# **SwiftMR**<sup>®</sup>

# **User Manual**

**Product Model** 

A20-CL



SwiftMR User Manual, English A20-UM-EN Revision 2 (2021-08) ©2021 AIRS Medical Inc. All rights reserved.

# Contents

1. lr 1.1		ection
1.2	. Inte	ended Use5
1.3	. Lin	nitations5
1.4	. Fui	nctionalities5
1.5	. Mir	nimum System Requirements for the Software5
1.6	. Syı	nbols Glossary5
1.7	. Pre	ecautions6
1.8	. Ab	breviations7
		9 Install or Uninstall
2.2	. Ho	w to uninstall SwiftMR Client App11
3. F 3.1		ons
3.2		tomated Logout
3.3		in Page
3.4		itus
3.5		rm17
3.6	. Us	er Settings Settings 18
3	8.6.1.	General Settings
3	8.6.2.	Appearance Settings
3	8.6.3.	Profile Settings A Profile
3	8.6.4.	Device Settings
3	8.6.5.	Protocol Settings
3	8.6.6.	Software Information \$\$\mathcal{S}\$ S/W Info
3.7	. Sys	stem Admin Settings
3	8.7.1.	General Settings

	3.7.2.	QC Settings	25
	3.7.3.	User Management	26
	3.7.4.	PACS Settings	27
	3.7.5.	Device Settings	28
	3.7.6.	Protocol Settings	29
3	3.8. Ima	age Processing	31
5. 6.	Trouble Mainte	security eshooting nance Assurance	33 34
	•		

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**

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

#### Certified Use

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

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

### 1. Introduction

#### 1.1. Product Overview

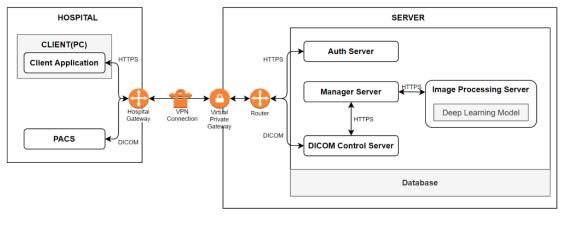
SwiftMR provides automated image quality enhancement for MR images acquired from various environments. This device is indicated for use only by trained radiology technologists.

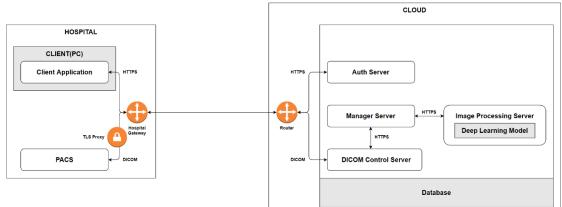
SwiftMR automates below procedures:

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

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

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





**SwiftMR** 

#### 1.2. Intended Use

SwiftMR is a stand-alone software solution intended to be used for acceptance, enhancement and transfer of brain MRI images in DICOM format. It can be used for noise reduction of MRI images or increasing image sharpness for non-contrast enhanced MRI images. This device is indicated for use only by trained radiology technologists. SwiftMR is not intended for use on mobile devices.

#### 1.3. Limitations

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

#### 1.4. Functionalities

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

#### 1.5. Minimum System Requirements for the Software

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

#### 1.6. Symbols Glossary

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



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

Symbols	Meaning
Note	Indicates useful information about features of the software.
Caution	Indicates potentially hazardous situations for the patient or user that
$\triangle$	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)
l	The link that directs users to this user manual is alongside the symbol.
REF	Catalog number
LOT	Lot number. Version number of the software.
	Unique Device Identifier
UDI	
By Only	Indicates that SwiftMR is a prescription device
Rx Only	

#### 1.7. Precautions

#### • Warning

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

#### General Caution

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

#### Caution for Use

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



#### 1.8. Abbreviations

The following abbreviations are used in this User Manual.

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

### 2. How to Install or Uninstall

#### 2.1. How to Install SwiftMR Client App

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

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

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

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

💮 SwiftMR Setup	– 🗆 X
	Welcome to SwiftMR 1.0.0 Setup
	Setup will guide you through the installation of SwiftMR. It is recommended that you close all other applications before starting Setup. This will make it possible to update relevant system files without having to reboot your computer. Click Next to continue.
	Next > Cancel

(2) Check "I accept the terms of the License Agreement" and click Next.

