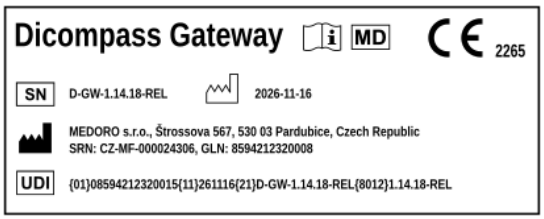
Instructions for use

Dicompass Gateway



Verze: 1.14.18-REL • Datum: 2026-11-16 • Autor: Medoro s.r.o.

Introduction

Purpose of this document

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

The user manual is intended for professional users, i.e. for trained operators of SW Dicompass Gateway, i.e. trained medical and intermediate medical personnel. User training is carried out once after the implementation of the MD and then with each released version with a change in the MAJOR number, i.e. the first number of the versioning format.

Administration of SW Dicompass Gateway does not apply to the regular user, therefore it will not be described here. It is described in detail in the Administrator's Guide.

Please read this manual carefully before using the Dicompass Gateway 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.

Name and address of the 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

Reporting serious incidents

According to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following:

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

Any serious incident 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 a serious incident, contact us using the HelpDesk, by phone on +420 775 324 005, or by email at dicompass@medoro.org.

Description of the intended purpose of use

The intended purpose of SW Dicompass Gateway:

The specialized modular software Dicompass Gateway 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 Dicompass Gateway software is an active medical device that does not come into contact with the patient and its purpose is to display and work with image medical documentation. The Dicompass software is thus intended for all groups of patients undergoing radiological or other (e.g. endoscopic) examinations that generate image documentation.

The Dicompass Gateway software is used for the diagnosis of health conditions requiring radiological or other (e.g. endoscopic) examination generating image documentation.

The indication for the use of MD Dicompass Gateway 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 - Patients in whom it is not possible to obtain evaluable imaging documentation.

Warning: The use of Dicompass is conditioned by the training of users.

Dicompass Gateway is a certified tool for archiving, viewing and postprocessing DICOM data acquired using DICOM modalities, such as X-ray, CT, MR, SONO, ECG and others. This SW uses web technologies and for its purpose it is necessary to use standard HTML browsers (current versions) supporting WebGL (Edge, Chrome, Firefox) across all system platforms (Windows, Apple iOS, Linux, Android). The program's interface aims at user convenience and clarity.

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

CE 2265

Dicompass Gateway is a purely web-based DICOM tool that, in addition to a web browser, does not require any additional support resources installed on the workstation. Thanks to traceless technology, it leaves no traces on the user's PC.

Considering the HTML technology used, it can also be operated on any mobile device (a tablet or a smartphone), both inside and outside of your medical facility.

Dicompass Gateway is a very sophisticated tool for remote consultations and all work performed within this SW is fully audited.

Not only does it contain the basic tools for viewing and working with DICOM images, such as distance measurement, area measurement, windows, annotations, rotation options, screen splitting, support of multiple monitors, including diagnostic ones, etc., but also supports image captions, any image filters, or a wide variety of image displays.

In multiple windows, it is possible to use synchronized image viewing or browsing images marked as important.

Dicompass Gateway supports a number of standardized formats such as JPEG, PNG, SR, MPEG2, MPEG4 and more. Images or recordings can be exported to an external device, burned to a CD/DVD, or sent via metropolitan exchange ePACS / ReDiMed to another medical facility. Dicompass Gateway also supports multiple PACS archives at once. You don't have to search and switch between different functions. The search dialog allows you to set exact parameters. The overall

browser settings can be saved to each user account. After logging in, your labels or measurement tools will not be shuffled by your colleagues previous usage.

Thanks to use of web technology, all image documentation is not stored on the end device of the doctor's diagnostic workstation in advance, thus, when it is opened, there may be a delay before loading. This delay is affected by the speed of the internet connection or the response of the line of the internal network of the medical facility.

MD Dicompass Gateway 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 Gateway 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.

