1 CT ASPECT Scoring Application

Before You Begin

About the Product

Performance Characteristics

CT ASPECT Scoring is a SaMD (Software as a Medical Device) intended to assist the clinician in the assessment and characterization of brain tissue abnormalities using non-contrast CT (NCCT) images according to the Alberta Stroke Program Early CT Score (ASPECTS) for adults (>18 years), acute (≤ 6 hours from onset) stroke patients with a known Large Vessel Occlusion (LVO) such as a Mid Cerebral Artery (MCA) or Internal Carotid Artery (ICA) occlusion.

For additional performance characteristics of CT ASPECTS, please refer to the Measurement Accuracy section, which includes measuring function.

CT ASPECTS is intended to be launched from AVW environment. AVW is a software medical device that allows multiple users to remotely access clinical applications from compatible computers on a network. The system allows networking, selection, processing, and filming of multimodality DICOM images. This software is for use with off-the-shelf PC computer technology that meets defined minimum specifications. The AVW communicates with imaging systems of different modalities using the DICOM-3 standard.

About Screen

NOTICE

The images used in this section are examples only. For information on the version and build of your software, refer to the actual About screen of CT ASPECT Scoring.

1. To display the About screen which displays labeling and product information, open the application, select Help  and from the menu, select About.

- To change the displayed language of this screen, select a language from the drop down list in the upper right corner (1).
- To view labeling information for specific countries, use the **Other country labeling** dropdown (2).

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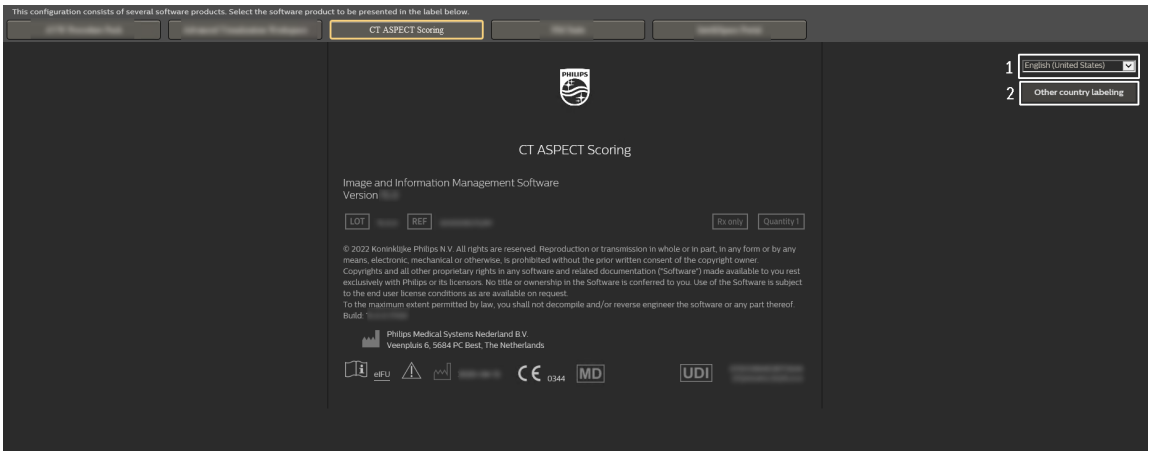

About the Instructions for Use

This Instruction for Use is intended to assist users in the safe and effective use of the Philips software product described. The user is considered to be not only the body with authority over the software product but also for those persons who use the software product. This Instruction for Use does not describe the use of the IT equipment on which the Philips software product is installed. Please refer to the documentation of the IT equipment concerned.

Before attempting to use this medical device software, you must read these Instructions for Use thoroughly, paying particular attention to all WARNINGS, Cautions and Notes it contains. You must pay special attention to all the information given, and procedures described in the Safety chapter. In addition, you must pay special attention to onscreen messages and help information containing WARNINGS, Cautions and Notes that may be related to the functions that are being executed.

When you see this symbol, refer to the “Instructions for Use” manual that came with your system.

WARNING

Warnings are directions, which if not followed, could cause moderate to serious injury to a user, patient or any other person, or could lead to a misinterpretation, and/or loss or damage of patient-related data.

CAUTION

Cautions are directions, which if not followed, could cause damage to the product described in these Instructions for Use and/or any other device.

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NOTICE

Notices highlight unusual points as an aid to an operator.

The "Instructions for Use" for the CT ASPECT Scoring application is supplied electronically and/or in printed volumes.

Accessing Instructions for Use

The applicable CT ASPECT Scoring Application Instructions for Use documents can be easily accessed via the Philips IFU web site:
http://www.philips.com/IFU

It is also possible to search the internet for the Philips Document Library.

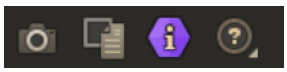
The link for the PDF files appears in the CT ASPECT Scoring Application **About** box. See below for additional information.

NOTICE

The images used in this section are examples only.

Accessing the CT ASPECT Scoring Application Instructions for Use

1. Click on the **Open Help** icon  in the CT ASPECT Scoring Workflow Bar.

2. Select  **Advanced Visualization Workspace Help** from the displayed list.

   The **Help** tabs appear.

3. Select the **Product Info** tab and select CT ASPECT Scoring.

   The About Box opens.