License Agreement			Num
Please review the license terms before inst	alling SwiftMR.		U
Press Page Down to see the rest of the ag	reement.		
SWIFTMR SOFTWARE END-USER LICENSE (September 10, 2020 version)	AGREEMENT		^
AIRS Medical, Inc. (the "Licensor") is willing individual, the company or the legal entity "Licensee") only the on the condition that License Agreement ("Agreement"). License collectively the "Parties". Throughout this as "You" or "Your". This Agreement govern Software is the exclusive property of the L	that will be utilizing th you accept all of the t or and Licensee are ea Agreement, the Licens the Licensee's use of	e Software (the erms of this End Use ch a "Party" and see may be referred	i to
			t the
If you accept the terms of the agreement, agreement to install SwiftMR.	click I Agree to contin	ue. You must accep	it uie
	click I Agree to contin	ue. You must accep	it the



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

🐨 SwiftMR Setup —	
License Key Enter valid license key provided by AIRS Medical.	(interest of the second
SwiftMR License Key	
SwiftMR 1,0,0	Cancel

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

🗑 SwiftMR Setup	- 🗆 X
Choose Install Location Choose the folder in which to install SwiftMR.	
Setup will install SwiftMR in the following folder. To install in a and select another folder. Click Install to start the installation.	
Destination Folder C:\WProgram Files\WSwiftMR	Browse
SwiftMR 1,0,0	Install Cancel

- SwiftMR Setup
   —
   ×

   Installing
   Please wait while SwiftMR is being installed.
   Image: Comparison of the set of
- (5) Installation process runs. Once the installation is complete, click Next.

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

🗑 SwiftMR Setup	— 🗆 🗙
	Completing SwiftMR Setup
	SwiftMR has been installed on your computer. Click Finish to close Setup.
	Run SwiftMR
	< Back <b>Finish</b> Cancel

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

	ļ
	(
SwiftMR	
SWITCHIN	
User ID Enter User ID	
Password Enter Password	
500 M	
<b>NIRS</b> Contact support@airsmed.com	

#### 2.2. How to uninstall SwiftMR Client App

Choose one of the following methods to uninstall the program.

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

### 3. Functions

#### 3.1. Login and Logout

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

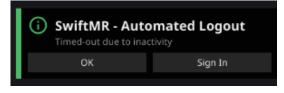
	- G ×
SwiftMR	
SWIICIVIK	
User ID AIRSCrew01	
Password ******	
SIGN IN	
<b>NIRS</b> Contact support@airsmed.com	
AIRS Contact support@airsmed.com	

- Login: Enter ID and password provided by system admin and then click SIGN IN. When login succeeds, main page will appear.
- Logout: You can log out from SwiftMR to prevent unauthorized access by clicking
   Logout ( Description 100 200 -

<u>Note</u>	<b>Note:</b> User account is created by System admin. Upon first login, the user is required to reset the password to prevent unauthorized access.
$\triangle$	<b>Caution:</b> When invalid ID or password is entered into the input field, login will fail and an error message will show up. If you forget your ID or password, contact the System admin or the IT manager.
$\triangle$	<b>Caution</b> : 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.
$\triangle$	<b>Caution:</b> When the login attempt fails 10 times, you are not allowed to login for the next 5 minutes.

#### 3.2. Automated Logout

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



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

#### 3.3. Main Page

Main page of SwiftMR is constructed as follows:

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

WI1	tMR						🕕 🙆 ABC G	vanak Ali	RSAdmin01 MF	<u>.</u> 2	Profile 🗯 Settings	(i) S/W Info
ite Ra 20-11-	nge ③ 19 ∰ — <u>2020-11-26 (</u>	Patient ID Enter patient ID		Patient Na Enter pati			Modality MR	Body Part • Brain	Stat 👻	us	•	1
udy	Table 👍											ast Updated 2020-11-26
			KIM HYEON JEONG				MRA-BRAIN	AIRS BRAIN				
			KIM HYEON JEONG				MRA-BRAIN	AIRS BRAIN				
		12341234	KIM HYEON JEONG				MRA-BRAIN	AIRS BRAIN			201112341234	Completed
							MRA-BRAIN	AIRS BRAIN				ERROR
						1997-04-24	MRA-BRAIN	AIRS BRAIN				
							MRA-BRAIN	AIRS BRAIN			201112341234	
							MRA-BRAIN	AIRS BRAIN				Completed
		12341234					MRA-BRAIN	AIRS BRAIN			201112341234	Completed
		12341234					MRA-BRAIN	AIRS BRAIN			201112341234	Completed
10	2020-11-26 17:37:21	12341234	KIM HYEON JEONG	Š.	25	1997-04-24	MRA-BRAIN	AIRS BRAIN	6	192	201112341234	Completed
erie	s Table (5)								Detailed Info 🌀		Notification 🕜	
								Status	Enhancement Result Status : Process paused		Daily QC Success	
			AX_T2_Flair_Sv	vift	AX_T2	2_Flair_Swift		Completed	Processing start time : 202	0-12-31 15:00	2020 11-60 0639 • Completed - Patient [D 1234123412341 (243/243) 2020 11-60 0630 • Error - Patient [D 1234123412341 2020 11-60 0630 • Process Paused 2020 11-60 0630	
			AX_T2_Flair_Sv	vift	AX_T2	2_Flair_Swift		Completed	Processing end time :			
			AX_T2_Flair_Sv	vift	AX_T2	2_Flair_Swift		Completed				
			AX_T2_Flair_Sv	vift	AX_T2	2_Flair_Swift		Completed				
			AX_T2_Flair_Sv	vift	AX_T2	2_Flair_Swift		Completed			Process Resumed 2020-11-06 06:30	
			AX_T2_Flair		AX			Not Supported			Completed · Patient ID 1234123412341 (243/243)	
			AX_T2_Flair_Sv	vift	AX_T	2_Flair_Swift		Completed				4123412341 (243/24
			AX_T2_Flair_Sv	vift	AX_T	2_Flair_Swift		Completed				
		2020-11-26 17:37:21	AX T2 Flair Sv	uife .	AY TO	2 Flair Swift		Completed				4125412341 (243/24

No	Function	Item	Description		
1	Status Bar	$\odot$	Network connectivity (Blue: Connected, Red: Disconnected)		
		ABC Gwanak	Institution name		
		AIRSAdmin01	Logged in User name		
		MR 1	MRI devices selected by user		
2	User Menu	<b>ی</b> Profile	User Profile		
		Settings	Software settings		
		(i) S/W Info	Software information (license, version), User manual download		
		➔ Logout	Logout		
3	Filter/Search	Date Range	Selects the study date range for MR Study to be displayed		
		Patient ID	Text input field to search by patient ID		
		Patient Name	Text input field to search by patient name		
		Modality	Dropdown multi-select list for modality selection		
		Body Part	Dropdown multi-select list for body part selection		
		Status	Dropdown multi-select list for status selection		
			• All		
			Completed		
			Error		
			In Progress		
			Not Supported		
		Q	Button to execute search by the selected conditions		
4	MR Study	Study Date	Study scan date (YYYY-MM-DD hh:mm:ss)		
	Table	Patient ID	Patient ID		
		Patient Name	Patient name		
		Sex	Patient sex		
		Age	Patient age		
		Date of Birth	Patient date of birth (YYYY-MM-DD)		
		Requested Procedure	Requested procedure		
		Study Description	Name of study protocol		
		Number of Series	Total number of series in a study		
		Number of Total	Total number of images in a study		
		Images			
		Accession number	Unique identification number of each image		
		Status	Image processing progress on MR study level		
			In Progress		
			Completed		
			Not Supported		

Detailed functions on the main page are as follows.



			Error
5	MR Series	Series number	Order number of each series in a selected study
5	Table	Series Date	· · · · · · · · · · · · · · · · · · ·
	Table		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	SwiftMR Process ID	Unique task ID given by SwiftMR
		Enhancement Result	Enhancement result on MR series level
			Status: Completed, Not supported, Error
			<ul> <li>Processing start time</li> </ul>
			<ul> <li>Processing end time</li> </ul>
7	Notification	Notification	Notifications on image processing result
			(success/failure), image processing status
			(pause/resume), daily QC result (success/failure),
			etc.



