MedDream
USER MANUAL
(version 8.3.0)
Table of Contents

Table of Contents ........................................................................................................................................... 3
General information ........................................................................................................................................ 4
  Personal data security breach ...................................................................................................................... 5
  Serious incidents reporting ......................................................................................................................... 5
  Availability of documentation ................................................................................................................... 5
  Questions ................................................................................................................................................... 6
  Explanation of symbols used ....................................................................................................................... 6
  Summary of clinical evaluation report ...................................................................................................... 11
List of applicable standards ........................................................................................................................ 12
Warnings regarding residual risks ............................................................................................................... 16
Short product description ............................................................................................................................ 18
  Product customization ............................................................................................................................... 20
  Product labeling ...................................................................................................................................... 20
  License agreement and registration .......................................................................................................... 21
  Access to user documentation ................................................................................................................. 21
Product installation ...................................................................................................................................... 22
  MedDream viewing functionalities minimal hardware requirements ...................................................... 22
    Server-side ........................................................................................................................................... 22
    Client-side ........................................................................................................................................... 22
  Minimal MedDream video viewing and converting functionalities hardware requirements .................. 23
  Minimal SendToPACS functionalities hardware requirements ............................................................... 24
  Minimal PACS functionalities hardware requirements ............................................................................ 24
    Server-side ........................................................................................................................................... 24
    Client-side ........................................................................................................................................... 24
Installation verification ................................................................................................................................ 25
  MedDream viewing functionalities ............................................................................................................ 25
  MedDream Video viewing functionalities .................................................................................................. 25
  MedDream PACS functionalities .............................................................................................................. 25
  MedDream SendToPacs functionalities ..................................................................................................... 26
IT security measures ................................................................................................................................... 27
MedDream functionalities: list of annexes .................................................................................................... 29
Table of Figures ........................................................................................................................................... 30
Index ............................................................................................................................................................ 31
General information

This user’s manual describes MedDream functionalities and operation with MedDream.

Seeking to ensure patient safety, software should be used by intended use. You should therefore ensure that you are thoroughly familiar with the user manual before setting up and using MedDream for the first time.

MedDream is dedicated only to show ePHI (Electronic protected health information) contained in study file. MedDream does not replace medical professionals and could be used only as an additional tool. No special facilities or special training of the medical software MedDream users are required.

Please note that medical images quality, sharpness, accuracy and other parameters, relevant to the users, directly depends on the technical capabilities of medical device, which is generating medical images, on the monitor and printer technical capabilities.

MedDream is a software – picture archiving and communication system – intended to display, process, read, report, communicate, distribute, store and archive medical data which are available as DICOM or/ and non-DICOM data, including mammographic images and bio signals. MedDream converts case related non-image documents, archives them as DICOM data and serves as a vendor neutral archive. MedDream supports the medical professionals in diagnosis.

### INTENDED USE FOR ALL COUNTRIES EXCEPT UNITED STATES OF AMERICA

MedDream is a software intended to aid in diagnosis by visualization various medical images, video and signals, measuring data in DICOM images and management DICOM images, when the patient is not in life-threatening state of health, time is not critical for medical decision and no major therapeutic interventions are required.

**Indications for use:** MedDream is a software intended to aid in diagnosis by visualization various medical images, video and signals, measuring data in DICOM images and management DICOM images, when the patient is not in life-threatening state of health, time is not critical for medical decision and no major therapeutic interventions are required.

Contraindications: None.

**Work environment:** The device is provided for the professional user. MedDream is intended for medical professionals and is provided to use in professional environments dedicated for medical diagnosis. Device is dedicated for continuous work.

### INTENDED USE FOR UNITED STATES OF AMERICA

MedDream does not replace medical professionals and could be used only as an additional tool. No special facilities or special training of the medical software MedDream users are required.

Please note that medical images quality, sharpness, accuracy and other parameters, relevant to the users, directly depends on the technical capabilities of medical device, which is generating medical images, on the monitor and printer technical capabilities.

**Indications for Use:** MedDream is a software only Medical Image Management and Processing System intended to display, process, read, report, communicate, distribute, store, and archive medical data which is available as DICOM or HL 7 data, including mammographic images, and bio signals. MedDream also converts case-related non-image documents, archives them as DICOM data, and serves as a vendor-neutral archive.

It supports the physician in diagnosis.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

⚠️ **NOTE.** Web based image distribution on mobile device display of mammographic images are not intended for diagnostic purposes.

**For users in the United States of America:** Mobile device display is not intended for diagnostic purposes.

⚠️ **WARNING!** Mobile device display is intended for informational purposes only, not for diagnostic purposes.
WARNING! Software usage not by intended use may cause patient death, potential injury or serious health impairment, requiring professional medical intervention.

CAUTION! Consider country specific regulations regarding monitors and their maintenance.

CAUTION! In the U.S., for primary image diagnosis in Mammography only uncompressed or non-lossy compressed images must be used.

Types of use: MedDream is intended for multiple patient multiple use.

MedDream Catalogue number: MDSY.

Known limitations:
- MedDream viewing functionalities may not be used with Internet Explorer 11 browser;
- MedDream viewing functionalities may be blocked by browser security if launched in iFrame.

Risk and Benefit: Using MedDream by its intended use does not cause risk, which could influence patient health status or health changes, but facilitate work of medical professionals, provide a better opportunity for accurate diagnosis.

Clinical data are collected, stored and managed as described below:
- By implementing post market clinical follow-up studies;
- By analyzing results of collected preclinical data;
- By implementing competitor analysis and literature analysis;
- By managing risk;
- By managing complaints and problems;
- By collection vigilance system data;
- By implementing biomedical research.

MedDream is continually tested. All critical issues are corrected immediately and users are informed about software functionality limitations and risks.

In case of MedDream bugs please immediately contact to Softneta support at this email: support@softneta.com.

Personal data security breach

In case of personal data breach (including but not limited to cybersecurity breach) please immediately (but not later than during 24 hours) inform medical software Manufacturer Softneta UAB by using below mentioned contacts:
SOFTNETA Data Protection Officer (contacts of Data Protection Officer are public available www.softneta.com).
Name, Surname: Raimundas Mikalauskas
Tel. +370 630 06808
Mail: dpo@softneta.com

Serious incidents reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (via email: support@softneta.com) and the competent authority of the Member State in which the user and/or patient is established.

Availability of documentation
Electronic version of MedDream User Manual in Lithuanian and English is free available on the Softneta UAB website (www.softneta.lt / www.softneta.com in the “Products” section) as well as access to the supporting software versions. Instructions are included in the “Product description” part in the section “Downloads”. User Manual could be opened in a browser or saved in pdf format and downloaded to Your computer. Software Install Manual and Integration Manual are added as a separate document to the User Manual. If You require paper version of User Manual, please ask us by email: support@softneta.com. Paper version of these documents will be sent not later than in 72 hours after receiving Your request (to the address You specify).

Questions

Please visit out F.A.Q. in Softneta UAB webpage for answers to frequently asked questions or problems.

⚠️ **WARNING!** In the event of malfunction of the device or changes in its performance that may affect safety, contact to manufacturer.

⚠️ **CAUTION!** Incorrectly installed software could cause inconvenience to medical professionals using the software and disruption of the medical professional activities.

If you have any questions or comments regarding MedDream functionalities or this user`s manual, please contact Softneta UAB Customer support: support@softneta.com.

