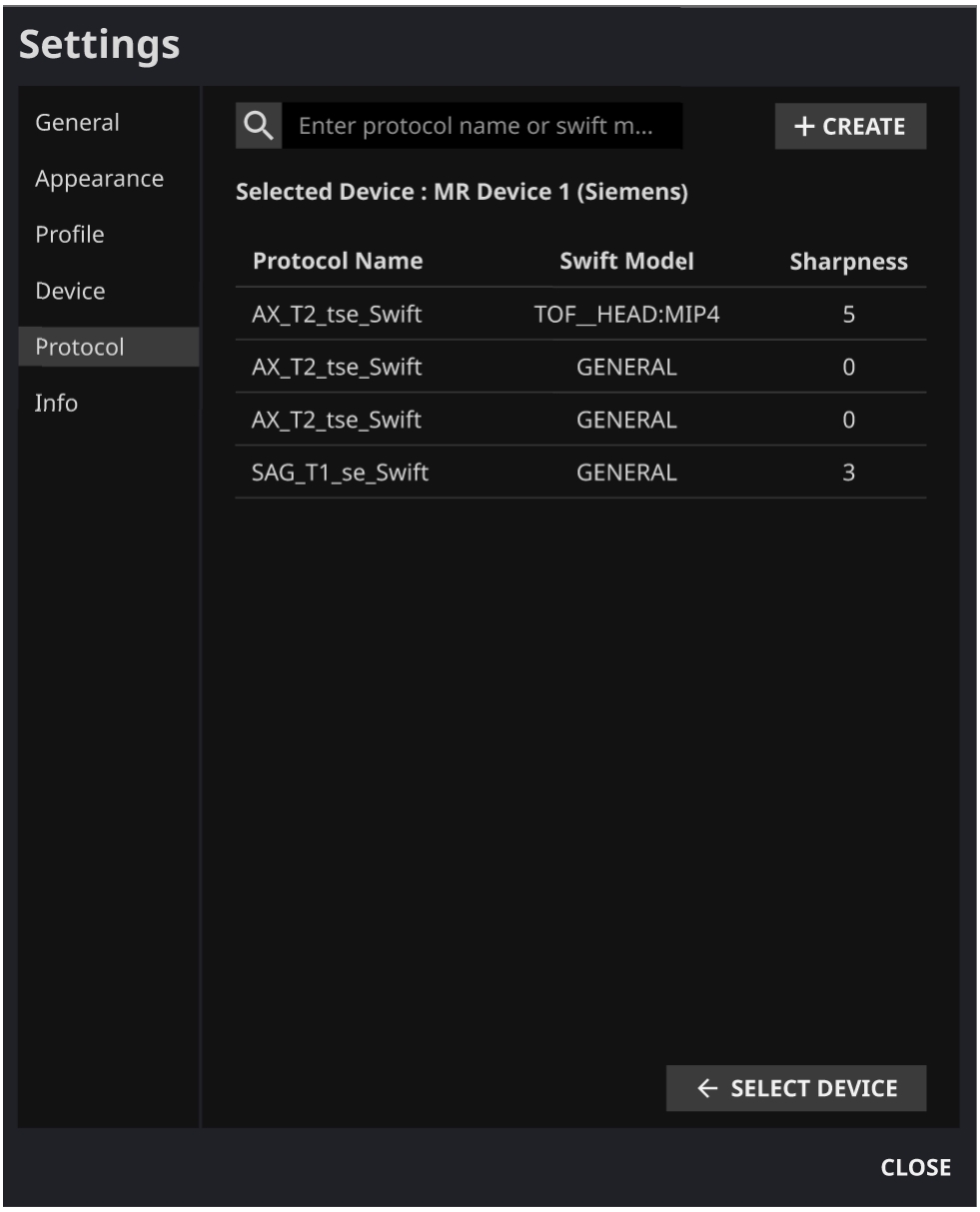


Note	**Note:** Each user can select multiple MR devices to receive notification for. For example, a radiological technician in charge of MR Device 1 and 2 can select the two devices to receive notifications only for those two devices.