~

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

	<b>Warning</b> : When network connection status icon is marked as . , it may cause problems regarding image processing. Contact IT manager or manufacturer as soon as possible.
$\triangle$	<b>Caution</b> : 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.
$\triangle$	<b>Caution</b> : 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.
$\triangle$	<b>Caution</b> : All personal information saved in SwiftMR will be anonymized 24 hours after registration. If you want to inquire patients' information about the MR studies processed by SwiftMR, please use the PACS viewer.

#### 3.4. Status

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

lcon	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 while processing images in the study.
() Paused	Paused
	System admin has paused all the image processing for the institution.
Not Supported	Not supported
	There is no SwiftMR supported MR series in the study.

#### 3.5. Alarm

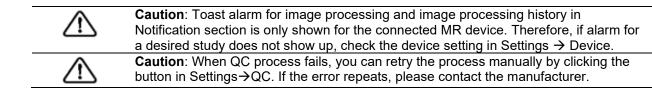
Users are notified of significant processing results with a toast alarm and through the Notification section. Toast alarms for each situation are as follows:

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

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

**SwiftMR** 

/!\



#### 3.6. User Settings



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



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

#### 3.6.1. General Settings

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

Settings	
General	Auto Logout
Appearance	Log out after 10 minutes 👻 of inactivity
Profile	
Device	
Protocol	
Info	
	CLOSE SAVE CHANGES

#### 3.6.2. Appearance Settings

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

Settings							
General	Font		<b>•</b> • • •				
Appearance	Time	O Small	O Medium	🖲 Large			
Profile	Weight	💿 Normal	⊖ Bold				
Device		2	SwiftMR Sample 1	ſext			
Protocol							
Info	Colors						
	Notification	🔘 Dark	() Lig	ght			
		SwiftMR - QC Succe	SS Swit	ftMR - QC Success			
		ок		ОК			
	Table						
	Weight	Study Date					
		Patient ID Patient Nai					
		Sex	ne				
		🖸 Sex					
		Date of Bir	th				
		🗹 Requested	Procedure				
		 Study Desc					
		🗹 Number of	Series				
		🗹 Number of Total Images					
		🗹 Accession Number					
			CLOSE	SAVE CHANGES			

# 3.6.3. Profile Settings

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

Settings				
General Appearance Profile Device Protocol	<b>Basic Info</b> Name ID E-mail Created at Description	Kang Juyeon AIRSCrew01 AIRSCrew01@airsmed.com 2020-11-01 AIRS Medical, Radiological Technician		
Info	Description       AIRS Med         Change Password          Current Password          New Password          Repeat New Password		**********	
			CLOSE	SAVE CHANGES

 Note: Only English is supported in the Description field.

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



#### 3.6.4. Device Settings

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

Settings	Settings						
General	Q Ente	er user ID, nam	ne, description				
Appearance Profile	🗹 De	evice Name	Description				
Device	MF	R Device 1	Located in the Ro	00m1			
Protocol	MF	R Device 2	Located in the Ro	pom2			
Info	MI MI	R Device 3	Located in the Ro	bom3			
			CLOS	SE SAVE CHANGES			

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



#### 3.6.5. Protocol Settings

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

Settings		
General	Q Enter protocol name or sv	vift m
Appearance	Protocol Name	Swift Model
Profile	AX_T2_FLAIR_FS_TIR_SWIFT	GENERAL
Device	AX_T2_tse_SWIFT	GENERAL
Protocol	AX_T1_se_SWIFT	GENERAL
Info	AX_T1_FLAIR_tir_Swift	GENERAL
	AX_DWI_epse_SWIFT	GENERAL
		CLOSE

 $\triangle$ 

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



# 3.6.6. Software Information ? S/W Info

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

Settings	
General	
Appearance	SwiftMR
Profile	
Device	Software Version 1.1.0
Protocol	
Info	License info
	Belongs to AIRS Clinic ABC Gwanak
	Manufactured by
	Full Name AIRS Medical Inc.
	E-mail support@airsmed.com
	<b>SwiftMR</b> Picture archiving and communications system, software (GMDN: 41670)
	REF         A20-CL         LOT         1.1.0         Rx Only
	<b>UDI</b> (01)08801234123457 (10)1.1.0
	Name : AIRS Medical Inc. Address : 8-9F, CS Tower, 1838, Nambusunhwan-ro, Gwanak-gu, Seoul, 08788 Korea
	CLOSE

# 3.7. System Admin Settings

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

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

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

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

#### 3.7.1. General Settings

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

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



To resume image processing by SwiftMR, click resume

Settings		
General	Auto Logout	
QC	Log out after 10 minutes 👻 of inactivity	
Appearance		SAVE CHANGES
Profile	Process Status	
User Management	⊘ Running	PAUSE
PACS		
Device		
Protocol		
Info		
		CLOSE



#### 3.7.2. QC Settings

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

check the results by clicking on Execute QC (Execute QC

• When done, click **SAVE CHANGES**.

