



deepcOS AIDA (v2.0)

These instructions were put together with great care. If you should still find details here, which do not agree with how the system is handled, we would appreciate it if you let us know so that we can correct the discrepancies as quickly as possible.

Should there be a serious incident or undesirable side effects during handling and use of the product which is not specified in these instructions for use, please report these to us with a detailed description of the incident or side effects. Please use the contact details below for this purpose.

The specifications and figures in this user manual are subject to change due to optical or further technical developments.

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In order to order more copies of the IFU please send an email with the request to support@deepc.ai

Information about the product and the manufacturer

deepcOS AIDA (v2.0)
A product of
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Content

1.	Scope of Delivery	4
	1.1 Standard Scope of Delivery	4
2.	Product Description	4
	2.1 Intended Purpose	4
	2.1.1 Intended Patient Population	4
	2.1.2 Medical Indications	4
	2.1.2.1 Contraindications	4
	2.1.3 Intended User	4
	2.1.4 Intended Use	4
	2.1.4.1 Compatibilities	5
	2.1.4.2 Precautions	5
	2.1.5 Clinical Claims	5
	2.1.6 Non-Clinical Claims	5
	2.1.5.1 Disclaimer	5
	2.2 Functional Description	5
	2.2.1 The Worklist	6
	2.2.2 DICOM Viewer	7
	2.3 Labelling	8
3.	Safety Instructions	11
	3.1 General Remarks	11
	3.2 Operation of the Device	12
	3.3 Side Effects and Contraindications	12
4.	Initial Operation	13
	4.1 Installation	13
	4.2 Configuration	13
	4.3 Verification Before Usage	13
	4.4 Release for Usage	14
	4.5 User Login	14
5.	. Operation	14
	5.1 Making the Product Ready for Operation	14
	5.2 Application to the Patient	14
	5.3 Displays and Signals	14
	5.4 Data Logging	14
	5.5 Maintenance	14
	5.6 Uninstallation	15
	5.7 Data Retention & Backup	15
6.	Functional Check	15
7.	Malfunctions and their Removal	15
8.	Declaration of Conformity	17



1. Scope of Delivery

1.1 Standard Scope of Delivery

Part/Trade Name	Description	Part/Order Number
deepcOS AIDA (v2.0)	Patient data management software with a DICOM viewer.	

Table 1.1 Standard Scope of Delivery

2. Product Description

2.1 Intended Purpose

2.1.1 Intended Patient Population

Patients who have been through a medical image acquisition procedure, such as X-Ray, MRI, CT-scan, among others.

2.1.2 Medical Indications

deepcOS AIDA (v2.0) is a software used for the display of medical images and clinical information provided by external medical devices using the DICOM format. The information displayed can be used by physicians to make patient management decisions.

2.1.2.1 Contraindications

 Please follow all contraindications defined by the manufacturers of the external medical devices for a correct analysis of the imaging files and clinical information.

2.1.3 Intended User

The software is designed to be used by trained professionals (including radiologists, physicians and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

2.1.4 Intended Use

deepcOS AIDA (v2.0) is a software used for the display of medical images and clinical information provided by external medical devices using the DICOM format. The information displayed can be used by physicians to make patient management decisions.



2.1.4.1 Compatibilities

deepcOS AIDA (v2.0) is communicating with external devices and components via the DICOM standard.

This ensures compatibility with external medical devices, including Al products, so their outputs are in a specific format to be correctly displayed by *deepcOS AIDA* (v2.0).

2.1.4.2 Precautions

- The clinical information is not provided by *deepcOS AIDA* (v2.0), but by external medical devices.
- All clinical information has a certain accuracy level that must be revised with the external medical devices' manufacturers or respective documentation.
- Only DICOM files can be used for the display of digital images.
- There might be inaccuracies and precision limitations of the data displayed, as the quality of the data depends on the information received, user interaction and the features in the display device.
- The prioritisation of the patients based on the clinical information is performed by the user, not by *deepcOS AIDA* (v2.0).
- Do not use *deepcOS AIDA* (v2.0) if the IT installation requirements have not been met.

