

Federal law restricts this device to sale by or on the order of a physician.

FEDERAL COMMUNICATIONS COMMISSION (FCC) UNINTENTIONAL EMITTER PER FCC PART 15

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in an office installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions in the user manual, may cause harmful interference to radio or television reception. However, there is no guarantee that interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a different circuit from that to which the receiver is connected.
- Consult Accutome Ultrasound, Inc. or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation of this product is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION:

Changes or modifications not expressly approved by Accutome Ultrasound, Inc. could void the FCC compliance and negate your authority to operate the product.

Authorized Representative in Europe (for regulatory affairs only):

The A-Scan Plus Connect is Manufactured by: Accutome, Inc. 3222 Phoenixville Pike Malvern, PA 19355 USA Toll Free (USA): 1-800-979-2020 International: 610-889-0200 Fax: 610-889-3233



EMERGO EUROPE Molenstraat 15 2513 BH, The Hague The Netherlands



All Accutome A-Scan Plus Connect units are manufactured by Accutome, Inc. at:

3222 Phoenixville Pike Malvern, PA 19355 USA

DICOM

DICOM

The DICOM (Digital Imaging and Communications in Medicine) standard enables communication of medical imaging devices by specifying a protocol for network communications, media communications, file formats and other information. DICOM conforming equipment has the capability to supply data in a standard format to a common server in such a way that the data can then be used by other DICOM conforming equipment.

The Accutome A-Scan Plus Connect software is DICOM compatible and this feature is easily activated with only a few requirements. Please review the following directions for how to properly install and activate the DICOM feature in the A-Scan Plus Connect software.

New Software Installation

Please see the A-Scan Plus Connect Installation packet for all Windows operating system installations. The installation packages are included in the carrying case that the unit shipped in. The installation packet and instructions are also available at the Accutome support site (https://support.accutome.com).

Software Key

In order to activate the DICOM function of the A-Scan Plus Connect software you must have a software version 7.00.00 or later and an activation key. Without this key the DICOM function will not operate. To obtain a DICOM software activation key or update the current software please do one of the following options:

- 1. Contact the Accutome sales representative that covers your region.
- 2. Call in to the Accutome home office at 800-979-2020.
- 3. Email your request to info@accutome.com

Once the software activation key is obtained, please follow the activation instructions below.

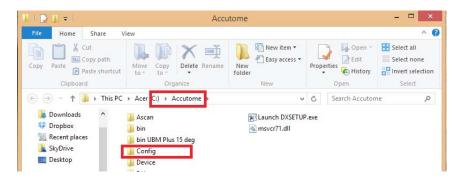
DICOM Activation

Follow the steps below in order to activate the DICOM capabilities within the A-Scan Plus Connect software. Please note that this information is very specific, the server settings and DICOM activation should be completed by your IT staff or DICOM server administrator.

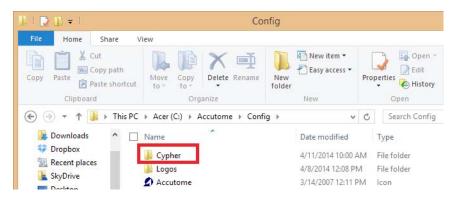
- 1. Copy the software key.
 - a. The software key is electronic and can be supplied in a variety of manners (email, electronic transfer, memory stick). Once the key is supplied, please right click on the file and choose copy.
- 2. Paste the software key in the specified file location.
 - a. With every A-Scan Plus Connect software installation, an Accutome file folder is placed on the computer desktop. Navigate to the Accutome file folder and double click.



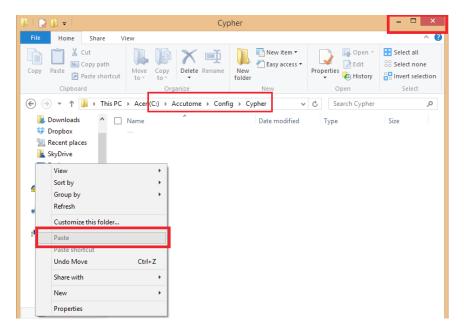
b. Navigate to the **Config** file folder (should be near the top) and double click.



c. Find the **Cypher** file folder (should be the top file location) and double click.



d. Once within the **Cypher** file folder, right click on any white portion within the window and choose paste. The copied file will placed in the Cypher file folder.



- e. Close the file location by clicking on the red **X** in the top right hand corner of the window.
- 3. Launch the A-scan Plus Connect software.
 - a. Double click on the A-Scan icon on the desktop.



