Dicompass Camera 2 - User manual

Software manufacturer:

MEDORO s.r.o., Štrossova 567, 530 03 Pardubice, Czech Republic, ID: 26002612, VAT number: CZ26002612, http://www.medoro.org, http://www.dicompass.cz, e-mail: info@medoro.org

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Introduction

This document is a user manual in electronic form, describing the functions and operation of the SW Dicompass Camera 2.

The user manual is intended for professional users, i.e. for medical and intermediate medical personnel.

Please read this manual carefully before using the Dicompass Camera 2 medical device.

If necessary, this instruction manual is provided in paper form, at no additional cost to the user, within 7 days of receiving the request. The request can be sent by email to helpdesk@medoro.org.

In this user manual you will find all the information on the following topics:

- application functions
- installation and first start-up
- application settings

Reporting serious adverse events

According to Regulation 2017/745 of the European Parliament and Council (EU) from 5th April 2017 on medical devices, amending Directive 2001/83/ES, Regulation (ES) No 178/2002 and Regulation (ES) No 1223/2009 and repealing Council Directives 90/385/EHS and 93/42/EHS, serious adverse event refers to an event which directly or indirectly leads to, may have or may lead to one of the following consequences:

- 1. death of a patient, user or other person
- 2. temporary or permanent deterioration of patient's, user's or other person's health
- 3. serious threat to public health

Any serious adverse event that has occurred in connection with the device in question should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

In the event of an adverse event, contact us using the HelpDesk, by phone on +420 463 356 445, or by email at helpdesk@medoro.org.

Description of the intended purpose of use

The intended purpose of SW Dicompass:

The specialized modular software Dicompass is intended as a tool for working with image data for the purposes of diagnostic and therapeutic actions in the healthcare sector. Dicompass contains not only a DICOM viewer, but also modules for a complete solution for video digitization from endoscopes, ultrasounds, microscopes, as well as other devices that do not have a direct DICOM output, conversion of recordings from digital cameras, scanners and cameras into DICOM format (DICOMization). Dicompass also offers functions for radiodiagnostics and radiotherapy.

The indication for the use of MD Dicompass is connected with the need for a specialized doctor to diagnose the deteriorated condition of the patient using imaging methods. Dicompass enables this image documentation to be archived and subsequently worked with.

Contraindications are not known.

Warnings are not known.

The software is classified and certified as a Class IIb medical device in accordance with applicable legislative requirements.

C€ 2265

MD Dicompass is a separate device and for its intended purpose of use does not use additional accessories and is not part of the system or kits.

MD Dicompass does not contain a medicinal substance, including derivatives of human blood or plasma, or tissue or cells of human origin or their derivatives, or tissues or cells of animal origin or their derivatives. It is not intended for introduction into the human body.

MD Dicompass is not a single-use resource. It is supplied non-sterile and is not intended for sterilization.

MD Dicompass is delivered exclusively electronically and thus does not use a storage requirement.

System requirements

The chart describes the minimum required configuration on a mobile device to operate SW Dicompass Camera 2:

Parameter	Requirement
Android	min ver. 9
iOS	min ver. 13
HW	Camera
	Microphone
	Network connection
HDD	200MB

For the ZP Dicompass Camera 2 to work properly, it is required to allow the application to access audio and video recording and data access. It is also necessary to be connected to the network.

Installation and configuration of the ZP Dicompass Camera 2 is performed by the user, according to this user manual.

Requests can be reported in three ways, by creating a request directly in the Helpdesk system at:

- https://helpdesk.medoro.cz/
- by email at helpdesk@medoro.org
- by phone +420775324005, or to a specific service technician, who then enters the request into the Helpdesk system

Regular maintenance is carried out on the basis of released resource updates and their installation.

For the correct and safe functioning of the device, it is not necessary to calibrate MD for the entire specified period of its life.

There are no risks for persons involved in the installation, calibration or servicing of the devices.

The security measures of the MD Dicompass resource are determined by the Linux operating system used and its native firewall, which is configured when the system is implemented. Access to the server part of the system is only allowed to trained service technicians by the manufacturer using SSH key encryption. Access to the user part of the system is protected by two-factor user authentication or by connecting to the customer's LDAP/AD.

Application functions

Dicompass Camera 2 is primarily intended to take pictures and videos of the patient's external findings via various platforms and send them to the hospital's archive. Complete information about the product can be found at https://dicompass.cz/dicompass-camera

An application running on Android or iOS that allows you to capture an image through the device's camera, convert the image to DICOM format and send it to the archive using WIFI or mobile data. Header data can be obtained via the Worklist modality, manual input or via a QR/BAR code.