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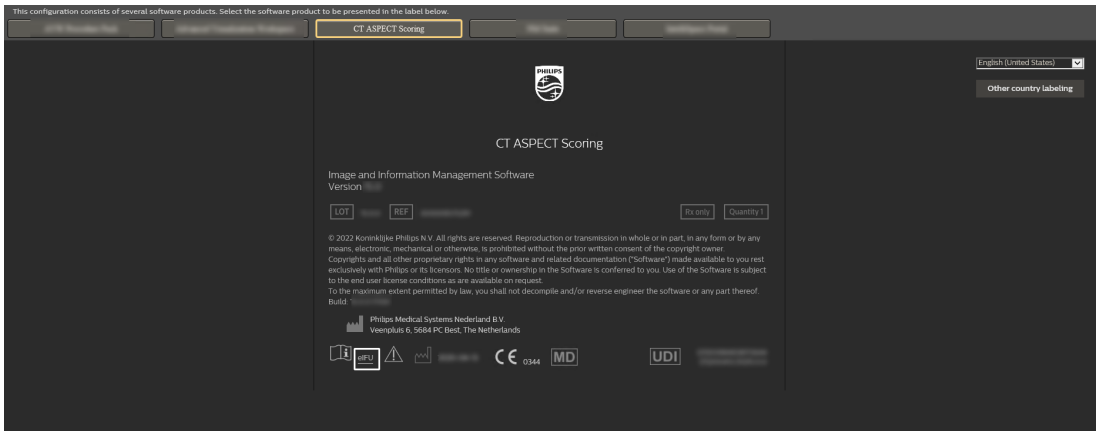
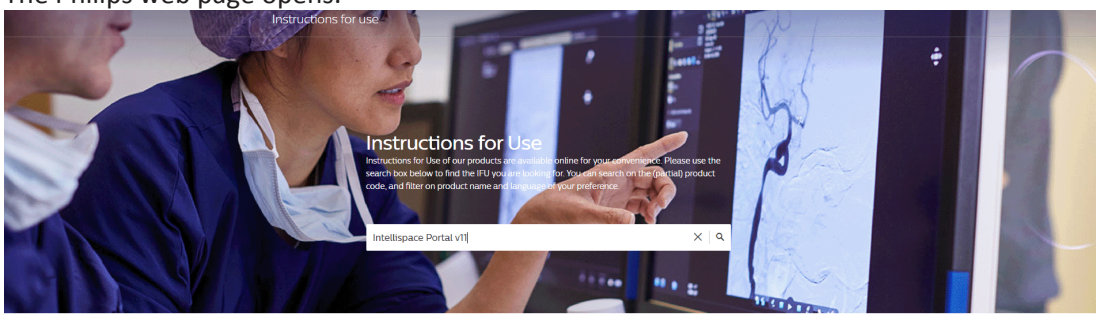
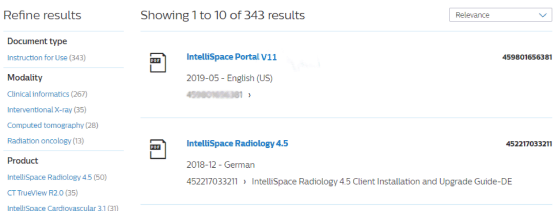


4. Click on the 

eIFU hyperlink located at the bottom of the page.

   The Philips web page opens.





5. Use the search field to locate the required IFU document. It is recommended to type in the product name and version (e.g., CT ASPECT Scoring) to display the list of applicable IFUs.

   A list of results appears.

6. Once the required IFU is located and displayed in the results area of the screen, click on the document hyperlink.

NOTICE

It is possible to refine the results using the options on the left side of the page. Results can be refined according to Document type, Modality, Product and Language.

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NOTICE

The CT ASPECT Scoring application also provides online help, which can be accessed from the Help menu.

Ordering Printed Instructions for Use

You can contact your local Philips representative for a printed IFU.

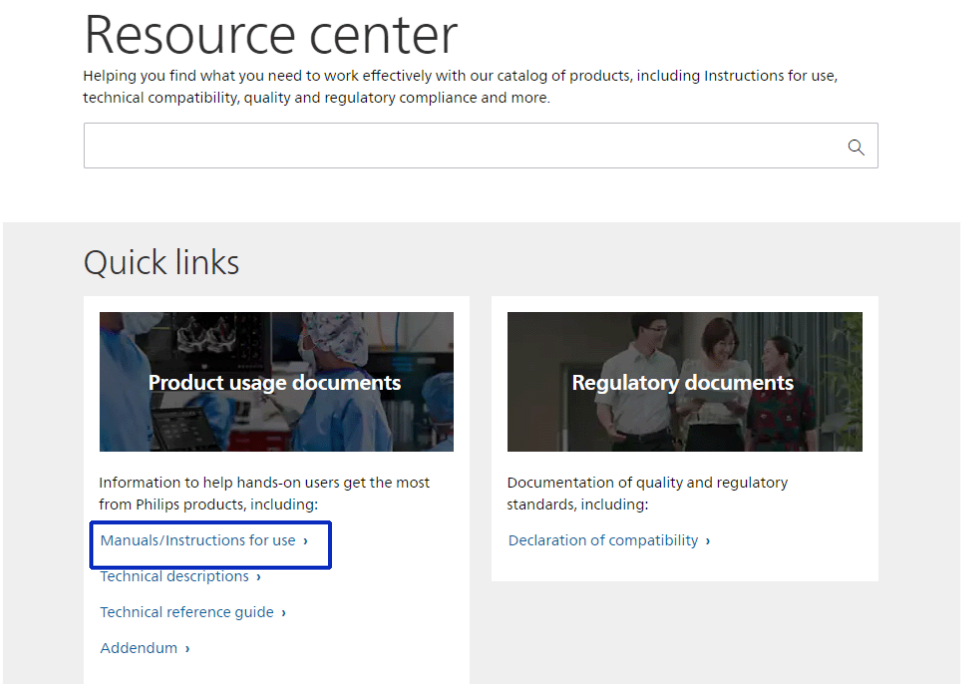
A printed IFU can be also obtained by:

