HOLBERG EEG

autoSCORE

Version 1.0

Instructions for Use

Legal Manufacturer:
Holberg EEG AS
Fjøsangerveien 70A
5068 Bergen, Norway

Website: www.holbergeeg.com

Contact information:
info@holbergeeg.com

Table of Contents

1. About the Instructions for Use (IFU)

The purpose of this document is to describe the use of autoSCORE, version 1.0.

2. Intended use and device description

2.1. Intended use

2.1.1. 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 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 probability that EEG recordings and sections of EEG recordings include abnormalities, and which type(s) of abnormality they include.

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 is not intended to 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.

2.1.2. Indications for Use

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

2.1.3. Intended Users

The intended user is a suitably trained professional who is qualified to clinically review EEG recordings.

2.1.4. Intended Patient Population

For use with patients over 3 months of age.

2.1.5. Intended Use Environment

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

2.1.6. Contraindications

autoSCORE has no contraindications.

2.1.7. 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 EEG recordings and sections of EEG recordings include abnormalities, and categorizes these abnormalities into predefined types.

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.

2.2. Warnings

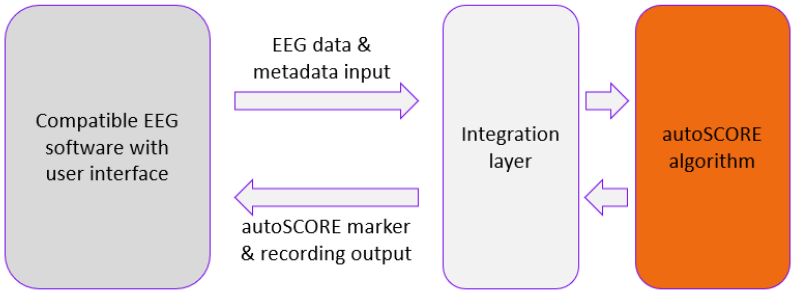
No warnings are associated with this product.

2.3. Incident reporting

Any serious incident that occurs in relation to the autoSCORE software should be reported to the manufacturer as soon as possible. Please refer to the contact details on the first page of this document.

2.4. autoSCORE interaction diagram

The image below shows a schematic representation of the interaction between the autoSCORE algorithm and external components.



3. Using autoSCORE

3.1. Prerequisites to using autoSCORE

A working proficiency with EEG- and computer systems is assumed for using autoSCORE.

Once the autoSCORE software is installed on your 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 a third option.

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.

3.2. 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.

3.3. 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.

3.4. Availability of the autoSCORE output

The autoSCORE output is presented in the user interface of the compatible EEG software with a delay compared to the time of EEG recording.

For EEG recordings with a duration shorter than 4 hours of recorded time, the autoSCORE output is always presented after the recording is completed.

For EEG recordings with a duration of 4 hours of recorded time or longer, autoSCORE can be configured in the EEG software to present output during the recording. In this case the output is presented in blocks of 2 hours, starting 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.

For ongoing studies in which autoSCORE output is presented in blocks of 2 hours, no output will be presented for the last part of the recording while the recording is still in progress. 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.

In addition to the fixed delay described above, a shorter delay may be introduced for the autoSCORE output presentation, which will depend 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 duration of this shorter delay 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.

4. Viewing the autoSCORE output

4.1. Normal or abnormal

For each EEG recording, autoSCORE generates the estimated probability that the recording contains abnormality, presented as a percentage.

autoSCORE indicates one of four levels of abnormality for the recording and the corresponding probability value in percentage. The levels of abnormality are sorted from lowest to highest probability:

- Normal EEG
- Probable normal EEG
- Probable abnormal EEG
- Abnormal EEG

4.2. Types of abnormality

If the EEG is estimated to contain abnormality, then autoSCORE also indicates which type(s) of specific abnormality it is estimated to contain, and the corresponding probability value(s) as a percentage. autoSCORE indicates this for each EEG recording as well as for each individual marker within the recording.

autoSCORE can indicate the following types of abnormality:

Abnormality type	Abbreviation
Focal epileptiform abnormality	EpiFoc
Generalized epileptiform abnormality	EpiGen
Focal non-epileptiform abnormality	NonEpiFoc
Diffuse non-epileptiform abnormality	NonEpiDiff

For each type of abnormality that is presented, autoSCORE indicates one of two levels of abnormality. autoSCORE generates this output for each abnormal EEG recording as well as for each marker. The levels of abnormality per type are sorted from lowest to highest probability, e.g.

- Probable focal epileptiform
- Focal epileptiform

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.

4.3. 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.

4.4. General notes on the autoSCORE output

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.

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.

