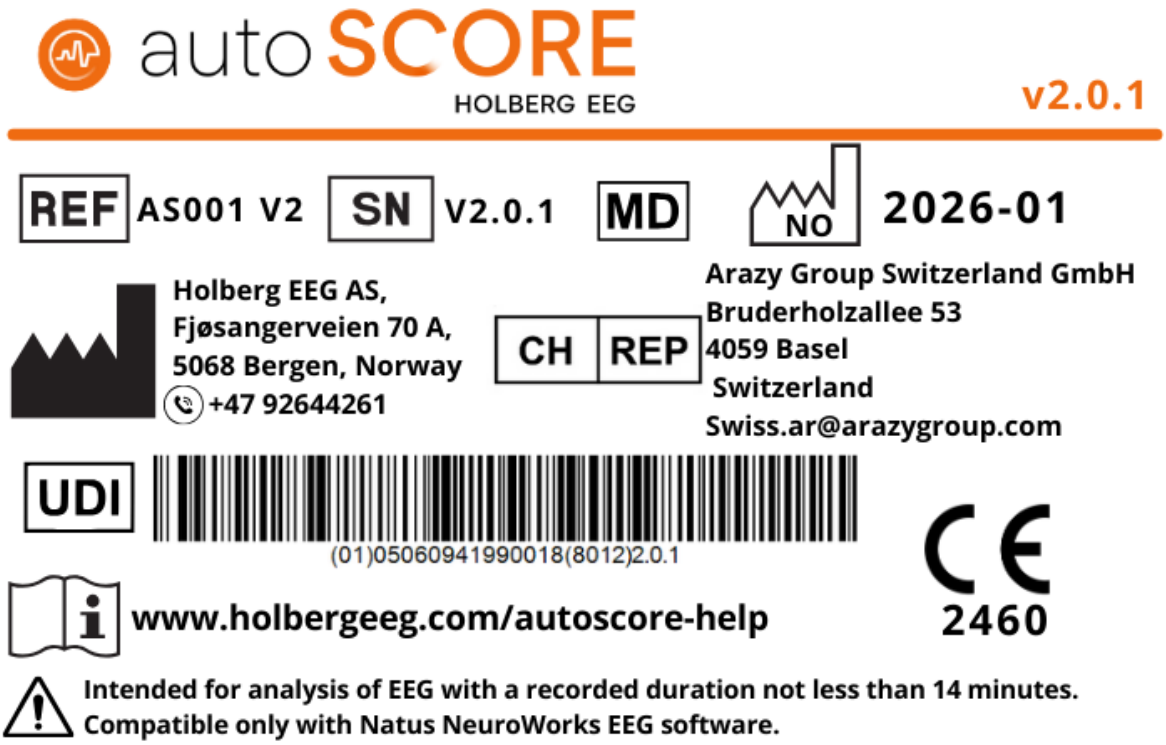
HOLBERG EEG

autoSCORE

Instructions for Use



Device Label reference: HB-002118-RA Issue 6

Symbol	Description	Symbol	Description
REF	Catalogue Number		Country of Manufacture
UDI	Unique Device Identifier		Consult Electronic Instructions for Use
SN	Serial Number		Warning
MD	Medical Device	CE 2460	CE Mark
	Legal Manufacturer	CH REP	Swiss Authorised Representative

Contents

1. About the Instructions for Use

The purpose of this document is to describe the use of autoSCORE, version 2.0.2

2. Intended use and device description

2.1. Intended Use

autoSCORE is a software-only decision support product intended to be used with compatible EEG software. It is intended to assist the user when reviewing EEG recordings by assessing the probability that the previously acquired sections of EEG recordings contain abnormalities and classifying these into pre-defined types of abnormality. autoSCORE sends this information to the EEG software to indicate where markers indicating abnormality are to be placed in the EEG.

autoSCORE also provides an overview of the probabilities that EEG recordings between 14 minutes and 4 hours include any abnormalities and the probabilities of specific predefined type of abnormalities they include. For EEG recordings of duration more than 4 hours, autoSCORE indicates the number of segments with duration of 2-4 hours that include any abnormalities and the total number of analyzed segments. The overview for EEG recordings of duration more than 4 hours also provides the number of segments that include specific pre-defined types of abnormalities and the total number of analyzed segments.

The user is required to review the EEG and exercise their clinical judgement to independently make a conclusion supporting or not supporting brain disease.

autoSCORE cannot detect or classify seizures. The recorded EEG activity is not altered by the information provided by autoSCORE. autoSCORE is not intended to provide information for diagnosis but to assist clinical workflow when using the EEG software.

2.2. Indications for Use

autoSCORE is indicated for assisting clinical review of scalp EEG recordings acquired by suitably trained and qualified professionals to collect data supporting or not supporting brain disease.

2.3. Intended Users

The intended users are suitably trained professionals who are qualified to clinically review EEG recordings.

2.4. Intended Patient Population

autoSCORE use is restricted to EEG recordings from patients over 3 months of age.

autoSCORE cannot be used for EEG recordings from neonatal patients.

autoSCORE is not intended to be used for comatose intensive care unit (ICU) patients.

There are no other restrictions regarding the patient population.

2.5. Intended Use Environment

autoSCORE is intended to be used in environments where clinical EEGs are acquired or reviewed by suitably trained and qualified professionals.

autoSCORE is intended to be used for the analysis of EEG that has been recorded in environments suitable for adult and pediatric Routine EEG, Long Term Monitoring, and Ambulatory EEG recordings according to best clinical practice, excluding acquisition environments for ICU and neonatal recordings.

2.6. Contraindications and unwanted side effects

autoSCORE has no contraindications or unwanted side effects.

2.7. Operating Principle

autoSCORE is a locked algorithm trained to indicate if sections of EEG include abnormalities by using standard deep learning principles.

autoSCORE requires the input of previously acquired EEG sections as well as EEG metadata like patient age and gender.