2.7.5. Protocol Settings

- Users can view the protocol settings for SwiftMR processing per MR Device from the Protocol tab of Settings.
- 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.
- Contact Customer Support (support@airsmed.com) to modify protocol settings.

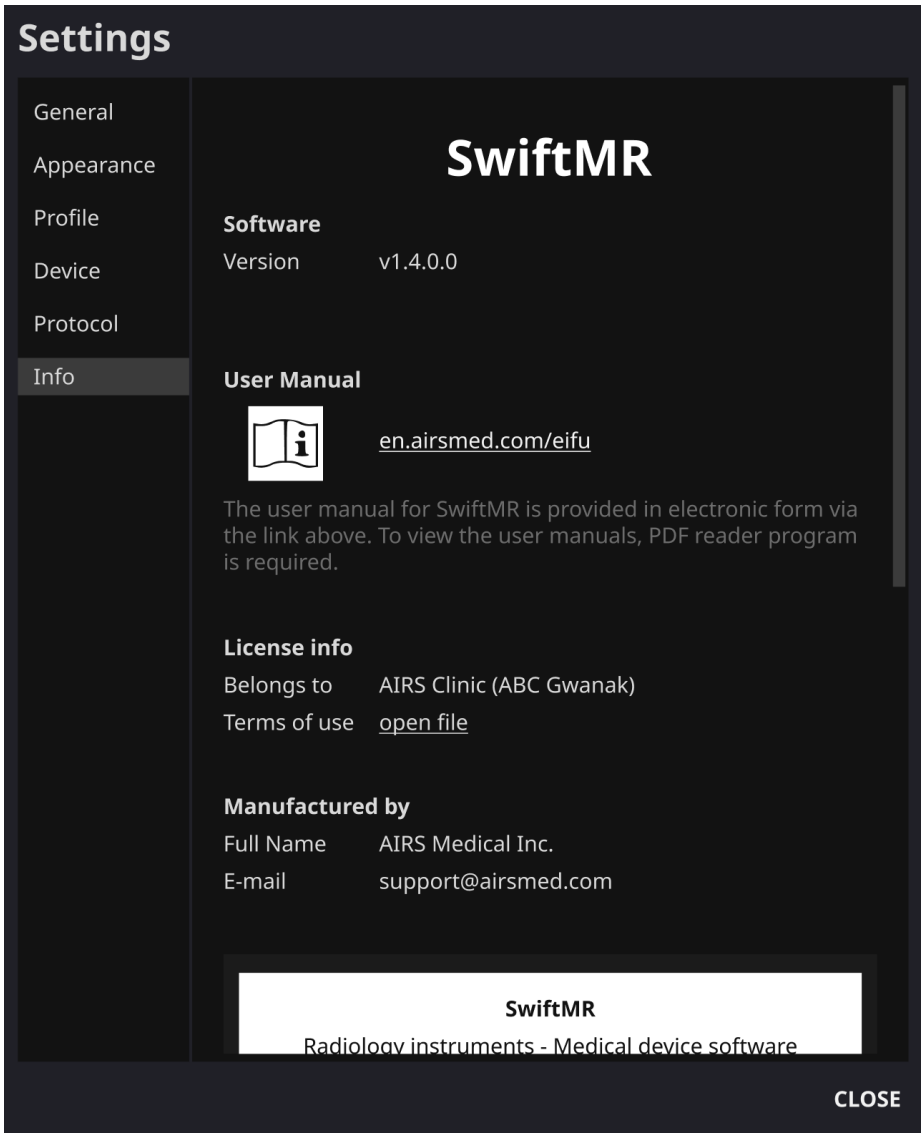




⚠	**Caution:** Users should scan images with supported scanner model, pulse sequences, and scan parameters. Otherwise, image processing performance cannot be guaranteed.
⚠	**Caution:** Image processing will not be proceeded if the applicable protocol rules are not registered properly. Please do not make diagnostic judgments on images that have not been processed as intended. Contact Customer Support (support@airsmed.com) to request for modifications on protocol rule settings.