Explanation of symbols used

During MedDream usage please pay attention to important information, related to patient safety, which is warning about software functions, whose implementation errors may pose a risk to patient health. The symbols in this User Manual are intended to alert user about possible errors in the software or its use. Please read the information carefully as you see the symbols described below.

⚠️ **WARNING!** This indicates a hazardous situation which may cause patient death, potential injury or serious health impairment, requiring professional medical intervention.

⚠️ **CAUTION!** This indicates a hazardous situation which may cause minor potential injury, not requiring professional medical intervention, or simply cause inconvenience to medical professionals using software without affecting patient health status or health changes.

⚠️ **NOTE!** Information, hints and advice for a better understanding of the instructions to be observed in the operation of the instrument.

Additional Symbols:

- FDA cleared product, which means the manufacturer can demonstrate that the product is substantially equivalent to another (similar) legally marketed device that already has FDA clearance or approval
- Product certified according to the Regulation (EU) 2017/745 by notified body TÜV Rheinland LGA Products GmbH
- Country of manufacture
- Medical device class
- Unique device identifier
- Release date
- Distributor
- Contacts of representative in Switzerland
General information

End user contacts
Success message sign
Info message sign
Warning message sign
Error message sign
Tick box
Search
Export
Forward
View icon
Ascending/Descending
System menu
Language menu
Notifications menu
Patient history
Windowing
Histogram
Scale of histogram
Synchronize windowing
Invert
Color palette selection
Zoom
Fit to screen

Original resolution
Zoom selection
Pan
Align Left
Align Right
Align Center
Align & Lock Left
Align & Lock Right
Channels
Scroll
Magnifier
Digital Subtraction
Montage
Delete selected montage image
Save montage
Layout
Multi image
Reset
MPR (multi-planar reconstruction)
Show/Hide axes
Move axes to center
MPR layout with 3D image
MPR layout for three 2D image
Show 3D MPR image
<table>
<thead>
<tr>
<th>General information</th>
</tr>
</thead>
</table>

- **Show 2D MPR image**
- **Change image order in MPR layout**
- **Change 3D image to CPR image**
- **Reference line**
- **Crosshair**
- **Rotate**
- **Rotate right**
- **Rotate left**
- **Flip horizontal**
- **Flip vertical**
- **DICOM**
- **Link scrolled series**
- **Automatic link**
- **Manual link**
- **Sync actions**
- **Measure**
- **Line**
- **Polyline, CPR polyline**
- **Angle**
- **Area**
- **Volume**
- **Height Difference**
- **Ellipse**
- **Rectangle**

- **Velocity Time Integral (VTI)**
- **Cobb Angle**
- **Tibial Plateau Angle**
- **Norberg Angle**
- **Verbal Heart Scale**
- **Hip distraction index**
- **Tibial tuberosity advancement**
- **Cardiothoracic ratio**
- **Text annotations**
- **Region of interest, Closed polygon**
- **Repulsor**
- **Spine Labeling**
- **Vertebra Angle**
- **Flexpoly**
- **Pencil**
- **Arrow**
- **Flatfoot**
- **Goniometry**
- **TT-TG Distance**
- **Time-Intensity Curve**
- **Calibration line**
- **Show Angles**
- **Continuous measurement**
- **Intensity**
<table>
<thead>
<tr>
<th>Icon</th>
<th>Text</th>
<th>Icon</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Trash Bin]</td>
<td>Delete all or selected measurements</td>
<td>![Checkmark]</td>
<td>Measurement</td>
</tr>
<tr>
<td>![Save]</td>
<td>Save annotation</td>
<td>![Star]</td>
<td>QT points</td>
</tr>
<tr>
<td>![Key]</td>
<td>Key objects</td>
<td>![Share]</td>
<td>HR</td>
</tr>
<tr>
<td>![Library]</td>
<td>Share files via DICOM Library</td>
<td>![Live Share]</td>
<td>QRS Axis</td>
</tr>
<tr>
<td>![Copy]</td>
<td>Live share</td>
<td>![Copy Live Share Link]</td>
<td>Filter</td>
</tr>
<tr>
<td>![Copy]</td>
<td>Copy live share link</td>
<td>![Info Labels]</td>
<td>Change horizontal scale (mm per second)</td>
</tr>
<tr>
<td>![Fusion]</td>
<td>Info Labels</td>
<td>![Change Vertical Scale]</td>
<td>Change vertical scale (mm per mV)</td>
</tr>
<tr>
<td>![Cine Mode]</td>
<td>Fusion</td>
<td>![ECG View Scrollbar]</td>
<td>ECG view scrollbar</td>
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<tr>
<td>![Series]</td>
<td>Cine mode</td>
<td>![Pause]</td>
<td>Pause</td>
</tr>
<tr>
<td>![Series]</td>
<td>Series</td>
<td>![Play]</td>
<td>Play</td>
</tr>
<tr>
<td>![Plugins]</td>
<td>Series</td>
<td>![Previous Instance]</td>
<td>Previous Instance</td>
</tr>
<tr>
<td>![4D Tools]</td>
<td>Plugins</td>
<td>![Next Instance]</td>
<td>Next Instance</td>
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<td>![4D Tools]</td>
<td>4D tools</td>
<td>![Frame Rate]</td>
<td>Frame rate in multi-frame</td>
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<tr>
<td>![4D Tools]</td>
<td>Construct 4D Series; virtual series thumbnail icon</td>
<td>![Stop Playback]</td>
<td>Stop playback</td>
</tr>
<tr>
<td>![4D Tools]</td>
<td>Show 4D slider</td>
<td>![Volume On]</td>
<td>Volume on</td>
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<tr>
<td>![Full Screen]</td>
<td>Full Screen</td>
<td>![Volume Off]</td>
<td>Volume off</td>
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<td>![Theme]</td>
<td>Theme</td>
<td>![All, Reported and Not Reported, Studies]</td>
<td>All, reported and not reported, studies</td>
</tr>
<tr>
<td>![Thumbnails]</td>
<td>Thumbnails</td>
<td>![Not Reported Study, Create Report]</td>
<td>Not reported study, Create report</td>
</tr>
<tr>
<td>![Preload Series]</td>
<td>Preload series</td>
<td>![Reported Study, Open/Edit Report]</td>
<td>Reported study, Open/Edit report</td>
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<td>![Print]</td>
<td>Print</td>
<td>![Paste to Report]</td>
<td>Paste to report</td>
</tr>
<tr>
<td>![Apply Previous Hanging Protocol]</td>
<td>Apply previous Hanging protocol</td>
<td>![Delete Report Template, Segment]</td>
<td>Delete report template, segment</td>
</tr>
<tr>
<td>![Apply Next Hanging Protocol]</td>
<td>Apply next Hanging Protocol</td>
<td>![Download]</td>
<td>Download</td>
</tr>
<tr>
<td>![Show Next Comparison Study]</td>
<td>Show next comparison study</td>
<td>![Burn Disk]</td>
<td>Burn disk</td>
</tr>
<tr>
<td>![Copy Measurement]</td>
<td>Copy measurement</td>
<td></td>
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</tr>
</tbody>
</table>
General information