- Personally printing the printable PDF file provided.
- Placing an order through the public website http://www.philips.com/IFU .

To place an order for a printed IFU:

1. Naviage to the site: http://www.philips.com/IFU and select the **Manuals/Instructions for use** link.

   The site that opens is dependent upon your location. The images provided here are examples only.



   The Search results page opens.

2. Scroll down the **Search results** page until you find the **Request documentation** button.

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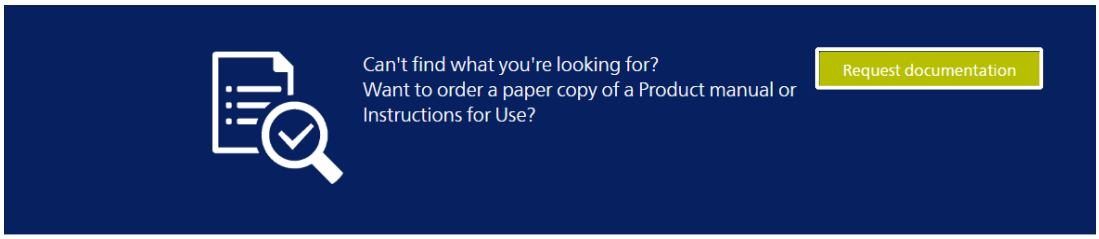
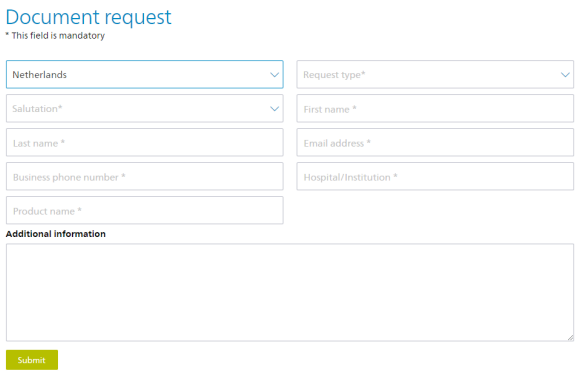


3. Click the **Request documentation** button.

   A document request form appears.

4. Fill in the required information and select **Submit**.



The printed IFU order will be provided within seven days using expedited delivery within the European Union.

Ordering Printed Instructions for Use

You can contact your local Philips representative for a printed IFU.

A printed IFU can be also obtained by:

- Personally printing the printable PDF file provided.
- Placing an order through the public website http://www.philips.com/IFU .

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   The site that opens is dependent upon your location. The images provided here are examples only.

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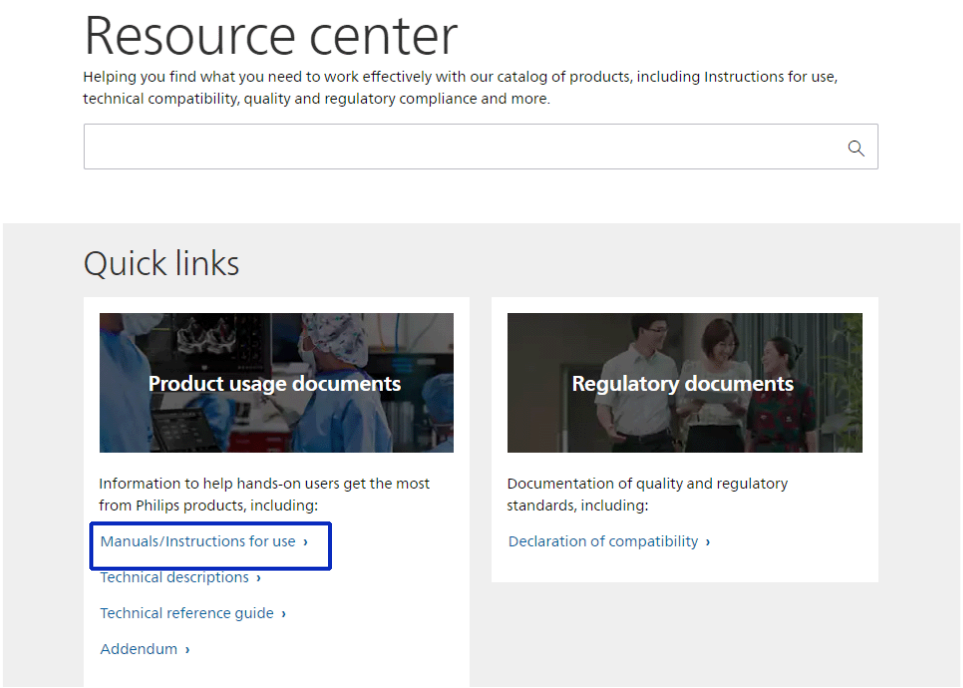
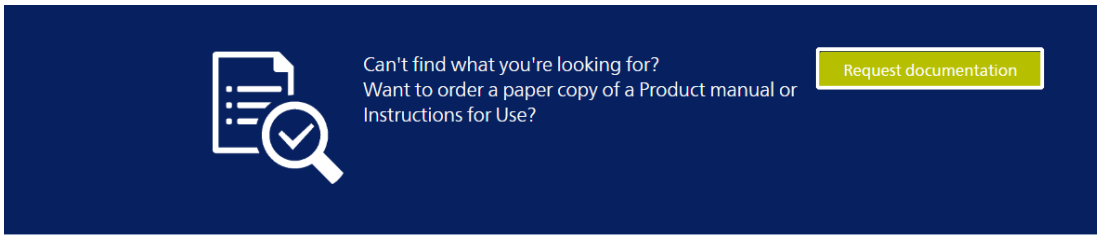


