

AIRAscore 2.4.0

Instructions for Use



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1 Customer Information

Dear customers,

The software AIRAscore is a certified medical device with CE mark according to council directive (EU) 93/42/EEC, which is placed on the market in accordance with transitional provision of regulation (EU) 2017/745 on medical devices. AIRAmEd has established a quality management system according to ISO 13485 and is certified therefor.

This customer information applies as instructions for use, describes the basic features of our evaluation report and provides information on the correct use of AIRAscore. It describes the correct indication, the appropriate reference set, and basic warnings that must be followed. The customer information is intended for all physicians with knowledge of MR anatomy of the brain who use the AIRAscore report to check segmentations and place the output measurements in the clinical context (primary users).

All users and administrators of the software who use the software or install and maintain it must have access to these instructions for use and be familiar with their contents.

If you have any questions beyond this customer information, please do not hesitate to contact us:

service@airamed.de

<https://www.airamed.de>

phone number: +49 7071 53 933 40



2 General Customer Information

2.1 General Specifications

It is your responsibility as the user to inform the patient of the service and the associated transfer of image data to AIRAmed and to take appropriate local protective measures to prevent unauthorized third parties from accessing AIRAmed's service and patient data.

2.1.1 Intended Purpose

AIRAscore is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images.

2.1.2 Indication

The software AIRAscore is intended to be used for MR image data of patients between the ages of 18 and 85 for which a physician requires a volume quantification of brain structures.

2.1.3 Contraindications

The device is not intended to be used for segmentation of brains with structural abnormalities (e.g., tumor, arachnoid cyst, postoperative-, posttraumatic-, postischemic-, or posthemorrhagic defects, brain development disorders and neuronal migration disorders).

2.1.4 Availability

AIRAscore is usually available 24 hours a day and operates fully automated.

We usually perform scheduled maintenance Monday through Friday from 0:00 to 4:00 (CET) or all day on weekends. Scheduled maintenance is announced at least 24 hours in advance. Unscheduled maintenance can be performed at any time without notice if the security of the system is affected.

We keep downtime as low as possible.

If you have any questions, our support is available Monday through Friday from 9:00am to 4:00pm (CET) by phone or email.

2.1.5 Avoidable Misuse and Abnormal Use



- AIRAscore is not suitable for evaluating image data that is not based on a T1 data set.
- Image datasets after administration of contrast agents are not suitable for evaluation and may lead to erroneous findings.
- Any mass lesion (e.g., tumor, hemorrhage, arachnoid cyst) or any lesion that is characterized by a defect of the brain tissue (e.g., defects after trauma, ischemia) may lead to severe missegmentation and also cannot be evaluated against the reference set.

Corresponding patient image data must NOT be evaluated with AIRAscore!



Age and natural sex of the patients are essential for a correct classification of the volumes. Changes to the DICOM metadata should therefore be avoided, since AIRAmed has no possibility to check the correctness of the DICOM data. In the case of anonymized data or research data, it is therefore essential to ensure that age, sex and the interval between examination date and date of birth are correctly preserved in the DICOM data.



Reports of the same patient are only comparable with regards to the progression if they were acquired with the same scanner and the same sequence. Even minor changes in scan parameters can lead to strong contrast changes and discrete shifts in the gray-white boundary, which make segmentation comparability impossible. Information on measurement inaccuracy due to rounding can be found in the customer note of each evaluation report on the last page.



The automated quantitative evaluation of brain structures can only support the assessment by a qualified physician (specialist), and by no means replaces it.



2.1.6 Clinical Benefit

The automated labeling, visualization and quantification of segmentable brain structures replaces time-consuming manual segmentation by the attending physicians.

2.1.7 Ordering AIRAscore MS

In order to add the multiple sclerosis analysis to the general AIRAscore structure report, we need a T2-FLAIR dataset in addition to a T1 dataset. After installing our software (see AIRAscore Client Installation Instructions), two new PACS nodes will be available, the names of which will be determined by the person performing the installation. The node for the AIRAscore structure report will only accept T1 datasets and will start processing immediately if a valid dataset is found. The node for AIRAscore MS expects a T1 dataset as well as a T2-FLAIR dataset that meet the requirements listed in the next paragraph. You can send the datasets in any order, but there should be no more than two hours between the two datasets, otherwise the order will be discarded.

i AIRAscore MS is not intended for diagnosis of multiple sclerosis, but rather is a tool for quantitative analysis of MR images in patients with existing diagnosis of MS.