Settings	
General	<b>Daily QC</b> Execute quality check automatically at selected time and days.
QC	Time AM 06:30 🕓
Appearance	Days s M T W TH F SA
Profile	
User Management	Manual QC Execute quality check manually.
PACS	Result
Device	
Protocol	
Info	
	CLOSE SAVE CHANGES

#### 3.7.3. User Management

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

Settings				
General	Q Enter us	er ID, name, des	cription	+ CREATE
QC	Created at	ID	Name	Action
Appearance	2020-10-10	AIRSAdmin	Lee Sohee	11
Profile	2020-10-10	AIRSCrew01	Kang Juyeon	1
User Management	2020-10-10	AIRSCrew02	Kim Jihoon	/ 1
PACS	2020-10-10	AIRSCrew03	Kim Dongho	/ 🗊
Device	2020-10-10	AIRSCrew04	Jeong Sumin	/ 🖹
Protocol				
Info	Basic Info			
	Name	Jeong Sumin		
	ID	AIRSCrew04		
	E-mail	AIRSCrew04@a	irsmed.com	
	Created at	2020-10-10		
	Description	AIRS Medical, R	adiological Technic	;ian
	Change Pass	word		
	New Passwo	ord	Confirm Passy	word
				SAVE
				CLOSE

#### 3.7.4. PACS Settings

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

Settings									
General	Q Enter a	aliast, AE titl	e				+	CREA	TE
QC	Alias	IP Addres	s	De	scripti	on		Acti	on
Appearance		255.255.255			aaa			1	Î
Profile			235		000			•	-
User Management									
PACS									
Device									
Protocol									
Info									
	Application	Entity							
	Alias	Enter A	lias						
	IP Address	0		0		0		0	
	Query	AE Title	Enter	AE TI	tle		Port	Port	
	Store SCP	AE Title	Enter	AE TI	tle		Port	Port	
	Store SCU	AE Title	Enter	AE Ti	tle				
	Store SCO								
	Description	Enter D	escripti	on					
		Enter D	escripti	on				SAV	/E

#### 3.7.5. Device Settings

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

Settings					
General	Q Enter user ID, name, description + CR				
QC	🔽 Device N	Jame	Description	Action	
Appearance	MR Devic		Located in the Room		
Profile	MR Devid	ce 2	Located in the Room	m2 🖍 📋	
User Management	MR Devid	ce 3	Located in the Roon	n3 🖍 📋	
PACS				1	
Device					
Protocol					
Info					
	Basic Info				
	Name	MR D	evice 4		
	Serial Number	32145	5562		
	Description	Locat	ed in the Room 4		
				SAVE	
			CLOSE	SAVE CHANGES	