The Search results page opens.

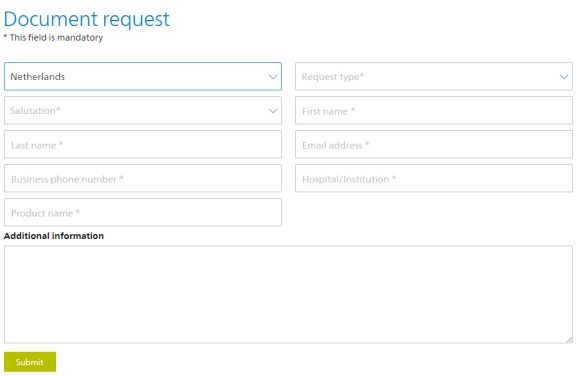
2. Scroll down the **Search results** page until you find the **Request documentation** button.



3. Click the **Request documentation** button.

   A document request form appears.

4. Fill in the required information and select **Submit**.



The printed IFU order will be provided within seven days using expedited delivery within the European Union.

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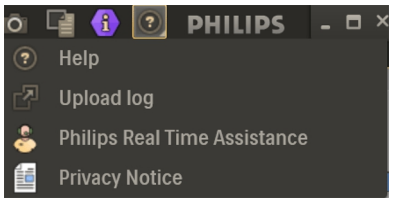
Accessing the Online Help

NOTICE

The images used in this section are examples only.

1. From the CT ASPECT Scoring Workflow Bar (right side of screen), click on the **Open Help** icon.

2. Select **Help** from the list.



The About Box opens.

3. Select **CT ASPECT Scoring Help** from the list.

The **Help** tabs appear.

4. Select the **Operation Manual** tab.

The Online Help opens.

Intended Use/Purpose

The CT ASPECT Scoring application is a Software as a Medical Device (SaMD) intended to assist the clinician in the assessment and characterization of brain tissue abnormalities using non-contrast CT (NCCT) image according to the Alberta Stroke Program Early CT Score (ASPECTS).

Intended Users

The CT ASPECT Scoring (ASPECTS) application is intended to be used by adequately trained and qualified medical professionals, including but not limited to physicians and medical technicians. The main clinicians or medical and para-medical professionals who use the Philips CT ASPECTS application are listed below:

- Radiologists in the Radiology department/clinic
- 3D technologists in the radiology department

Other clinicians/roles using the CT ASPECT Scoring are listed below:

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- Neuroradiologists and Neuro-interventional radiologists
- Neurologists and interventional neurologists
- Emergency medicine and Neurocritical care specialists
- Referring physicians

Intended Patient Population

The CT ASPECT Scoring application is intended for adult (>18 years), acute (≤ 6 hours from onset) stroke patients with large vessel occlusion.

Indications for Use

CT ASPECT Scoring is a SaMD intended to assist the clinician in the assessment and characterization of brain tissue abnormalities using non-contrast CT (NCCT) images according to the Alberta Stroke Program Early CT Score (ASPECTS) for adult (>18 years), acute (≤ 6 hours from onset) stroke patients with a known Large Vessel Occlusion (LVO) such as a Mid Cerebral Artery (MCA) or Internal Carotid Artery (ICA) occlusion.

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CAUTION

- **ASPECTS is not intended for primary interpretation of CT images; it is used to assist physician evaluation.**
- **ASPECTS has been validated for stroke patients with known MCA or ICA (LVO) Occlusion.**
- **Use of the ASPECTS Module in clinical settings other than early brain ischemia (within 6 hours from onset) caused by known ICA or MCA occlusions has not been tested.**
- **Excessive motion may lead to artifacts. Make sure the scan is technically adequate.**

Residual Risk

There were no reportable residual risks identified for the CT ASPECTS product.

Benefits

When used as specified in the Intended Use under the circumstances and conditions as specified in the Indications for Use, the CT ASPECTS application assists the user with the assessment and characterization of brain tissue abnormalities using non-contrast CT (NCCT) image according to the Alberta Stroke Program Early CT Score (ASPECTS). More specifically, by automating and standardizing the Alberta Stroke Program Early CT Scoring (ASPECTS), the application helps stroke teams across hospital sites and referral networks to quickly assess patient eligibility for thrombectomy.

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Undesirable Side Effects

No undesirable side-effects related to the CT ASPECT Scoring Application have been identified.