2.7.6. 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. User manuals for SwiftMR are provided in electronic form via the link displayed in the software information settings.



2.8. Image Processing

2.8.1. General Information

- The intended patient population is adults over 21 years of age.
- MRI scanning is performed using the scan protocols provided by AIRS medical. Before scanning, select the MR Device that is planned to be used in the protocol settings of the Client application, and check whether the applicable protocol name for the scan is registered on the UI. If the protocol name is correctly registered, only then proceed with the scan.

- After the SwiftMR cloud receives the original MR images from PACS or MR Device, the images are processed using SwiftMR's deep learning model. The processed image files are again saved in PACS in the form of DICOM files, and at this time, they can be saved as a new series in an existing study, or as an independent study. This save option can be determined during the discussion between the institution and AIRS Medical prior to bonding a contract.
- When the image processing is completed, you can check that the processing has been completed through a toast message in the client application. SwiftMR does not provide a separate viewer program, so please use the existing DICOM image viewer to view the images.
- SwiftMR applies the denoising function to the original image and additionally applies the sharpening function to it. The degree of noise reduction is single and the user cannot select it. Sharpening has 0-5 levels depending on the degree of sharpness increase.
- In level 0, the sharpening function is not applied to the image, only the denoising function is applied. In steps 1 to 5, the sharpening function is applied to the images that are already denoised by the deep learning model. The higher the sharpening level, the sharper the processed image. However, since the sharpening function sharpens the entire image, there is a risk of amplifying the residual artifacts included in the image as the sharpening level gets higher. In addition to this, the higher the sharpening level, the higher the image contrast compared to a normal MRI image, so it may look unnatural. Even if a low sharpening level is selected, a desired degree of image enhancement can be obtained depending on the user. When setting the protocol, the user should contact the Customer Support (support@airsmed.com) to select the desired sharpening level.
- The sharpening level is not user selectable, but our service engineer selects it. The sharpening level can be set from level 0 to 5 irrespective of the imaging protocols. The initial value of sharpening level is set according to the user's request. If you want to change the sharpening level, please contact Customer Support (support@airsmed.com).
- 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. 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. For sharpness, SwiftMR decreases FWHM of the tissue boundaries by 0.43% (level 1), 1.7% (level 2), 2.3% (level 3), 3.6% (level 4), 4.5% (level 5) or more for at least 90% of the dataset.
- Noise reduction performance was validated by comparing the original image and the image to which the denoising function was applied (ie, the image to which the sharpening function level 0 was applied).
- 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.
- The range of bodyparts and pulse sequences supported by SwiftMR is as follows. For scan parameters such as tr, te, slice thickness, resolution, and acceleration factor, SwiftMR can be applied as long as it is within the range normally used when scanning SOC images for each bodypart and pulse sequence.

- Brain

Vendor	Field Strength	2D Pulse Sequence									3D Pulse Sequence			
		AX T1	AX CE T1	AX T2	AX FLAIR	AX GRE	SAG T1	SAG CE T1	COR CE T1	CORT2	AX TOF	AX SWI	AX 3D T1	SAG 3D T1
SIEMENS	1.5T	v	v	v	v		v	v	v		v	v		v
	3T	v	v	v	v		v	v	v		v	v	v	
GE	1.5T	v	v	v	v		v	v	v				v	v
	3T	v	v	v	v	v	v	v	v	v	v		v	
PHILIPS	1.5T	v	v	v	v		v	v	v				v	
	3T	v	v	v	v		v	v	v		v	v	v	

- C-spine (All sequences are 2D)

