

ARES Software Customization Guide

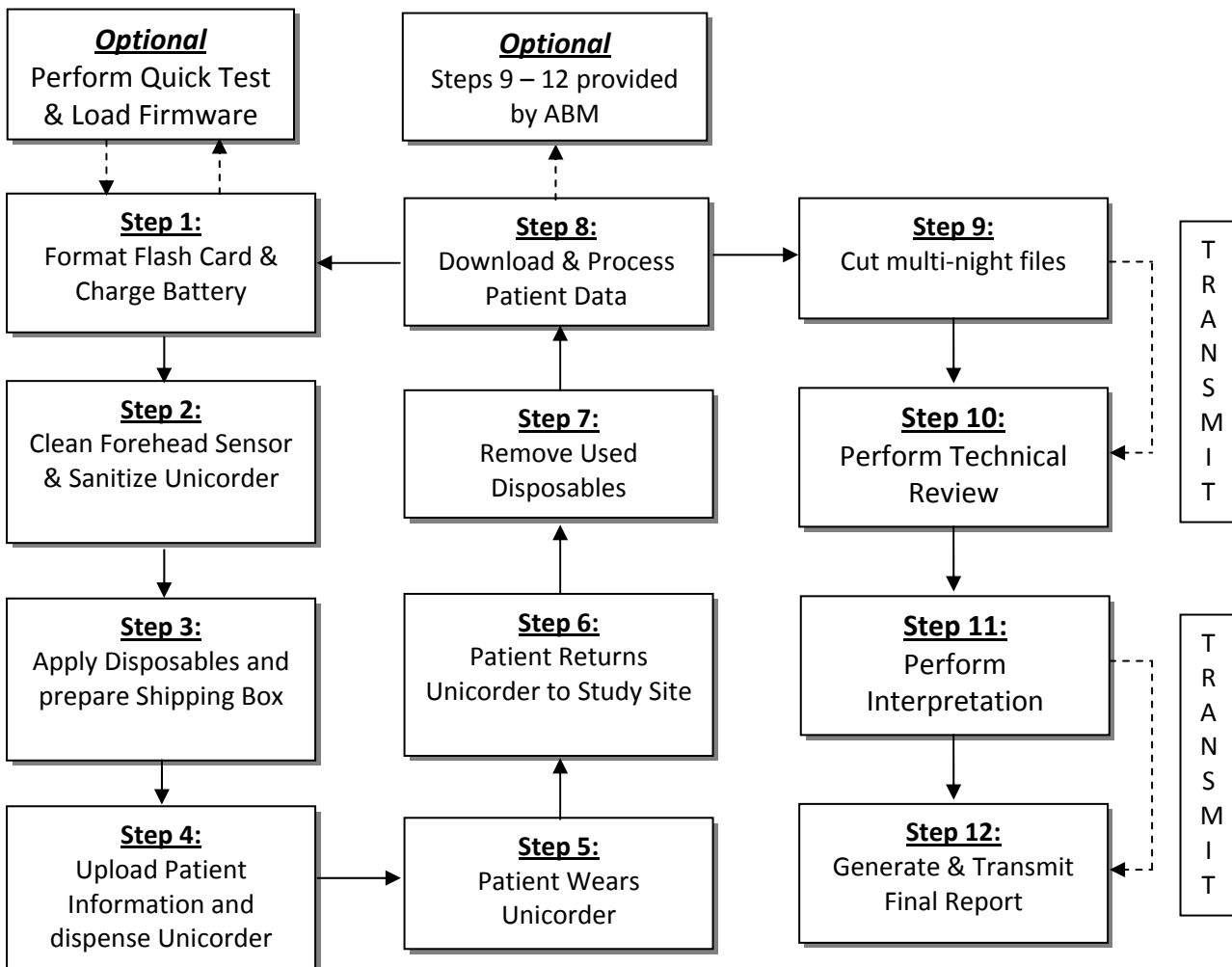
A. Overview

ARES Organizer provides a number of features that can be configured for your specific needs. The key features that need to be considered in designing your implementation include whether you wish to:

- a) create individual screens (called views) which will contain only the sleep study data and action icons that the user needs to see to perform the processing task,
- b) save time by using existing patient data obtained with the ARES Screener (if available) to prepare a Unicorder for a study,
- c) acquire a single night or multiple nights (e.g., 2, 3 or 4) nights of data,
- d) download and process data in a single step or wish to use batch processing capabilities,
- e) transmit data to a third part of technical review or interpretation,
- f) configure the ARES report format for your needs, and
- g) require user name and log ins to open the application and whether you wish to control access to information based on the user name and password.

Below, we have provided a list of queries and information to help you plan your ARES implementation and identify the features you wish include during your set up.

ORDER PROCESSING WORKFLOW



B. Selecting a software installation configuration

Background:

The ARES software utilizes a database to store patient information, study results used to generate reports, and the file path for the study data to be recalled for presentation. The method used to install the software depends in large part on the sophistication of the local area network. In hospitals and offices with full time IT staff, users are generally not provided administrative rights to install software or determine how best to configure the software. The questions below will help smaller offices determine how best to configure the software for their users.

Questions:

1. Do you have a trained IT professional who manage your network? If yes, then they will know how to set up the configuration and you don't need to continue with these questions.
2. Do you have a dedicated network server? Will multiple people be accessing the ARES data?
 - a. If yes, then you should load the database on the server.
 - b. If no, then you could load the data on a reliable computer with at least 1 MB of RAM and a 2.0 MHz processor.
3. Do you have someone who is skilled in performing software upgrades? Are all users on the same network?
 - a. If yes, then you should install ARES software on each computer and have each computer write to the server database.
 - b. If no, then you should load all of the software on one local computer or server. To provide access to ARES Organizer, make sure the hard disk is shared and path short-cuts to access the software across the network on each computer.

C. Selecting views for processing studies

Background:

The data processing steps are presented in the flow chart above.

Feature Benefit:

- Single view: shows all studies and all action icons needed to process studies in one view. Ideal if only one person is doing all of the processing.
- Multiple views: Provides custom views configured to perform each of the main steps described above. Each view is configured to present only those studies that require processing at that step along with the action icons required to perform the step(s) and study information (fields) useful in performing that step(s). Once the user has completed the step/task, the status changes, releasing the study to the next processing step/view and removing it from the current view.

Questions:

1. Do you plan on having multiple personnel involved in processing the study?
2. Will different users be responsible for specific steps in the study processing?
3. Do you wish to identify the studies that are in queue for the user responsible for performing each step?
4. Do you wish to use the log-in features to limit access to specified views/tasks by user?

D. Selecting the number of nights per study

Background:

The ARES is capable of recording up to four nights of data. It automatically turns off after 8-hours if a "one-night study" is selected, and 7-hours if more than one night is selected. With a fully charged battery, it can record 14-hours of data. The battery is recharged using a wall charger and charging

cable. The software automatically assigns file folders and determines which report format to use depending on the study type (i.e., number of nights) selected. Additionally the cutting routine that automatically segments the file by night uses the study type in the logic (i.e., it will force a third night into Night 2 if a two-night study type is selected).

Feature Benefits:

- 1 night study: Allows more studies to be performed per week with the same Unicorder.
- 2 night studies: preferable for reducing the influence of night-to-night variability for the diagnosis of mild to moderate OSA.
- 3 night studies: must be selected to utilize the three-night comparison report ideal for mandibular repositioning device (MRD) titration studies.
- 3+ night studies: provides analysis of 3 or 4 nights of data, with nights 1 and 2 combined and nights 3 and 4 combined into two reports.

Questions:

1. Are you performing both diagnostic and treatment outcome studies?
2. Do you have a mechanism in place to notify the person who is uploading patient information and selecting the study type how many nights planned for the patients?