Contraindications

The application is not intended to be used on patients with hemorrhagic transformation or patients that have a hematoma.

The application is not intended to be used on patients with very thin or no ventricles.

Limitations for Use

Rx only

CAUTION

In the United States, Federal law restricts this device to sale by or on the order of a healthcare practitioner.

WARNING

- **Wrong region segmentation may lead to an inaccurate ASPECT score.**
- **Confirm LVO, verify slice detection, segmentation and score for each region.**
- **Confirm LVO, verify head symmetry, slice detection and region segmentation for automatic results.**
- **Verify head symmetry, slice detection and region segmentation for automatic results.**
- **Wrong slice detection or wrong segmentation may lead to inaccurate ASPECT score results. Please verify correctness.**
- **Operation of the product with improperly configured components could expose the patient to safety hazard(s) and could result in non- serious injury.**
- **Do not use the CT ASPECTS application until you have read, understood and know all the safety information, safety procedures and emergency procedures contained in this SAFETY section .**
- **Do not use the CT ASPECTS application until you have received adequate and proper are training in its safe and effective operation. If you unsure of your ability to operate this equipment safely and effectively DO NOT USE IT. Operation of this equipment without proper and adequate training could lead to clinical misinterpretation.**
- **Do not use the CT ASPECTS for any purpose other than those for which it is intended. Operation of the CT ASPECTS for unintended purposes, or with incompatible equipment, could lead to clinical misinterpretation.**
- **Use of this product in a way not described in these Instructions for Use, could lead to clinical misinterpretation.**

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Compatibility

The CT ASPECT Scoring application is intended to be launched from Advanced Visualization Workspace.

For additional information on Compatibility, please refer to the Compatibility section of the Advanced Visualization Workspace System IFU.

Your local Philips representative or manufacturer can be contacted for any questions regarding compatibility with specific devices and/or components. Information on significant restrictions related to compatibility can be found in the Release Notes accompanying this Instructions for Use. Philips is not responsible for running compatibility validation of non-supported third-party software.

Compliance

The Philips CT ASPECTS Scoring application complies with relevant international and national standards and laws. Information on compliance is supplied on request by your local Philips representative, or by the Manufacturer.

Symbols Glossary

The following symbols may appear in the product documentation or on the labels attached to the product:

Symbol	Symbol Name	Symbol Description	Standard Number & Name	Symbol Reference Number
	Manufacturer	Indicates the name and address of the manufacturer.	EN ISO 15223-1:2021	5.1.1
	Translation Indication	Indicates that the information has undergone a translation which supplements or replaces the original information	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, section 16.3	NA
	Date of manufacture	Indicates the date when the device was manufactured.	EN ISO 15223-1:2021	5.1.3

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Symbol	Symbol Name	Symbol Description	Standard Number & Name	Symbol Reference Number
	Batch code	Indicates the Software Release/ Version number.	EN ISO 15223-1:2021	5.1.5
	Code number	Indicates the manufacturer's catalog number so that the device can be identified.	EN ISO 15223-1:2021	5.1.6
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	EN ISO 15223-1:2021	5.4.3
 **eIFU Indicator**	eIFU Indicator	Indicates an instruction to consult an electronic instructions for use (eIFU). The “consult instructions for use” symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer’s eIFU website or any other appropriate indication on the use of eIFU (e.g. “IFU Kit”).		
	Warning/Caution/ Notice Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	**WARNINGS** are directions which if not followed could cause moderate to serious injury to an operator, patient or any other person, or could lead to a misinterpretation and/or loss or damage of patient-related data.. **CAUTIONS** are directions which if not followed could cause damage to the product described in this Instructions for Use and/or any other device. **NOTICES** highlight unusual points as an aid to an operator.	EN ISO 15223-1:2021	5.4.4

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Symbol	Symbol Name	Symbol Description	Standard Number & Name	Symbol Reference Number
CE 0344	CE Marking of Conformity	A marking by which a manufacturer indicates that a product is in conformity with the applicable requirements set out in European Union's harmonization legislation providing for its affixing.	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices)	Annex V of MDR
Rx only	Prescription Device	Caution: In the United States, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	21 CFR 801.109(b) (1) Prescription Devices	
MD	Medical Device Indication	An indication that the device is a medical device.	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	
UDI	UDI symbol	This symbol is used on the device label next to the UDI human readable indication (HRI) string.	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	
	Importer	The symbol will be followed by the medical device importer contact details: name and address.	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Article 13 (3)	

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Symbol	Symbol Name	Symbol Description	Standard Number & Name	Symbol Reference Number
CH REP	Authorized Representative in Switzerland	Indicates the authorizes representative in Switzerland.	Not Applicable	

Glossary References: 1 EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements.

Training

Users of the Philips CT ASPECT Scoring Application must have received adequate training on its safe and effective use before attempting to operate the software product described in this Instructions for Use.

Training requirements for this type of software product will vary from country to country. It is for users to make sure that they receive adequate training in accordance with local laws or regulations which have the force of law.

If you require further information about training in the use of this software product, please contact your local Philips representative, or the Manufacturer.

Safety

Philips products are designed to meet stringent safety standards. However, all software medical devices require proper operation and maintenance, particularly with regard to human safety.

It is vital that you follow strictly all safety directions under the heading **Safety** and all **Warnings** and **Cautions** throughout this "Instructions for Use", to help ensure the safety of both patients and operators.