2.1.8 Technical Requirements for the Dataset

To process your image data, AIRAscore structure requires datasets with the following properties:

- T1 dataset, native, DICOM format: *MR Image IOD*
- Clear gray-white contrast between gray and white matter and, if possible, hypointense representation of cerebrospinal fluid (CSF)
- 3D dataset
- Device manufacturer: GE, Philips or Siemens
- Field strength: 1.5 or 3 Tesla
- Resolution of image data in each spatial direction < 2mm and voxel size $\leq 2.4\text{mm}^3$
- The head must be completely captured
- The head should not be captured tilted if possible
- No pronounced artifacts should be visible in the image (motion, folding, etc.)

If you decide to use AIRAscore MS, we require a corresponding T2-FLAIR dataset with the following properties in addition to each T1 dataset:


- T2-FLAIR dataset, DICOM format: *MR Image IOD*
- 2D or 3D dataset
- Device manufacturer: GE, Philips or Siemens
- Field strength: 1.5 or 3 Tesla
- Resolution of image data $\leq 1.5\text{mm}$ in x and y direction and $\leq 6\text{mm}$ in slice direction
- The head must be completely captured
- The head should not be captured tilted if possible
- No pronounced artifacts should be visible in the image (motion, folding, etc.)

For a detailed list of all requirements for DICOM data, please refer to the separate DICOM Conformance Statement.

2.1.9 Automated Control of Image Data and Accountability of the Requesting Physician

All image data are automatically checked after being received by AIRAm. For this purpose, in addition to the actual image data, the technical data of the sequence, the age and the gender of the patient from the DICOM header are transferred. Other patient-related data, such as the name, are not transmitted to AIRAm and remain locally and encrypted on your system. The majority of possible technical errors are detected automatically. However, this does not exclude the residual risk that datasets for which the technical requirements are not met or datasets of patients with contraindications are nevertheless processed. Also, despite all due care, incorrect segmentation may occur in rare cases.




 All reports must be **checked** for plausibility and accuracy by a **qualified physician** (specialist) with sufficient knowledge of neuroanatomy and MR imaging of the head. The identity of the patient should also be checked.

The original images are overlaid with the results of the segmentations performed by AIRAscore structure. These are displayed in the report for verification purposes. If you have ordered AIRAscore MS, the segmentation of lesions and their categorization into juxtacortical, periventricular and infratentorial will be presented in a similar way. In addition, the segmentations are provided in the PACS. The hippocampus is reported as a distinct structure. The hippocampus and cingulate gyrus are not included in the frontal or parietal lobes.

For viewing you need a PACS and a connected DICOM viewer including a monitor that can display the DICOM formats *Encapsulated PDF IOD* as well as *Secondary Capture Image IOD* in color and is approved for reporting.

