

Product Model A20-CL Version v2.0.1.X



SwiftMR User Manual, English A20-CL-UM-ID-EN Revision 1 (2022-09) ©2022 AIRS Medical Inc. All rights reserved.

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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.

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- 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.



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.

1.2. Intended Use

Software used in devices that store, enlarge, reduce, view, transmit, process, and output medical images. However, separately classified software is excluded here.

1.3. Limitations

SwiftMR is only available in certain countries.

This product meets the regulation of MoH of Indonesia for medical device software.

1.4. Functionalities

- Worklist view
 - o 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
 - o Enhance image quality
 - Download the enhanced MR images to PACS



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 RAM: 4GB and above Storage: 2GB available Memory: 500MB 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. Labeling

Symbol	Definition
[]i	'User Manual' reference symbol. This product is provided with the electronic instructions for use (eIFU). After signing up and being approved by the administrator at the AIRS Medical's eIFU homepage (https://en.airsmed.com/eifu), you can view the user manuals via PDF Reader.

1.7. Warnings and Cautions

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

Symbols	Definition		
<u>Note</u>	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.		



1.8. 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.
- o Do not turn off the power of the PC or programs during use.
- o After use, be sure to log out of the program.

1.9. Abbreviations

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

	<u> </u>	
DICOM Digital Imaging and Communications in Medicine		
MRI Magnetic Resonance Imaging		
PACS	Picture Archiving and Communication System	



2. Functions

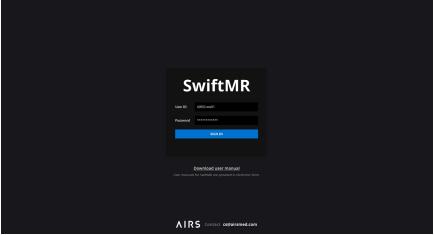
Client Application can be accessed through Google Chrome or Microsoft Edge browser in the hospital where SwiftMR is installed. You can access it through [SwiftMR server's IP address in the hospital]: 50000/swiftmr-client or the shortcut icon created during the installation process.



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.



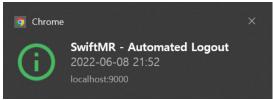
- Login: Enter ID and password provided by AIRS Medical and then click SIGN IN. When login succeeds, the main page of SwiftMR will appear.
- **Logout:** You can log out from SwiftMR to prevent unauthorized access by clicking the Logout button (Description). When logout succeeds, you will be directed 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 (<u>Download user manual</u>).

<u>Note</u>	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.
\triangle	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 (cs@airsmed.com).
\triangle	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.
<u> </u>	Caution: When login attempts fail 10 times, the user is restricted from login for the next 5 minutes.
\triangle	Caution: Please contact Customer Support (<u>cs@airsmed.com</u>) 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.

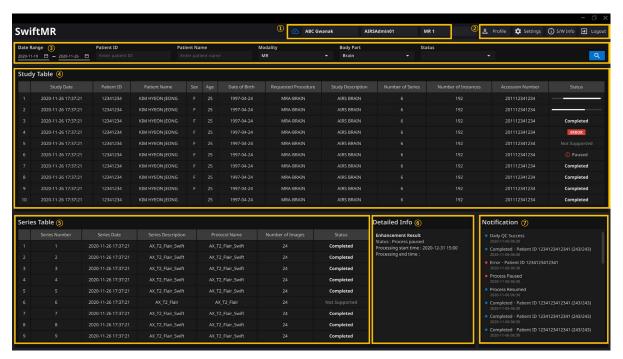


The Toast Message for automated logout disappears after a certain period, or it can be removed by clicking the **X** button at the top right corner.

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	
		ABC Gwanak	Institution name	
		AIRSAdmin01	Name of the accessed user	
		MR 1	Name of the connected MR device(s)	
2	User Menu A Profile Use		User Profile	
		(i) Settings	Software settings	
		S/W Info	Software information	
		→ Logout	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	
		Q	Button to execute the search by the selected conditions	
4	MR Study	Study Date	Study scan date (Year-Month-Day-Time)	
	Table	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	
			Not Supported	
	AAD C	6	• 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	
	1			



		Number of Images	Total number of images in a series	
		Status	Image processing status of the series	
6	Detailed	Enhancement Result	Enhancement result	
	Info		 Status: Completed, Not supported, 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: SwiftMR supports worklist synchronization with PACS for 7 days at maximum. Studies that have passed this amount of period, will be excluded from the worklist and will not be able to be inquired.



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 a PACS viewer.

2.4. Image Processing Status

Image processing status is classified as follows.