Paste measurement
Stop copy and paste measurement action
Copy viewport content to the clipboard
Copy original image to the clipboard
Save viewport content as secondary capture DICOM
Copy measurement values to clipboard
Segmentation
Segmentation tool
Bounding Box
Segmentation Smart Paint
Create 2D Bounding Box segment
Create 3D Bounding Box segment
Create Free Draw or Smart Paint segment
Duplicate segment
Locate segment
Show/Hide segment
Group / Ungroup by Series
Change color
Click to Edit
Click to Send to Background
Hover to Select
Erase segment contour
Contour
Interpolation
Paintbrush
Paintbrush with Reference Pixel
Fill Color
Fill Paintbrush
Smooth Edges
Segment measurement
Copy values to clipboard in CSV format
Copy all annotation measurements as CSV
Save segments
Undo last action
Assign shortcut
Edit
To start recording
Take snapshot while recording
Delete images or complete video
Expand patient record
Close study
Open not saved (not converted to DICOM format) study in CURRENT STUDY window for more changes
Open already saved (converted to DICOM format) study in DICOM VIEWER window
Export the study to local or external drive
Forward study to hospital DICOM archive (requires to setup remote DICOM archive in 7.1.2 Network settings)
New study in the list, not reviewed
Study is not stored in hospital DICOM archive
Study is stored in hospital DICOM archive
Summary of clinical evaluation report

The device’s risks were managed according to UAB “Softneta” internal risk management work instruction, which is based on the ISO 14971:2019 standard. During the risk management activities, the device was:

- Classified according to the Regulation (EU) 2017/745 on medical devices Annex VIII as a CLASS IIb medical device (the device’s risk management file);

- Identified according to the EU 2007/47/EC directive and requirements defined in the ISO 14971:2019 standard’s Appendix C (the device’s risk management file);

- Ensured risk managed (implemented risk analysis, risk mitigation actions, residual risks verification) (the device’s risk management file);

- Tested and verified for residual risks (retested) according to the risk management results and UAB “Softneta” Testing work instruction (software tests, user acceptance tests, clinical tests), (the device’s risk management file).

- All the risk management activities were carried out by the risk management team.

Softneta gathers production and post-production information using the following Quality management system’s areas: product realization; measurement analysis and improvement; change and problem management; auditing; post market data results. The above-mentioned activities ensure, that internal and external environments (in which the product exists) are constantly monitored and if changes occur all associated risks are re-managed. Residual risks (hazard) with the “minor” severity (Results in injury or impairment requiring professional medical intervention) are mentioned in the section „Warning regarding residual risks“. We don’t have any residual risk with “serious” (or higher) severity.

Calculated risk-benefit ratio (percentage) value is lower than 1 (one), therefore it is considered that the software benefit outweighs the risk that may be encountered while using the software.
## List of applicable standards

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN ISO 13485:2016 + A11:2021</td>
<td>Medical devices - Quality management systems - Requirements for regulatory purposes</td>
</tr>
<tr>
<td>EN ISO 14971:2019</td>
<td>Medical devices – Application of risk management to medical devices</td>
</tr>
<tr>
<td>ISO/TR 24971:2020</td>
<td>Medical devices – Guidance on the application of ISO 14971</td>
</tr>
<tr>
<td>IEC 82304-1:2016</td>
<td>Health software – Part 1: General requirements for product safety</td>
</tr>
<tr>
<td>IEC/TR 80002-1:2009</td>
<td>Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software</td>
</tr>
<tr>
<td>IEC/TR 80002-2:2017</td>
<td>Medical device software — Part 2: Validation of software for medical device quality systems</td>
</tr>
<tr>
<td>EN 62366-1:2015 + AMD 1:2020</td>
<td>Medical devices - Application of usability engineering to medical devices – Amendment 1</td>
</tr>
<tr>
<td>EN ISO 15223-1:2021</td>
<td>Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements</td>
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<tr>
<td>EN ISO 12052:2017</td>
<td>Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management</td>
</tr>
<tr>
<td>EN ISO 14155:2020</td>
<td>Clinical investigation of medical devices for human subjects - Good clinical practice</td>
</tr>
<tr>
<td>ISO 20417:2021</td>
<td>Medical devices – Information to be supplied by the manufacturer</td>
</tr>
<tr>
<td>ISO 17664-2:2021</td>
<td>Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices</td>
</tr>
<tr>
<td>IEC 82079-1:2019</td>
<td>Preparation of information for use (instructions for use) of products</td>
</tr>
<tr>
<td>ISO 80001-1:2021</td>
<td>Application of risk management for IT-networks incorporating medical devices — Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software</td>
</tr>
<tr>
<td>IEC/TR 80001-2-1:2012</td>
<td>Application of risk management for IT-networks incorporating medical devices — Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples</td>
</tr>
<tr>
<td>AAMI HE75</td>
<td>Human Factors Engineering - Design Of Medical Devices. This recommended practice covers general human factors engineering (HFE) principles, specific HFE principles geared towards certain user-interface attributes, and special applications of HFE (e.g., connectors, controls, visual displays, automation, software–user interfaces, hand tools, workstations, mobile medical devices, home health care devices</td>
</tr>
<tr>
<td>ISO 7000:2019</td>
<td>Graphical symbols for use on equipment — Registered symbols</td>
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<tr>
<td>ISO 7010:2019</td>
<td>Graphical symbols — Safety colors and safety signs — Registered safety signs</td>
</tr>
<tr>
<td>2017/745</td>
<td>Directive concerning medical devices</td>
</tr>
<tr>
<td>MDCG 2023-3</td>
<td>Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices</td>
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<tr>
<td>MDCG 2022-21</td>
<td>Guidance on periodic safety update report (PSUR) accorgid to regulation EU 2017/745 (MDR)</td>
</tr>
<tr>
<td>Document Reference</td>
<td>Title and Description</td>
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<tr>
<td>MDCG 2022-7</td>
<td>Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746</td>
</tr>
<tr>
<td>MDCG 2021-13 Rev 1</td>
<td>Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers</td>
</tr>
<tr>
<td>MDCG 2021-20</td>
<td>Instructions for generating CIV-ID for MDR Clinical Investigations</td>
</tr>
<tr>
<td>MDCG 2021-25</td>
<td>Application of MDR requirements to ‘legacy devices’ and devices placed on the market prior to 26 May 2021</td>
</tr>
<tr>
<td>MDCG 2021-26</td>
<td>Q&amp;A on repackaging &amp; relabelling activities under Article 16</td>
</tr>
<tr>
<td>MDCG 2022-4</td>
<td>Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD</td>
</tr>
<tr>
<td>GHTF/SG1/N055:2009</td>
<td>Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer</td>
</tr>
<tr>
<td>GHTF/SG1/N063:2011</td>
<td>Summary Technical Documentation (STED) for Demonstrating conformity to the Essential Principles</td>
</tr>
<tr>
<td>MDCG 2020-7</td>
<td>Clinical Investigation and Evaluation: Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies (EC)</td>
</tr>
<tr>
<td>MDCG 2020-10/1</td>
<td>Clinical Investigation and Evaluation: Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745 (EC)</td>
</tr>
<tr>
<td>MDCG 2020-10/2</td>
<td>Clinical Investigation and Evaluation: Clinical Investigation Summary Safety Report Form v1.0 (EC)</td>
</tr>
<tr>
<td>MDCG 2020-6</td>
<td>Clinical Investigation and Evaluation: Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies (EC)</td>
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<tr>
<td>MDCG 2020-1</td>
<td>Clinical Investigation and Evaluation: Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software (EC)</td>
</tr>
<tr>
<td>IMDRF MDCE WG/N56FINAL:2019 (IMDRF)</td>
<td>Clinical Investigation and Evaluation: Clinical Evaluation</td>
</tr>
<tr>
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<td>Clinical Investigation and Evaluation: Clinical Investigation</td>
</tr>
<tr>
<td>IMDRF MDCE WG/N55FINAL:2019 (IMDRF)</td>
<td>Clinical Investigation and Evaluation: Clinical Evidence</td>
</tr>
<tr>
<td>MDCG 2021-28</td>
<td>Substantial modification of clinical investigation under Medical Device Regulation</td>
</tr>
<tr>
<td>MDCG 2021-20</td>
<td>Instructions for generating CIV-ID for MDR Clinical Investigations</td>
</tr>
<tr>
<td>MDCG 2021-08</td>
<td>Clinical investigation application/ notification documents</td>
</tr>
<tr>
<td>MDCG 2021-6</td>
<td>Regulation (EU) 2017/745 – Questions &amp; Answers regarding clinical investigation</td>
</tr>
<tr>
<td>2023/C 163/06</td>
<td>Commission Guidance on the content and structure of the summary of the clinical investigation report</td>
</tr>
<tr>
<td>MDCG 2020-13</td>
<td>Clinical evaluation assessment report template</td>
</tr>
<tr>
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<td>Software as a Medical Device (SaMD): Clinical Evaluation</td>
</tr>
<tr>
<td>IMDRF/GRRP WG/N52FINAL:2019 (IMDRF)</td>
<td>Labelling: Principles of Labelling</td>
</tr>
<tr>
<td>MDCG 2018-5</td>
<td>UDI: UDI Assignment to Medical Device Software (EC)</td>
</tr>
<tr>
<td>MDCG 2018-6</td>
<td>UDI: Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation 2017/745 and the In-Vitro Diagnostic Medical Devices Regulation 2017/746 (EC)</td>
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<tr>
<td>MDCG 2018-1 Rev.4</td>
<td>Guidance on basic UDI-DI and changes to UDI-DI</td>
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<td>MDCG 2021-12</td>
<td>FAQ on the European Medical Device Nomenclature (EMDN)</td>
</tr>
<tr>
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<td>The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices</td>
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<tr>
<td>MDCG 2021-19</td>
<td>Guidance note integration of the UDI within an organisation’s quality management system</td>
</tr>
<tr>
<td>MDCG 2021-24</td>
<td>Guidance on classification of medical devices</td>
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<td>IMDRF/UDI WG/N48FINAL:2019 (IMDRF)</td>
<td>UDI: UDI system</td>
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<td>IMDRF/UDI WG/N7 FINAL:2013 (IMDRF)</td>
<td>UDI: UDI Guidance</td>
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<tr>
<td><strong>MDCG 2019-1</strong></td>
<td>MDCG guiding principles for issuing entities rules on basic UDI-DI</td>
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<tr>
<td><strong>MDCG 2021-13 Rev.1</strong></td>
<td>Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR</td>
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<tr>
<td><strong>MDCG 2021-1 Rev.1</strong></td>
<td>Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional</td>
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<td><strong>MDCG 2020-15</strong></td>
<td>MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States</td>
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<td><strong>MDCG 2019-5</strong></td>
<td>Registration of legacy devices in EUDAMED</td>
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<td><strong>MDCG 2019-4</strong></td>
<td>Timelines for registration of device data elements in EUDAMED</td>
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<td><strong>MDCG 2019-9</strong></td>
<td>Summary of safety and clinical performance</td>
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<td><strong>MDCG 2019-7</strong></td>
<td>PPRC: Guidance on Article 15 of the Medical Device Regulation (MDR) and in vitro Diagnostic Device Regulation (IVDR) regarding a ‘person responsible for regulatory compliance’ (PPRC) (EC)</td>
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<tr>
<td><strong>MDCG 2019-16</strong></td>
<td>Guidance on Cybersecurity for medical devices</td>
</tr>
<tr>
<td><strong>MDCG 2020-3 (rev.1, May 2023)</strong></td>
<td>Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD</td>
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</table>

