SwiftMR

User Manual

Product Model
A20-CL
Version v3.0.X.X

AIRS MEDICAL

SwiftMR
User Manual, English
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Thank you for using AIRS Medical's Product.

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

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- AIRS Medical Inc. may change or modify the specifications of the product and the contents of the manual without prior notice.

1. Introduction

1.1. Product Overview

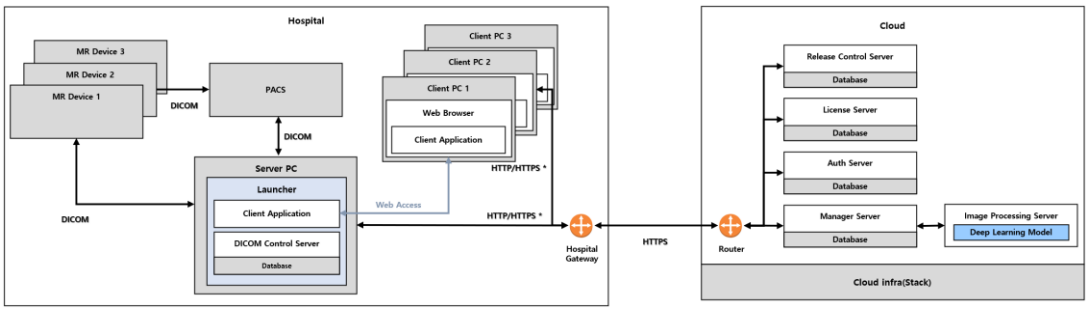
SwiftMR provides automated image quality enhancement for MR images acquired from various environments. This device should be used only for professional purposes.

SwiftMR's automated processes are as follows:

- Uploading MR images in DICOM format after completions of MR scans
- Enhancing image quality using deep learning model
- Downloading enhanced MR images in DICOM format

Integration of PACS inside the institution with the manufacturer's Cloud server is necessary at the first installation of this product. Afterwards, 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 figures below depict the overall architecture of SwiftMR.



- 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 all body parts 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. Limitations

SwiftMR is only available in certain countries.

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/MR Device
  - Enhance image quality
  - Download the enhanced MR images to PACS/MR Device

1.5. Minimum Requirements for the Software Operating Environment

Item	Launcher	Client Application
OS	Microsoft Window 10 64 bit	N/A
Hardware	CPU: Intel i3 above RAM: 4GB and above Storage: 250GB available	N/A
Web Browser	N/A	Google Chrome 92.0.4515 version or later Microsoft Edge 92 version or later
Network	Ethernet-based Intranet/internet connection	
Monitor	N/A	1600X900 resolution with 8-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.
	Lot number. Version number of the software.

1.7. Cautions

- **Warning**
  - SwiftMR is designed for trained radiology technologists. Those who are not trained should not use this product.
  - Images that have already been quality-enhanced should not be processed again. This may cause damage to the images.

- **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 follows the user manual. Please preserve this user manual well.

- **Caution for Use**
  - Check before use to see if the Quality Check, that the system conducts automatically at a specified time each day or conducted manually, has successfully been completed.
  - Do not turn off the power of the PC or programs during use.
  - After use, be sure to log out of the program.

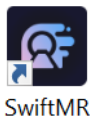
1.8. Abbreviations

The following is the definitions of the abbreviations used in this User Manual.

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

2. Functions

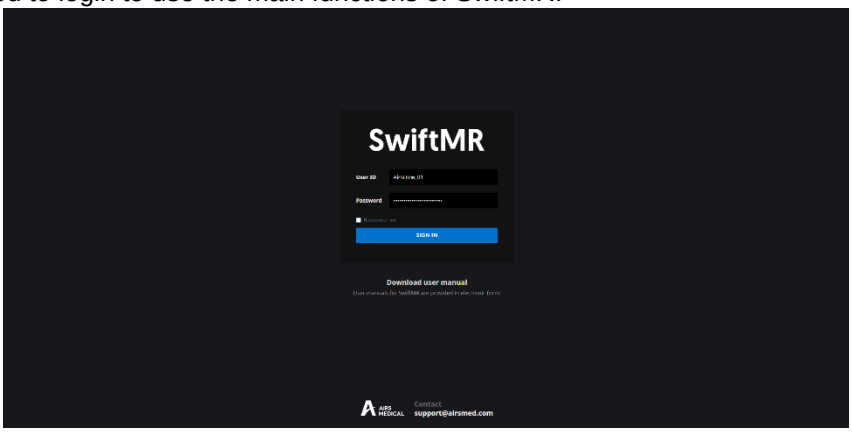
Client Application can be accessed through Google Chrome or Microsoft Edge browser in the hospital where SwiftMR is installed. You can access it through *[SwiftMR server's IP address in the hospital]: 50000/swiftmr-client* or the shortcut icon created during the installation process.



The main functions of the Client Application are as follows.

2.1. Login and Logout

You need to login to use the main functions of SwiftMR.



- **Login:** Enter ID and password provided by AIRS Medical and then click **SIGN IN**. When login succeeds, the main page of SwiftMR will appear.
- **Logout:** You can log out from SwiftMR to prevent unauthorized access by clicking the Logout button (

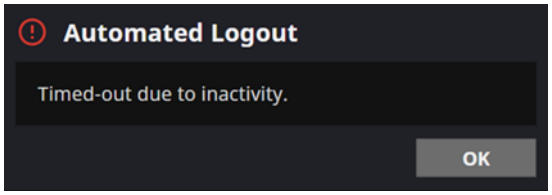
). When logout succeeds, you will be directed to the login page.
- **User Manual:** You can access the e-IFU download page of AIRS Medical by clicking on the "Download user manual" button (

).

Note	**Note:** User account is created by **AIRS Medical**. After an account is created, you will be able to use it after resetting the password upon first login.
⚠	**Caution:** If login fails because an invalid ID or password was entered into the input field, an error message will show up. If you forget your ID or password, contact Customer Support (support@airsmed.com).
⚠	**Caution**: SwiftMR does not allow simultaneous logins of the same account. If you try to login to an already logged-in account, the previously accessed session will be terminated.
⚠	**Caution:** When login attempts fail 10 times, the user is restricted from login for the next 5 minutes.
⚠	**Caution:** Please contact Customer Support (support@airsmed.com) if you cannot access the eIFU download page.

2.2. Automated Logout

Users inactive for a certain period will be automatically logged out from SwiftMR to prevent unauthorized access. In the event of an automated logout, a Toast Message will appear and the screen will return back to the login page.