In particular, you must read, understand and know the information described in this Safety section before using this device.

You should also note the following information:

- Intended use of Philips CT ASPECT Scoring application. See section “Intended Use/Purpose” on page 12.
- Contraindications. See section “Contraindications” on page 14.
- Training for operators of the CT ASPECT Scoring application. See section “Training” on page 18.

NOTICE

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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Network Safety, Security, and Privacy

Please refer to the **Network Safety, Security, and Privacy** section of the *Advanced Visualization Workspace System IFU*.

System Description

The CT ASPECT Scoring Application is intended to be launched and operated from Advanced Visualization Workspace.

For information on the Advanced Visualization Workspace system and requirements, please refer to the System Description section of the Advanced Visualization Workspace System IFU.

Screen Resolution

The CT ASPECT Scoring Application is intended to be launched and operated from Advanced Visualization Workspace.

For information on the Advanced Visualization Workspace Screen Resolution, please refer to the Screen Resolution section of the Advanced Visualization Workspace System IFU.

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Overview

The CT ASPECT Scoring (ASPECTS) application is used to assist physicians in the assessment and characterization of brain tissues using the imaging features of a non-contrast computed tomography (NCCT) brain image. The application automatically segments and analyzes 10 regions of interest in two standardized axial CT slices. The imaging features are then used to automatically compute a score based on the Alberta Stroke Program Early CT (ASPECT) guidelines. The CT ASPECTS application operates in two modes: the Automatic ASPECTS results creation and the interactive application. Results editing options are available in the interactive application.

For additional information see section “Configuration of CT ASPECT Scoring Results” on page 21 and section “Automatic ASPECTS Results Creation” on page 20.

Results are displayed as described below.

- A dedicated layout for reviewing the automatically segmented ASPECT regions, the layout displays both inferior and superior slices side by side (left side of screen).
- A summary table displays the total ASPECT score for the loaded NCCT data and probability of a lesion for each ASPECT region or the score per region (right side of screen).
- Mean Hounsfield Units (HU) values for each ASPECT region are shown on the image and in a summary table.

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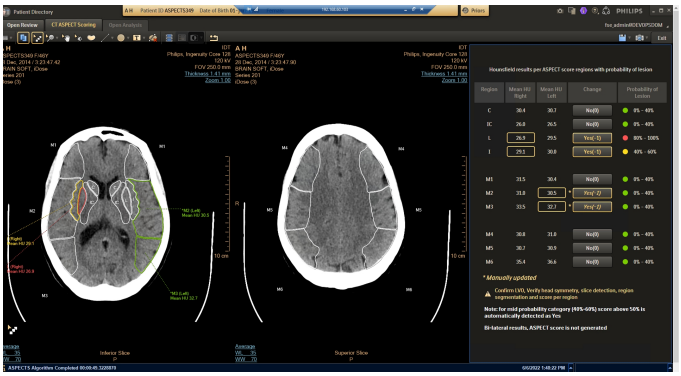

Key Features

CT ASPECT Scoring application includes the following key features:

- Allows visualization of NCCT data with axial orientation
- Results can be exported in various output formats
- Results can be exported by email and to mobile devices
- Automated ASPECT region classification
- Automated image Tilt Correction
- Automated Ischemia detection

Valid Studies for CT ASPECT Scoring Results

For optimal results in the CT ASPECT Scoring application, the following acquisition parameters are recommended:

- Non-Contrast CT (NCCT) images
- Supine orientation (HFS or FFS)
- Slice thickness of 0.5 to 5 mm
- In-plane voxel resolution of 0.4 to 0.5 mm
- Interslice distance of 1 to 5 mm
- Vertical field of view should be larger than 100 mm
- Supported kVP range: 120 – 140
- Gantry tilt to be removed in a pre-processing step
- Anatomical coverage of full skull or only minor parts missing (e.g. eyes)

Automatic ASPECTS Results Creation

It is possible to enable automatic results creation on the arrival of relevant data to Advanced Visualization Workspace.

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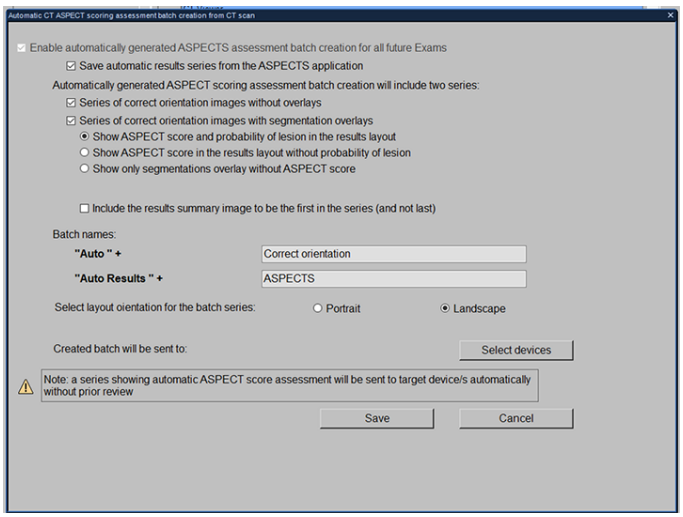
Once relevant data (as configured in Preferences) arrives at the Advanced Visualization Workspace, AVW recognizes the data as suitable for Automatic ASPECTS results creation. The Automatic ASPECTS results are generated in the background and are auto-sent to the devices configured by the user. For configuration information, see section “Configuration of CT ASPECT Scoring Results” on page 21.