A full list of Safety Instructions, including caution and warning messages are defined in Section 3 of this document.

2.1.5 Clinical Claims

 While software cannot have a direct clinical benefit for patients, deepcOS AIDA (v2.0) has the indirect clinical claim to help physicians make a more accurate diagnosis and improve treatment planning for patients by displaying digital images from various sources with image manipulation tools, such as grayscale windowing and level, zooming, panning and annotations.

2.1.6 Non-Clinical Claims

- Patient data management.
- Collection of post-market surveillance data regarding the accuracy of the output of the external certified products.

2.1.5.1 Disclaimer

- The information displayed via *deepcOS AIDA* (v2.0) is dependent on the quality and accuracy of the incoming data provided by external sources, and is <u>not</u> intended to be the only source of information for taking decisions with diagnostic purposes.
- Patient data is stored only within the local infrastructure of the medical facility where deepcOS AIDA (v2.0) is installed. The storage time can be modified during installation according to the customer's specifications upon request.

2.2 Functional Description

deepcOS AIDA (v2.0) is a patient data management software with a DICOM viewer.



The software enables physicians to see a worklist where certified external artificial intelligence (AI) solutions provide a classification of suspected clinical findings, which is used as input to prioritise studies according to the user's specifications. Further information is shown through *deepcOS AIDA* (v2.0)'s DICOM viewer, which also includes visualisation tools for easier recognition and treatment planning.

The way that deepcOS AIDA (v2.0) works is described in the following steps:

- Prior to installation, the user defines which of the clinical findings are to be displayed as urgent.
- 2. Once *deepcOS AIDA* (v2.0) is installed, it receives input (DICOM files), upon which an external AI solution classified the image with one or more clinical findings. *deepcOS AIDA* (v2.0) then prioritises the patient studies according to the user's specifications defined in step 1.
- Through deepcOS AIDA (v2.0)'s user interface, physicians can then scroll through the prioritised worklist to read the patient-specific clinical findings provided by the AI output.
- 4. By selecting the desired study/patient, the user can access its DICOM viewer to display the selected study and confirm or reject the clinical findings provided by external certified products.

2.2.1 The Worklist

The worklist that *deepcOS AIDA* (v2.0) provides to the physicians includes the following information: *Priority, Study Time, Clinical Findings, Patient Name, Description, Patient ID, AI processing, Date of Birth* and *Study Date*. A screenshot of its User Interface can be seen below:

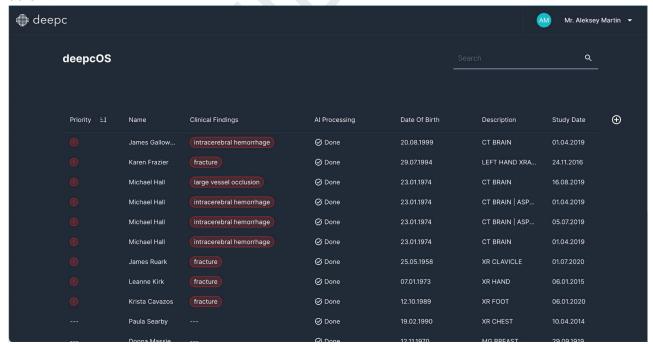


Fig. 1 deepcOS AIDA (v2.0)'S Worklist

The first column, *Priority*, is either given as 'urgent' using an exclamation mark symbol or left blank. The assignment of 'Urgent' is intended to act as a filter so that physicians can prioritise the most urgent patients according to their suspected/predicted conditions. This



prioritisation is provided by the users; for example, prior to installation, a user selects the order on which the patients shall be listed based on the clinical findings (e.g., patients with suspected tumours first, then aneurysms, then bone fractures, and so on).

Clinical Findings display the suspected or predicted conditions by the external Al solutions with short terms and a clear format for easy reading.