Upon receiving this data, autoSCORE indicates the probability that previously acquired sections of EEG recordings contain abnormalities and classifying these into pre-defined types of abnormality. autoSCORE sends this information to the EEG software to indicate where markers indicating abnormality are to be placed in the EEG. The spike detection component of autoSCORE is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes.

autoSCORE also provides an overview of the probabilities that EEG recordings between 14 minutes and 4 hours include any abnormalities and the probabilities of specific predefined type of abnormalities they include. For EEG recordings of duration more than 4 hours, autoSCORE indicates the number of segments with duration of 2-4 hours that include any abnormalities and the total number of analyzed segments. The overview for EEG recordings of duration more than 4 hours also provides the number of segments that include specific pre-defined types of abnormalities and the total number of analyzed segments.

autoSCORE is integrated with a compatible EEG software to present the abovementioned autoSCORE output to the user. The autoSCORE output is visualized in the EEG software's user interface.

2.8. Conditions for Use

autoSCORE does not interact with the patient or the user. autoSCORE is available as a feature in the compatible EEG reviewing software.

- autoSCORE can be used only with a compatible EEG reviewing software. It cannot be installed by a clinical user but only by a technician who can install the EEG reviewing software. autoSCORE cannot be installed separately.
- An EEG reviewing software is deemed compatible if it can
    - Provide the required input to autoSCORE (patient age, gender, EEG recorded with the expected sampling rate according to section 3.1 and EEG sensors)
    - Display the autoSCORE output (including markers, start and stop of segments, probability values, user messages)
    - Display the autoSCORE label and IFU
- autoSCORE can be used with an EEG Reviewing software only when the System Integration Protocol is determined to be passed and accepted by HOLBERG EEG AS.
- autoSCORE can be used only on scalp EEG recordings.
- autoSCORE can be used only on patient population of age greater than 3 months.
- autoSCORE can be used only on EEG recordings with a recorded duration of 14 minutes or longer.
- autoSCORE should not be used on EEG recordings from comatose ICU patients.

2.9. Warnings and restrictions of use

autoSCORE use is restricted to EEG recordings with a recorded duration of 14 minutes or longer. When a completed EEG recording has a recorded duration outside these limits, autoSCORE will generate no output for it. Instead, it will generate an error message to inform the user about the invalid recording duration.

autoSCORE use is restricted to EEG recordings from patients over 3 months of age. autoSCORE cannot be used for EEG recordings from neonatal patients.

autoSCORE use is restricted to EEG recordings acquired in environments that are considered suitable for Routine EEG, Long Term Monitoring, and Ambulatory EEG recordings acquisition according to best clinical practice, excluding recordings from comatose ICU patients and neonatal recordings.

autoSCORE is not intended to be used as a monitoring device or for the real-time surveillance of EEG. autoSCORE output is presented in the user interface of the compatible EEG software after the EEG recording is completed if it meets the prerequisites for autoSCORE analysis. For live EEG recordings longer than 4 hours, results can be given for previously acquired sections of the recording with a delay of 2 hours.

autoSCORE cannot replace the examination by a physician. As for any other automatic procedure, there can be inaccuracies during the analysis with autoSCORE for example due to artifacts. The original EEG still needs to be used for evaluation, and the results of autoSCORE need to be confirmed based on a qualified review of the EEG.

autoSCORE does not provide any diagnosis or diagnostic recommendation, conclusion, or prediction of the patient's state. The diagnosis and treatment are the responsibility of the physician.

3. Cybersecurity

autoSCORE does not meet the definition of a cyber device. It does not transmit any data over wired or wireless networks and does not have the ability to connect to the internet. autoSCORE does not interface or collect any protected health information.

autoSCORE is fully integrated into the compatible EEG software via a development kit that is provided for the developers and not intended for individual end users of this software.

4. Installation warning and error messages

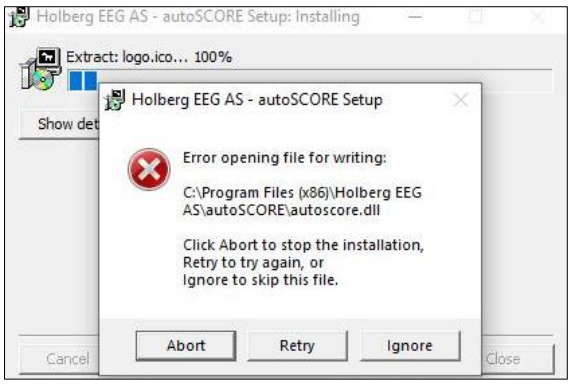
When the system requirements are not met while running the installer, one or several warnings will be displayed. The table below lists the warnings and the suggested action to take when these appear. After these actions you can retry running the installer.

Note: The warnings allow to continue the installation without taking additional action. However, this may compromise the performance of autoSCORE and is not recommended.

Warnings	Suggested actions
The installed Windows version is not supported	Install Windows 10 or newer on the computer
Microsoft Visual C++ 2015 is not installed	Install Microsoft Visual C++ 2015 or newer **Note:** When Microsoft Visual C++ Redistributable version 2015 is not installed and the installation is continued, then warnings will be displayed for all other system requirements even when these are fulfilled.
Insufficient number of logical processors	• Physical machine: upgrade to a new processor • Virtual machine: increase the number of logical processors to a total of 4 or more in the virtual machine's settings
The installed RAM is less than 1 GB	• Physical machine: add RAM to a total of 1 GB or more • Virtual machine: increase the RAM size to a total of 1 GB or more in the virtual machine's settings

Warnings	Suggested actions
The available RAM is less than 500 MB or the percentage of RAM in use exceeds 95%	• Verify that the paging file is switched on • Close other programs with high RAM usage if possible • Restart the computer • Use a trustworthy antivirus- or malware protection software to scan the computer in case malicious software is causing memory issues • If these actions have no result, you could increase the installed RAM
The available disk space is less than 800 MB	• Verify if the computer has more than 800 MB disk space • Manually delete temporary files and any unnecessary programs or files • Run Windows Disk Cleanup or another clean up software • Move less used files to an external storage disk • Disable hibernation in Windows to free up space occupied by hiberfil.sys • If the computer has sufficient RAM (4 GB or more), disable the virtual memory in Windows to free up space occupied by pagefile.sys • Use a trustworthy antivirus- or malware protection software to scan the computer in case suspicious software is occupying disk space • If these actions have no result, you could add a disk for physical machines, or increase the disk size in the settings for virtual machines

The upgrading or reinstalling of autoSCORE cannot take place while autoSCORE is in use. If that is attempted, then the installer will display the error message below.