2014/30/EU Directive 2014/30/EU, Electromagnetic Compatibility (EMC)


MEDDEV 2.12/1 Rev8 Report Form: Field Safety Corrective Action. Medical Devices Vigilance System

MEDDEV 2.12/1 Rev8 Report Form: Manufacturer’s Incident Report. Medical Devices Vigilance System

MEDDEV 2.12/1 Rev8 Report Form: Manufacturer’s Periodic Summary Report (PSR). Medical Devices Vigilance System

MEDDEV 2.12/1 Rev8 Report Form: Manufacturer’s Trend Report. Medical Devices Vigilance System

MEDDEV 2.12-1 rev 8 Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD) reporting template version 7.2. Device specific vigilance guidance. New MIR form.

- Template for a Field Safety Notice

207/2012 of 9 March 2012 Commission regulation on electronic instructions for use of medical devices


21 C.F.R. Part 803 U.S. FDA Medical Device Regulation: 21 C.F.R. Part 803 (The Medical Device Reporting (MDR))


FDA Overview of Regulatory Requirements: Medical Devices

FDA Software related documentation: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

FDA General Principles of Software Validation: Final Guidance for Industry and FDA Staff

FDA FDA guidelines to User Manual

2016/679 General Data Protection Regulation (GDPR; Regulation (EU) 2016/679)


- Guidance on Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software

- Postmarket Management of Cybersecurity in Medical Devices (Contains Nonbinding Recommendations)

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Guidance for Industry and Food and Drug Administration Staff
<table>
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<tr>
<th>Nr.</th>
<th>Data ir pasakai</th>
<th>Taisyklos kurys</th>
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<td>2020-11-13</td>
<td>Biomedicininių tyrimų etikos įstatymas / Biomedical Research Ethics Law</td>
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<td>Įsakymas dėl prašymo išduoti leidimą atlikti biomedicininį tyrimą, paraškos</td>
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<td>formų patvirtinimo / Order on the biomedical research forms approval: for of request</td>
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<td></td>
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<td>for permission to implement biomedical research; biomedical research ethical</td>
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<td>evaluation form.</td>
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<td>T1-683</td>
<td>2017 m. gegužė</td>
<td>Įsakymas dėl Valstybinės akreditavimo sveikatos priežiūros veiklai taisybos prie</td>
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<td></td>
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<td></td>
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<td>Įsakymo nr. T1-136 „Dėl pranešimų apie neatitinkančius reikalavimų medicinos</td>
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<td>prietaisams (budra) patiekimio tvarkos aprašo patvirtinimo“ pakeitimo / Order on the</td>
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<tr>
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<td>changes in vigilance system</td>
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<td>T1-564,</td>
<td>2016-04-12</td>
<td>Įsakymas „Dėl laisvos prekybos pažymėjimų išdavimo medicinos priemonėms</td>
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<tr>
<td>T1-568,</td>
<td>2016-04-13</td>
<td>(prietaisams) tvarkos aprašo patvirtinimo“ / Order “On Approval of the Description</td>
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<td></td>
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<td>of the Procedure for Issuing Free Trade Certificates for Medical Devices“</td>
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<tr>
<td>T1</td>
<td>2019-01-01 redakcija</td>
<td>LR asmens duomenų teisinės apsaugos įstatymas / Law on Legal Protection of Personal Data of the Republic of Lithuania</td>
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<td>73(1.12.E)</td>
<td>2018-07-30</td>
<td>Duomenų subjekto teisių gauti informaciją, susipažinti su asmens duomenimis, reikalauti išstaišytį ar ištrinti asmens duomenis ir apribožių jų tvarkymą įgyvendinimo, kai duomenų subjektas šias teises įgyvendina per Valstybinę duomenų apsaugos inspekciją, tvarkos aprašas. 2018-07-30 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-73(1.12.E) / A description of the procedure for the data subject's right to receive information, access to personal data, request for the correction or deletion of personal data and the restriction of their processing when the data subject implements these rights through the State Data Protection Inspectorate. Order of the Director of the State Data Protection Inspectorate on July 30, 2018.</td>
</tr>
</tbody>
</table>
## Warnings regarding residual risks