#### 3.7.6. Protocol Settings

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

Vendor	Field	Numbe	Sequence			Scan Pa	rameters		
	Strength	r of Coils		Accelerati on Factor*	TR (ms)	TE (ms)	Resolutio n (mm)	Slice Thickness (mm)	Matrix Size
GE	1.5T	~8	Axial T1	1~2	333.3~800. 0	8.0~21.0	0.43~0.94	5.0~5.0	256x256~5 12x512
			Axial T2	1~1	3000.0~78 83.3	92.2~123.9	0.43~0.47	5.0~5.0	512x512~5 12x512
			Axial FLAIR	1~1	8002.0~10 002.0	120.4~150. 3	0.43~0.94	3.0~5.0	256x256~5 12x512
			Axial GRE	1~1	667.0~667. 0	15.0~15.0	0.47~0.47	5.0~5.0	512x512~5 12x512
			Sagittal T1	1~1	316.7~184 4.5	9.0~27.6	0.43~1.02	4.0~6.5	256x256~5 12x512
GE	3.0T	~32	Axial T1	1~2	700~1763. 9	9.0~22.2	0.43~0.86	5.0~5.0	256x267~5 12x512
			Axial T2	1~3	700.0~643 3.0	15.0~114.7	0.43~0.86	5.0~5.0	256x256~5 12x512
			Axial FLAIR	1~2	8800.0~11 002.0	85.6~155.6	0.43~0.94	5.0~5.0	256x256~5 12x512
			Axial GRE	1~1	375.0~445. 0	4.3~7.0	0.47~0.47	5.0~5.0	512x512~5 12x512
			Sagittal T1	1~2	416.7~315 2.5	6.1~17.0	0.43~0.51	4.0~7.0	512x512~5 12x512
			Coronal T2	1~2	5035.5~68 00.0	99.9~109.0	0.47~0.47	3.0~3.0	512x512~5 12x512
			Axial TOF	2~2	20.0~20.0	3.4~3.4	0.41~0.45	1.2~1.2	512x512~5 12x512
PHILIP S	1.5T	~20	Axial T1	1~1	400.0~613. 0	10.0~12.0	0.45~0.92	5.0~5.0	256x256~5 12x512
5			Axial T2	1~1	2268.8~54 00.0	100.0~110. 0	0.22~0.94	5.0~5.0	256x256~1 024x1024
			Axial FLAIR	1~1	6000.0~11 000.0	120.0~142. 0	0.43~0.96	5.0~5.0	240x240~5 60x560d
			Sagittal T1	1~1	450.0~812. 8	12.0~18.0	0.45~0.86	5.0~5.0	256x256~5 12x512
PHILIP S	3.0T	~32	Axial T1	1~1	400.0~719. 0	10.0~10.8	0.43~0.76	4.0~5.0	288x288~5 12x512
0			Axial T2	1~1	3000.0~38 31.7	80.0~110.0	0.43~0.45	5.0~5.0	512x512~5 60x560
			Axial FLAIR	1~1	9000.0~11 000.0	110.0~125. 0	0.43~0.69	5.0~5.0	320x320~5 12x512
			Sagittal T1	1~1	350.0~500. 0	6.6~10.0	0.43~0.94	4.0~5.0	256x256~5 60x560
			Axial TOF	1~1	20.0~20.0	3.5~3.5	0.21~0.41	1.2~1.2	512x512~1 024x1024
SIEME NS	1.5T	~20	Axial T1	1~1	406.0~642. 0	8.7~17.0	0.45~0.94	5.0~6.0	256x192~5 12x416
			Axial T2	1~1	3720.0~64 70.0	85.0~113.0	0.26~0.75	5.0~5.0	320x320~8 96x812
			Axial FLAIR	1~1	8000.0~10 000.0	73.0~130.0	0.38~0.90	5.0~5.0	256x204~6 40x560
			Sagittal T1	1~1	450.0~650. 0	9.4~17.0	0.72~0.94	5.0~6.0	256x256~3 20x320
			Sagittal MPRAGE	1~1	2530.0~25 30.0	3.1~3.1	1.00~1.05	1.3~1.3	256x256~2 56x256
			Axial TOF	2~2	25.0~30.0	7.0~7.2	0.27~0.62	0.5~0.5	384x288~7 68x616
SIEME NS	3.0T	~64	Axial T1	1~3	500.0~180 0.0	9.0~9.8	0.57~0.69	4.0~5.0	320x270~3 84x348
			Axial T2	1~2	2690.0~10 070.0	86.0~100.0	0.21~0.34	4.0~5.0	640x540~1 024x928
			Axial FLAIR	1~2	8000.0~90 00.0	97.0~105.0	0.29~0.57	4.0~5.0	384x348~7 68x696

Sagittal T1	1~1	450.0~550. 0	6.9~9.8	0.29~0.62	5.0~5.0	384x384~7 68x768
Axial SWI	2~2	28.0~29.0	20.0~20.0	0.46~0.57	2.5~2.5	384x300~4 80x434
Axial TOF	2~2	22.0~25.0	3.7~4.2	0.43~0.54	0.5~0.6	448x348~5 12x416