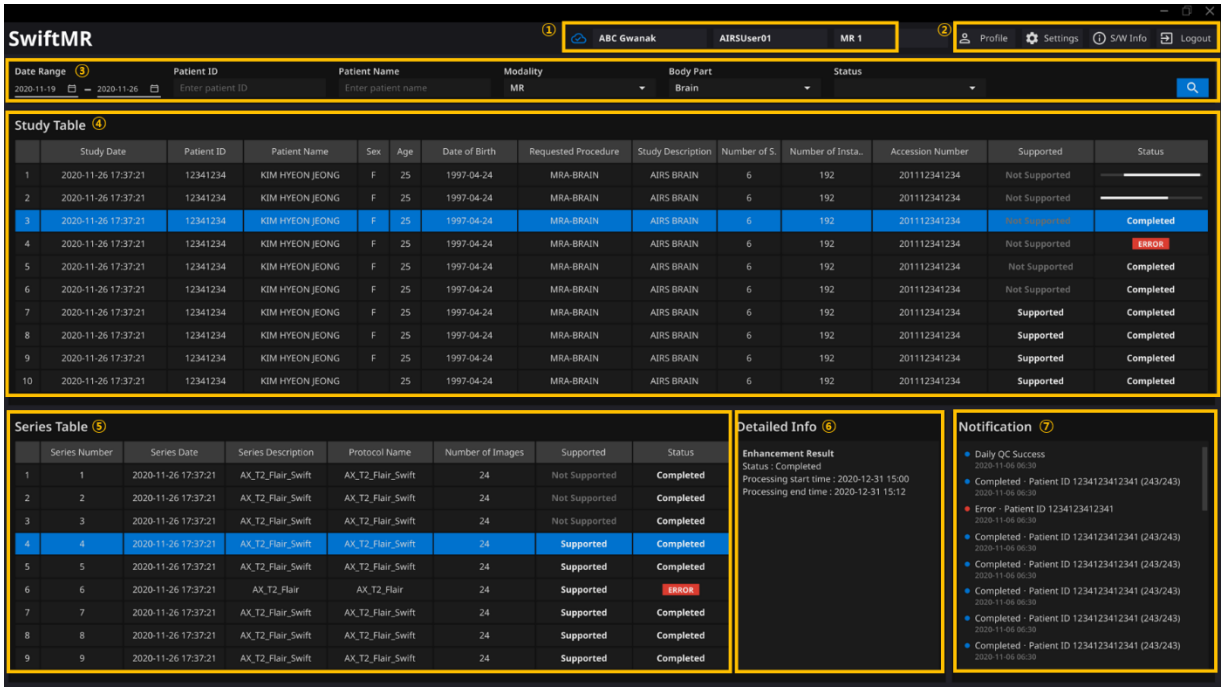


The Toast Message for automated logout disappears after a certain period, or it can be removed by clicking the **OK** button at the top right corner.

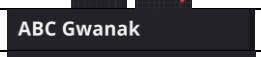
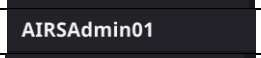
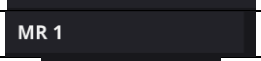
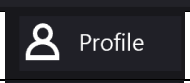
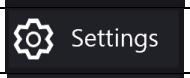
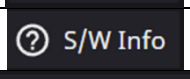
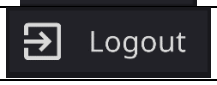
2.3. Main Page

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 easily search for an image of interest, and view 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 the Detailed Info section.



Detailed functions are as follows.

No	Function	Item	Description
1	Status Bar		Network connectivity status
			Institution name
			Name of the accessed user
			Name of the connected MR device(s)
2	User Menu		User Profile
			Software settings
			Software information
			Logout
3	Filter/Search	Data Range	Function to search the worklist by date range.
		Patient ID	Function to search the worklist by patient ID
		Patient Name	Function to search the worklist by patient name
		Modality	Function to search the worklist by modality
		Body Part	Function to search the worklist by body part
		Status	Function to search the worklist by image processing status
			Button to execute the search by the selected conditions
4	MR Study Table	Study Date	Study scan date (Year-Month-Day)
		Patient ID	Patient ID
		Patient Name	Patient name
		Sex	Patient sex
		Age	Patient age
		Date of Birth	Patient date of birth (Year-Month-Date)
		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 status • In Progress • Completed • Error
5	MR Series Table	Series number	Sequence number of the series within the study selected from the study table
		Series Date	Scan date of each series
		Series Description	Detailed description of the scanned sequences for each series
		Protocol Name	Protocol name of the scanned sequences for each series
		Number of Images	Total number of images in a series

		Supported	Image process support
		Status	Image processing status of the series
6	Detailed Info	Enhancement Result	Enhancement result • Status: Completed, Error • Processing start time • Processing end time
7	Notification	Notification	Notification window displaying image processing status, Daily QC results, etc.

⚠	**Caution**: The network connection status icon shows the connection between the institution's network and the cloud server of SwiftMR. If a problem occurred with the internet connection of the PC running the software, you will not be able to check this through the network connection status icon, and you will be automatically logged out.
⚠	**Warning**: When network connection status icon is marked red, it may cause problems regarding image processing. Resolve the problem as soon as possible by contacting the IT manager or the manufacturer.
⚠	**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 selected MR devices.
⚠	**Caution:** Personal information stored in SwiftMR is anonymized 24 hours after registration. Use the PACS Viewer to inquire patient information about MR studies processed by the product.

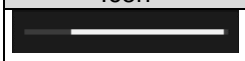
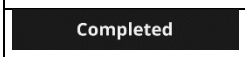
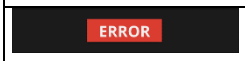
2.4. Image Processing Availability

- Image processing availability is classified as follows.

Icon	Description
Supported	**Image Processing - Supported** • **Study Table:** If there is at least one SwiftMR-supported series among the series in the applicable study, the "Supported" icon will be displayed. • **Series Table:** If the series is supported by SwiftMR, then the "Supported" icon will be displayed.
Not Supported	**Image Processing – Not Supported** • **Study Table:** If there is no SwiftMR-supported series among the series in the applicable study, the "Not Supported" icon is displayed. • **Series Table:** If the series is not supported by SwiftMR, then the "Not Supported" icon will be displayed.