<table>
<thead>
<tr>
<th>No</th>
<th>Hazard</th>
<th>Warning/ Caution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Illegal access / Vulnerability of e-PHI (electronic personal health information)</td>
<td><strong>CAUTION!</strong> Running MedDream software on shared user’s account can lead to unauthorised access to patient’s medical data. <strong>CAUTION!</strong> Incorrectly installed software could cause inconvenience to medical professionals using the software and disruption of the medical professional activities. <strong>CAUTION!</strong> Please notice, that closing the program without Log Off (using browser window close ‘x’ button) is not safe and may lead to unauthorized access to medical data. <strong>CAUTION!</strong> The system does not anonymize the content of shared images and entered message. You take responsibility for sensitive data in shared information. <strong>CAUTION!</strong> The system grants to the guests the access to all the studies, that are opened in host’s Viewer window when starting live sharing, and these studies will be displayed in the thumbnail panel of the guests’ Viewer window. Opening or closing the studies, while sharing is on, is not supported.</td>
</tr>
<tr>
<td>2</td>
<td>Inadequate filtration process</td>
<td><strong>CAUTION!</strong> Be aware, that access to the storages may be restricted by the user rights. The storages list contains only the storages, that are granted for the user. Searching is performed only in the granted storages, if the All storages option is selected. <strong>CAUTION!</strong> Be aware, that access to the storages may be restricted by the user rights. If search for patient studies is configured in all storages, searching is performed in the storages, that are granted for the user.</td>
</tr>
<tr>
<td>3</td>
<td>Incorrect configuration</td>
<td><strong>CAUTION!</strong> Depending on application configuration, in case of corrupted frame the system may either show warning, or ignore the corrupted frame and show the last not corrupted frame instead. Contact your system administrator for system configuration. <strong>CAUTION!</strong> Do not activate multiple profiles for the same video input source. For e.g. added camera to profile A and the same camera to profile B and enabled both of them, to be active in VS application. In this situation, just profile A will start and profile B will fail, because input signal will be busy. It is possible to have A and B profiles active at the same time, if card allows this (for example, play input signal via windows direct show and other via capture card interface, if this exist). However, it does not make any sense to have 2 the same signals recording and it can cause unstable input stream recording process. <strong>CAUTION!</strong> The system shows warning before launching the import of the DICOM files from the external source, if the DICOMDIR file with the directory content is not present in the source media.</td>
</tr>
<tr>
<td>4</td>
<td>3rd party libraries / internal components work incorrectly / not available</td>
<td><strong>CAUTION!</strong> PDF file is opened with default PDF reader. Some Web browsers have built-in readers. In other cases, the additional software for pdf reading and displaying, like Adobe Acrobat Reader, should be deployed in user workplace. <strong>CAUTION!</strong> On Windows OS it is recommended to have at least more than 2GB free space to function properly.</td>
</tr>
<tr>
<td>5</td>
<td>Component / function is missing</td>
<td><strong>CAUTION!</strong> Export, and Forward functionality may be disabled. Contact the system administrator to verify the configuration, if export or forward is missing. <strong>CAUTION!</strong> Annotations functionality may be disabled. Contact the system administrator to verify the configuration, if annotation functionality is missing.</td>
</tr>
<tr>
<td>6</td>
<td>Software usage problem</td>
<td><strong>CAUTION!</strong> In the U.S., for primary image diagnosis in Mammography only uncompressed or non-lossy compressed images must be used. <strong>WARNING!</strong> In the event of malfunction of the device or changes in its performance that may affect safety, contact to manufacturer. <strong>CAUTION!</strong> You cannot change the size of particular image that is opened as one of multi images. If the viewport size is changed, the size of multi images is automatically adjusted. <strong>CAUTION!</strong> Note, that MedDream cannot guarantee that the manual series linking displays the images of the same patient and at the corresponding position. <strong>CAUTION!</strong> Until not saved, the created, deleted or edited segments are held in program temporary storage and will be lost, if closing the Viewer or closing the study, that has segmentations with unsaved changes. <strong>CAUTION!</strong> System tries to achieve the requested fps when playing multi-frame. If achieving the requested fps is not possible due to hardware or software limits, some frames may be skipped and not displayed to the user while playing. To see all frames, reduce the fps or use instance by instance navigation. <strong>CAUTION!</strong> The size limits for one attachment file and one-time upload package, that are defined in system configuration, cannot be exceeded.</td>
</tr>
</tbody>
</table>
### Warnings regarding residual risks

<table>
<thead>
<tr>
<th>No</th>
<th>Hazard</th>
<th>Warning/ Caution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No Hazard</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Software usage not by intended use may cause patient death, potential injury or serious health impairment, requiring professional medical intervention.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Mobile device display is intended for informational purposes only, not for diagnostic purposes.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>When connecting pedal and keyboard, review SNAPSHOT or PLAY/STOP KEY settings and try to avoid pressing configured keys.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Please make sure Windows Firewall, Antivirus or other software do not block MedDream SendToPACS communication. It is recommended to turn off all blocking services in the Configuration and testing phase, to be sure that software will not be blocked. Also, it is important to make sure PACS server is not blocking DICOM communication by checking whether the communication is allowed in both sides – MedDream SendToPACS PC and Receiving PC.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Use the patient’s name, dates, anatomical direction and other information, which is displayed in the viewport labels, to ensure that you are viewing the right image.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Be cautious and ensure, that you are viewing the right place, if working with a zoomed image.</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>MedDream cannot guarantee the accuracy of calibration data received from the modality. Note, that MedDream cannot guarantee that the manual calibration which is performed by users is done accurately.</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>The accuracy of the measurements is affected by the calibration status of the monitor. Monitor calibration ensures that tones that are lighter than black are displayed clearly separately from true black, and tones that are darker than white are clearly distinguished from true white. How to calibrate the monitors is described in the software installation instructions, which are provided separately in this user guide.</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Note, that measuring functions in MedDream is approximate.</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Be cautious and verify the content before saving annotation. All the measurements and text annotation, including the zoomed outside of the currently viewed area, are saved and shared with other users viewing the study.</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Be aware that system automatically opens the annotation after saving, as well as maintains the active measurement and text objects, that overlap with opened annotation.</td>
<td></td>
</tr>
</tbody>
</table>
Short product description

MedDream is a HTML based package for PACS server which is designed to aid professionals in every day’s decision-making process, connecting all the medical data into a unified and fast performing network. MedDream ensures a fast and reliable way to search, present and analyze the medical data (images and video files) on various devices: computers, smart phones, tablets and so forth. Intuitive user interface, simple, but very powerful software controllable by touchscreen Medical Panel PC. Storing locally more than 125 hours of HD videos and up to 100,000 of still images.

MedDream covers: radiology, cardiology, oncology, gastroenterology and many other fields of medical application. It seamlessly integrates with various medical imaging devices, such as: ultrasound (US), magnetic resonance (MRI), positron emission tomography (PET), computed tomography (CT), endoscopy (ES), mammography (MG), digital radiography (DR), computed radiography (CR), ophthalmology, and so forth. Core MedDream uses are:

• Replacement of hard copies, e.g. film archives, paper documents, etc.
• Remote access. MedDream provides a possibility to be mobile and work from any place in the world where the Internet is accessible. More than one person can access and view medical records at one time. Such functionality speeds up the collaboration among the professionals. So, that a doctor in the hospital and a doctor that is in the different location may view the medical data and discuss about it simultaneously. The patient’s medical history, various studies and images are found much faster comparing to the conventional paper-based methods.