Al Processing has 3 options: processing, completed, N/A; where the latter state refers to a solution being unavailable either because there is no Al solution applicable or there was an error. The processing state is specifically under the control of the external Al vendors integrating with a local API/SDK.

The rest of the columns show the patient's information. DICOM nomenclature here is adopted for describing the various image levels: multiple slices make up an image series with multiple series being attached to a study. Rather than using the DICOM attribute *study description*, which is not standardised and often left blank, *modality* and *body part* have been taken from the DICOM attributes, which tend to be more reliably filled out.

The worklist also allows various combinations of column filters to be applied (sequentially from left to right) to limit the overall results of the worklist so as to allow prioritisation for the attending physician. In addition, there is a global search bar if the user wants to specifically look for something without using the filters in order to accelerate the search process.

In order to assist physicians when creating a report or communicating AI findings via text, a copy text to clipboard functionality is enabled on an individual or multiple cell level. This functionality is enabled over HTTPS and by using the right click on the mouse to trigger the menu appearing. Text over a single cell or multiple columns can be copied to the clipboard and pasted into any text reading program.

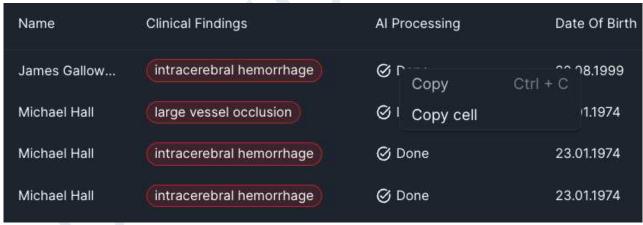


Fig. 2 deepcOS AIDA (v2.0)'s Copy to Clipboard functionality

2.2.2 DICOM Viewer

deepcOS AIDA (v2.0)'s DICOM viewer displays medical, digital imaging files and offers basic imaging functions, such as zoom-in, zoom-out, contrast adjustment, annotation, among others. Zoom-in/out allows the user to examine in more detail any potential pathologies that need to be quickly addressed. As does the contrast tool which might display more or less information depending on the density of the tissue examined and the image modality being examined (MR, CT, X-Ray). It does this by adjusting the window and level of grey levels in the image. Additionally, the DICOM viewer allows physicians to quickly toggle between findings in the image and annotations that might be made either by AI or the user. These tools are intended to be triggered by toggling somewhat subjectively (with mouse shortcuts



to facilitate efficiency) and not necessarily in sequence i.e. back and forth as the user sees fit for maximum flexibility. The purpose of these tools are to help physicians make a more accurate diagnosis and improve the efficiency of the treatment planning for patients.

The viewer also has a section placed on the right side of the user interface where a summary of the patient's information, imaging exam and clinical findings are displayed in three different tabs. The CLINICAL tab provides the patient's general information. The EXAM tab provides information regarding the imaging exam (e.g., X-Ray orientation AP/lateral). The REPORT tab allows the physician not only to see the clinical findings provided by the external AI solutions, but also to verify them, accept/reject them and add any extra findings and/or annotations, if needed. A screenshot of *deepcOS AIDA* (v2.0)'s user interface can be seen below:

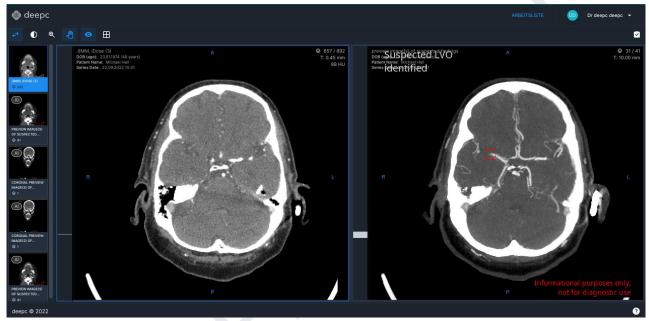


Fig. 3 deepcOS AIDA (v2.0)'s Medical Imaging Viewer

2.3 Labelling

Symbol	Meaning
MD	Medical Device



-	
	Manufacturer Supplementary see DIN EN ISO 15223-1
deepc.	Manufacturer Logo
	Date of Manufacture Supplementary see DIN EN ISO 15223-1
SN	Serial Number Supplementary see DIN EN ISO 15223-1
C E 0123	CE label
i	Consult Instructions for Use or consult electronic Instructions for Use Supplementary see DIN EN ISO 15223-1
LOT	Batch code (in this case used for version number)