4.1. Installation report

Upon successful installation, the autoSCORE installation report will be generated in text document format named 'autoscore_install' in the autoSCORE installation directory, which by default will be C:\Program Files (x86)\Holberg EEG AS\autoSCORE unless it was changed during installation. If the installation fails, then a diagnostic report will be created in text document format named 'autoscore_install' in C:\Users\AppData\Local\Temp.

4.2. Uninstalling autoSCORE

autoSCORE can be uninstalled via the standard Windows feature for uninstalling programs. Navigate to 'Control Panel > Programs and Features', then select 'Holberg EEG AS – autoSCORE' from the list and click on 'Uninstall'.

It is also possible to uninstall autoSCORE by navigating to the autoSCORE installation folder and double clicking on the 'uninstall' executable file. The autoSCORE installation folder is by default located in C:\Program Files (x86)\Holberg EEG AS\autoSCORE.

A confirmation box will appear in which you can click 'OK' to proceed with permanently removing autoSCORE. Once the uninstallation is completed you can click 'Close' to close the window.

5. Using autoSCORE

5.1. Prerequisites to using autoSCORE

A working proficiency with EEG- and computer systems is assumed for using autoSCORE. Once the autoSCORE software is installed on a computer in combination with a compatible EEG software, then autoSCORE can be accessed through the EEG software's user interface. Accessing autoSCORE will depend on the specific configuration of your EEG software. Please refer to the EEG software's Instructions for Use for more details.

The autoSCORE software accepts a recorded EEG signal and its metadata as input for a session, without which autoSCORE will not run.

autoSCORE expects the following EEG metadata to be available in the EEG recording:

- Patient age of 90 days or over - autoSCORE is not intended for neonatal patient recordings.
- Patient gender defined as male, female or unknown.

The autoSCORE software also expects the following properties to be present in the EEG recording:

- Sampling rate between 256 Hz and 2048 Hz.
- EEG recording duration of 14 minutes or longer.
- Recorded channels commonly used in the 10-20 system (Fp1, Fp2, F7, F3, Fz, F4, F8, T3 or T7, C3, Cz, C4, T4 or T8, T5 or P7, P3, Pz, P4, T6 or P8, O1, O2) plus an ECG or EKG channel, as a minimum.

The autoSCORE session will not start the session and will generate an error message unless these conditions are met.

For optimal autoSCORE results, it is highly recommended that a trained and qualified professional evaluates the quality of the EEG recording and confirms that it is suitable for clinical EEG reviewing by human experts. EEG recordings not regarded suitable for clinical review should not be used for autoSCORE analysis.

5.2. Starting an autoSCORE session

Once the prerequisites are met, and depending on the configuration of your EEG reviewing software, autoSCORE will either be initiated automatically or will require the user to initiate autoSCORE. Please refer to the EEG software's Instructions for Use for more details.

5.3. Stopping an autoSCORE session

Once the autoSCORE session has been started, it will stop automatically when autoSCORE has generated the output for the recording or when an error has occurred. No manual action is required to end the session. It is not recommended to stop the session manually before analysis is completed on the full duration of the EEG recording as this will result in only partial analysis of the EEG recording.

5.4. Availability of the autoSCORE output

The user shall have the option to run the autoSCORE analysis when the EEG recording starts or after the EEG recording has been completed. The availability of the autoSCORE output in the compatible EEG software's user interface will depend on this configuration as well as the total duration of the EEG recording.

For EEG recordings with a duration between 14 minutes and 4 hours of recorded time, the autoSCORE output is always presented after the recording is completed.

If the EEG recording has a final recorded time shorter than 14 minutes then autoSCORE will generate an error and no output will be presented.

If the EEG recording has a duration longer than 4 hours of recorded time and the autoSCORE analysis is configured to run when the EEG recording is started, then autoSCORE will generate partial output while the EEG recording is ongoing. In this case the output is presented in segments of 2 hours duration, except the last segment which will have a duration of 2-4 hours. The autoSCORE output will start after 4 hours of recorded time. For example:

- After **4 hours** of recorded time, autoSCORE output is presented for the **first 2 hours** of recorded EEG.
- After **6 hours** of recorded time, autoSCORE output is presented for the **first 4 hours** of recorded EEG.
- After **8 hours** of recorded time, autoSCORE output is presented for the **first 6 hours** of recorded EEG.

Note that for an ongoing EEG recording, autoSCORE always generates output with a 2-hour delay, for part of the recorded EEG data only. In this situation, an information message will be displayed to indicate for which part of the recording the output has been generated. The absence of autoSCORE output in the last part of the ongoing recording must not be interpreted as an absence of abnormality.

Additional delay in output availability can be introduced for all recording durations and modes of analysis. This delay may vary depending on:

- the total duration of the EEG recording
- the technical specifications of the system
- the configuration of autoSCORE in the EEG software

As these parameters may vary per session, the exact delay of output presentation cannot be specified. In case it differs significantly from the expected delay, the manufacturer can be contacted. Please refer to the contact details on the first page of this document.

6. Viewing the autoSCORE output

6.1. autoSCORE Output Visualization

Figure 1, 2 and 3 show how autoSCORE outputs are visualized for EEGs ≤4 hours and >4 hours.