• Multiplanar and 3D reconstruction from series of images 3D perspective together with views in reconstructed planes enables viewing the region of interest from several perspectives, and allows more accurate and faster diagnostic.
• MedDream can be used as a standalone WEB Viewer or integrated into PacsOne PACS, dcm4chee Archive, Conquest PACS, ClearCanvas PACS systems. Moreover, MedDream can be adapted to client’s PACS system and easily integrated into RIS/HIS workflow.
• MedDream has multiple functions such as search of studies, viewing, analyzing, saving, exporting, forwarding images and videos, etc.

• High-quality video recording into DICOM by using MPEG2 and MPEG-4 AVC/H.264 compression.
• Record/take multiple low and high (full HD) quality video/snapshots during the surgery or other procedures.
• Live stream video during the procedure.
• Record, stream, play video and take snapshots at the same time.
• Record video/take images from multiple connected devices (special video card needed).
• Flexible patient data assignment: selecting already existing patient, manually entering the patient details or selecting from hospital DICOM worklist server.
• Possibility to start a new study recording, while other video/snapshots is in progress for saving to DICOM or sending to DICOM archive.
• Review medical images/video during the surgery or other procedures.
• Trim the recorded video.
• Recorded studies can be stored locally, sent to the hospital DICOM archive (PACS) or exported to other storage devices.
• View saved images/videos with integrated DICOM Viewer.
• Image to DICOM feature. Convert BMP, PNG, TIF, JPG images and send to PACS.
• Video to DICOM feature. Convert AVI, MPG, MPEG, WMV, MOV, MP4, H264, MKV, FLV video files and send to PACS.
• Possibility to update patient information in DICOM files before sending to PACS.
• Possibility to add additional information field (additional custom DICOM tag) to image.
• Possibility to configure only Worklist usage for Non-DICOM studies.
• Possibility to configure Institution name (tag (0008,0080)) and Station name (tag (0008,1010)) and use it in DICOM files.
• Possibility to set files filter (set custom file extension in application.properties file).
• Detailed information about files to be converted: image preview, image info view, DICOM info and DICOM tags view, DICOM pixel data extraction.
• Archive file’s support. Automatically extract archive: ZIP. Supports 7z, ISO archives, but requires install 7-Zip software.
• Automatic DICOM files recognition (exclude DICOMDIR and unknown files).
• Supported patient information: patient ID, full patient name (alphabetic, ideographic and phonetic), birthdate and sex.
• Supported study information: study UID, study ID, date, time, accession number, description, series number, modality and character set.
• Possibility to specify character encoding: supported all extended character sets defined in the DICOM standard.
• Allows append existing study with new files (select study and patient information from scanned DICOM files).
• Supports Modality Worklist Information (C-FIND), Query/Retrieve Information, Verification (Echo).
• Support Drag and Drop interface.
• Querying patient information from HIS using external API (HTTP request).
• Possibility to initiate actions from other app by using REST API: Modality Worklist search, non-DICOM convert to DICOM, send to PACS.
• Windows explorer context menu (right mouse button) support.
• File conversion and forward process logs.
• Supporting Enterprise license.

Features of MedDream software:
• Multi language support (EN, LT);
• System administration via WEB interface;
• User identification by username and password, user rights;
• Ability to save image viewing settings;
• Secure data transfer (SSL support);
• Ability to open more than one study at a time;
• Image transformation (rotate, flip, align, pan, scale)
• Image inversion;
• Intensity (density of the point) measurement;
• Changing the Level/Window values;
• Measurements: Line, Reference line, Angle, Area, Volume, Cobb angle, Velocity time integral (VTI), Heart cardiothoracic ratio (CTR);
• Tools for localization of the images in intersecting planes;
• Multiplanar reconstruction (MPR);
• Additional data for image support (annotation and key object);
• ECG support (Tools: Beats per minute (bpm), time (s), millivolts (mV), QT points, heart rate (HR), QRS axis);
• Reports for study;
• Hanging protocols.

Product customization

Customizing the MedDream software allows providing the required set of functionalities to the system user:

• MedDream Viewing functionalities;
  • MedDream Video viewing and converting functionalities;
• MedDream PACS functionalities;
• MedDream SendToPACS functionalities.

System appearance, and availability of tools may be also customized by changing the settings. See the detail functionalities description and description of Settings in annexes of this document.

Product labeling

The information about the product is provided to the system user in the About window:

• Contacts of product distributor.
• Licensing information: organization that owns the license of current product installation, and dates, until the current license is valid and will receive updates.
• Product information: product name, product version, release date.
• Unique Device Identifier.
• Certification information: Catalogue number, Medical device class, ID of the notified body, and FDA cleared mark.
• Contacts of product manufacturer.
• Warning regarding not using mobile display for diagnostic of mammographic images.
• Explanation of safety signs.
• Certification bodies designated agents contacts are available in REP (representatives) tab.
License agreement and registration

⚠️ NOTE! License registration is required for legal software use. The access to the Software License Agreement (EULA) and license registration is provided to the end user in the system. To register the license or license update, the user should do the following:

- apply for the license and receive the valid license number from system administrator or system provider,
- read the Software License Agreement and agree with it,
- enter the license information and register license.

See the detail description of license registration steps in annexes of this document.

⚠️ NOTE! The internet connection and access to license server should be ensured for successful license registration.

Access to user documentation

The user manual user is available in MedDream under the Help menu. See the detail description how to access Help menu in annexes of this document.
Product installation

MedDream viewing functionalities minimal hardware requirements

Server-side

MedDream software is intended to be installed on PCs, servers or other hardware systems. Minimal hardware requirements as well as OS and other supporting software requirements for MedDream viewing functionalities are listed below:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimal Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPU*</td>
<td>Intel® Core™ i5, 4 Core, 2.00 GHz</td>
</tr>
<tr>
<td>RAM</td>
<td>8+ GB Additional RAM memory must be reserved for OS, Database, PACS and/or other services if installed in the same machine.</td>
</tr>
<tr>
<td>Storage space</td>
<td>1 GB of available hard-disk space for installation; + minimum 2 days of accessible study amount. For better performance preparation cache service can be used: additional free space required for local archive and image caching (see cache management description). Storage disk performance (used for caching) directly affects image open speed (SDD, RAM or HI speed disk storage recommended).</td>
</tr>
<tr>
<td>Network Bandwidth</td>
<td>100+ Mbit/s</td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows Server 2019, Windows Server 2022, Windows 10, Windows 11 (64 bit only) and above, Debian 11, Ubuntu 22.04 LTS, CentOS 7.9-2009, Fedora 37</td>
</tr>
</tbody>
</table>

*Minimal hardware requirements depend on number of concurrent users:

<table>
<thead>
<tr>
<th>Concurrent Connections</th>
<th>CPU cores</th>
<th>RAM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 connection</td>
<td>4 cores</td>
<td>8 GB</td>
</tr>
<tr>
<td>2 connections</td>
<td>4 cores</td>
<td>8 GB</td>
</tr>
<tr>
<td>5 connections</td>
<td>4 cores</td>
<td>8 GB</td>
</tr>
<tr>
<td>10 connections</td>
<td>4 cores</td>
<td>12 GB</td>
</tr>
<tr>
<td>20 connections</td>
<td>6 cores</td>
<td>16 GB</td>
</tr>
<tr>
<td>30 connections</td>
<td>8 cores</td>
<td>32 GB</td>
</tr>
<tr>
<td>60 connections</td>
<td>16 cores</td>
<td>32 GB</td>
</tr>
<tr>
<td>60+ connections</td>
<td>+1 core per 10 connections</td>
<td>+1 GB per 5 connections</td>
</tr>
</tbody>
</table>

⚠️ **NOTE!** Minimal hardware requirements depend on number of concurrent users, workload and image types. It is recommended to allocate 20-80% more resources for unusual work load or specific data types.