Supplementary see DIN EN ISO 15223-1

Table 2.1 Labelling



3. Safety Instructions

Please read these instructions for use carefully. They are part of the device and must be available at all times. Do only use the device for the intended purpose described in this document (see chapter Intended Purpose).

For your own safety as well as for the safety of your patients and according to the requirements of the Medical Device Regulation, please observe the following:

WARNING Important safety or performance information or immediate response operator required.	
CAUTION	Other important information with or without the need of operator response.

3.1 General Remarks

CAUTION: deepcOS AIDA is not intended to be the only source of information. The information provided by deepcOS AIDA is not intended to be the only source of information for taking decisions with diagnostic purposes. deepcOS AIDA is limited to the display of imaging data and suspected clinical findings, and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.
CAUTION: deepcOS AIDA is not responsible for the prioritisation order of suspected clinical findings. The flagging and prioritisation order of suspected clinical findings is defined by the user during installation and not based on any criteria defined by deepcOS AIDA.
CAUTION: The clinical findings are not defined by deepcOS AIDA, but by the external certified AI solutions. All clinical findings are received as input provided by third-party AI solutions.





<u>WARNING:</u> All clinical findings have a certain accuracy level that must be revised with the external certified AI solutions providers.

This information is defined in the IFU and/or labels of the third-party AI solutions, given to end users directly by the third-party AI solution manufacturers, or during the installation of *deepcOS AIDA*.

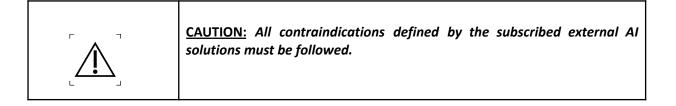
Table 3.1 General Remarks

3.2 Operation of the Device

CAUTION: Images displayed might be compressed. Use for informational purposes only. Images that are previewed through a viewer might be compressed and are for informational purposes only and not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests.
CAUTION: Data displayed might be inaccurate and have precision limitations. There might be inaccuracies and precision limitations of the data displayed, as the quality of the data depends on the information received, user interaction and the features in the display device.
CAUTION: Imaging file not compatible deepcOS AIDA can only process and display imaging files in DICOM format.

Table 3.2 Operation of the Device

3.3 Side Effects and Contraindications





Please follow all contraindications defined by the subscribed external AI solutions for a correct analysis of the imaging files and/or suspected clinical findings.
WARNING: Use only when all IT installations requirements have been met. Do not use deepcOS AIDA if all the IT installation requirements defined in 07_00_022_Installation Guide_AIDA_2_0 have not been met.

Table 3.3 Side Effects and Contraindications

4. Initial Operation

4.1 Installation

deepcOS AIDA (v2.0) is not installed by the user. The installation of deepcOS AIDA (v2.0) is conducted by deepc GmbH along with the IT department of the medical facility.

deepcOS AIDA (v2.0) can only be used with a suitable on-premise IT infrastructure of the medical facility. The IT infrastructure must be capable of receiving and sending the medical imaging files in DICOM format. The setup of this interface is carried out by deepc GmbH, as part of the general installation.

As part of the installation, deepc GmbH makes sure that the medical imaging files of patients included within the device's intended purpose (see Section 2.1) are automatically routed to *deepcOS AIDA* (v2.0) with the outcome of the external AI solutions.

Minimum requirements for using *deepcOS AIDA* (v2.0) is an up-to-date antivirus software.

All information regarding the operating environment of *deepcOS AIDA* (v2.0) can be found in 07_00_022_Installation Guide_AIDA_2_0.