Vendor	Field Strength	AX T1	AX CE T1	AX T2	AX T2 FS	SAG T1	SAG CE T1	SAG T2	SAG T2 FS
SIEMENS	1.5T	v		v		v		v	v
	3T		v	v		v	v	v	v
GE	1.5T			v		v		v	v
	3T		v	v	v	v	v	v	v
PHILIPS	1.5T		v	v	v	v	v	v	v
	3T			v	v	v		v	v

- T-spine (All sequences are 2D)

Vendor	Field Strength	AX T1	AX CE T1	AX T2	AX T2 FS	SAG T1	SAG CE T1	SAG T2	SAG T2 FS
SIEMENS	1.5T	v		v		v		v	
	3T	v	v	v		v	v	v	
GE	1.5T	v		v		v		v	v
	3T		v				v		
PHILIPS	1.5T	v	v	v	v	v	v	v	v
	3T	v	v	v	v	v	v	v	v

- L-spine (All sequences are 2D)

Vendor	Field Strength	AX T1	AX CE T1	AX T2	AX T2 FS	SAG T1	SAG CE T1	SAG T2	SAG T2 FS
SIEMENS	1.5T	v		v	v	v		v	v
	3T		v	v		v	v	v	v
GE	1.5T	v		v		v		v	
	3T		v	v	v	v	v	v	v
PHILIPS	1.5T			v	v	v		v	v
	3T	v	v	v		v	v	v	v

- Knee (All sequences are 2D)

Vendor	Field Strength	AX T1	AX CE T1	AX T2	AX PD	AX T2 FS	AX PD FS	SAG T1	SAG CE T1	SAG T2	SAG PD	SAG T2 FS	SAG PD FS	COR T1	COR CE T1	COR T2	COR PD	COR T2 FS	COR PD FS
SIEMENS	1.5T		v				v	v		v			v	v		v	v	v	v
	3T		v		v		v	v	v	v			v		v	v	v	v	

GE	1.5 T						v				V	v		v					v
	3T																		
PHILIPS	1.5 T	v	v	V		v	v	v	v	v			v		v	v	v	v	
	3T			v	v	v	v	v		v	v	v	v	v		v	v	v	v

- Shoulder (All sequences are 2D)

Vendor	Field Strength	AX T1	AX CE T1	AX T2	AX PD	AX T2 FS	AX PD FS	SAG T1	SAG CE T1	SAG T2	SAG PD	SAG T2 FS	SAG PD FS	COR T1	COR CE T1	COR T2	COR T2 FS	COR PD FS
SIEMENS	1.5T			v			v	v				v	v					
	3T		v				v	v				v		v	v		v	
GE	1.5T						v			v		v				v		v
	3T	v	v			v	v	v	v			v		v	v		v	
PHILIPS	1.5T		v				v	v	v			v		v	v		v	
	3T		v	v	v		v	v	v	v	v	v	v	v	v		v	v

- Ankle (All sequences are 2D)

Vendor	Field Strength	AX T1	AX CE T1	AX T2	AX PD	AX T2 FS	AX PD FS	SAG T1	SAG CE T1	SAG T2	SAG PD	SAG T2 FS	COR T1	COR CE T1	COR T2	COR PD	COR T2 FS	COR PD FS
SIEMENS	1.5T	v	v				v			v	v					v		
	3T	v	v	v		v		v	v	v		v		v	V		v	
GE	1.5T	v		v		v	v	v		v		v	v		V	v	v	v
	3T	v		v		v		v		v		v	v		V		v	
PHILIPS	1.5T		v	v		v		v	v	V		v	v	v	V		v	
	3T	v	v	v	v	v		v	v	V		v	v	v	V		v	

- Hip (All sequences are 2D)