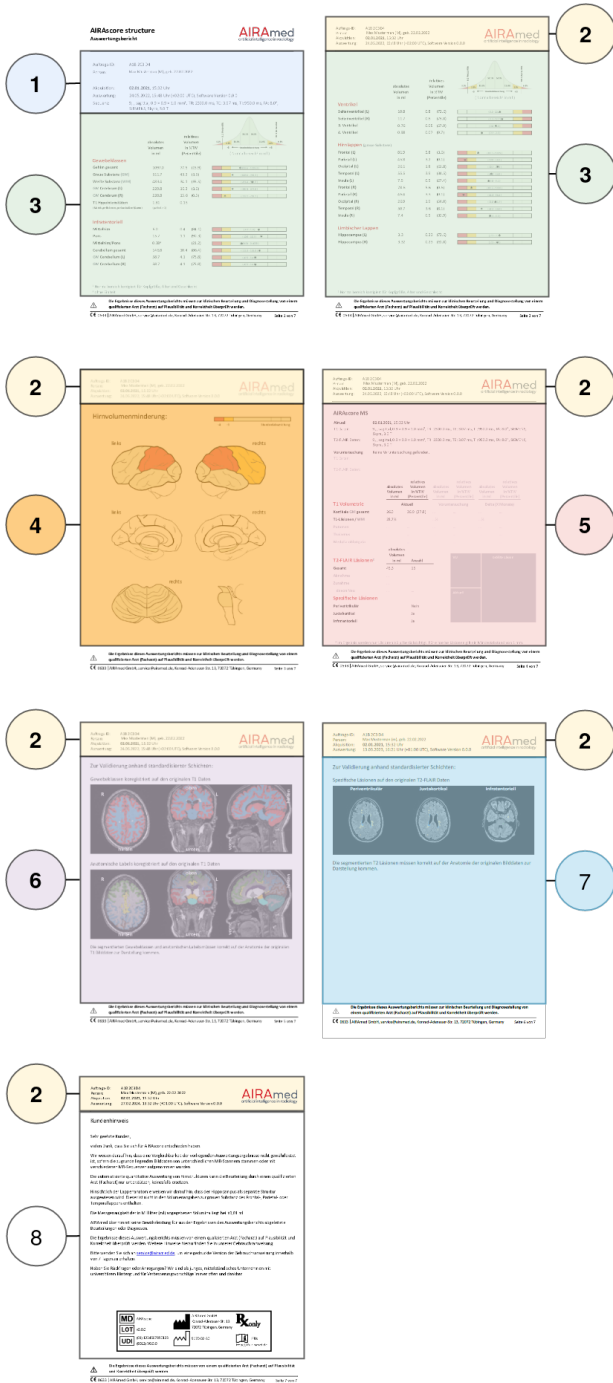
Usually, you will receive the results within a few minutes, although the actual time also depends on your internet connection. If you do not receive an evaluation within one hour after sending the data, please contact us directly. In rare cases, datasets may not be sent to us, or may not be sent completely, and thus processing may not take place.

If you are of the opinion that there is a safety-relevant malfunction in the product, please contact our customer service immediately.

 AIRAm does not assume any warranty for assessments or diagnoses derived from the evaluation results of the evaluation report and cannot be held liable for this.



2.1.10 Structure of the Report



The AIRAscore structure report has 5 pages, and 7 pages with AIRAscore MS. The respective page number is listed on the bottom right.

The individual sections of the report are described below:

① Examination Summary:
 Contains the order ID*, personal data of the patient and the sequence on which the report is based.

② Headers:
 The headers also list the most important identification parameters and relevant data again.

③ Volume Report:
 Contains the volume evaluation for each segmented anatomical area - the absolute volume in ml, the relative volume (absolute volume normalized by the total intracranial volume), and the percentile for the patient compared to the reference set**.

④ Schematic Overview of Reference Comparison:
 Quick overview of z-scores for brain areas. For values smaller than two or three standard deviations compared to the reference set, areas are shown in yellow or red, respectively**.

⑤ MS Report:
 This page is optional and is only issued to customers requesting AIRAscore MS. It shows the number and volume of lesions and their categorization. Grayed-out elements represent functionality not included in this version.

⑥ Quality Control Images:
 The quality control images are used for the traceable validation of our segmentation results. These quality control images must always be checked for plausibility. In the event of discrepancies or inexplicable volume data, the plausibility of the overlays provided in the PACS should also be checked.

⑦ MS Control Images:
 This page is optional and is only issued to customers requesting AIRAscore MS. It displays slices with the largest juxtacortical, periventricular and infratentorial lesions for reference.

⑧ Customer Notices:
 The customer notices contain information on the use of the report, the accuracy of the results and contact options for AIRAmEd GmbH.





















i * The individual order ID allows us to make a reliable assignment if required. Apart from the pseudonymized order ID and the pure image data as well as age and gender for the assignment of the correct reference values, AIRAmed does not store any personal data in the image archive. Without individual order ID of your patients, no assignment of image data in the long-term archive or in our log files is possible. All our processes meet the requirements of the GDPR.

** If the patient age is not between 18 and 85, no comparison to the reference set will be performed and the percentile will not be shown in the report. The page "Schematic Overview of Reference Comparison" will be omitted. Furthermore, a watermark "Not released for clinical evaluation" will be shown in the report, if the patient is younger than 18 years.

2.1.11 Color-Coded Segmentation Results

Several DICOM series are also available for visual control. All customers receive the two DICOM series Anatomy Map and Tissue Map. Customers requesting AIRAscore MS receive an additional DICOM series T2-Lesion Map. All available series can be found in the same study as the PDF report. If there are several segmentations, you can identify the correct assignment via the name of the initial series.