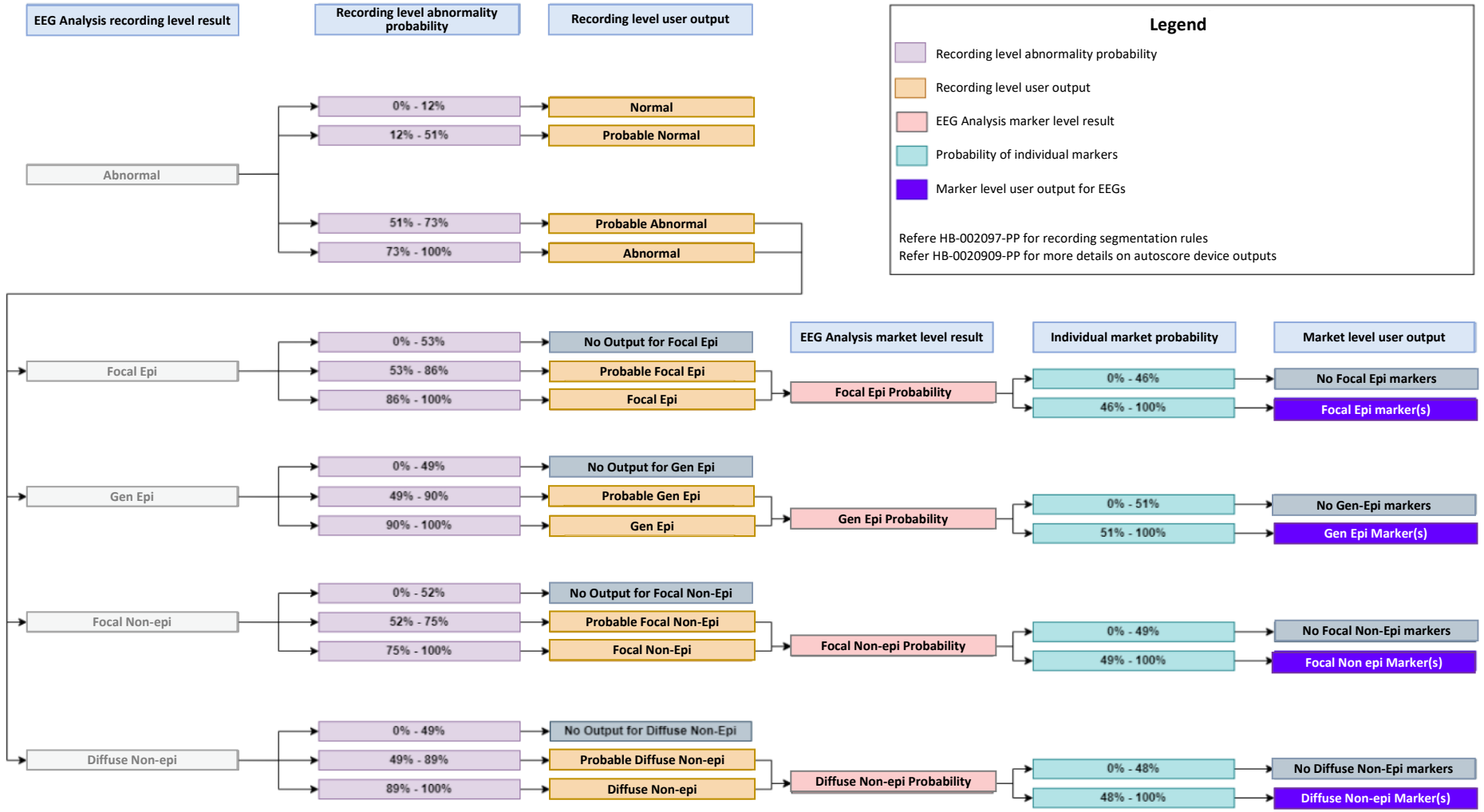


Figure 1 – This flowchart shows the hierarchical organization of the autoSCORE outputs and the thresholds which determines classification into categories of normal or abnormal, type of abnormality and associated markers for recordings with duration of less than four hours. The arrows indicate dependencies, for example: a marker of type Focal Epi is only given if the recording level output also is above threshold for Focal Epi.