E. Optimizing the uploading of patient data

Background:

The ARES Screener is commonly used to predict those in need of a sleep study and the probable severity of OSA based on an analysis of questionnaire responses. If patient information from the Screener, such as the first and last name, gender, birth date, etc, has already been entered into the database, then it can be automatically uploaded onto the Unicorder to avoid reentry.

Feature Benefits:

- If an ARES Screener was entered prior to the study, then the time to prepare the Unicorder for use can be reduced.
- ARES Screener includes the capability to scan responses and utilize hand-writing recognition software to speed up the process of entering data.

Questions:

1. Do you routinely plan to enter ARES Screeners into your database prior to identifying patients who need an ARES sleep study?
2. Do you plan to perform consecutive/extensive screening with limited staff availability to enter responses?

F. Transferring files for technical review/interpretation

Background:

The ARES provides the capability to transmit files to third parties to perform technical review/interpretation via secure FTP or encrypted E-mail.

Feature Benefit:

- When properly configured, files can be automatically transmitted during the downloading and processing steps.
- After the files are interpreted, they can be transferred back to you for importation into your database with the files automatically saved in the designated folder(s), and the study status updated so final reports can be generated.
- If clinicians log in and perform interpretation on ABM's servers, the sleep study reports can be made available to your clients via ARES Quest, a secure portal.

Questions:

1. Do you plan to have technical review/interpretation performed by a third party and need to securely transfer the files off-site to perform this service?
2. Would you clients prefer to access their data from a web-service after receiving an email notifying them a report is ready for download?

G. Selecting the appropriate download and processing routine**Background:**

Downloading data from the Unicorder to the computer takes approximately 3 minutes for a one-night study, 6 minutes for a two-night study and 9 minutes for a three night study. The processing time needed to generate the file(s) for tech review/interpretation and a preliminary report (based on auto scoring) is 2 minutes with 1 GB of RAM and 5 minutes with 512 MB of RAM for a one-night study. For a two night study the processing is 5 minutes with 1 GB of RAM and 13 minutes with 512 MB of RAM. Typically, responses to the ARES History and Physical questionnaire are entered prior to generation of the preliminary report.

Feature Benefit:

- Single Study Processing: perform the download and process routine in a single step with a prompt to enter the ARES H&P responses.
- Batch Processing: Use combinations of action icons to download studies and enter H&P responses one at a time, and process multiple studies in batch mode. You will be notified when all of the studies have been processed.

Questions:

1. How many Unicorders do you plan on processing daily?
2. Will you be rushed to prepare a Unicorder for reuse soon after it has been returned by the patient?
3. Have you designated a computer with the resources needed for processing? Will this computer be available on a limited basis?

H. Choosing default settings for report formats**Background:**

The ARES provides default settings for the selection of report generation options. The majority of the settings impact the format and type of the information included in the Physician report. Other settings provide for automated generation of ancillary reports (e.g., patient report).

Features:

- Provide AHI results for up to two desaturation setting (i.e., AHI-4% and AHI-1%) on the front page.
- Include standard treatment recommendations based on AHI severity and positional influences.
- Automatically insert the interpreting physician's name and diplomat status. Generate a cover page that includes the digital signature of the physician and his/her impressions, comments and recommendations.
- Append the report with snap-shots of the physiological signals with an optional time scale (i.e., 4, 2, 1 hour or 15-minute period per snapshot)
- Insert the predicted CPAP pressure or predicted MRD post-treatment AHI with the treatment recommendations.
- Obtain a multi-night comparison of all sleep study statistics including the Apnea Index and multi-desaturation threshold Apnea/Hypopnea Indexes, hypoxemia, snoring, and pulse rate information.
- Generate special reports designed for a limited number of customers (e.g., physician report in text format to be copied into electronic medical records, 3-night report).