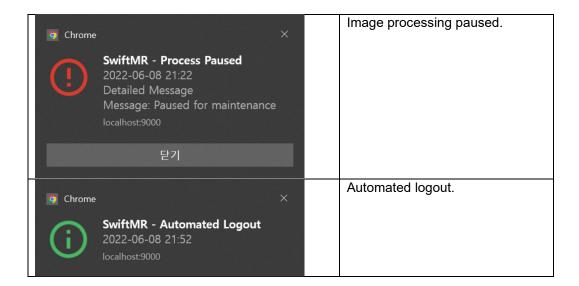
Icon	Description				
	In progress				
	Image processing progress is indicated with a progress bar				
Completed	Completed				
	Image processing of all supported series in the study is successfully completed				
ERROR	Error				
	An error occurred during image processing.				
① Paused Paused					
	Image processing is forcibly paused by the administrator while the image processing was in progress.				
Not Supported	Not Supported 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
Chrome		×	Image processing complete.
\odot	SwiftMR - Completed (30 / 30) AX_Test 11 localhost:9000		
	닫기	•	
Chrome		×	Image processing failed.
•	SwiftMR - Process Error 2022-05-03 20:52 Error Detail Code : 0006 Message: error occur during com localhost:9000	npleti	
	닫기		
Ochrome		×	Daily QC succeeded.
\odot	SwiftMR - QC Success 2022-06-08 19:40 10.0.11.12:50000		
Chrome		×	Daily QC failed.
<u>•</u>	SwiftMR - QC Error 2022-06-08 19:40 Detailed Message Unexpected Error 10.0.11.12:50000		
	닫기		
o Chrome		×	Image processing resumed.
⊘	SwiftMR - Process Resume 2022-06-08 21:25 localhost:9000		





Caution: Toast messages for the image processing results are only displayed for the connected MR devices. If images that are scanned through a desired device cannot be viewed, check the device setting in Settings → Device.



Caution: Toast message for image processing and image processing history in the Notification section is only shown for the connected MR devices. Therefore, if toast message for a desired study does not show up, please reset the device for which you want to be notified through the device settings in Section 2.6.4.



2.6. Settings

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

2.6.1. General Settings

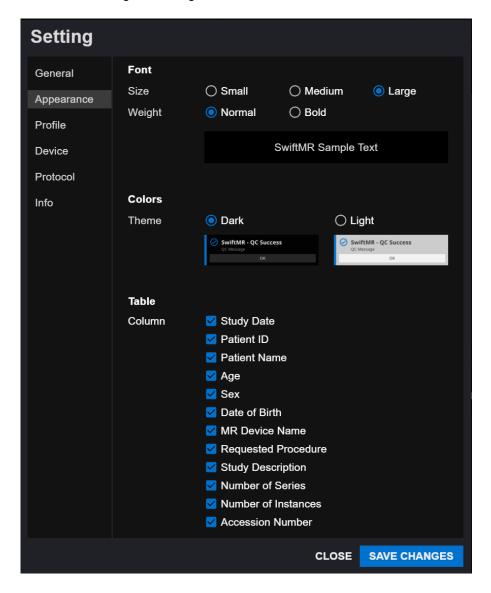
 Auto logout time settings: User can set the automated logout time from the General tab of Settings. Choose the time of the inactive period in which automated logout will occur afterwards from the drop-down menu and click on the SAVE CHANGES button.





2.6.2. Appearance Settings

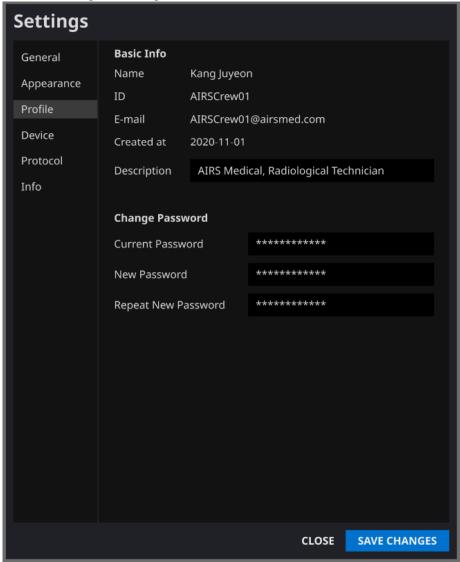
- User can set the appearance of the main page from the Appearance tab of Settings.
 - o Font:
 - Size Choose from Small, Medium, and Large Weight Choose between Normal and Bold
 - Colors: Settings for the background color of the Toast Messages. Choose between Dark and Light.
 - Table: Select the columns to be shown in Worklist Table.
- After establishing the settings, click on the SAVE CHANGES button.





2.6.3. Profile Settings

- Users can view or modify his/her own profile by clicking on the Profile button
 (Profile) or from the Profile tab of Settings.
- Users can change his/her password by entering the previous and the new password.
- After establishing the settings, click on the SAVE CHANGES button.