4.2 Configuration

deepcOS AIDA (v2.0) requires no calibration. Any configuration to deepcOS AIDA (v2.0) prior to installation is done between deepc's installation team and the IT department of the medical facility.

4.3 Verification Before Usage

Correct usage of *deepcOS AIDA* (v2.0) is verified by deepc Gmbh along with the IT department of the medical facility before its first usage.



4.4 Release for Usage

deepc GmbH releases the product for usage.

4.5 User Login

A username and password is initially assigned by deepc GmbH. This password can later be changed by the user, if preferred.

No different user roles (with different privileges) are applicable to *deepcOS AIDA* (v2.0). Only one type of user role is available and is the one given at installation.

5. Operation

5.1 Making the Product Ready for Operation

To make use and display the results provided by the external Al solutions, as well as the imaging DICOM files, a compatible PACS is necessary.

5.2 Application to the Patient

deepcOS AIDA (v2.0) is only applied to patient data, not directly to the patient. Therefore, there is no direct interface to the patient.

5.3 Displays and Signals

As described in Section 2.2, deepcOS AIDA (v2.0) sends the following types of outputs:

- A worklist, flagging suspected critical clinical findings, as well as displaying information regarding the patient and imaging study.
- DICOM viewer, displaying the imaging files of the study, along with the suspected clinical findings provided by the external AI solutions.

5.4 Data Logging

Data logging includes post-market surveillance information* regarding the accepted/rejected clinical findings by the end-user. This information is forwarded on demand to the external AI partners for the improvement of their AI models. It is the responsibility of the AI partners to perform a backup of this data.

*Note: This information does not contain any personal patient or user-related data.

5.5 Maintenance

deepc GmbH performs automatic update releases which are done remotely and do not require any actions from the users, unless specified, for which the users will be contacted by one of our team members. More information regarding maintenance can be found in 07_00_018_Maintenance Specifications_AIDA_2_0, if requested.



5.6 Uninstallation

To uninstall deepcOS AIDA, please follow the instructions defined in *07_00_022_Installation Guide AIDA 2 0*.

5.7 Data Retention & Backup

Due to cybersecurity and data protection requirements, the storage time of DICOM images is set according to the user's specifications during installation. When the defined storage duration time has been reached, the DICOM data is deleted from the database and the metadata (i.e., patient name and age) is anonymised.

The patient metadata is kept anonymised in the database for reporting purposes indefinitely, this storage time could also be further modified upon user's request.

No further backups of any information are performed and kept by deepcOS AIDA.

6. Functional Check



Check if you are using an updated version of your internet browser and have a stable internet connection.

7. Malfunctions and their Removal

Malfunction	Cause of the Malfunction	Removal of the Malfunction	
logs.viewer.studyNotFound	Server-side errors with multiple causes	If this error occurs, please contact support@deepc.ai	
pages.viewer.notifications.dic omLoadFailed	Could not render DICOM slice	If this error occurs, please contact support@deepc.ai	
pages.viewer.notifications.un knownError	Errors not related to load, read or rendering of DICOM slices. Very unlikely to be experienced	If this error occurs, please contact support@deepc.ai	
logs.account.setCurrentUserE rror	Server-side errors with multiple causes	If this error occurs, please contact support@deepc.ai	



logs.account.setCurrentUserL anguageError

Server-side errors with multiple causes

If this error occurs, please contact support@deepc.ai

In case of failures which cannot be eliminated directly, have the device repaired by the manufacturer or your specialist distributor. Do not continue to operate the device in order to avoid major damage.

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.



8. Declaration of Conformity

Declaration of Conformity

(according to Regulation (EU) 2017/745 on medical devices, annex IV dated May 2017)

deepc GmbH SRN: DE-MF-000006984

> Blumenstraße 28 80331, Munich Germany

declares under its sole responsibility that the product

4260683024007UW deepcOS AIDA

Intended as a software used for the display of medical images and clinical information provided by external medical devices using the DICOM format. The information displayed can be used by physicians to make patient management decisions.