Questions:

1. Do you normally report the AHI using the Medicare desaturation threshold (4%) or the AASM threshold (3%) and/or include the RDI based on Chicago criteria (ARES equivalent AHI1%)?
2. Will the reports be interpreted? Is the interpreting physician boarded in sleep medicine?
3. Will the reports be provided to a third party who wishes to review the signal patterns of sleep disordered breathing associated with the report summary?
4. Is laboratory CPAP or APAP titration unavailable but an initial CPAP pressure is needed?
5. Do you recommend mandibular positioning therapy for patients with OSA? Would your treatment recommendation benefit from predicting the outcome assuming the optimal titration endpoint is achieved?
6. Do you plan to experiment with different conditions on each night that you wish to compare?
7. Do you want to provide your patient with a report that presents a simplified summary of his/her sleep study data and snapshots of the recordings?
8. Are you a Veteran's Administration service provider and need to insert sleep study results into the patient's electronic record?
9. Are you performing a three night diagnostic study?

I. Processing Options:

1. Fast and easy way to figure out how to manage the processing without having to read the manual:
 - Click on the Help Icon and watch the videos that explain how to perform each task.
2. Segregate patients by referral source or study group to allow for filtering and exporting of data for analysis:
 - Assign a new group for each new study/or account and make sure you select the appropriate group when you upload patient information.
3. Use the automated report transfer capabilities (i.e., electronic FAX, FTP or encrypted email):
 - Assign a new group for each client/referral source and enter the applicable information needed for automated transmission (e.g., method of transfer, FAX number, etc.).
4. Expect multiple Unicorders to arrive at the same time each day (e.g., UPS delivery), and you need a quick turn around to quickly prepare the Unicorders for reuse, then:
 - Start with the "Download Patient Data" icon and use the New ARES SA-H&P icon to enter the Questionnaire responses while the data are being downloaded (4-7 minutes). Then use the "Format Unicorder" icon to clear the flash card (1-minute) and begin charging the battery. The fast charging cable will complete the task in half the time (2 hours) of the standard data cable.
 - After the data are downloaded from all of the Unicorders, use the "Generate Pre Report" icon to process all of the studies in a batch mode on a dedicated computer.
5. Plan to prepare multiple Unicorders for use on the same day with the patient information preloaded:
 - Use the "Print Label" option to generate ½" x 2 ¼" labels with the patients name and study number for placement on the Unicorder box, all paperwork, etc. to avoid study mix-ups.
6. Need to confirm all of the Unicorder sensors are working properly, given the device is being worn by patients in their home and the device may get inadvertently damaged during use.
 - Use the functional test rig and ARES Manager software to confirm the reflectance sensor, accelerometers, microphone and nasal pressure transducer are working properly.
7. Use ABM's secure FTP service to make files available for technical support/interpretation, then:
 - Configure the FTP set-up during the software installation and perform the FTP data exchange test.
 - Select the view which includes the Download, Process and Send button for data processing.
8. Email data directly to a 3rd party for interpretation:

- Enter the 3rd party as a group.
 - Follow the procedures to transfer the encryption key to the 3rd party and save the 3rd parties encryption key on your computer/server.
 - Use the “Send for Edit” button and the data will be automatically transmitted to the 3rd party, and the 3rd party will use the “Transfer Edited Files” to return the files to you.
9. Export data from the database in Excel format for analysis:
- Configure a view with the fields that you wish to export and analyze (a listing and description of all fields is available)
 - Sort by group (if applicable) to isolate the data set of interest
 - Highlight the studies you wish to export, check “select all” to export all studies that appear on the screen.
 - Use the “Export to Excel” feature and a file will be automatically created.
10. Rerun the sleep study data at a later date with improved ARES algorithms and auto-scoring software for publishing purposes:
- Use the “Pre Rpt any Status” to reprocess the original EDF (raw data) file and generate new ASI files (used for tech editing).
 - Export the tech edits from the final report ASI and apply to the new ASI.
 - When acquiring multi-night studies, use the “Cut EDF” icon rather than “Cut ASI” icon so that each night of data can be reprocessed in this manner. Note: If you use the “Cut ASI” the EDF will remain a single file containing two or more nights of data.
11. Unlock a record that occurred as a result of a software conflict while automatically protecting the file during processing to avoid simultaneous editing:
- Highlight the study and select the “Unlock Study” icon.