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

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

We recommend using the Dicompass Gateway measurement function only on calibrated images by the modality manufacturer. For non-calibrated images, the results of the MD Dicompass Gateway measurement function are only informative, and to clarify the result, we recommend using the calibration tools of the used modality.

The technical description of the device is part of the service manual.

System requirements

The chart describes the minimum required configuration per server for SW operation Dicompass Gateway:

PARAMETER	REQUIREMENT
OS	Rocky Linux in a supported version
CPU	4 cores
RAM	8 GB
HDD	according to desired volume of data
Network interface	1 Gbps

The chart describes the minimum required configuration of a PC for SW operation Dicompass Gateway:

PARAMETER	REQUIREMENT
OS	Windows 10, 11 (64 bit) with current updates
	MacOS with current updates
Internet browser	Google Chrome (current stable version)
	Microsoft Edge (current stable version)
	Mozilla FireFox (current stable version)
	Safari (current stable version)
CPU	2 cores

PARAMETER	REQUIREMENT
RAM	4 GB
HDD	0.5 TB
Network interface	100 Mbps

For the correct functionality of MD Dicompass Gateway, it is required that no restrictions be applied to the amount of data transferred or to the number of requests.

The installation and configuration of the MD Dicompass Gateway is carried out according to the service manual, and a handover protocol containing its validation is kept on the correctness of the installation and the functionality of the device at the customer's place. Installation and configuration of the device is performed only by service technicians trained by the manufacturer.

Based on the terms of the customer's service contract, MD Dicompass Gateway is remotely monitored and serviced 5/8, 24/7, or according to other agreed conditions.

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.

Safety precautions and product life cycle

1. Security precautions and environment context

The security of the Dicompass Gateway relies on a combination of internal mechanisms and the customer's protected infrastructure. From a product perspective, security is provided by the Linux operating system and an integrated firewall management tool (iptables / UFW), which is configured during implementation. Access to the server part of the system is only granted to trained service technicians of the manufacturer (secured by an encrypted SSH key). User access is protected by two-factor authentication (2FA) or integration with the customer's LDAP/AD.

To ensure the declared level of security, it is necessary for the operator's IT department to ensure the following operating conditions: * Physical security: The server infrastructure with virtual machines must be located in a secure room with controlled access. * Network isolation: The product must run on a dedicated VLAN, whose communication is strictly controlled by the healthcare facility's central firewall. * Remote service: The customer must provide secure access (VPN) for updates and service by the manufacturer.

1. Instructions for secure software removal

Due to the closed architecture of the system, users do not have access to the application's file system. When you stop using the product (take it out of service), proceed as follows: * Contact the manufacturer's service department, whose technicians will ensure the professional and secure migration of all patient data and the following complete deletion of application data from the system. * After confirmation of data deletion, the customer's IT department is responsible for securely removing the relevant virtual machine (VM) from the hypervisor and permanently revoking the associated network permissions (firewall rules, VPN access).

List of terms and abbreviations used

List of used terms and abbreviations

TERM	EXPLANATION
AD	Microsoft Active Directory
AE	Application Entity
DICOM	Digital Imaging and COmmunication System - it is a standard for imaging, distribution, storage and printing of medical data
DPGW	Dicompass Gateway
DVR	Direct Volume Rendering - in addition to color, it also uses transparency and can display everything at once. All voxels of volume contribute to the final image
HP	Hanging Protocol - a protocol enabling to change and automate the form of display of the opened study based on many parameters (type of examination, image position ...)
MinIP	Minimum Intensity Projection
MIP	Maximum Intensity Projection
MPR	Multiplanar reconstruction
MWL	a service enabling transmission of patient demographic data within the DICOM protocol - Modality worklist
SSD	Shaded Surface Display, 3D projection way, voxels with a density higher than the given limit contribute to the resulting image
SSO	Single Sign On - automatic user login with their identity logged in the operating system
ID	Patient ID number
VRT	Volume Rendering Technique, 3D projection way