The segmentation results are displayed as colors overlaid on top of the original input image. See the used colors below:

Anatomical Regions Anatomy Map		Tissue Classes Tissue Map		Lesion Categories T2-Lesion Map	
 Midbrain	 Frontal lobe	 Gray matter	 Periventricular		
 Pons	 Parietal lobe	 White matter	 Juxtacortical		
 Superior cerebellar peduncle *	 Occipital lobe	 T1 Hypointensities	 Infratentorial		
 Cerebellum	 Temporal lobe		 Unspecific		
 Ventricle	 Insula				
 Hippocampus	 Deep gray matter *				
 Cingulate gyrus *					

i *) Volume of this structure is not reported.

2.1.12 Reported Structures and Their Definitions

This section describes all structures reported in the report.

2.1.12.1 AIRAscore structure: Reported Structures

Reported Structure	Definition of Structure
Tissue Type	
Total brain volume	Summed volume of white matter, gray matter and T1 hypointensities based on the Tissue map
Gray matter (GM)	Volume of gray matter based on the Tissue map
GM cerebrum (L)/(R)	Summed GM volume of left or right hemisphere of temporal, frontal, occipital, parietal, and insula lobes, cingulate gyrus, and hippocampus based on the Anatomy map



Reported Structure	Definition of Structure
White matter (WM)	Volume of white matter based on the Tissue map
T1 hypointense lesions	Volume of T1 hypointensities based on the Tissue map
Infratentorial	
Midbrain	WM volume of midbrain based on the Anatomy map
Pons	WM volume of pons based on the Anatomy map
Midbrain / Pons	Ratio of midbrain to pons
Total cerebellum	Summed GM and WM volumes of left and right hemisphere cerebellum based on the Anatomy map
GM cerebellum (L)/(R)	GM volume of left or right hemisphere cerebellum based on the Anatomy map
Ventricles	
Lateral ventricle (L)/(R)	Cerebrospinal fluid (CSF) volume of left or right hemisphere lateral ventricle based on the Anatomy map
Third ventricle	CSF volume of third ventricle based on the Anatomy map
Fourth ventricle	CSF volume of fourth ventricle based on the Anatomy map
Brain Lobes (Gray Matter)	
Frontal (L)/(R) *	GM volume of left or right hemisphere frontal lobe based on the Anatomy map
Parietal (L)/(R) *	GM volume of left or right hemisphere parietal lobe based on the Anatomy map
Occipital (L)/(R)	GM volume of left or right hemisphere occipital lobe based on the Anatomy map
Temporal (L)/(R)	GM volume of left or right hemisphere temporal lobe based on the Anatomy map
Insula (L)/(R)	GM volume of left or right hemisphere insula lobe based on the Anatomy map
Limbic Structures	
Hippocampus (L)/(R) *	GM volume of left or right hemisphere hippocampus based on the Anatomy map

i * The hippocampus is not included in the volume of the temporal lobe. The cingulate gyrus is not included in the volume of the frontal lobe or parietal lobe.

2.1.12.2 AIRAscore MS: Reported Structures

Reported Structure	Definition of Structure
T1 Volumetry	
Total cortical GM	Summed volume of GM cerebrum (L) and GM cerebrum (R)



T2 Lesions	
Total absolute volume and count	Summed volume of voxels segmented as lesions independent of their location in the brain. Only lesions $\geq 5 \mu\text{l}$ are taken into account in the total absolute volume and count. A minimum distance of 1 mm applies to all individual lesions.
Periventricular lesion	Voxels of a lesion that borders the ventricles
Juxtacortical lesion	Voxels of a lesion that borders the cerebral cortex
Infratentorial lesion	Voxels of a lesion with an infratentorial position

2.1.13 Volume Comparison to the Reference Set

If the patient age is between 18 and 85, a comparison to an age- and sex-specific reference set is performed. We calculate the following metrics for the reported structures:

Metric	Definition
Z-score	A value that represents how many standard deviations the computed relative volume falls below or above the reference mean.
Normal range lower limit	The 5th percentile of the reference set volume converted to absolute volume in ml using the patient's total intracranial volume.
Normal range upper limit	The 95th percentile of the reference set volume converted to absolute volume in ml using the patient's total intracranial volume.
Percentile	Percentage of values from the reference set that fall below the computed z-score assuming a normal distribution.