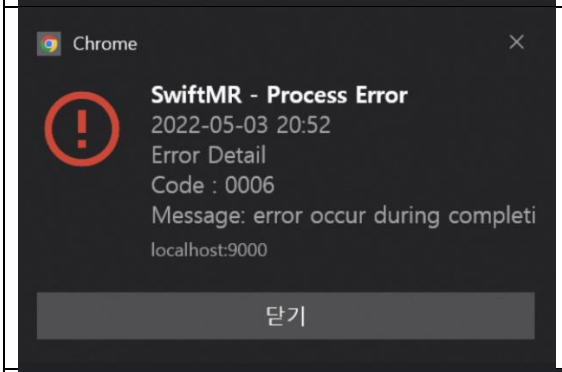
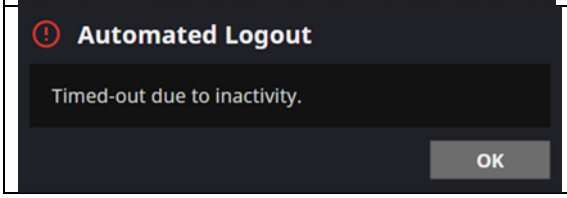
2.5. Image Processing Status

- Image processing status is classified as follows.

Icon	Description
	**In progress** Image processing progress is indicated with a progress bar
	**Completed** • **For Supported Studies:** Indicates that image processing has been completed and that the processed images are successfully stored to the selected DICOM AE (PACS, MR Device). • **For Not Supported Studies** Indicates that unsupported images are successfully stored to the selected DICOM AE (PACS, MR Device).
	**Error** An error occurred during image processing.

2.6. 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:

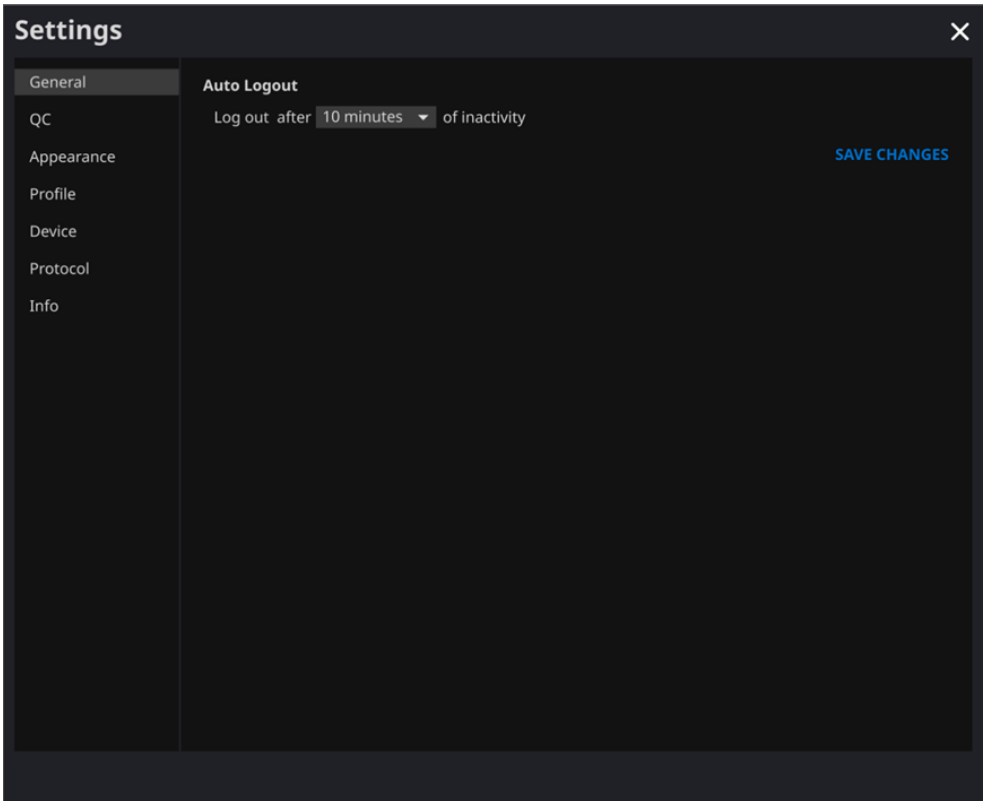
Toast Message	Description
	Image processing complete.
	Image processing failed.
	Automated logout.

2.7. Settings

Users can open settings by clicking on the software preferences button (Settings). Users can set various environment settings related to software operation in the software settings window. Software settings of the user consists of General, QC, Appearance, Profile, Device, Protocol, and Info tabs.

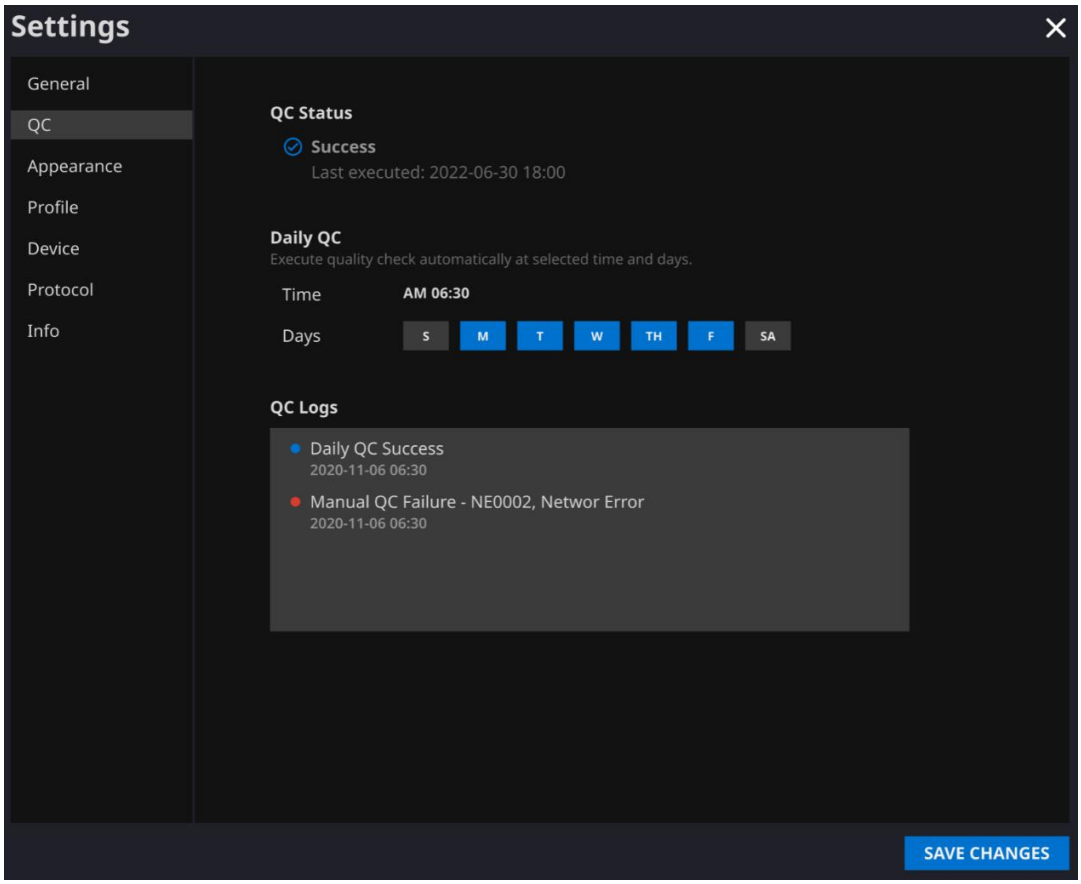
2.7.1. General Settings

- **Auto logout time settings:** User can set the automated logout time from the General tab of Settings. Choose the time of the inactive period in which automated logout will occur afterwards from the drop-down menu and click on the **SAVE CHANGES** button.