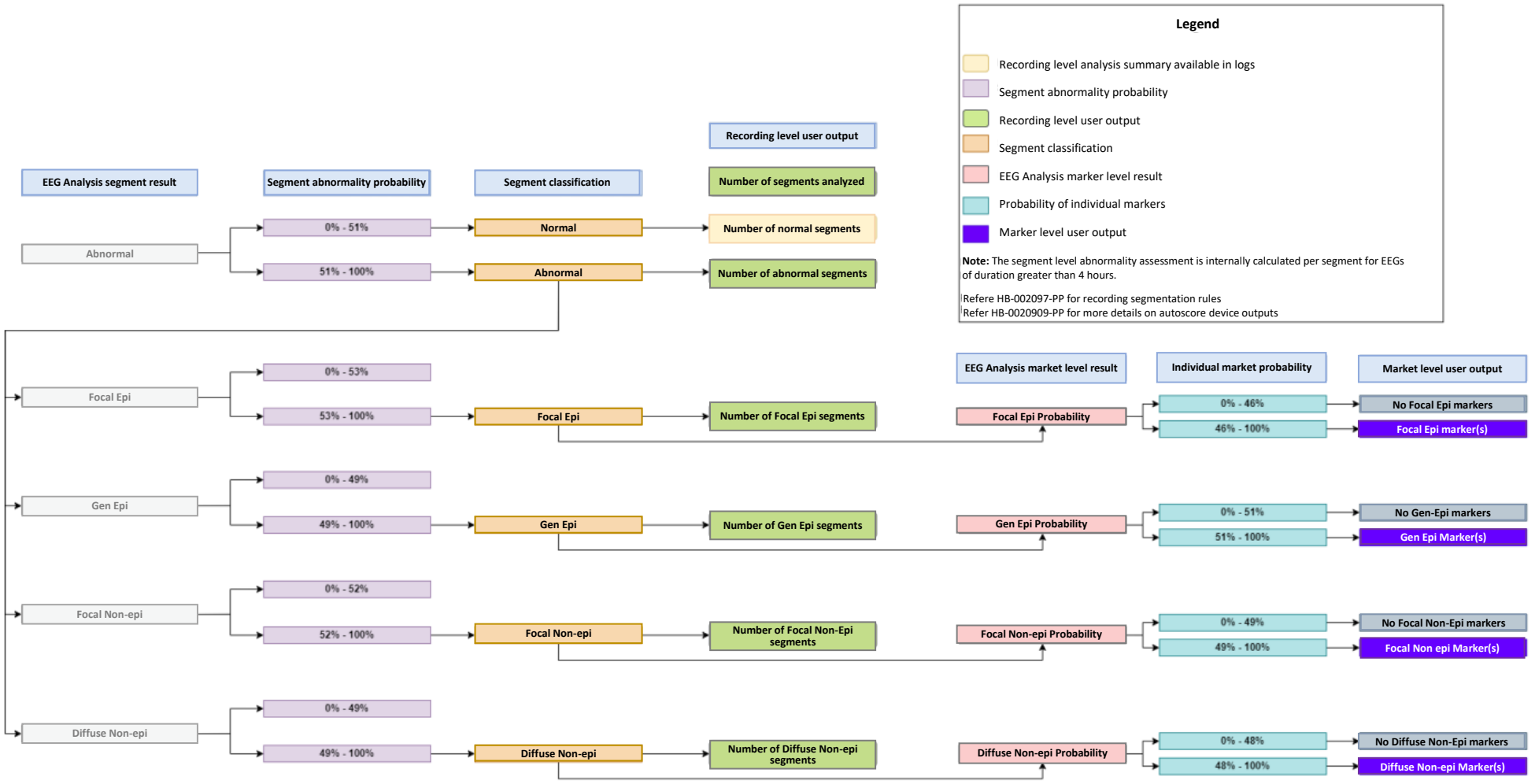


Figure 2 – This flowchart shows the hierarchical organization of the autoSCORE outputs and the thresholds which determines classification into categories of normal or abnormal, type of abnormality and associated markers for recordings with duration of four hours and longer. The arrows indicate dependencies, for example: a marker of type Focal Epi is only given if the associated segment level output also is above threshold for Focal Ep

HOLBERG EEG

ID	Name	Duration	as Info	Abnormality	Focal Epi	Gen Epi	Focal Non-Epi	Diff Non-Epi
1	Patient 1	>4h		0/17 segments				
2	Patient 2	>4h		7/7 segments	7/7			
3	Patient 3	>4h		5/10 segments	5/10	1/10		
4	Patient 4	<4h		94 %	74%	90%	70%	82%
5	Patient 5	<4h		5 %				

Figure 3: Recording Level output for EEGs ≤4h (Patients 4 and 5) and >4h (Patients 1-3). autoSCORE outputs for EEGs containing one or more types of abnormalities are shown in red, while EEGs classified as normal (not containing any type of abnormalities) are shown in green.

6.2. Normal or abnormal

For each EEG recording autoSCORE indicates if EEG contains abnormality. EEGs longer than 4 hours are divided into 2 hours segments, except for the last segment, which can have a duration between 2 and 4 hours. For these recordings results are given per segment. Segments start and stop times are provided to the compatible EEG reader. The table below summarizes the information provided by autoSCORE.

autoSCORE Feature	EEG recoding duration between 14 minutes and 4 hours	EEG recording longer than 4 hours (minimum 2 segments)
Normal/Abnormal	Normal or Abnormal	Number of abnormal segments Number of analyzed segments
Confidence-based levels of abnormality	Normal EEG Probable normal EEG Probable abnormal EEG Abnormal EEG	Not provided for segments
Probability	Estimated probability that recording contains abnormality is provided as percentage	Not provided for segments

6.3. Types of abnormality

For each EEG recording which is estimated to contain abnormality, autoSCORE also indicates which type(s) of specific predefined abnormality it is estimated to contain. autoSCORE can indicate the following types of abnormality:

Abnormality type	Abbreviation
Focal epileptiform abnormality	Focal Epi
Generalized epileptiform abnormality	Gen Epi
Focal non-epileptiform abnormality	Focal Non-Epi
Diffuse non-epileptiform abnormality	Diff Non-Epi

For each type of abnormality present in the EEG following information are provided:

autoSCORE output	EEG recoding duration between 14 minutes and 4 hours	EEG recording longer than 4 hours (minimum 2 segments)
Containing [abnormality type]	If no information given then [abnormality type] not found	Number of segments containing [abnormality type] Number of analyzed segments
Confidence-based levels of abnormality	Probable [abnormality type] [Abnormality type]	Not provided for segments
Probability	Estimated probability that recording contains [abnormality type] is provided as percentage	Not provided for segments

In exceptional cases, autoSCORE indicates that the EEG recording may contain abnormal activity, but cannot indicate any specific abnormality type(s) for the EEG recording, and will not place any specific type(s) of markers in the EEG recording. This is an expected scenario, estimated to occur in less than 1% of the EEG recordings.

6.4. Notes on autoSCORE markers

The minimum duration of an autoSCORE marker is 8 seconds regardless of the visible duration of the related abnormality in the EEG.

autoSCORE markers may be overlapping in time within the EEG recording. Please refer to the compatible EEG software's Instructions for Use regarding the visual presentation of overlapping markers.

6.5. General notes on the autoSCORE output

The visual presentation of the autoSCORE output may vary depending on the user interface of Compatible EEG software. For more information, please refer to the EEG software's Instructions for Use.

The autoSCORE software uses a locked algorithm, which will always produce identical output provided that the input is identical. The algorithm is not designed to change or update within the same software version.