4. Click on the **Setup** tab



5. Click on the **DICOM** tab.

24							Accuto	me A-Sc	an Plus (Connec	t) Versio	on 7.00.00 RC1	1
Exa	ms	Ме	asurement		IOL Calculation		Setup						
Options	ions Import/Export DICOM Snaps		apshots / Reports	Facilities	Physicians	Users	EyeT	ypes	es Personalize IOL				
					(Connect) Exa anPlusConnect					Sele	ect	Defaults	

The practice information should be listed at the top of the DICOM settings page. If it is not, please call Accutome support at 800-979-2020. See figure below.

- 6. Ensure that local AE (application entity) title is listed as **A-Scan Connect**. This field should never change.
- 7. Setup the remote server settings to match the connected DICOM server.
 - a. The list of associated servers will be blank. You must enter a new server name for it to appear on the server list. To do this, click on the **New Server** box and an undefined server will appear in the list field.
 - b. Add the server name by adjusting the name in the field listed Display as.
 - c. Click on the AE title field and fill it with the appropriate name.
 - d. Fill the IP address of the DICOM server
 - e. Supply the appropriate port number for the field.
 - f. If you are not sure how to name your server, AE title, IP address or port number, please contact your network or DICOM server IT personnel.

Exams	Me	Measurement		IOL Calculation		Setup								
Options Imp	ort/Export	DICOM	Snap	shots / Reports	Facilities	Ph	ysicians	Users	EyeTypes	Personalize IOL				
DICOM Information of Facility used in Exporting DICOM SOPs Name: Wills Eye Hospital Address: 800 Walnet Street, Philadelphia, PA 19104, USA Phone: 215-363-7000														
Local A Remote	Servers	ect New Server			■ IOL Calculations ■ Axial Measurements									
*KPACS	List of Remote Servers				Remove Selected			Axial Measurements QC Image						
Display & KPACS IP addre 10.108.0	play as			AE title KPServer Port number 104 Verify Connection			 Axial measurements de inlage ☑ IOL Calculations PDF ☑ Axial Measurements PDF Store Location ○ Remote Server ● Selected DICOM Folder 							
	lder C:	\Accutom	e\Aso	an\DICOM\						Select Folde	r			

- 8. Once remote server setup is complete, authenticate the connection by clicking on the **Verify Connection** button. A small pop up window will indicate if the connection was successful. If connection was unsuccessful verify that all the remote server information is correct.
- 9. If this is the default DICOM server, set it as the default by clicking on the set selected as default button. An asterisk should appear next to the name of the server in the list of remote servers field.
- 10. Set the selected service operating pairs (SOPs) to be exported with the data information.
 - a. On the right side of the screen you may choose any or all of 5 choices. If you are not sure which is the correct choice, please contact your network or DICOM server IT personnel.
- 11. Set the selected store location for the data by choosing either Remote **Server** or **DICOM folder** location. If desired, the default file folder location can be changed by clicking on **Select Folder** and navigating to the proper location.
- 12. Save configuration by clicking on Save at the bottom of the page.

Name: Wills Ey	e Hospital /alnet Street,	ed in Exporting D Philadelphia, PA 1						
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IP address or 10.108.0.191	host name	Port numbe	r	- -	Locat	ion —— Server		
Set Selec	ted as Defaul	t Verify Cor	nnection	• Se	lected	DICOM F	older	
DICOM Folder	C:\Accutom	ie\Ascan\DICOM\					Select Folder	

The DICOM activation is now complete.

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DICOM Exporting

The A-Scan Plus Connect can now export patient data via the DICOM network. In order to use this function please follow the steps listed below. Existing Patients:

- 1. Click on the existing patient within the patient list that you would like to export (multiple patients can be exported by pressing the shift key and clicking on multiple patients) the name now is highlighted.
- 2. Click on the export to DICOM icon located at the top of the screen. A small window will appear stating that the selected data is being stored.
- 3.If exporting is a success then the following window will display. If exporting was not done correctly an error message will display.



New patients

- 1. Start a new patient by following the instructions listed in the user manual.
- 2. Once patient testing is complete and all information is gathered save the patient.
- 3. Click on the existing patient within the patient list that you would like to export (multiple patients can be exported by pressing the shift key and clicking on multiple patients). The name now is highlighted.
- 4. Click on the export to DICOM icon located at the top of the screen. A small window will appear stating that the selected data is being stored.

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Exams	Measure	ment IOL C	alculation	Setup						
	Version 5.0	Version 4.0		-						
ĽA	Delete Selected	Export to IOLMaster	Export to DICOM	New	Copy from Selected					
A-Scan Plus (Connect)	Ver. 5.0 Folde	C:\Accutome\Asc	anvascaneiusConr	ect Exams\				1	Selec	Reset
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		Patient	Name		ID	DOB	Date_Time_Saved	Scans	Calc.	Imported
LITTLE, nate							4/3/2014 9:47 PM	Yes	No	N/A

The patient data has now been sent to the DICOM server and can be reviewed with your DICOM viewer.