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

4.5. autoSCORE user messages

The autoSCORE software will display user messages when applicable. These messages can be errors, alerts, or information messages.

The messages for errors and alerts will include a code, which can be used to look up specific details about the error or alert 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. Alerts will allow the autoSCORE session to continue, but the performance of the system or the autoSCORE software may be affected.

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 recording is 14 minutes or longer
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 is 90 days of age or older
404	Invalid channel details	Ensure that all required EEG channel labels are present in the recording, spelled correctly (not case sensitive) and without any duplicates
405	Invalid recording duration details	Contact support if this error persists
406	Invalid or unknown session	
407	Invalid or unknown recording segment	
408	Recording segment output is unavailable	
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
411	Directory does not exist or write access is denied	Ensure that the file directory exists and that autoSCORE has access to it
412	Invalid patient gender	Ensure that the patient gender has been entered
413	Recording ID is empty	Contact support if this error persists
414	Invalid recording type	
420	Failed to verify sha256 checksum	
421	Decryption failed	
422	Encryption failed	
430	OpenSSL error	
431	OpenSSL returned error on context initialization	
432	OpenSSL returned error on decrypt initialization	
433	OpenSSL returned error on encryption initialization	
434	OpenSSL returned error on decryption operation	
435	OpenSSL returned error on encryption operation	
436	OpenSSL returned error on decryption finalization	
437	OpenSSL returned error on encryption finalization	
440	Incorrect packet sample rate	
441	Missing input packet channel	
442	Incorrect input packet config	
443	Overlapping input packets	
444	Input packet inconsistency	
445	Sample num or duration mismatch	

The table below shows a list of the autoSCORE alerts.

Code	Alert details	Suggested action
301	Operating system not supported	Ensure that system requirements are met, or contact support if this error persists
302	Physical memory installed is insufficient	
303	Physical memory that can be used is insufficient	
304	Percentage of physical memory in use is beyond acceptable threshold	
305	Number of logical processors available are insufficient	
306	The processor does not support SSE3 instructions	
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 generating output for 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

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.

5. System Requirements

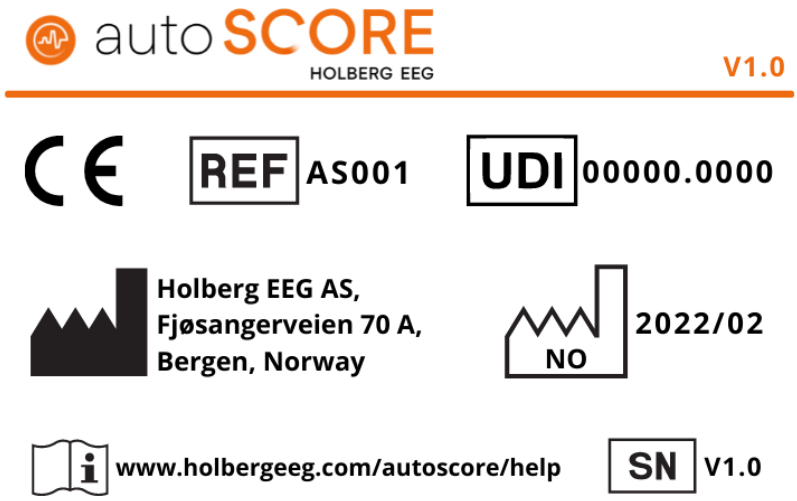
The table below shows the system requirements for optimal performance of the autoSCORE software.

Operating System	Windows 10
Minimum installed RAM	1 GB
Minimum allocateable 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

autoSCORE is intended to be used with compatible EEG software. Please contact the EEG software manufacturer regarding IT security measures necessary to run the software as intended, including protection against unauthorised access.

6. autoSCORE label

In this section the autoSCORE label is presented.



7. Symbols

The table below shows the definition of the symbols that are used on the label of the autoSCORE product. This information can also be found online at http://www.holbergeeg.com/autoscore-help

Symbol	Definition of the symbol
	Legal manufacturer
	Unique Device Identifier
	Catalogue number
	Country of Manufacture
	Serial Number
	Consult Electronic Instructions for Use

8. Glossary of terms

Term	Description
Algorithm	Process or set of rules to be followed in calculations or other problem-solving operations
EpiFoc	Focal epileptiform abnormality
EpiGen	Generalized epileptiform abnormality
ICU	Intensive Care Unit
Metadata	Data that describes and gives information about other data
NonEpiFoc	Focal non-epileptiform abnormality
NonEpiDiff	Diffuse non-epileptiform abnormality
NPV	Negative Predictive Value
PPV	Positive Predictive Value