Configuration of CT ASPECT Scoring Results

The Preference settings of the application configures the naming of the results, display options and determine where results will be saved.

1. Select **Viewing Applications** from Advanced Visualization Workspace **Preferences**.
2. Scroll to the **CT ASPECT Scoring batch creation from CT** section and select **Settings...**.

   The **Automatic CT ASPECT Scoring Assessment Batch Creation from CT Scan** window opens.



Enable automatically generated ASPECTS assessment batch creation for all future studies: Enables application to automatically generate ASPECTS assessment batches.

Automatically generated scoring assessment batch creation will include two series:

- **Series of correct orientation images without overlays**: This option results in sending a separate series (for this batch only) with corrected orientation and without image overlay of ASPECTS and results.
- **Series of correct orientation images with segmentation overlays**: This option results in sending a separate series (for this batch only) with corrected orientation and with image overlay of ASPECTS and results.

  Display in Summary table can be configured using one of the following options:

  – Show ASPECT score and probability of lesion in the results layout
  – Show ASPECT score in the results layout without probability of lesion
  – Show only segmentation overlay without ASPECT score.

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- **Include the results summary image to be the first in series (and not last)**: Determines order of the results summary image.
- **Name the automatic series batch**: Determines batch series name and description.
  - The batch description will have the fixed prefix: **Auto +**
  - The Results description will have the fixed prefix: **Auto Results +**
- **Send the batch to the following devices**: Determines destination device for saved results. Click **Select devices** to choose a destination device.

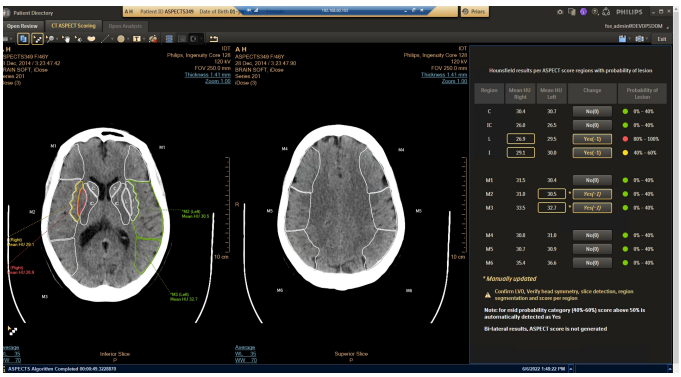
NOTICE

Series showing automatic ASPECT score assessment are sent to the target devices automatically without prior review.

User Interface

Results are displayed as:

- The inferior and superior ASPECTS slices featuring the segmentation of ASPECTS regions on the selected slice (left side of screen). The application provides a dedicated layout for reviewing the automatically segmented ASPECT regions. The layout displays both inferior and superior slices side by side.
- A summary table displaying results for each ASPECTS region (right side of screen). The summary table displays the total ASPECT score for the loaded NCCT data and probability of a lesion for each ASPECT region or the classification per region.



ASPECTS Images

The applications opens with the Inferior and Superior slices displayed, with overlay.

Ten anatomical areas (regions) of the brain are displayed:

- Three upper (inferior) areas of brain
- Seven lower (superior) areas of brain

Each of the ten regions is clearly labeled in the image with the Region name. A corresponding **Region** column appears in the Summary Table.

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The regions are shown on the image; related measurements in the table are labeled.

Regions that are affected are highlighted with a **Yes** label. Affected areas are represented with the same color coding.

Annotations appear on the image, including the Region name and HU mean values.

Summary Table

The Summary Table displays the following:

- **Region**: Specific brain region name
- Mean HU Right
- Mean HU Left
- **Change**: The application compares the right and left sides of the same areas. If an area is affected, the region is reduced by a value of one.
  - A **Yes (-1)** indicates the area was affected.
  - A **No (0)** indicates that there was no change to the area.

    The maximum score is 10, with one point removed for each affected area.
- Probability of Lesion
  - The probability of lesion is intended to assist the reader in reviewing the score per region and provides a range of probability that a particular region will be affected.
  - A probability of lesion is provided for each ASPECTS region and presented as a percentage scaled between 0-40%, 40-60%, 60-80% and 80-100%.
  - 0-40% indicates a lower probability that this region is affected, whereas 80-100% indicates a very high probability that the region is affected.
  - The areas marked as 40-60% and 60-80%, colored in yellow and orange respectively, indicate a medium to high probability.
  - If the probability of lesion is displayed in the table, the labeled color matches the color labeled in the image.

NOTICE

The probability of lesion for the range of 40%-60% might vary (could be marked as either Yes or No). This is directly related to the actual value that was calculated for the probability.

NOTICE

For the mid-probability category (40%-60%), scores above 50% are automatically detected as **Yes**.

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Automatic ASPECTS Results Workflow

NOTICE

If the application recognizes that the series was scanned/reconstructed with sub-optimal parameters (e.g. non-supported orientation, scan parameters etc.), automatic results are not created. The user is notified why results were not created for the loaded data.