Vendor	Field Strength	AX T1	AX CE T1	AX T2	AX T2 FS	AX PD FS	SAG CE T1	SAG T2	SAG T2 FS	COR T1	COR CE T1	COR T2	COR T2 FS
SIEMENS	1.5T						v				v		
	3T	v		v	v			v	v	v		v	v
GE	1.5T	v		v		V		v	v	v		v	v
	3T												
PHILIPS	1.5T	v		v	v			v	v	v		v	v
	3T	v	v	v	v			v	v	v	v	v	v

2.8.2. About Sharpness Increase Function

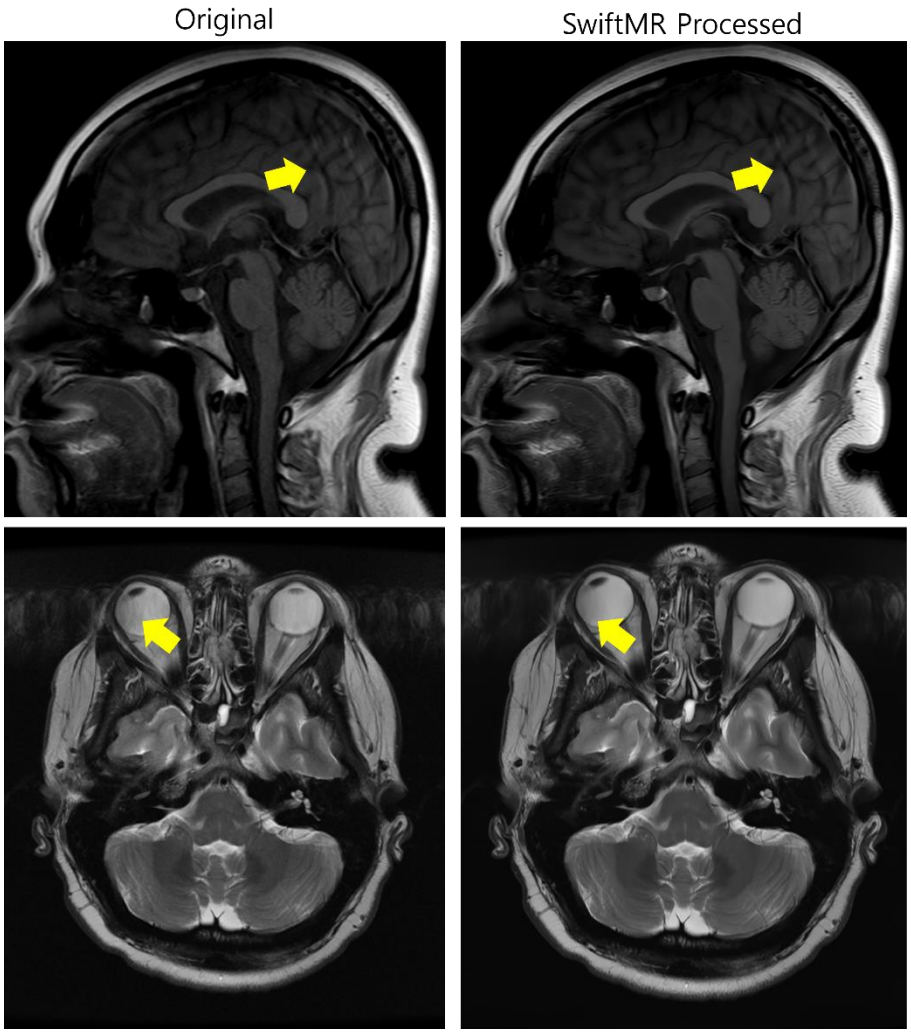
- We used FWHM (Full Width Half Maximum) of structure boundaries as an index to validate the sharpness increase performance of the product. A decrease in FWHM means an increase in sharpness.
- The acceptance criteria for FWHM reduction rate for individual data was 0.43% (level 1), 1.7% (level 2), 2.3% (level 3), 3.6% (level 4), 4.5% (level 5). Although all test groups passed the criteria, the degree of sharpness increase may sometimes not be appreciable as the acceptance criteria values are not large.