Software version: 2.x.x

to which this declaration relates is in conformity with the following regulation:

Evaluation procedure according to Regulation (EU) 2017/745 on medical devices, annex IX

Classification according to Regulation (EU) 2017/745 on medical devices, annex VIII:

Active standalone software for long term use, classified as Class IIa according to Rule 11

This product fulfils the CS (Common Specifications) and has been CE-labelled due to the fulfilment of the general safety and performance requirements according to Regulation (EU) 2017/745 on medical devices, annex I.



TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339, Munich, Germany

deepc GmbH, Efraín Salinas Hernández deepc GmbH, Dr. Franz Pfister
PRRC: signature, date, location Managing Director & CEO: signature, date, location

01_01_002_Declaration of Conformity_AIDA_2_x_230817

01_01_002_Declaration of Conformity_V03

Printed version is not subject to change management. Always use the up-to-date document.

Page 2 of 2



*****Document Approval and Document History of the template. Delete at Approval. *****

Document Approval			
Role	Name	Date	Signature
Author	Efraín Salinas Hernández	08/09/2023	Efrain Salinas Hemandez
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			Section 2.1.4.2
			Changed Section's title to <i>Precautions</i> .
			Added reference to Section 3.
			Section 2.1.5.1
			Updated information related to storage time.
			Section 3.1
			Updated last <i>Caution</i> to <i>Warning</i> .
			Section 3.3
			Updated reference to Installation Guide.
			Section 4.5
			Changed Section's title to <i>User Login</i> .
			Section 5.5
			Added reference to 07_00_018_Maintenance Specifications_AIDA_2_0.
	1	1	I I



			-
			Updated reference to Installation Guide.
06	17.08.2023	Efraín Salinas Hernández	·
			Removed PACS provider, added IT department.
			Section 4.4
			Removed reference to partners.



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SignNow Web Application Invite Sent to: efrain@deepc.ai		efrain@deepc.ai	09/08/2023 16:18:34 pm UTC	09/08/2023 16:18:33 pm UTC	88.217.133.224
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SignNow Web Application	Document Saved	efrain@deepc.ai	09/08/2023 16:18:42 pm UTC	09/08/2023 16:18:42 pm UTC	88.217.133.224
SignNow Web Application	Signed the Document	efrain@deepc.ai	09/08/2023 16:18:42 pm UTC	09/08/2023 16:18:42 pm UTC	88.217.133.224
SignNow Web Application	gnNow Web Application Viewed the Document		09/08/2023 16:43:10 pm UTC	09/08/2023 16:43:10 pm UTC	95.90.192.234
gnNow Web Application Added a Text		julia@deepc.ai	09/08/2023 16:43:20 pm UTC	09/08/2023 16:43:19 pm UTC	95.90.192.234
ignNow Web Application Signed the Document		julia@deepc.ai	09/08/2023 16:43:20 pm UTC	09/08/2023 16:43:19 pm UTC	95.90.192.234
SignNow Web Application Added a Text		julia@deepc.ai	09/08/2023 16:43:20 pm UTC	09/08/2023 16:43:19 pm UTC	95.90.192.234
SignNow Web Application	gnNow Web Application Document Saved		09/08/2023 16:43:20 pm UTC	09/08/2023 16:43:19 pm UTC	95.90.192.234
SignNow Web Application	Signed the Document	julia@deepc.ai	09/08/2023 16:43:20 pm UTC	09/08/2023 16:43:19 pm UTC	95.90.192.234
SignNow Web Application Signer julia@deepc.ai received a signed document copy		julia@deepc.ai	09/08/2023 16:43:27 pm UTC	09/08/2023 16:43:19 pm UTC	95.90.192.234
SignNow Web Application Sender efrain@deepc.ai received a signed document copy		efrain@deepc.ai	09/08/2023 16:43:27 pm UTC	09/08/2023 16:43:19 pm UTC	95.90.192.234