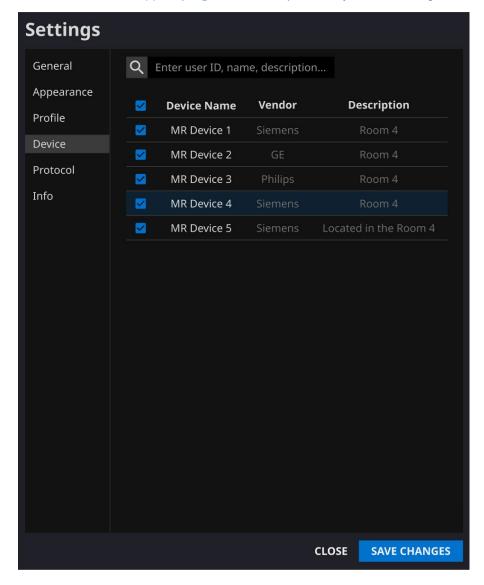
Note: Only English is supported in the Description field.

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



2.6.4. Device Settings

- Users can select the MR devices to receive notifications for image processing results among the list of registered MR devices connected to the software's PACS 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 (cs@airsmed.com) to modify device settings.

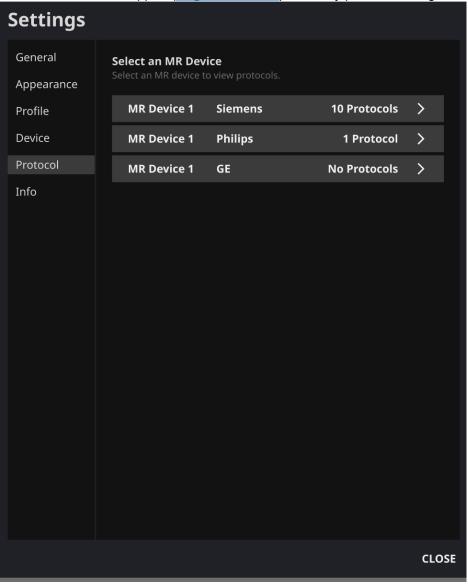


Note: Each user can select multiple MR devices to receive notifications for.

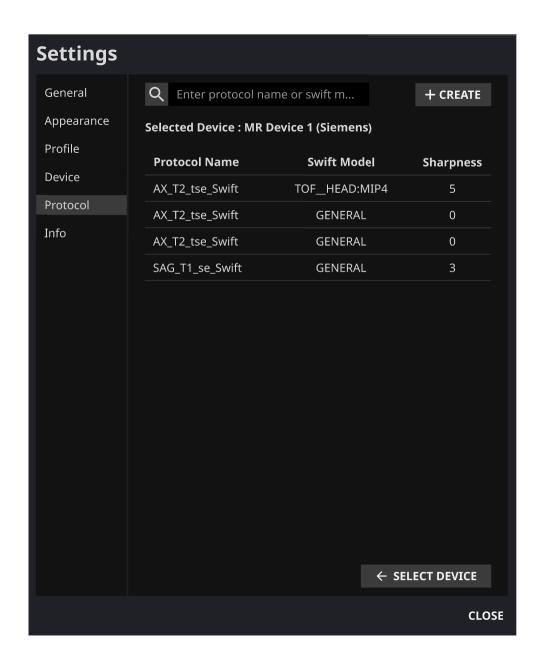


2.6.5. Protocol Settings

- 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 protocol for image processing before using SwiftMR.
- Contact Customer Support (<u>cs@airsmed.com</u>) 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.

2.6.6. 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.

3. User Account Management

Passwords of user accounts can be changed in their profile settings (refer to Section 2.6.3). If you want to create a new user account or modify the basic information of an existing user account, please contact Customer Support (cs@airsmed.com).

4. MR Scans and Image Processing

If you have completed the establishment of the settings to be suitable for the institution's circumstances by following the instructions of Section 2, you can now receive processed images by using SwiftMR.

4.1. MRI Scans

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 the scan is finished, the images are sent to the SwiftMR server through a specified path.

4.2. Image Processing

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 to 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.



5. 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.

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

6. Trouble Shooting

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

Category	Symptom	Cause & Measure	
Integrity anomaly	SwiftMR X Checksum failed The file may be corrupted and cannot be opened. Reinstall the program. OK	Part of the installation files may be damaged or lost. Reinstall the program or contact the manufacturer.	
Network Connection	Network connection status icon is Automatically logged out even when the set time for automatic	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. There may be a problem with the Internet connection of the PC where the Client	
	logout has not elapsed.	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].	



7. 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.

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 a warranty service, please refer to the contents of this user manual first, and then contact us through Customer Support.

• Customer Support: cs@airsmed.com





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