- SwiftMR takes the Protocol Name of an MR image to decide whether to process it. When the description matches a series in the Protocol Settings page, processing is carried out whereby the enhancement method will follow the Swift Model predefined in the Protocol setting.
- There are two types of selectable Swift Model: GENERAL and TOF. Supported pulse sequences that correspond to each Swift Model are as follows.
  - GENERAL: Axial T1, Axial T2, Axial FLAIR, Axial GRE, Sagittal T1, Coronal T2, Sagittal MPRAGE, Axial SWI
  - TOF: Axial TOF
- Before use, be sure to check the protocol for image processing.
  - If the existing protocol in the MR device is to be used, SwiftMR Protocol Name needs to be updated to match the MR device protocol.
  - If a new protocol is to be created in the MR device, it is recommended to use the Protocol Name shown as default in Protocol tab of Settings.
    - + CREATE
- Create protocol: Click . Enter new Protocol Names to register and select the Swift Model that corresponds to the Protocol Name.
  - In the case of A<u>20-C</u>L, Swift Model "Brain Routine" is recommended.
- **Modify protocol**: Click **C** on the righthand side of the protocol and modify as needed.
- **Delete protocol**: Click **Delete protocol**: Click **Delete protocol**.
- When done, click **SAVE CHANGES**.

Settings			
General	Q Enter protocol	+ CREATE	
QC	Protocol Name	Swift Model	Action
Appearance	AX_T2_tse_Swift	GENERAL	/ 1
Profile	AX_T1_se_Swift	GENERAL	1
User Management	AX_T1_FLAIR_tir_Sw	ift GENERAL	1
PACS	COR_T1_se_Swift	GENERAL	1
Device	COR_T2_tse_Swift	GENERAL	1
Protocol	SAG_T1_se_Swift	GENERAL	1
Info			
	Rule Settings		
	Protocol Name	SAG_T1_se_Swift	
	Swift Model	GENERAL	-
			SAVE
			CLOSE

	<b>Caution</b> : Users should scan images with supported scanner model, pulse sequences, and scan parameters. Otherwise, image processing performance cannot be guaranteed. For supported acquisition conditions, see 3.7.5 and 3.7.6 of the user manual.
$\wedge$	Caution: When performing image processing on MR images with our product, make
<u>د</u> ب	sure to set the protocol with the values provided by us on the MR device. After
	applying the correct settings, it is recommended to attach a suffix to the protocol name
	such as <b>swift</b> to distinguish them.
$\mathbf{\Lambda}$	Caution: MR images of protocol name registered in protocol settings are processed in
	SwiftMR cloud. Therefore, if you want to process with SwiftMR, be sure to check
	whether the protocol name is registered in the settings before conducting an MRI scan.
$\overline{\mathbf{A}}$	Caution: Users should select Swift Model between GENERAL or TOF according to the
	protocol to be registered

#### 3.8. Image Processing

- The intended patient population is adults (greater than 21 years of age) only.
- SwiftMR simultaneously performs noise reduction and increasing sharpness functions on processed images. User cannot choose between the two functions.



- Image enhancement process is fully automatic. When the DICOM images captured by the MRI equipment are stored in PACS, SwiftMR cloud server automatically imports them to enhance the image quality and saves them in PACS again.
- There is no configuration setting for de-noising and sharpening functionalities. There is only one level of enhancement for de-noising and sharpening functionalities.
- After image processing, both the original image and the enhanced image are stored in PACS. For enhanced Image, the phrase '\_recon' is added at the end of the protocol name and series description of the DICOM tag. Users can distinguish between original images and enhanced images by looking at the DICOM tag and depending on whether there is '\_recon'.
- The performance of SwiftMR both for noise reduction and sharpness increase was validated for the supported acquisition conditions described in 3.7.5 and 3.7.6. As a result of the test, it was demonstrated that SwiftMR increases the SNR of original image by 40% or greater than that on average, and sharpness was increased in original images for at least 90% of the dataset.

# 4. Cybersecurity

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

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

# 5. Troubleshooting

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

Category	Symptom	Cause & Measure
File verification	SwittMR × Checksum failed The file may be corrupted and cannot be opened. Reinstall the program.	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).



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

## 6. Maintenance

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

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

# 7. Quality Assurance

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

AIRS Medical Inc. does not guarantee the following items:

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

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

Customer Support: <u>support@airsmed.com</u>



#### **AIRS Medical Inc.**

8-9F, CS Tower, 1838, Nambusunhwan-ro, Gwanak-gu, Seoul, 08788 Korea

Tel. (+82) 70 7777 3186 Fax. (+82) 02 6280 3185

www.airsmed.com

support@airsmed.com