Dicompass Camera 2 functions:

- Manually entering a patient or selecting a patient from the Worklist
- Automatic completion of patient data from PACS
- HL7 communication
- Image format JPEG or uncompressed (Little Endian)
- Video recording in MPEG4 format
- Image cropping and video editing tools
- Image queue you can take images even without a WIFI connection and the images are automatically sent when connected
- Retrieve patient ID from QR/BAR code
- Specify output modality type
- Tags and localization of findings
- Import data from the device gallery
- Select light/dark application mode

Installation and first start-up

Installation for Android operating system

The Dicompass Camera 2 app is available at - http://play.google.com

To find the app for the Android operating system, enter "Dicompass Camera 2" in the search box and then click "download" or "install". Agree on everything you need and install it on your device.

Installation for iOS operating system

The Dicompass Camera 2 app is available at - https://apps.apple.com/

To find the app for the iOS operating system, enter "Dicompass Camera 2" in the search box and then click "download" or "install". Agree on everything you need and install it on your device.

Starting the application



To launch the app, click on the Dicompass Camera 2 icon on the device desktop (see above).

License activation

The installed application is only a Demo version for non-clinical use. All photos taken will have a watermark embedded.

The product can be activated through payment portals google pay or app store.

<	Settings Licence
SELECT	LICENSE PERIOD
۲	1 month
You are p license f	planning to purchase a limited or Dicompass Camera 2
SELLER	
MEDORO) s.r.o.
Štrossov	ra 567
530 03 P	ardubice
Czech Re	epublic
	2612

After clicking on the menu on the top left, a menu bar will appear, where we select the "License" item. You will be offered 1 month. After that, the whole process is done through the payment terminal of the company and the device.

Once the payment has been made, the application must be restarted to load the license correctly. You can check the purchased license in the same "License" section, where the license validity period and license ID will be listed.



Homepage

On the home page you will find the following 5 items:



- 1. Action to proceed to patient selection and photo capture
- 2. Application license information
- 3. Information about the device connection to the internal network or GSM
- 4. Action to display the queue of unsent data to be sent to the PACS archive
- 5. Application menu

Creating patient image documentation

Patient data selection

Patient data can be selected in 3 ways:

1. The first option is to select a patient from the worklist. This contains patients who are pre-registered, scheduled or waiting to be examined. The image below shows the patients waiting to be examined from the worklist. From the patient list, simply click on the patient and continue on to determine the localization.

13:5	54	.ull 📚 💷
<	Modality wo	orklist 🥠
ç	PESLOVA ZDENKA 05.02.1927	ID: 275205484
θ	JIRCHAROVA ANNA 11.04.1929	ID: 295411412
ď	BURDA ZDENEK 06.10.1978	ID: 7810064526
ç	HUBACKOVA JANA 29.03.1982	ID: 8253294588
ç	BELLOVICOVA MARIE 09.03.1929	ID: 295309443
ď	HLOZEK JOSEF 27.06.1946	ID: 460627466
ç	PROKESOVA BOZENA 13.06.1933	ID: 335613408
ç	KOCICOVA LUDMILA 18.02.1932	ID: 325218418
ç	HORAKOVA ANNA 29.03.1923	ID: 235329482
ď	ROZUM MILOS 18.07.1946	ID: 460718448
-	HAPALA EMIL	ID: 261010963
	Whenever	Manual entry

2. The second option is to manually enter the patient's information. Patient ID (birth number), Last Name, First Name and Study Description are required. Gender and date of birth are automatically filled in by the software according to the correctly entered birth number. Everything is shown in the figure below.

Defined ID #	
Patient ID *	>
Family name *	
	>
Given name *	
	>
Sex Other	
/ Date of birth	>
Study description	
Media	>



3. The last option for patient selection is to retrieve from QR or BAR codes. These codes are usually placed on the patients wristband. To retrieve, click on the "Scan QR Code" action in the manual entry option. The device's camera opens and we point it at the desired code. We fill in the other necessary information and confirm the "Confirm" action on the bottom right.



Determination of localization

The localization is determined on an image of the human body. Click on the location to determine the position of the external finding for photographing. After clicking, a more precise localization option is offered.

Example: clicking on a face will show options for specifying the location in the form of eyes, ears, nose, mouth, cheeks, whole face, etc... After selecting a more precise location, the location will be highlighted in red.



Then you can attach a name label to the finding. This is done by selecting from a list of labels. This list is user configurable and can be changed in the settings. The localization and tags information is placed by the DICOM tag in the Series Description.



Capturing images

Once the location is determined, the app switches to camera mode and the user uses the shutter button to take the desired picture or video. The video is toggled at the bottom above the shutter button.



The photos and videos you take are sorted into a gallery, which can be displayed by clicking on the circle in

the bottom left corner with the number of images created. The images are fragmented and after fragmented are sorted according to the chosen localization.



In the gallery, you can re-categorize images and videos under different labels, and you can crop a photo or cut out only part of a video.