The autoSCORE software may present output that differs from the user's assessment. The EEG reviewer is required to exercise their own expertise to independently evaluate if their final EEG report is in line with their clinical judgement. The EEG reviewer should not include autoSCORE results in an EEG report if the reviewer disagrees with these results.

In exceptional cases, autoSCORE indicates that the EEG recording may contain abnormal activity, but does not indicate any specific abnormality type(s) for the EEG recording and does not place any specific type(s) of markers in the EEG recording. This is an expected scenario estimated to occur in less than 1% of the EEG recordings.

autoSCORE is not intended to detect or classify seizures. Absence of markers should therefore not be assessed as absence of seizures.

autoSCORE is not intended to provide output in line with ICU EEG terminology.

6.6. autoSCORE development and performance validation

6.6.1. autoSCORE AI model development

autoSCORE was developed by creating a convolutional neural network model with the ability to:

- distinguish normal from abnormal scalp EEG recordings from patients of 3 months of older
- classify the abnormal EEG recordings into four categories relevant for clinical decision making
- indicate where classified abnormalities are assessed to be present in the EEG time series
- generate a probability value for each assessment, indicating how certain the model is about the assessment

The deep learning model was trained on a large dataset of EEG recordings that were annotated with SCORE EEG, a standardized software tool for annotating EEG recordings using common data elements. Further details about the development of the neural network model can be found in the publication Tveit J et al. Automated interpretation of clinical electroencephalograms using artificial intelligence. JAMA Neurol 2023 Aug 1; 80:805. https://doi.org/10.1001/jamaneurol.2023.1645.

6.6.2. autoSCORE performance validation

The model was validated by comparing its output to the EEG assessment of humans who are considered experts in the field of clinical EEG reviewing. Two independent test datasets were used for this validation: a multi-center dataset of 100 representative EEG recordings evaluated by 11 human experts, and a single-center dataset of 9875 EEG recordings evaluated by 14 human experts. All EEG recordings had duration between 14 minutes and 4 hours. The validation results shown in the table below (100 EEGs, 11 HEs) present results confirming that agreement between autoSCORE and HE consensus is similar to agreement between 11 HEs based on AC1 statistics.

Category	autoSCORE vs HE consensus	HE vs HE
Normal	0.903 (0.820, 0.987)	0.723 (0.649, 0.796)
Focal Epi	0.757 (0.634, 0.880)	0.723 (0.643, 0.803)
Gen Epi	0.928 (0.865, 0.991)	0.901 (0.854, 0.949)
Diffuse Non-Epi	0.738 (0.608, 0.868)	0.630 (0.539, 0.721)
Focal Non-Epi	0.775 (0.657, 0.893)	0.587 (0.499, 0.674)

An additional validation was performed by comparing the autoSCORE output to three previously published artificial intelligence models, two of which have already been marketed legally as a medical device in the USA. As these models were designed to detect interictal spikes, the comparison focused on autoSCORE output for epileptiform abnormalities only. The dataset for this validation consisted of 60 video-EEG recordings (average duration 20 minutes) including the habitual clinical episodes as well as interictal “spike candidates”. An external independent assessment was derived from the video-EEG of the episodes to evaluate the presence or absence of epilepsy which also defined if the interictal “spike candidates” were true positive (in the patients with epileptic seizures) or false positive (in the patients with non-epileptic episodes). The accuracy of autoSCORE was 88.3%; (95% confidence interval: 79.2-94.9%).

7. autoSCORE user messages

The autoSCORE software will display user messages when applicable. These messages can be errors, warnings, or information messages. Error and warning messages will be displayed with a code which can be used to look up specific message details in one of the tables in this section. The codes and details can be used to resolve or report issues more efficiently.

Errors will end the autoSCORE session. Warnings will allow the autoSCORE session to continue, but the performance of the system or the autoSCORE software may be reduced.

The table below shows a list of the autoSCORE errors.

Code	Error details	Suggested action
400	Unknown error	Contact support if this error persists
401	Invalid recording duration	Ensure that the recorded time of the EEG is longer than 14 minutes
402	Invalid sampling rate	Ensure that the recording has a sampling rate between 256 Hz and 2048 Hz
403	Invalid patient age	Ensure that the patient was 90 days of age or older when the EEG was recorded
404	Invalid channel details	Ensure that all required EEG channel labels are present in the recording and are spelled correctly without duplicates – case sensitivity does not apply
409	Recording data input cannot be received	Restart the autoSCORE session or contact support if this error persists
410	File path is wrong or read access is denied	Ensure that the file exists and that autoSCORE has access to it
412	Invalid patient gender	Ensure that the patient gender has been entered

Code	Error details	Suggested action
420	Failed to verify sha256 checksum	Contact support if this error persists
421	Decryption failed	

The table below shows a list of the autoSCORE warnings.

Code	Warning details	Suggested action
301	Operating system not supported	Ensure that system requirements are met, or contact support if this error persists
302	Insufficient installed physical memory	
303	Insufficient available physical memory	
304	Percentage of physical memory in use is beyond acceptable threshold	
305	Insufficient number of available logical processors	
307	Available disk space is low	

The table below shows a list of the autoSCORE information messages.

Code	Information message	Note
201	autoSCORE is analyzing the recording. Output will appear after the recording is completed or after 4 hours of recorded time for ongoing recordings	autoSCORE will display this message while analyzing recordings of less than 4 hours of recorded time
202	autoSCORE is analyzing the recording. Output has been provided for the first x hours of recorded time. Additional output will be provided every 2 hours of recorded time or after the recording is completed	autoSCORE will update the x value in this message dynamically while generating output for recordings of 4 hours of recorded time or longer
203	autoSCORE stopped analyzing the recording, output has been provided for the first x hours of recorded time only	autoSCORE will display this message in combination with an error when no output could be generated for part of the ongoing or completed recording
204	autoSCORE completed the analysis, output for all recorded time has been provided	autoSCORE will display this message when all output for the recording has been generated without errors

Information messages will be displayed without a code in the EEG software's user interface. They may be displayed in combination with alerts or errors. The visual presentation of messages may vary depending on the compatible EEG software's user interface. For more information, please refer to the EEG software's Instructions for Use.