J. Fields in the views:

1. Monitor how long a Unicorder has been with a patient:
 - Compare the information presented in the “Date Data Uploaded” and “Date Data Downloaded” fields.
2. Assess turn around time for processing sleep studies:
 - Compare the “Date Data Downloaded” field to the “Date Tech Reviewed” to assess the turn around for this step.
 - Compare the “Date Tech Reviewed” to the “Date Interpret” fields to assess how quickly the studies are being interpreted.
 - Compare the “Date Final Rpt Req’d” to the “Date Report Transmitted” fields to monitor the final step.
3. Monitor turn around time when you’re transmitting studies to a 3rd party for technical review /interpretation:
 - Compare the data in the “Date Data Transmitted” and the “Date Data Received” fields.
4. Assess whether a patient was wearing the Unicorder at the correct setting? This would be helpful in explaining signal quality problems and monitoring how well you staff is following the dispensing instructions:
 - Use the “Strap Error N1” field, a positive (negative) value means the strap was looser (tight) than the recommended setting. A value > (<) 1 suggests the instructions were not properly followed/ communicated.
5. Ensure the ARES H&P responses have been entered before generating reports:
 - Use the “H&P OSA Risk” and “H&P OSA Severity” fields, if these are blank, then the responses have not been entered.
6. Determine if the sleep study should be automatically repeated because the study length was too short:

- Use the “PA Valid Time” derived from the automated algorithms to generate the preliminary (PA) report. Note: Periods may be automatically excluded from valid time (e.g., poor quality airflow, patient is upright) that may be corrected during technical review that can result in an increase in valid recording time.
7. Assess whether patient responses were inconsistent from the ARES Screener to the ARES H&P resulting in differences in the predicted OSA risk and severity:
 - If the order for a sleep study is base on an ARES Screener result, then you want to have the OSA risk and OSA severity used to establish the medical necessary to appear on the Sleep Study report. On occasion patient responses from the ARES H&P filled out in their home results in a less severe prediction than that obtained from responses at the clinicians office. To avoid this inconsistency, set default for the Sleep Study to use the Screener OSA risk and severity.
 - If you don’t use the ARES screener, or wish to use the feel the ARES Use the “H&P OSA Risk” and “H&P OSA Severity” fields, if these are blank, then the responses have not been entered.

K. Tech Review and Interpretation:

1. Fast and easy way to understand how the scoring software works without having to read the manuals.
 - Highlight a sample sleep study file, and click on Edit ASI.
 - Select Help and choose the video title that presents information of interest.
2. Add unique comments to be incorporated with the standard statements that appear on the ARES report:
 - Highlight the study and select the “Comments” icon, select the Add to Standard Messages tab and insert text into the Technical, Summary Findings, Desaturation Severity or Treatment Considerations fields. Your comments will be automatically appended to the standard messages when the final report is generated.
3. Insert the physician signature onto the ARES report:
 - Scan and reduce the signature to 200 x 50 pixels in GIF format and place in the ABM\ARES client data\ signature folder.
 - Use the “Comments” icon and select the signature file in the Physician Interpretation dialog box.
4. Generate an intermediate report which recalculates the AHI to assess changes which resulted from technical editing/ interpretation:
 - Highlight the study and select the “Generate Rpt All Nights” icon.
5. Generate a comparison report between two studies (each study could be one or the average of two nights):
 - Highlight the study and select the “Test-Retest Rpt” icon.
6. Generate a two- or three-night comparison report (for MRD titration studies):
 - Highlight the study and select the “Three-night Comparison Rpt” icon.
7. Generate a three-night comparison report but the study type was not correctly assigned as “three night study” when the patient information was uploaded:
 - Highlight the study and select the Edit Order icon, change the study type to “three night study”.
 - Highlight the study and select the “Three-night Comparison Rpt” icon.
8. Cancel a study because it was technically compromised and needs to be repeated:
 - Highlight the study and select the “Cancel Study - QC” icon.