- The average FWHM decrease rate and 95% CI for each test group are as follows:

Test Group	Avg FWHM decrease rate (%)
GE 1.5T (level 1)	8.15±16.36
GE 1.5T (level 2)	19.01±23.13
GE 1.5T (level 3)	30.64±29.04
GE 1.5T (level 4)	34.79±28.55
GE 1.5T (level 5)	43.08±30.94
GE 3.0T (level 1)	9.74±15.90
GE 3.0T (level 2)	17.73±20.87
GE 3.0T (level 3)	28.74±25.30
GE 3.0T (level 4)	38.78±29.17
GE 3.0T (level 5)	40.94±30.48
PHILIPS 1.5T (level 1)	5.45±10.91
PHILIPS 1.5T (level 2)	13.10±18.12
PHILIPS 1.5T (level 3)	21.56±22.65
PHILIPS 1.5T (level 4)	28.25±26.30
PHILIPS 1.5T (level 5)	32.34±27.17
PHILIPS 3.0T (level 1)	6.69±15.21
PHILIPS 3.0T (level 2)	13.65±18.81
PHILIPS 3.0T (level 3)	21.17±19.60
PHILIPS 3.0T (level 4)	27.19±21.71
PHILIPS 3.0T (level 5)	32.81±24.76
SIEMENS 1.5T (level 1)	19.91±28.69
SIEMENS 1.5T (level 2)	25.55±29.45
SIEMENS 1.5T (level 3)	33.70±30.45
SIEMENS 1.5T (level 4)	38.65±30.10
SIEMENS 1.5T (level 5)	41.91±31.89
SIEMENS 3.0T (level 1)	9.20±18.30
SIEMENS 3.0T (level 2)	15.34±21.71
SIEMENS 3.0T (level 3)	20.08±21.41
SIEMENS 3.0T (level 4)	26.53±25.91
SIEMENS 3.0T (level 5)	29.38±25.72

2.8.3. Caution – 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 2.8.1 for details.

2.8.4. Note – TOF pulse sequence

Note 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 2.8.1 for details.