The requirements for MedDream server, detail instructions, how to install MedDream and verify the MedDream functioning after system installation or restart, are provided in Install Manual. Current section provides the requirements for user workplace and instructions for verifying, that the user can access MedDream functionalities from his workplace.

Client-side

The table describes the requirements for computer, that uses MedDream viewing functionalities from remote MedDream server through the internet:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimal Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desktop Web</td>
<td></td>
</tr>
<tr>
<td>CPU</td>
<td>Intel® Core™ i3 4 core CPU or better</td>
</tr>
</tbody>
</table>
**Product installation**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimal Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAM*</td>
<td>8+ GB, 256+ MB of video memory</td>
</tr>
<tr>
<td>Storage space</td>
<td>10+ GB</td>
</tr>
<tr>
<td>Network Bandwidth</td>
<td>100+ Mbit/s</td>
</tr>
<tr>
<td>Web Browsers</td>
<td>Chrome 118+, Firefox 118+, Microsoft Edge 118+, Safari 16+</td>
</tr>
<tr>
<td><strong>Mobile device iOS Web</strong></td>
<td></td>
</tr>
<tr>
<td>RAM*</td>
<td>2+ GB</td>
</tr>
<tr>
<td>Storage space</td>
<td>2+ GB</td>
</tr>
<tr>
<td>Network Bandwidth</td>
<td>100+ Mbit/s</td>
</tr>
<tr>
<td>Web Browsers</td>
<td>Safari 16+, Chrome 118+</td>
</tr>
<tr>
<td><strong>Mobile device Android Web</strong></td>
<td></td>
</tr>
<tr>
<td>RAM*</td>
<td>2+ GB</td>
</tr>
<tr>
<td>Storage space</td>
<td>2+ GB</td>
</tr>
<tr>
<td>Network Bandwidth</td>
<td>100+ Mbit/s</td>
</tr>
<tr>
<td>Web Browsers</td>
<td>Chrome 118+, Firefox 118+</td>
</tr>
</tbody>
</table>

* For CT, MRI, PET-CT client side MPR/MIP rendering:
  - 64bit CPU and 64bit operating system;
  - Graphic board with >=1 GB video memory (hardware acceleration is enabled on the browser);
  - 12 GB of RAM to open more than 800 images;
  - 16 GB of RAM to open more than 1500 images;
  - 24 GB of RAM to open more than 3000 images (cardiac or functional imaging, MG Tomosynthesis).

* For MG Mammoography:
  - 64bit CPU and 64bit operating system;
  - Graphic board with >=1 GB video memory (hardware acceleration is enabled on the browser);
  - 16 GB of RAM.

* For MG Tomosynthesis:
  - 64bit CPU and 64bit operating system;
  - Graphic board with >=1 GB video memory (hardware acceleration is enabled on the browser);
  - 16 GB of RAM.

* Depending on the total amount of RAM on user’s workstation, the browser is allowed to allocate the restricted amount of memory, and therefore MedDream application may load not more than 16 GBytes of data. Due to these limitations, browser may run out of memory, if the user loads several large computed tomography, mammography or tomosynthesis studies.

⚠️ **NOTE!** Hardware acceleration should be enabled in web browser for better performance.

⚠️ **NOTE!** Mozilla Firefox browser has certain memory limitations: MIST MPR functionality will fail on series where uncompressed DICOM data is larger than 2 GB.

⚠️ **NOTE!** MedDream enables users to view all data stored with a bit depth of up to 16 bits per color channel. However, it displays 8 bits per color channel at a time due to web browser limitations (maximum display of 256 values per color channel). You can utilize the Window leveling tool to explore the entire data range within the images.

⚠️ **NOTE!** The MedDream viewing functionalities server system requirements are detailed in the Install Manual of the MedDream viewing functionalities.

---

**Minimal MedDream video viewing and converting functionalities hardware requirements**

The table describes the requirements for computer with locally installed MedDream video viewing and converting functionalities:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimal Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPU</td>
<td>Intel® Core™ i5 or i7</td>
</tr>
<tr>
<td></td>
<td>When using FHD streaming, recording and playing at the same time:</td>
</tr>
</tbody>
</table>
### Minimal SendToPACS functionalities hardware requirements

The table describes the requirements for computer with locally installed SendToPACS functionalities:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPU</td>
<td>1 GHz or faster with support for PAE, NX, and SSE2</td>
</tr>
<tr>
<td>RAM</td>
<td>1+ GB</td>
</tr>
<tr>
<td>Storage space</td>
<td>1+ GB</td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows 10, Windows 11</td>
</tr>
</tbody>
</table>

### Minimal PACS functionalities hardware requirements

#### Server-side

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPU</td>
<td>Intel® Core™ i5, 4 Core, 2.00 GHz</td>
</tr>
<tr>
<td>RAM</td>
<td>8+ GB</td>
</tr>
<tr>
<td>Storage space</td>
<td>• 20 GB available hard-disk space for installation;</td>
</tr>
<tr>
<td></td>
<td>• PACS storage calculator for data: <a href="https://dicomlibrary.com/dicom/pacs-storage-calculator/">https://dicomlibrary.com/dicom/pacs-storage-calculator/</a></td>
</tr>
<tr>
<td></td>
<td>• 0.5 % from calculated storage data for DB storage.</td>
</tr>
<tr>
<td>Network Bandwidth</td>
<td>100+ Mbit/s</td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows Server 2022</td>
</tr>
<tr>
<td></td>
<td>Windows 11</td>
</tr>
<tr>
<td></td>
<td>Debian 12, Ubuntu 22.04 LTS, CentOS 7.9-2009, Fedora 37</td>
</tr>
<tr>
<td>Database</td>
<td>MySQL Server 8.0</td>
</tr>
</tbody>
</table>

#### Client-side

The same requirements as MedDream Viewer functionality (excluding mobile).
Installation verification

Section provides short check list for verifying, that the user can access MedDream functionalities from his workplace, view studies and use MedDream tools, required for daily operations.

MedDream viewing functionalities

To verify the MedDream viewing functionalities, perform the following steps:
- Open study in MedDream.
- Use your usual way to connect to MedDream service and open the MedDream Viewing functionalities: execute the known valid study open URL, or login with your credentials and select the study in MedDream search window.
- If you usually are working with studies from several network storages, try opening studies from all the used network places.
- Check, that study is correctly opened: thumbnails are displayed instead of exclamation marks, the chosen images opens as well.
- Check the Viewer toolbar for the opened image: make sure, that you usually used tools are displayed in common place and accessible.
- Verify the working of functions and tools, that are critical to you daily operations (like measuring, patient history, zoom, pan).