8. Log messages and analytics

autoSCORE offers the option to save log messages and analytics on the computer for troubleshooting purposes.

The log messages can be saved as Event Logs in the Windows Event Viewer and as File Logs at a selected location. Each log message contains the message's severity level, timestamp, code and text. If applicable, the session ID will also be included. The next table shows an overview of message severity levels.

Nr.	Severity	Description
0	Debug	Used by Support for specific debug purposes only
1	Information	All autoSCORE information messages, abnormality output and the related EEG ID
2	Warning	All autoSCORE warning messages
3	Error	All autoSCORE error messages

The analytics consist of two comma-separated value files containing the autoSCORE output in a machine-readable format. Information is added to each of these two files when new autoSCORE output is generated. Metadata are included in the files to help identify the recording / analysis session for which the output was generated.

File name	Description
autoSCORE_recording_outputs.csv	Each row represents the autoSCORE abnormality assessment for one recording / analysis session
autoSCORE_marker_outputs.csv	Each row represents the autoSCORE abnormality assessment for one marker within a recording / analysis session

When autoSCORE is installed, default settings for logging and analytics are enabled. With the exception of the Event Log location, these settings can be changed by a user with administrative privileges as presented in the next table.

Log type	Default logging	Default severity levels	Default max log file size	Default location
File Log	Enabled	1-information 2-warning 3-error	5 MB	%APPDATA%\Holberg EEG AS\autoSCORE\Logs Note: If autoSCORE is used while the EEG recording is ongoing, the File Logs will be saved in: %systemroot%\SysWOW64\config\systemprofile\AppData\Roaming\Holberg EEG AS\autoSCORE\Logs
Event Log	Enabled	2-warning 3-error	N/A	Event Viewer\Applications and Services Logs\Holberg EEG AS Note: This location is not user-configurable and can be accessed through the Windows Event Viewer: press 'Windows key' and 'R' to open the 'Run' command window, then type 'eventvwr' in the text field and press 'Enter'.
Analytics	Disabled	N/A	N/A	%APPDATA%\Holberg EEG AS\autoSCORE\Analytics Note: If autoSCORE is used while the EEG recording is ongoing, the File Logs will be saved in: %systemroot%\SysWOW64\config\systemprofile\AppData\Roaming\Holberg EEG AS\autoSCORE\Analytics

8.1. Enabling or disabling the logs

The Windows Event Log and the File Log can be enabled or disabled by following these steps:

Press 'Windows key' and 'R' to open the 'Run' command window.

Type 'regedit' in the text field and press 'Enter' to open the 'Registry Editor'.

Navigate to HKEY_LOCAL_MACHINE\SOFTWARE\Holberg EEG AS\autoSCORE\Logging.

Locate in this folder the files 'enable_rolling_file_log' for File Logs and 'enable_win_event_log' for Event Logs.

Open the file for the log that you want to configure by double clicking it.

To enable the log, set the value to '1'. To disable the log, set the value to '0'.

8.2. Configuring the Windows Event Log

The Windows Event Log can be configured by following these steps:

Navigate to the registry HKEY_LOCAL_MACHINE\SOFTWARE\Holberg EEG AS\autoSCORE\Logging\win_event_log.

Use the key max_severity_level to configure the upper level of severity for the event log.

Use the key min_severity_level to configure the lower level of severity for the event log.

8.3. Configuring the File Log

The File Log can be configured by following these steps:

Navigate to the registry HKEY_LOCAL_MACHINE\SOFTWARE\Holberg EEG AS\autoSCORE\Logging\rolling_file_log.

Use the key log_folder to configure the location in which the file logs are saved.

Use the key max_severity_level to configure the upper level of severity for the file log.

Use the key min_severity_level to configure the lower level of severity for the file log.

Use the key rotation_size to configure the maximum size of each file log. Once a file log reaches this maximum size, a new file log will be automatically created.

8.4. Enabling or disabling the analytics

The analytics can be enabled or disabled by following these steps:

Press 'Windows key' and 'R' to open the 'Run' command window.

Type 'regedit' in the text field and press 'Enter' to open the 'Registry Editor'.

Navigate to HKEY_LOCAL_MACHINE\SOFTWARE\Holberg EEG AS\autoSCORE.

Locate in this folder the file 'enable_analytics' and open it.

To enable the analytics, set the value to '1'. To disable the analytics, set the value to '0'.

8.5. Archive and backup of logs and analytics

The total file size of analytics and file logs will gradually increase by using autoSCORE. Administrators can decide to archive older files on a regular basis to free up storage on the computer. It is also recommended to backup these files on a regular basis to mitigate the risk of file corruption by manual editing.

9. System Requirements and Compatibility

The table below shows the system requirements for optimal performance of the autoSCORE software.

Operating System	Windows 10
Minimum installed RAM	1 GB
Minimum allocatable RAM	500 MB
Maximum percentage of RAM in use when starting autoSCORE software or autoSCORE session	95%
Number of logical processors (processor cores) available	4
Processor must support	SSE3 instructions

Minimum available hard disk (storage) space	800 MB
List of compatible and interoperable EEG reviewing software	https://www.holbergeeg.com/compatible-eeg-reviewing-software

autoSCORE is intended to be used with a compatible EEG software. autoSCORE is only compatible only with Natus NeuroWorks software. autoSCORE does not change or influence the intended use of Natus NeuroWorks. Use only in accordance with the Natus NeuroWorks Instructions for Use.

Please contact the EEG software manufacturer regarding IT security measures necessary to run the software as intended, including protection against unauthorized access.

10. Reporting to Competent Authorities

If any serious incidents occur during the use of this medical device, the user shall report it to the Holberg EEG AS at quality@holbergeeg.com / support@holbergeeg.com and the competent authority of the country in which the user resides.