2.2 Precision and Accuracy

Metrics used for the precision and accuracy calculations include the intraclass correlation coefficient (ICC), 95% confidence interval (CI95%), 90th percentile (p90), median, sensitivity, and precision.

2.2.1 Precision

The precision of AIRAscore structure was calculated through the evaluation of a test-retest dataset consisting of 804 samples. The precision of lesion segmentations with AIRAscore MS was calculated using a dataset of 19 test-retest samples.

Precision metrics are calculated based on the absolute differences in volumes between segmentations of paired test-retest scans.

Label	Median [ml]	Median CI95% [ml]	ICC(2,1)	ICC(2,1) CI95%
Tissue				
Total brain volume	1.6	[1.4, 1.8]	0.99	[0.99, 0.99]
Gray matter (GM)	2.8	[2.4, 3.5]	0.99	[0.99, 0.99]
White matter (WM)	2.2	[1.8, 2.6]	0.99	[0.99, 0.99]
GM cerebrum (L)	1.4	[1.2, 1.8]	0.99	[0.99, 0.99]
GM cerebrum (R)	1.5	[1.2, 1.6]	0.99	[0.99, 0.99]
T1 hypointense lesions	0.101	[0.087, 0.112]	0.99	[0.99, 0.99]



Infratentorial				
Midbrain	0.040	[0.035, 0.046]	0.99	[0.99, 0.99]
Pons	0.053	[0.045, 0.059]	0.99	[0.99, 0.99]
Total cerebellum	0.31	[0.26, 0.36]	0.99	[0.99, 0.99]
GM cerebellum (L)	0.18	[0.15, 0.20]	0.99	[0.99, 0.99]
GM cerebellum (R)	0.22	[0.19, 0.24]	0.99	[0.99, 0.99]
Ventricles				
Lateral ventricle (L)	0.076	[0.068, 0.083]	0.99	[0.99, 0.99]
Lateral ventricle (R)	0.069	[0.059, 0.081]	0.99	[0.99, 0.99]
3rd ventricle	0.023	[0.021, 0.026]	0.99	[0.99, 0.99]
4th ventricle	0.026	[0.023, 0.029]	0.99	[0.99, 0.99]
Brain lobes (gray matter)				
Frontal (L)	0.64	[0.51, 0.82]	0.98	[0.98, 0.99]
Frontal (R)	0.75	[0.61, 0.87]	0.98	[0.98, 0.98]
Parietal (L)	0.44	[0.39, 0.51]	0.99	[0.98, 0.99]
Parietal (R)	0.45	[0.38, 0.52]	0.99	[0.99, 0.99]
Occipital (L)	0.17	[0.15, 0.19]	0.99	[0.99, 0.99]
Occipital (R)	0.19	[0.17, 0.22]	0.99	[0.99, 0.99]
Temporal (L)	0.31	[0.28, 0.35]	0.99	[0.99, 0.99]
Temporal (R)	0.32	[0.28, 0.37]	0.99	[0.99, 0.99]
Insula (L)	0.066	[0.060, 0.076]	0.99	[0.99, 0.99]
Insula (R)	0.066	[0.061, 0.073]	0.98	[0.98, 0.99]
T2 lesions				
Total lesion volume	0.083	[0.064, 0.153]	0.99	[0.99, 0.99]
Total lesion count	2 [†]	[1, 2] [†]	0.99	[0.98, 0.99]

[†] These values represent counts, rather than volumes. They show the absolute difference of detected lesions between segmentations of paired test-retest scans.

GPU-induced (graphics processing unit) random effects can lead to minor differences in volumes for the same image. These differences are smaller or equal to the 10th percentile of test-retest differences for all regions.

2.2.2 Accuracy

The accuracy of AIRAscore structure was evaluated by comparison with 18 samples that were manually segmented by experts. The average ICC(3,1) between AIRAscore structure segmentations and manual segmentations across all anatomy and tissue region volumes is 0.85 with a CI95% of [0.73, 0.91].