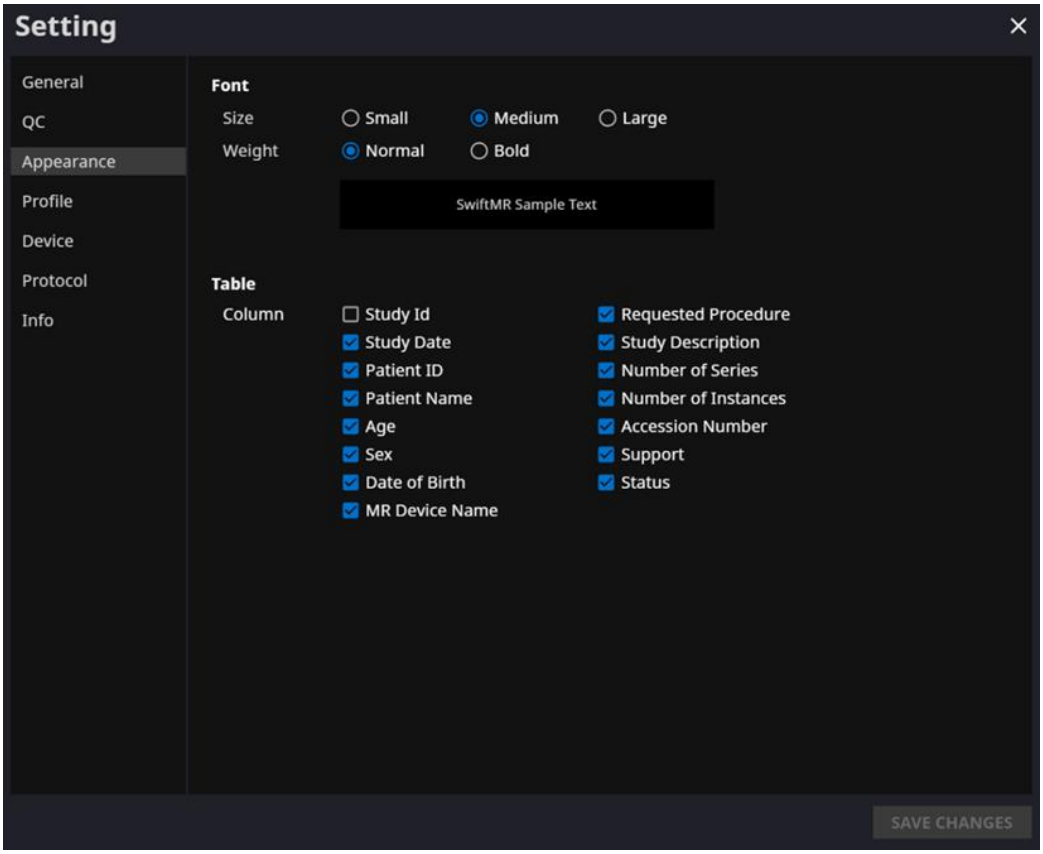
2.7.2. Quality Check (QC) Settings

- User can view the Quality Check settings and the results from the QC tab of Settings
    - **QC Status:** User can check the results and time of the most recently performed QC.
    - **Daily QC:** User can check how the QC time is set.
    - **QC Logs:** User can view the notifications regarding QC results.

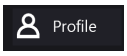


2.7.3. Appearance Settings

- User can set the appearance of the main page from the Appearance tab of Settings.
    - **Font**:
      Size – Choose from Small, Medium, and Large
      Weight – Choose between Normal and Bold
    - **Table:** Select the columns to be shown in Worklist Table.
- After establishing the settings, click on the **SAVE CHANGES** button.