Automatic Results Workflow

1. Configure Automatic Results (see section “Automatic ASPECTS Results Creation” on page 20).
2. Configure automatic pre-processing on AVW (see section “Automatic ASPECTS Results Creation” on page 20).
3. On PACS (or CT Viewer), open the automatic results and review the ASPECTS region and score per region.
4. If editing the results is required, open the CT ASPECT Scoring application.

CT ASPECT Scoring Application Workflow

NOTICE

If the application recognizes that the series was scanned/reconstructed with sub-optimal parameters (e.g. non-supported orientation, scan parameters etc.), automatic results are not created. The user is notified why results were not created for the loaded data.

CT ASPECT Scoring Application Workflow

1. Load NCCT series to the CT ASPECT Scoring application.
2. Review the Automatic classification for each region in a viewer.
3. Edit the classification per region if needed.

   For each manual update, an asterisk appears with annotation in the table. The image also displays an indication of manual update.
4. Once editing is completed, select the **Accept and calculate the ASPECT score**. The lower the score, the greater the likelihood for stroke.
5. Save the ASPECTS results

Viewing

The following viewing capabilities are available in the upper toolbar and/or Context Menu:

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- Pan, Zoom, Windowing, Show/Hide ASPECTS ROI's and Reset
- Show/Hide annotations
- Show/Hide overlay
- Change layout
- Scrolling

  When scrolling, an option in the Context Menu allows returning to the selected ASPECT slice (i.e inferior/superior) via the **Move back to the Inferior ASPECTS slice** (right view port moves to the inferior slice) or **Move back to the Superior ASPECTS slice** (left view port moves to the superior) option after scrolling. The selected viewport is updated.

Summary Table

To modify table results:

- In the **Change** column, click the **Yes** or **No** option if a change is required and select the correct option. A manually changed label is added.

Users can edit the results and calculate the total updated ASPECT score.

1. Right click on the table and the **Show in table Probability of Lesion** check box appears. Place a checkmark to display the Probability of Lesion column. The table and display are updated accordingly.
2. Click **Accept and Calculate** below the Summary Table after changes are completed.

Measurement Accuracy

Standalone Performance

Standalone performance of the ASPECT scoring of the CT ASPECTS application was evaluated internally on a set of 620 ASPECTS regions from 31 patients (63.4% male, mean age: 61.6 years (±18.98)). The test cases were rated (with two weeks between sessions) per region by five radiologists (out of which two are US Board certified) using both the Philips ASPECTS solution as well as the CT Viewer application of Advanced Visualization Workspace, providing no reading support similar to the standard of care (SOC). The Interclass correlation coefficient (ICC) is used as a metric for the evaluation of the agreement in between the automatic score, the voted consensus of the Experts (considered as ground truth) and the agreement between all of the experts in a SOC scenario.

	ICC	95% Confidence Interval: Lower Bound	95% Confidence Interval: Upper Bound
ASPECTS AI automated detection vs Voted consensus Score	.927	.875	.961
SOC Experts Agreements	.919	.859	.958

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The ICC is significantly above 0.8, indicating excellent agreement. This agreement of ASPECTS automated score with the voted consensus experts is similar to the agreement between expert observers using SOC (the Confidence Interval of the ICC Overlap completely).

Concurrent Reading Performance

The concurrent reading performance of the ASPECT scoring of the CT ASPECTS application was evaluated internally on a set of 840 aspects regions from a sample set of 41 patients (64.52% male, mean age: 63.29 years (±19.1)). The test cases were rated (with two weeks between sessions) per region by five radiologists (out of which two are US Board certified) using both, the Philips CT ASPECTS solution as well as the CT Viewer application of Advanced Visualization Workspace, providing no reading support similar to the standard of care (SOC). The Fliess' Kappa is used as a metric for the evaluation of the agreement in between the reading of the Experts with the CT ASPECTS application and the agreement in between all the experts in a SOC scenario.

	Fleiss' kappa	Lower 95% Asymptotic CI Bound	Upper 95% Asymptotic CI Bound
SOC	.651	.630	.673
ASPECTS AI	.720	.699	.741

The results above indicate that the automated detection significantly increased all the experts' agreement from fair to good (The 95% CI of the Fleiss' kappa do not overlap), and therefore significantly increased all of the experts' detection performance.

	Average number of Agreed regions per Case	Standard Deviation	Mean Paired Difference (of agreed number of regions per case)	95% Confidence Interval of the Difference Lower	95% Confidence Interval of the Difference: Upper	p-value
SOC All Experts	15.52	2.49	1.05	.20	1.89	.016
With AVW ASPECT AI	16.57	2.49				

With the CT ASPECTS application, all readers significantly agreed, on average, with more than one region more (1.05 – 95% CI 0.20-1.89, p-value=0.016, power>0.99) per scan than by using SOC.

Saving Results

Select the Save icon above the summary table to save results. The following options are available:

- Save selected image(s) as...
- Save screen snapshop as...

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- Save results as...
- Save batch of corrected orientation only
- Save batch with ASPECTS results

Glossary

Abbreviation	Description
AVW	Advanced Visualization Workspace
ASPECTS	**A**lberta **S**troke **P**rogram **E**arly **CT** Score
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine, the international standard for medical images and related information.
HU	Hounsfield unit
LVO	Large Vessel Occlusion
NCCT	Non-Contrast CT
PACS	Picture Archiving and Communication System
SaMD	Software as a Medical Device

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