11. Troubleshooting Potential Failure Modes

Following table list all the failure mode the user may face while using autoSCORE, Risk references listed below are Holberg EEG internal Risk file references.

RISK Reference	Potential Failure	Failure Cause	Recommendation to User
ASNI-3	Signal from recorded and analyzed EEG or ECG sensor might be degraded which results in autoSCORE providing incorrect results because it was fed incorrect signal input data by NeuroWorks EEG reader.	EEG or ECG sensor is faulty or not well connected during the recording and this results in unverified incorrect signal input being fed to autoSCORE.	Refer to Section 5.1 in IFU
ASNI-4	Signal from recorded and analyzed sensor might not represent the correct sensor location	The user mislabelled the sensor in the montage or applied it incorrectly on the patient	User is advised to always verify the electrode labels being connected to the patient's headbox and also verify the signals from all the sensors on the headbox in the montage settings.
ASNI-5	autoSCORE might analyze a different ECG/EKG signal than the user intended to use	The user mislabelled the sensor in the montage or applied it incorrectly on the patient	User is advised to always verify the electrode labels being connected to the patient's headbox and also verify the signals from all the sensors on the headbox in the montage settings. User is also recommended to verify that ECG signal is available in the EEG recording when the relevant montage is applied.

RISK Reference	Potential Failure	Failure Cause	Recommendation to User
ASNI-7	The recording level autoSCORE output might no longer be correct for the EEG recording that is displayed in the EEG software	EEG data are removed or added to the recording file after autoSCORE completed the analysis e.g. by pruning, merging, resuming the recording or appending data to it in the EEG software	It is advised that when the user modifies(prune, merge etc) an EEG after performing autoSCORE analysis, then the user shall re-analyze the EEG to update the autoSCORE results for the modified EEG.
ASNI-9	autoSCORE might not analyze all data of the EEG recording during the 'live' analysis mode in the EEG software	The user manually pauses the autoSCORE analysis one or several times while the EEG recording is ongoing	It is advised that when the user has paused the autoSCORE analysis during an ongoing live recording, then after the completion of the live recording session, the user shall re-analyze the EEG in batch mode so that autoSCORE results can be captured for the entire duration of recorded EEG.
ASNI-10	User might be exposed to conflicting output/results from autoSCORE when comparing the analysis during a live recording with a batch analysis performed on the same data.	When user pauses the autoSCORE analyser during a live recording and thereafter do a batch analysis, the input data to autoSCORE will not be the same as for batch processing as the pauses will not be accounted for.	It is advised that when the user has paused the autoSCORE analysis during an ongoing live recording, then after the completion of the live recording session, the user shall re-analyze the EEG in batch mode so that autoSCORE results can be captured for the entire duration of recorded EEG.
ASNI-19	The user might receive incorrect output.	When an analyzer montage uses different but synonymous sensor labels from those used during acquisition, NeuroWorks sends incorrect input data to autoSCORE. While NeuroWorks has mechanisms in place to prevent review montages from including sensors not used during acquisition, similar safeguards have not been implemented for analyzer montages.	To avoid this failure, users are advised to ensure the following: • In an EEG acquired using the sensors T3, T4, T5, and T6 (10-20 nomenclature), the autoSCORE analyzer montage should also use T3, T4, T5, and T6. • In an EEG acquired using the sensors T7, T8, P7, and P8 (10-10 nomenclature), the autoSCORE analyzer montage should use T7, T8, P7, and P8.

RISK Reference	Potential Failure	Failure Cause	Recommendation to User
ASNI-20	When a selected autoSCORE finding is highlighted in the NeuroWorks Annotation Viewer, it loses focus while navigating to adjacent pages the EEG if the annotations are sorted by marker probabilities and the Annotation Viewer's cursor is automatically relocated to the top of the marker list. This can cause users to lose track of their position during a systematic review of the markers	Code Implementation issue in NeuroWorks	Users are advised to click on the start or end marker in the EEG pane, which will restore the focus of the marker in the annotation list.
ASI-4 and DefectID AD-540, AD-865	autoSCORE installed version stops functioning in the scenario of a failed autoSCORE upgrade.	Failure in upgrade process of autoSCORE as a result of a known defect	User is advised to contact Natus Neuroworks to uninstall the existing version of autoSCORE and then re-install it from the package. User is advised to ensure that the autoSCORE installation and uninstallation shall always be carried out by authorized site administrator and all active instances of autoSCORE shall be stopped during the installation process.
DefectID AD-884	In this defect, NeuroWorks EEG Timeline in user interface might show gaps for the sections where the autoSCORE analyser was turned off but the Study Tool Bar and autoSCORE event duration will appear to span the entire time period.	This is as per intended design of the autoSCORE segmentation logic, where breaks in the EEG data do not affect the calculation of segment durations. The marker creation logic assigns the marker's end time to the start of the first data packet received after a break. If the subsequent data packets also contain the abnormality detected before the break, the marker's end time is further extended until the abnormality is no longer detected in the EEG data.	In the scenario of LIVE EEG analysis, the users are advised to NOT pause autoSCORE analyzer while the recording is ongoing because this could lead to the markers continuing in duration beyond the point of pause and extend the duration of the pause. Even in the rare event of this defect occurring, there will be no adverse impact on the correctness of the autoSCORE marker output as the extended marker will still contain the marked abnormality, and the only impact of the defect will be in the form of added inconvenience to the user in navigation. Therefore, users are advised to avoid pausing the autoSCORE analyzer.

12. Abbreviations

Term	Description
Diff Non-Epi	Diffuse non-epileptiform abnormality
EEG	Electroencephalogram
ECG or EKG	Electrocardiogram
Focal Epi	Focal epileptiform abnormality
Focal Non-Epi	Focal non-epileptiform abnormality
Gen Epi	Generalized epileptiform abnormality
GB	Gigabyte
Hz	Hertz
ICU	Intensive Care Unit
MB	Megabyte
RAM	Random-access memory