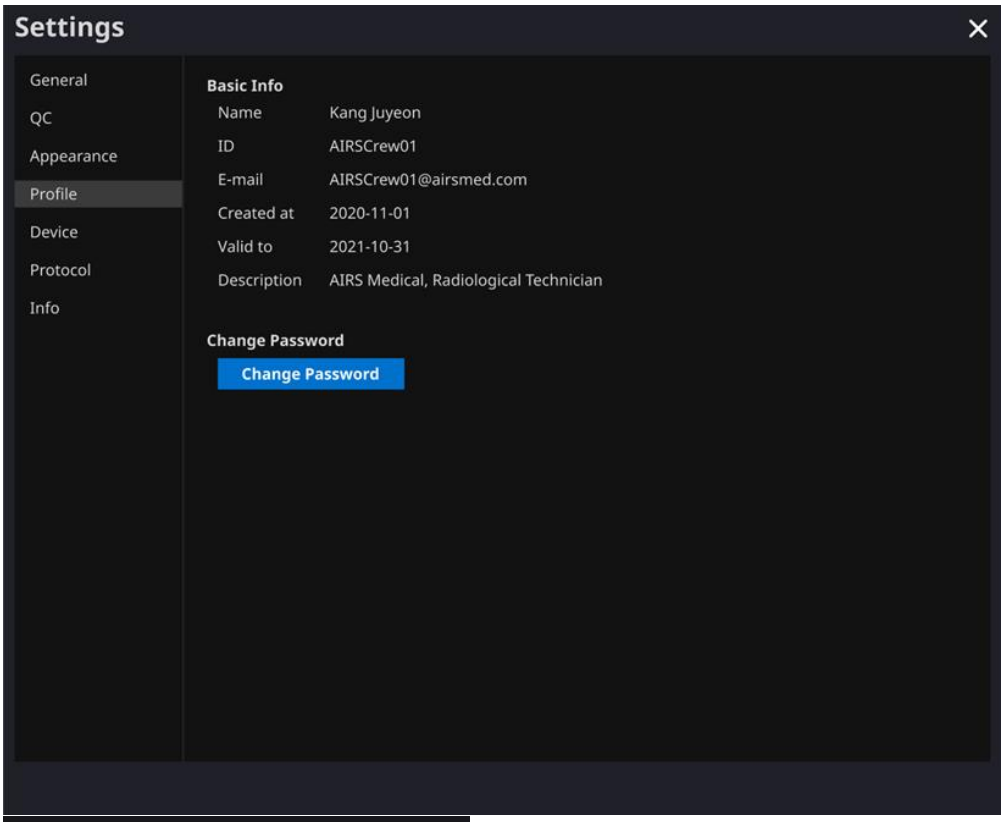


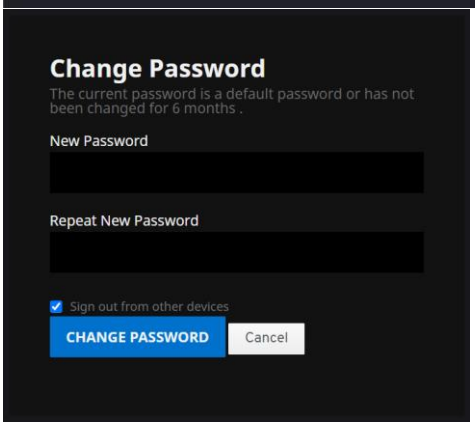
2.7.4. Profile Settings

- User can view or modify his/her own profile by clicking on the Profile button (

) or from the Profile tab of Settings.
- User can access the password change page through the password change button (

) and change the user's password from the password change page.
- After establishing the settings, click on the **SAVE CHANGES** button.

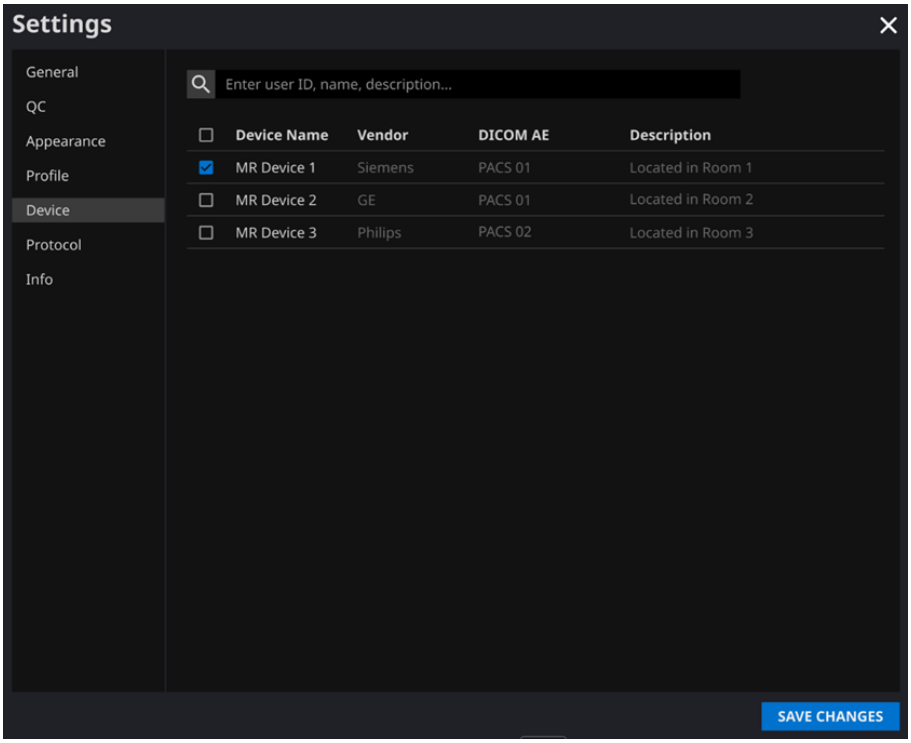




Note: Password must satisfy the password policy of having at least 8 characters including 1 letter, 1 number, and 1 special symbol.

2.7.5. Device Settings

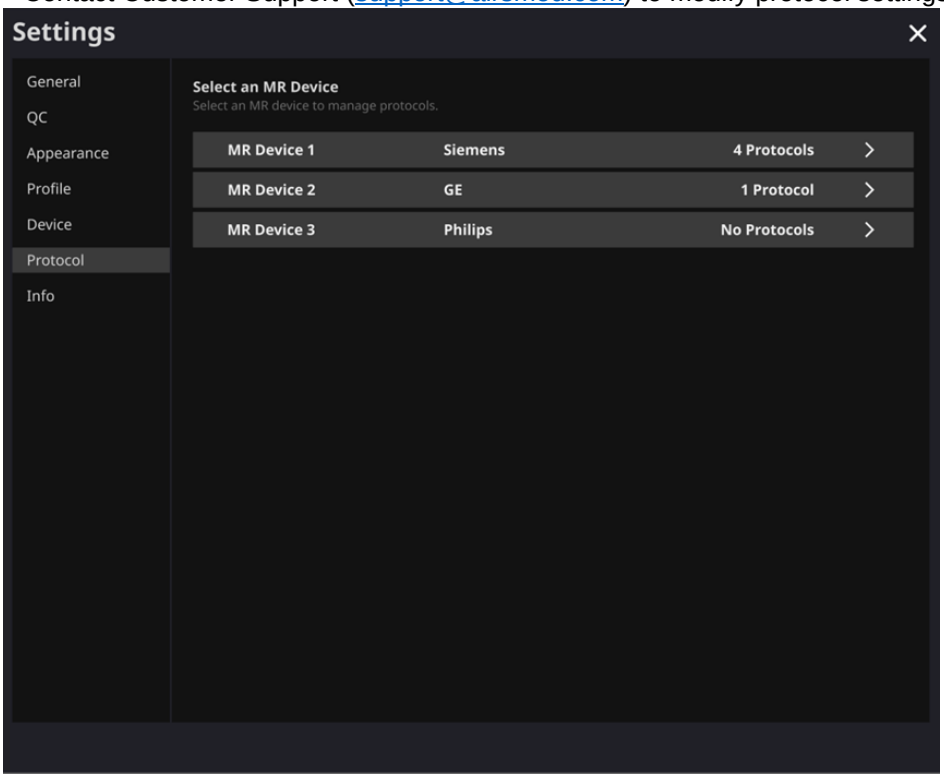
- Users can select the MR devices to receive notifications for image processing results among the list of registered MR devices from Device tab of Settings.
- All registered MR devices are selected by default.
- **Unselect**: Uncheck the device and click **SAVE CHANGES**.
- **Select**: Check the device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