The last step to save images and videos to the PACS archive is to press on the action in the top right corner "arrow icon in the circle" or button "Send"





All images will be moved to the upload queue, which can be found on the main page (point 4 below)



You can delete individual files in the upload queue, or delete everything when uploading. Once everything is sent, the queue is empty. If the upload fails, the application tries to upload images every time it is turned on or when new files are uploaded. The number of attempts is shown in the circle next to the file name

Application settings

The settings are divided into nine parts (connection, image, meta data, application, license, manual, about application, color scheme, link to dicompass.cz). Details about each setting and configuration can be found in the individual chapters.



Connection

This section allows us to configure the network parameters of the device.

10:23 🖻 🕅 🛄 • 🦉 🕸 💐 🗄	5⊊ ,ıı 61% ≞	10:23 🖪 🎮 📩 🔹	@ ☆ ¾ 59 .⊪ 61% 🛢
< Settings Connection		< Settings Connection	
LOCAL AE		Port 10104	>
AET CAVECODERS_AET	>	ARCHIVE AE	
Port 10104	>	AET CAVECODERS	>
ARCHIVE AE		IP demo.dicompass.cloud	>
AET CAVECODERS	>	Port 5480	>
IP demo.dicompass.cloud	>	Connection tes	st
Port 5480	>	MODALITY WORKLIST AE	
Connection test		Copy archive sett	ings
MODALITY WORKLIST AE		AET CAVECODERS	>
Copy archive settings		IP damo diagmagas algud	>
AET CAVECODERS	>	Port	>
IP demo.dicompass.cloud	>	Connection tes	st

Local AE

- ·

- AET unique device identification
- Port port number for DICOM communication

AE Archive

- AET application entity title unique DICOM node identification
- IP IP address
- Port port number for DICOM communication

Test connection - after selecting this action, the connection between the device and the PACS server is verified

Modality Worklist AE

Take from Archive settings - copies the previous AET, IP address and Port settings

- AET application entity title unique DICOM node identification
- IP IP address
- Port port number for DICOM communication

Test connection - after selecting this action, the connection between the device and the PACS server

Image

In this section you can configure image parameters.

10:43 📽	Settings Image	46 anii 50 a
GENERAL		
Show patient photo/record	information during	
IMAGES		
Format JPEG		>
Resolution 8 MPix (16:9)		>
VIDEOS		
Allow video		
Bitrate (kb/s) Default		>
FPS Default		>
Max. file size Maximal	[MB]	>
Video resolut	ion	>

General

enable/ disable the Display patient information when using capture/record function

Images

- Format format selection between JPEG and Little Endian
- Resolution select between resolutions (original, 8MPix, 2MPix, 1MPix)

Video

- Allow video enable/ disable funkcion video record
- Bitrate (kb/s) video quality selection
- FPS selection of FPS for video
- Max file size [MB] option to maximize the video file size for uploading to PACS
- Video Resolution selection of video resolution

Meta data

This section allows to configure parameters for patient selection, manual entry, whispering, Tags/localization and more.

10:48 🖤		46+ #++111 50 •
<	Settings	

Neta data	
WORKLIST	
Allow MWL patient selection	
AET filter	
Filter status SCHEDULED	
Filter current date	
Filter modality	
Modality Modality	>
Sort patients alphabetically	

MANUAL ENTRY

Allow manual patient entry

>

Study description

	Show	Require
Patient ID		
Family name	\checkmark	
Given name	\checkmark	
Middle name		
Date of birth		
Sex		
Accession number		
Study description		

AUTOCOMPLETE

ID code prefix Patient ID code prefix	>
Numeric patient ID	
Parse patient ID	
Add slash to patient ID	
Delete slash from patient ID	
Asciify texts	
Search patient ID in archive	
Search patient ID via API	

API server host:port	>
TAGS/LOCALIZATION	
Tags/Localization	>
OTHER	
Output modality xc	>
Use series description for study	

Worklist

- Allow MWL patient selection when disabled, patient can only be entered manually or via QR/Bar code
- AET filter patient selection from worklist will be directly on defined AET
- Filter status SCHEDULED worklist will be built according to parameters of SCHEDULED tag
- Filter current date worklist will be displayed with today's date by default (option to switch to "anytime")
- Filter modality Worklist will filter the list by modality type (e.g. XC, MR, etc.)
- Sort patients alphabetically option to enable/disable alphabetical sorting of patients in the list, default is from oldest to most recently added to the worklist

Manual entry

- Allow manual patient entry option to enable/disable manual patient entry, if disabled, patient selection from worklist only (cannot have both patient selection options disabled must always be worklist or manual entry enabled)
- Study Description predefined text for the study description of images and videos
- Display/Required items when manually entered:
- 1. Patient ID
- 2. Last name
- 3. First name
- 4. Middle Name
- 5. Date of birth
- 6. Gender
- 7. Accession number
- 8. Study description