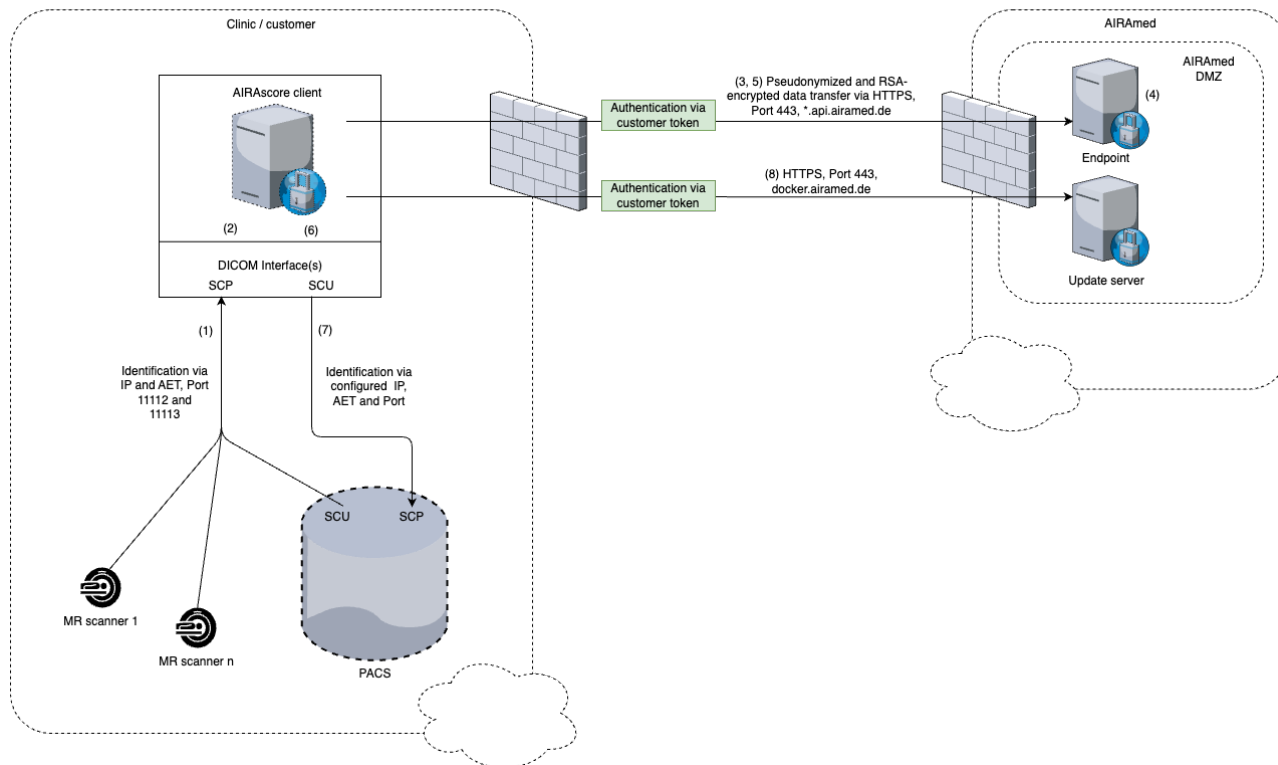
Accuracy metrics for AIRAscore MS were calculated by comparison to manual segmentation by experts of 10 samples from patients with MS. The sensitivity and precision of the total lesion count is 70% and 72%, respectively. The ICC(2,1) for the total lesion volume is 0.96 with a CI95% of [0.75, 0.99].



3 AIRAscore Client

AIRAmEd provides the AIRAscore Client software. The AIRAscore Client operates as the interface to AIRAmEd servers.

System Architecture Sketch for AIRAscore



General information

- Arrows indicate the direction of communication structure.
- Access to the DICOM interface of the AIRAscore client from IPs outside the customer network shall be prevented by appropriate firewall rules on the customer side.
- The front end has no dedicated graphical user interface. Instead, AIRAscore integrates into the customer's software. The process of sending data from the customer to AIRAmEd is comparable to selecting a printer.

3.1 Data Flow

The dataflow of the medical device begins with selected imaging data being transmitted from the customer's DICOM storage SCU or scanner to the AIRAscore client's DICOM storage SCP. Subsequently, the data undergoes pseudonymization and RSA encryption, with the encrypted patient data being stored locally on the customer's side. This pseudonymized and RSA-encrypted data is then transmitted via HTTPS Port 443 to *.api.airamed.de, with customer authorization facilitated through a customer token.