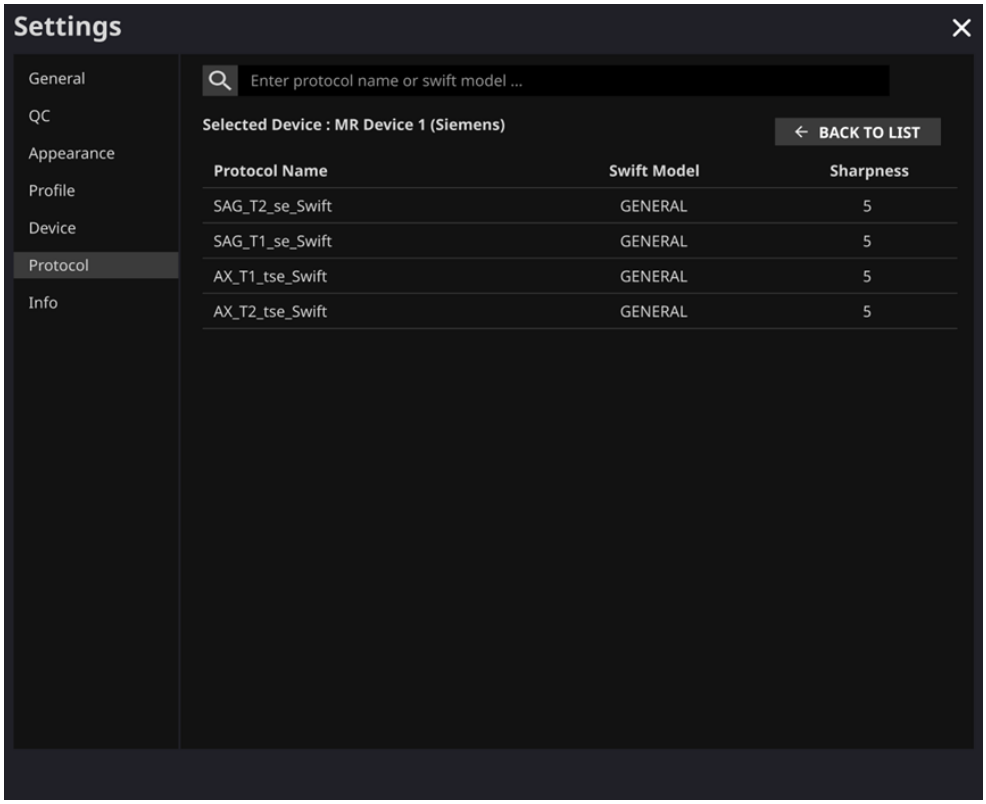


Note: Each user can select multiple MR devices to receive notifications for.

2.7.6. Protocol Settings

- Users can view the SwiftMR image processing standard protocols, set for the applicable MR Device by selecting the desired device in 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.
- The Denoising Level and Sharpness Level to be applied during the image quality improvement process can be set through Customer Support.
- Please check the protocols for image processing before using SwiftMR.
- Contact Customer Support (support@airsmed.com) to modify protocol settings.

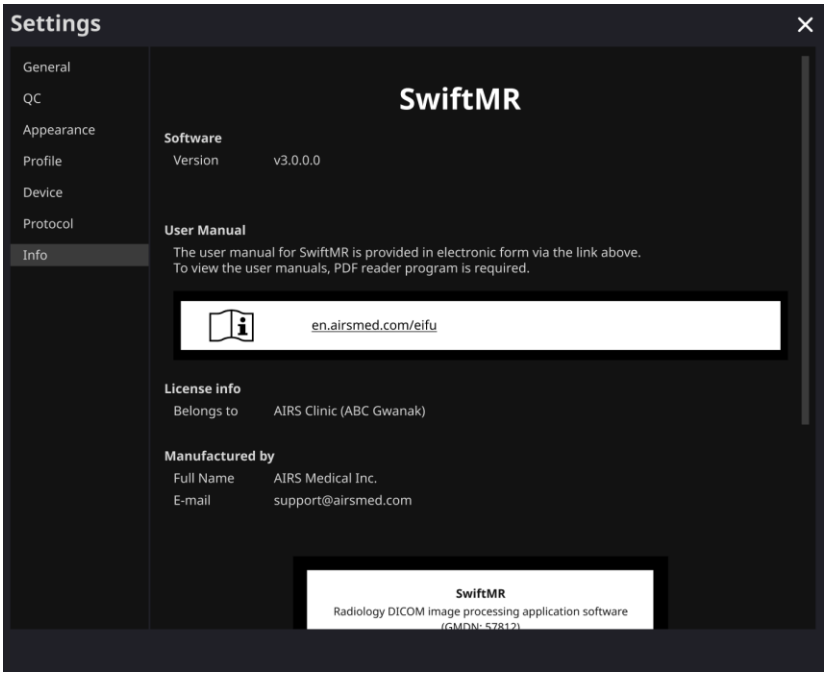


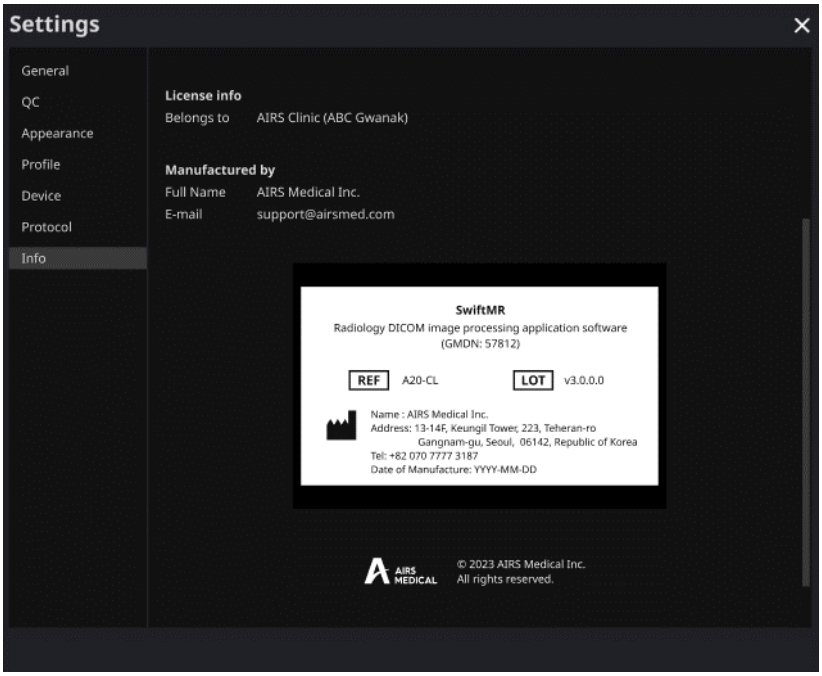


Caution: If the input MR images were not obtained with the recommended MR imaging settings, there may be performance degradation in the resulting processed images.