Autocomplete

- ID code prefix allows you to enter a prefix to the patient ID
- Numeric Patient ID when enabled, allows only numeric values to be entered in the Patient ID field
- Parse patien ID when enabled, allows you to automatically add data such as date of birth and gender of the patient according to the patient's ID number

- Add slash to patient ID adds a slash to the 7th position in the patient ID
- Delete slash from patient ID searches for and deletes a slash in the patient ID
- Asciify texts allows patient details to be entered without diacritics only, or deletes diacritics when sending to PACS
- Search patient ID in archive allows you to search all patient data in PACS by the first few numbers of the patient's ID
- Search patient ID via API allows to search patient data via different APIs
- API server host:port

Tags/Localization

• Tags/Localizations - allows you to select the option to add labels or location positions to images and videos upon entry or in the gallery



Capture images

• Localization and tags - enable/ disable for add before taking a photo/ video

In gallery

• Localization and tags - enable/ disable for add in gallery

Tags

• Tag mode - option to choose default or custom

12:14 🗑		46 1111 46
\otimes	Settings	
	Tags - Tag mode	
Default /	_oaded	
Custom		\bigcirc

• When choosing custom, in the previous setting is added the item "Edit custom tags"

10:59 📽	46 46.111 (50)
< Settings	
Tags/Localization - settings	
CAPTURE IMAGES	
Localization	
Tags	
IN GALLERY	
Localization	
Tags	
TAGS	
Tag mode Custom	>
Edit custom tags	>
Upload localization and tags (ZIF	⁽²⁾
Share tags/loc. files	
Share default tags/loc. files	

- Edit custom tags here is an option to add your own tags
- After writing, you need to press add, then the tag will be added under the input field, then confirm with the whistle in the upper right corner to save
- For delete a tag, just press the cross next to the given tag and confirm with the whistle in the upper right corner to save

12:15 🖤		46 46 11 46 1	12:15 🕏		46+ 1111 46
\otimes	Tags/Localization Edit custom tags	\odot	$\overline{\mathbf{x}}$	Tags/Localization Edit custom tags	\bigcirc
New tag —		Add	New tag —		Add
	4/32		Neck 😣	0/32 Back 🛛	





Other

- Output modality images and videos will have an associated modality under which they can be searched in PACS
- Use series description for study enable/ disable

Application

This section configures storage, login and application security

12:35 🖤		46 ##### [[[[[[[[[[[[[[[[[
<	Settings	
	Application	
GENERAL		
Storage Internal storage		>
Lock settings		
Lock app		
Allow import fro	om gallery	
PIN AUTHENTI	CATION	
Unlock PIN		>
APPLICATION L	LOGS	
Logging level		
	Share log	
LANGUAGE		
Language English		>

General

- Storage choice between internal and external storage (memory card, etc.)
- Lock settings after switching on, the application settings can only be accessed by entering a PIN
- Lock application after switching on, the application can only be used after entering the PIN
- Allow import from gallery enable/ disable (if is enable you can import media from gallery device)

PIN Authentication

• PIN to unlock - enter a PIN to unlock a setting or application

Application logs

• Logging level - log selection for developers (DEBUG, INFO, WARN, ERROR) *Share log* - when pressed, offers to send, share logs to the required persons

Language

• Language - option to choose the language of the application

License

Sections to purchase and view license expiration

13:48	Settin Licer	ngs nce	.ull 📚 🚳
SELECT	LICENSE PERI	OD	
۲	1 month		
You are license	planning to pu for Dicompass	rchase a li Camera 2	mited
SELLER			
MEDOR	0 s.r.o.		
Štrosso	va 567		
530 03	Pardubice		
Czech F	Republic		
ID: 2600)2612		
CONTAG	СТ		
Che	ck license	Bu	ıy

Manual

• After selection, the manual for the application opens, which can be shared or downloaded



About the app

A section to view the phone ID to purchase a license and all information about the developers. If a license is purchased, the medical device label is also displayed.



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APPLICATION VERSION

1.2.13

SELLER

MEDORO s.r.o.

Štrossova 567

530 03 Pardubice

Czech Republic

IČ: 26002612

CONTACT

helpdesk@medoro.org

Dicc	ompass Camera 2 📺 🔟 🕻 🧧 2265
SN	D-C-1.2.13
	MEDORO s.r.o., Strossova 567, 530 03 Pardubice, Czech Republic SRN: CZ-MF-000024306, GLN: 8594212320008
UDI	(01)08594212320022(11)240801(8012)1.2.13

Colour scheme

Select between light, dark or auto mode



Dicompass.cz

• Link to website Dicompass.cz

Version 1.2.17

created with the evaluation version of Markdown Monster