Upon arrival at AIRAmEd, the order is processed accordingly. Following this, the AIRAscore client periodically initiates requests to check the order status. Once the order is ready, the client retrieves the pseudonymized and RSA-encrypted results via HTTPS. These results are then depseudonymized on the customer side.

After depseudonymization, the results are transmitted back from the AIRAscore client's DICOM storage SCU to the PACS DICOM storage SCP. Additionally, AIRAscore initiates periodically checks for available updates, with any updates being fetched and installed accordingly to ensure the system remains up to date.

3.2 Installation

AIRAmEd provides you, the customer, with the AIRAscore Client software. The AIRAscore Client operates as the interface to AIRAmEd's servers. For instructions how to install AIRAscore Client, please refer to the AIRAscore Client Installation Instructions, which will be provided to you by AIRAmEd.



3.3 Configuration

The AIRAscore Client can be configured as follows.

3.3.1 Report Language

The report can be returned in one of the languages listed below. To change the configured language, please refer to AIRAscore Client Installation Instructions, section “Country Code”.

The formatting of the following information in the report is affected by the configured country code:

Country Code	Language	Patient Name Format	Date Format	Time Format
en_US	English	First_Name Last_Name	Mon dd, yyyy	AM/PM
de_DE	German	Last_Name, First_Name	dd.mm.yyyy	24-hour clock (military time)

3.3.2 Error Reports


Problems may occur during processing of datasets by AIRAm. In such a case, we will send a DICOM Secondary Capture image containing the error reason to your PACS. If you do not wish to receive error reports, we are happy to deactivate this feature for you. Please contact the AIRAm support in that case.

3.3.3 DICOM Structured Reports

The AIRAscore client supports the DICOM Structured Reporting feature. We provide the option to send the following DICOM Structured Reports to your PACS:

- Order confirmations
- AIRAscore reports
- Error reports

By default, no DICOM Structured Reports are sent to your PACS. If you wish to receive them, we are happy to activate this feature for you. Please contact the AIRAm support in that case.

 The DICOM Structured Report is only an add-on to the AIRAscore report and must not be used on its own.

3.4 Known Problems

The DICOM PatientOrientation field is set as an empty field for the segmentation results. However, the ImageOrientation (Patient) [0020,0037] and ImagePosition (Patient) [0020,0032] fields contain the relevant information.

The DICOM field IssuerOfPatientID contains the value *None* if it was not set in the input data.

3.5 Obligation to Report (Only for EU-Countries)

Please report all serious incidents (harms, injuries, etc) related to this medical device to the manufacturer and the responsible authority of the EU member state, that you are established in.











In Germany the responsible authority is the BfArM. The latest contact information can be obtained from the BfArM website at: <https://www.bfarm.de>.

3.6 Querying the UDI

The Unique Device Identification (UDI) for AIRAscore can be obtained by accessing the following URL: https://api.airamed.de/v1_0/udi. The response will include the UDI-DI (Device Identifier) as well as the UDI-PI (Production Identifier).



4 Glossary

Symbol	Symbol Title	Explanatory Text
	CE-Marking	This product complies with the applicable requirements set out in the European Union harmonization legislation on their affixing.
	Manufacturer	Indicates the medical device manufacturer.
	Manufacture Date	Indicates the date the medical device was manufactured.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Prescription only	Caution: US federal law restricts this device to sale by or on the order of a physician.
	Caution	Indicates that the current situation requires the user's attention to avoid undesirable consequences.
	Medical Device	Indicates that the item is a medical device.
	Batch code/Lot number	Indicates the manufacturer's batch code or lot number.
	Unique Device Identification	Indicates the Unique Device Identification information.
	Indication	Alerts the user to helpful information.

5 About AIRAscore Client

AIRAscore Client is used to connect to the AIRAscore software and is developed by AIRAmEd GmbH. All rights reserved.

AIRAscore Client uses the [Requests](#) library, Copyright 2019 Kenneth Reitz, in version 2.26.0.

AIRAscore Client uses [Watchtower](#), Copyright 2021 Simon Aronsson, in version 1.3.0.

AIRAscore Client uses the [fpdf2](#) library, Copyright 2013 Lucas Cimon, in version 2.5.1.