2.7.7. Info Settings

Users can view user manual, information of the license in use, software information, and manufacturer information by clicking on the **S/W Info** (S/W Info)button or from the Info tab of Settings.





2.8. Image Processing

2.8.1. General Information

- The intended patient population is all ages.
- The imaging is performed using the MRI scan protocols provided by the manufacturer. Before scanning, select the appropriate MR device in 'Settings → Protocol' from the Client Application, check whether the protocol name for the scan is registered and displayed on the UI, and then proceed with the MRI scan. When scan is finished, the images are sent to the SwiftMR server through a specified path.
- When images are received at the SwiftMR server, image processing is conducted using SwiftMR's deep learning model. The processed images are automatically saved in PACS in the form of DICOM files, and they can be saved as a new series in an existing study, or as an independent study that can be created and saved in PACS. The preference of this option will be defined during the discussion between the institution and the manufacturer prior the contract.
- When image processing is completed, this can be informed through a notification from the Client Application. SwiftMR does not provide a viewer program, so please use the existing DICOM image viewer used by the institution for viewing the images.
- SwiftMR applies the denoising function to the original image and additionally applies the sharpening function to it. The degree of noise reduction by deep learning model is single and the user cannot select it. The degree of sharpness increase by deep learning model is single and the user cannot select it. The degree of sharpness increase by sharpening filter has 0-5 levels depending on the sharpening filter of SwiftMR.
- Denoising function can be set to be turned off or set to increase the SNR by more than 40%, only our service engineers can adjust the settings.
- When denoising function is turned off, the denoising function by deep learning model is not applied to the image, only the sharpening function by deep learning model and the sharpening function by the sharpening filter are applied (when the sharpening filter level is 0, only the sharpening function by the deep learning model is applied in this case).
- In level 0 of sharpening filter, the sharpening function by sharpening filter is not applied to the image, only the denoising function and sharpening function by deep learning model are applied (when the denoising function is set to off, only the sharpening function by deep learning model is applied in this case). In steps 1 to 5, the sharpening function by sharpening filter is applied to the images that are already denoised and sharpened by the deep learning model. The higher the sharpening filter level, the sharper the processed image. However, since the sharpening function by sharpening filter sharpens the entire image, there is a risk of amplifying the residual artifacts included in the image as the sharpening filter level gets higher. In addition to this, the higher the sharpening filter level, the higher the image contrast compared to a normal MRI image, so it may look unnatural. Even if a low sharpening filter 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 (cs@airsmed.com) to select the desired sharpening filter level.
- The sharpening filter level is not user selectable, but our service engineer selects it. The sharpening filter level can be set from level 0 to 5 irrespective of the imaging protocols. The initial value of sharpening filter level is set according to the user's request. If you want to change the sharpening level, please contact customer support (cs@airsmed.com).
- After image processing, the enhanced image is stored in PACS for default, and the original image is stored in PACS for optional. 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 0.13% (sharpening filter level 0, only the sharpening function by deep learning model is applied), 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: vendor neutral
  - Field Strength: 3.0T or less
  - Scanner models: All 3.0T or less models of any vendor
- The scope of body parts and pulse sequences (image types) supported by SwiftMR is as follows.
  - Body parts: All body parts
  - Pulse sequences (image types): All image types
- For scan parameters such as tr, te, slice thickness, resolution, and acceleration factor, SwiftMR can be applied to SOC images and reduced scan time images.

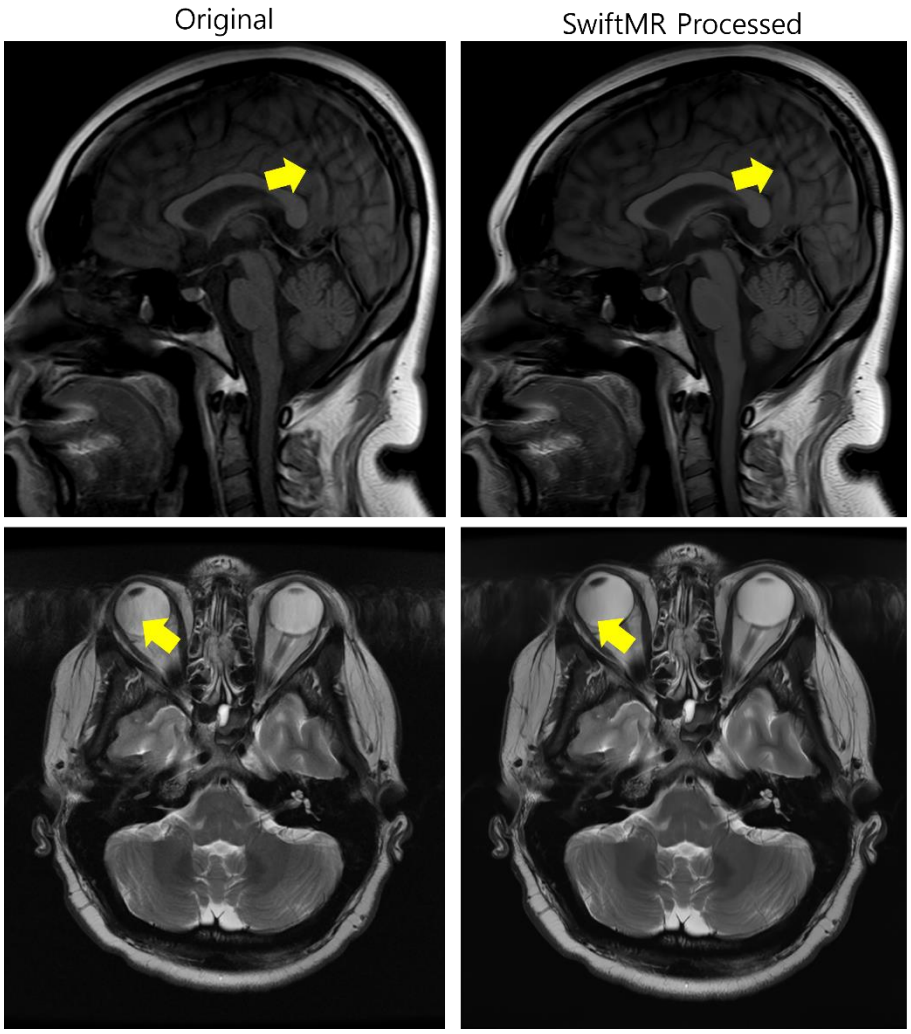
2.8.2. About Sharpness Increase Function

- 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 0.13% (sharpening filter level 0, only the sharpening function by deep learning model is applied), 0.43% (level 1), 1.7% (level 2), 2.3% (level 3), 3.6% (level 4), 4.5% (level 5). Although the test group 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 the test group (result from PT-04, 05 in performance test) are as follows.