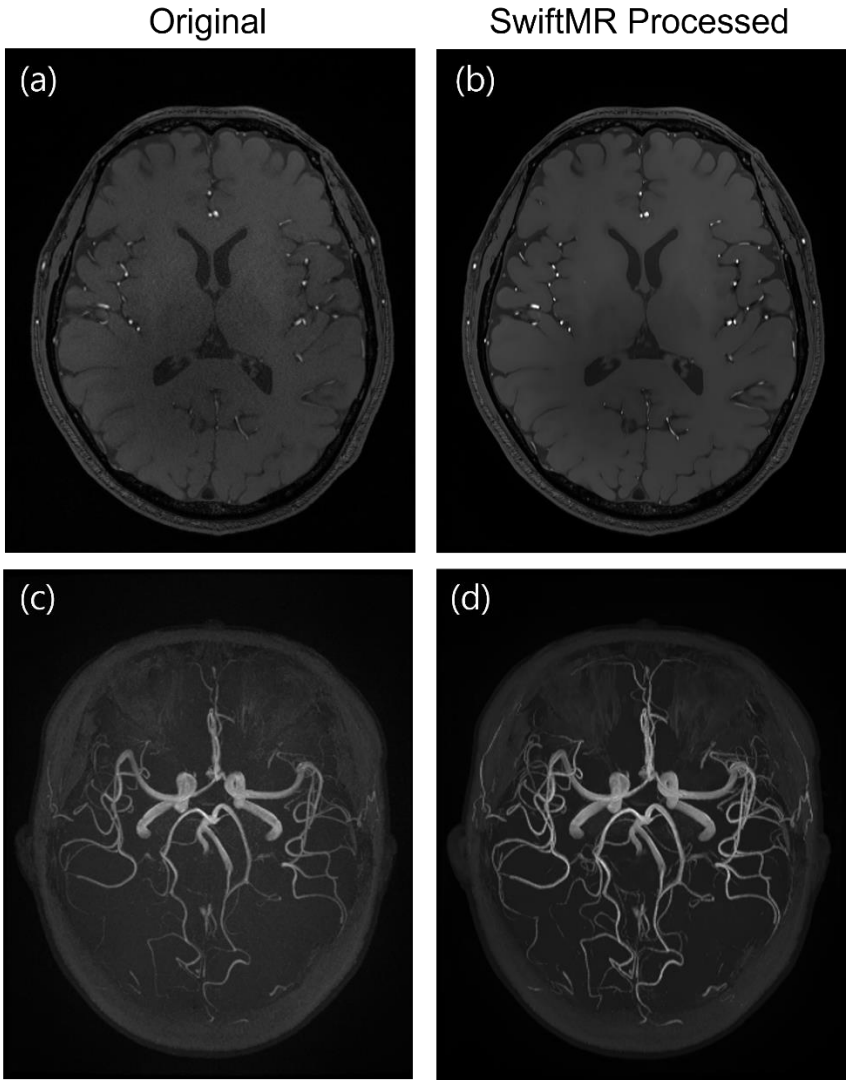


Figure. (a), (b): Slice image before and after SwiftMR processing. (c), (d): MIP image before and after SwiftMR processing

3. User Account Management

Passwords of user accounts can be changed in their profile settings (refer to Section 2.7.3). If you want to create a new user account or modify the basic information of an existing user account, please contact our Customer Support team (support@airsmed.com).

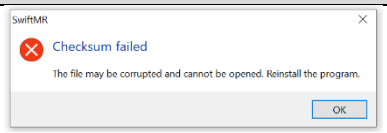
4. Cybersecurity

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.
- SwiftMR has the highest possible security settings selected by default.
- When there is a new update, Users 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, AIRS Medical can disconnect the applicable network (VPN, TLS Proxy, etc.) to protect critical functionalities and data.
- The main settings required to operate SwiftMR are stored in the DICOM Control Server. Therefore, even if a problem occurs in the client application, and reinstallation is performed, the main settings are maintained for intact product operation. The database files of the DICOM Control Server are also backed up, and thus in case of an error emergence, the backed-up database files can be restored to make the product operational.
- Even if a temporary error occurs while using the Client Application, image processing will still operate normally, due to the functioning server programs. DICOM Control Server turns off when the PC shuts down, but it automatically is executed when the PC is turned on again. The images that had not been processed during the time the DICOM Control Server was turned off, will be processed once they are resent to the server. In case of the server programs, uninterrupted operation is guaranteed via automatic restart or executing multiple instances during server shut down.
- Checksum validation is performed each time the SwiftMR application is executed, or when an update is conducted. Through this, the integrity check is performed, and if it is determined that there is a problem in the results, the program will automatically be terminated. In this case, please delete and reinstall the application or contact Customer Support (support@airsmed.com).
- 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 at the last page to contact Customer Support.

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	 File verification failed.	The installed files may be corrupted or missing. Reinstall the program. If that fails, contact the manufacturer.
Network	Network connection status 	The icon indicates disconnection between institution's network and cloud server of SwiftMR. Because it may cause a problem regrading image processing, contact IT manager or manufacturer.
	Automated logout even when the set time for automatic logout has not elapsed.	When the local PC where client application is installed is disconnected from internet, software forces automatic logout. Check your PC internet connection.
Worklist Synchronization	SwiftMR worklist not showing synchronized studies with PACS.	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).

Note	**Note:** 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. Incident Reporting

In case of a serious incident, please contact us through Customer Support (support@airsmed.com) and/or regulatory body that is applicable to the regulations where you have purchased and used SwiftMR.

8. 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@airsmed.com

SwiftMR CE 2460

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