Test Group	Avg FWHM decrease rate (%)
level 0	11.91±18.18
level 1	14.85±18.46
level 2	19.77±19.42
level 3	27.43±23.07
level 4	32.23±24.49
level 5	36.20±25.66

2.8.3. 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 2.8.1 for details.

2.8.4. 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 2.8.1 for details.

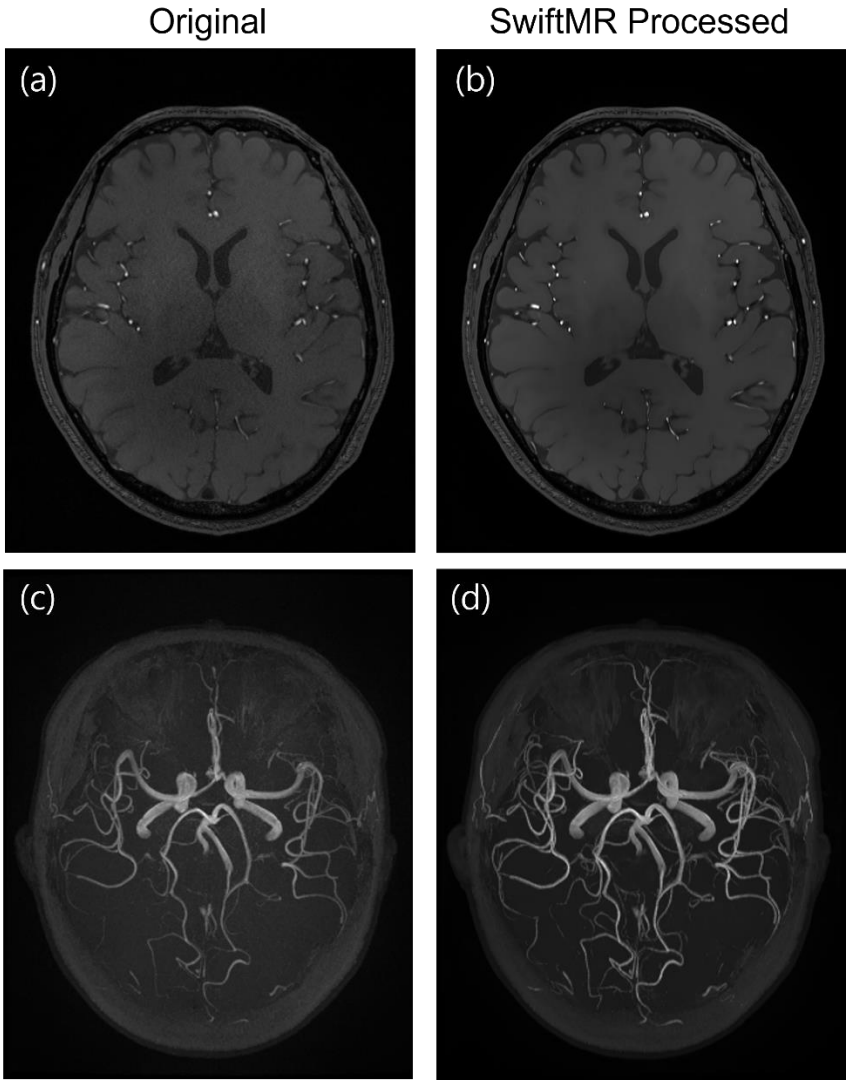


Figure. (a), (b): Slice image before and after SwiftMR processing. (c), (d): MIP image before and after SwiftMR processing

3. User Account Management

Passwords of user accounts can be changed in their profile settings (refer to Section 2.7.4). If you want to create a new user account or modify the basic information of an existing user account, please contact Customer Support (support@airsmed.com).

4. Cybersecurity

In order to ensure the cybersecurity of medical devices, SwiftMR meets the requirements of availability, confidentiality and integrity as follows.

- **Availability** implies that data should be readily available to an authorized user in the required format, whenever or wherever it is required.
- **Confidentiality** implies that data is not disclosed to an unauthorized person and is not used for unauthorized purposes. Even if data is disclosed by illegal methods such as an unauthorized inquiry or errors during data transmission/reception, SwiftMR makes it difficult to decrypt data through effective encryption and only allows authorized users to access the data. It also limits the range of data access according to the purpose and privileges of data users.
- **Integrity** implies that data is not altered or destroyed in any unauthorized manner. All information handled by SwiftMR should be accurate and complete, and the cybersecurity system of SwiftMR protects data from being distorted due to forgery or falsification. In addition, SwiftMR only allows authorized users to amend data handled in the system, and also manages logs and change history.

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

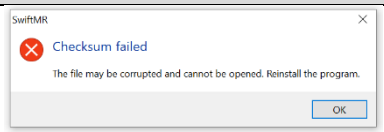
that had not been processed during the time the DICOM Control Server was turned off, will be processed once they are resent to the server. In case of the server programs, uninterrupted operation is guaranteed via automatic restart or executing multiple instances during server shut down.

- 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.

If you have any issues related to cybersecurity, please contact Customer Support (support@airsmed.com).

5. Trouble Shooting

If you have any problem that cannot be resolved through this user manual, please contact Customer Support (support@airsmed.com).

Category	Symptom	Cause & Measure
Integrity anomaly		Part of the installation files may be damaged or lost. Reinstall the program or contact the manufacturer.
Network Connection	Network connection status icon is	This indicates that there is a communication problem between the hospital network and the SwiftMR cloud server. This may cause problems in image processing, thus contact your IT administrator or the manufacturer.
	Automatically logged out even when the set time for automatic logout has not elapsed.	There may be a problem with the Internet connection of the PC where the Client Application is installed. Check the Internet connection of your PC.
Worklist Synchronization	MR images that have been scanned are not imported into the SwiftMR worklist	This may be because the applicable MR Device is not connected to SwiftMR. Check the device settings at [Settings → Device].
		This may be because the Protocol Name used in the MR scan is different from the one registered in the protocol settings. Check the protocol settings at [Settings → Protocol].

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 during use, the system will utilize the latest QC logs for conducting an abnormality check.

To fix bugs and to update image processing algorithms, it is recommended to upgrade the product at least once a year.

- In the case of the Cloud type model (A20-CL), all updates and upgrades are performed automatically on the server, so you can utilize the most up-to-date performance.

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 a 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

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