MedDream Video viewing functionalities

To verify the MedDream Video viewing and converting functionalities, perform the following steps:
- Use your usual way to connect to MedDream and open MedDream Video viewing functionalities: execute the app, video source should be connected to PC;
- Check the video signal in view window. If no signal is displayed, try to refresh signal, overthise check the chapter „Recording settings“ in Annex II MedDream video viewing and converting functionalities;
- Try to create a new patient, or Try to select patient from worklist – if worklist is available, check configuration chapter „Selecting patient from DICOM modality worklist“ in Annex II MedDream video viewing and converting functionalities;
- After patient is created or selected from worklist try to record video. If having problem, check chapter „Recording settings“ in Annex II MedDream video viewing and converting functionalities, otherwise contact system administrator or support@softenta.com.

MedDream PACS functionalities

To verify the MedDream PACS functionalities, perform the following steps:
- Use your usual way to connect to MedDream service and open the MedDream PACS functionalities.
- Find the study in the way you are regularly using:
  - Use unread studies page;
  - Browse the patients list and open the patient’s studies list;
  - Open search page, enter search criteria and find the study.
- Open the series page for the selected study.
- Check, if you are able to perform functions, you are regularly using. The functions to think about:
- Export studies;
- Import studies;
- Modify studies content.

**MedDream SentToPacs functionalities**

To verify MedDream SentToPACS functionalities, perform the following steps:

- Test non-DICOM file image converting and sending workflow:
  - Add one or more files to the files list. Use all the file types you regularly are working with;
  - Enter the DICOM info for non-DICOM files;
  - Select DICOM device;
  - Initiate converting and sending;
  - Check, that files are converted to DICOM and sent to the device, using the MedDream PACS functionalities or MedDream viewing functionalities.

- Repeat the non-DICOM file image sending workflow with all the DICOM devices you are regularly using.

- Test patient search in the Worklist workflow, if you are using these functions:
  - Select search in the non-DICOM files info window,
  - Enter or modify the search criteria to search specific patient. For testing purpose, use least specific criteria to see all patients available, like check ALL Modalities checkbox, uncheck Date checkbox, or search only by date;
  - select Worklist device from drop down list;
  - Press “Search” button to search in the Worklist server database;
  - Select the patient from the results list, and press “OK” to close Patient Search window. Check, if the selected patient`s data is inserted into corresponding Patient and Study information fields of the NON-DICOM files info window.

- Repeat the patient search in the Worklist workflow with all the Worklist devices you are regularly using.
IT security measures

The “Security considerations” section in the Install Manuals of the particular MedDream functionalities provides detail recommendations, how to install and configure the MedDream Viewing functionalities functionalities, MedDream Video viewing and converting functionalities, MedDream PACS functionalities, and MedDream SendToPACS functionalities in order to ensure the system security.

Current section describes actions, that should be taken by MedDream user, in order to secure his workplace and user’s account against unauthorized access:

• It is highly recommended to run MedDream only from the devices and accounts, that are authorized for the user by company’s security policy. Company’s security policy should ensure:
  – that work network and user’s workplace is secure – servers and workplaces (computers, mobile devices) have latest OS version with latest security patches,
  – that user’s workplace is free of viruses - required antivirus software is installed and run regularly,
  – that no extra peripheral devices are connected to the user’s workspace except the necessary for work,
  – that company’s network is protected with firewalls (Wi-Fi with strong passwords, limited access protocols) and other protection means,
  – all portable devices used for work (tablets, phones, notebooks) should be with strong passwords, encrypted storage and able to connected only to work environment thru secure network,
  – portable Devices must be physically locked or otherwise appropriately secured by its user/custodian when left unattended.

⚠️ CAUTION! Running MedDream software on shared user’s account can lead to unauthorized access to patient’s medical data.

• It is recommended to use the browser, that is authorized according company’s security policy, and is compatible with MedDream software:
  – If company’s security policy does not give recommendation for browser, we would recommend considering the Google Chrome or Mozilla Firefox as the most secure browser alternatives in the market at the moment while is up to date with latest security patches.
  – Browser should be configured to clear all data when closed, to prevent the data leak from work space data traces.

• The authentication is required for MedDream software. However, the authentication ways may vary. If you are using login and password authentication, keep the password safe from unauthorized access:
  – (if mobile devices used at work tool) before entering URL check that device connected to secure and exactly that network which was provided by system administrators;
  – before entering user name and password, check that URL address is correct and secure (https);
  – before entering user name and password, check the network connected;
  – don’t use short and simple passwords (12-16 symbols minimum). If system administrator didn’t give you secure password, ask for it;
  – do not expose the password to other persons;
  – do not allow the browser to save the password;
  – if you forgot your password, got the wrong password messages, or there is a chance that password can be compromised, stolen or publicly accessible, contact your system administrator to change the password as soon as possible.

• Use MedDream shutdown function, after finishing your work.

• Use MedDream log off function, after finishing your work and before closing browser window. Closing the program without Log Off (using browser window close ‘x’ button) is not safe and may lead to unauthorized
access to medical data. It is recommended after log out of MedDream to close browser completely, not only tab, but all browser window in order to clear browser data in memory.

⚠️ **NOTE!** Note for user, that share the computer and user’s account. MedDream is designed with “zero footprint” concept, meaning that no patient data is left on a client machine: after the end user logs out from MedDream, its cache does not contain any server responses with patient data. However, there are known browser’s security bugs, that allows to extract potentially sensitive data from browser’s memory cache after the user logs out and doesn’t close the entire browser application. Therefore, it is recommended to also close the entire browser (not just a particular tab or one of the windows) after logout.

- Contact your system administrator as soon as possible in case of unusual, malicious and suspicious behavior of software:
  - if there are any suspicions that work station can be compromised (computer miss behaving, have malware or popping random windows out of nowhere, being slower than usually), accessed by unknown person directly/remotely or stolen;
  - if there is network with similar name or devices connecting to wrong network;
  - if connection to MedDream looks insecure or address mismatch the one, that was given to you by your system administrator;
  - if some strange text messages, studies or links started to appear in MedDream viewer, buttons and shortcuts opens suspicious pages;
  - if MedDream viewer not opens, returns errors like "Page not found" or "Unable to connect", or loading time increased significantly;
  - if downloaded study files being alerted as infected or viruses. Files, downloaded from MedDream export functionality, can be checked with VirusTotal. Contact your system administrator if you need to install or update the VirusTotal software, which can be obtained from [https://www.virustotal.com/](https://www.virustotal.com/);
  - if portable work devices (phones, tablets, laptops) were stolen;
  - if portable work devices (phones, tablets, laptops) left unattended and have chance that devices security can be breached.

- In case of loss of the mobile device, the administrator must be informed immediately in order to completely remove the user’s access to patient data and prevent them from being made public.
MedDream functionalities: list of annexes

The section provides list of annexes, that describe in details usage and configuration of MedDream functionalities.

- Annex I: MedDream viewing functionalities;
- Annex II: MedDream video viewing and converting functionalities;
- Annex III: MedDream PACS functionalities;
- Annex IV: MedDream SendToPACS functionalities.

See each annex in a separate document.
Table of Figures

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Product labeling</td>
</tr>
</tbody>
</table>
Index

A
Access to user documentation ........................................................................................................ 21
Availability of documentation ........................................................................................................ 5

E
Explanation of symbols used ........................................................................................................... 6

G
General information ......................................................................................................................... 4

I
Installation verification .................................................................................................................... 26
IT security measures ......................................................................................................................... 28

L
License agreement and registration ................................................................................................. 21
List of applicable standards ............................................................................................................. 12

M
MedDream functionalities .................................................................................................................. 30
MedDream PACS functionalities ....................................................................................................... 26
MedDream SentToPacs functionalities .............................................................................................. 27
MedDream Video viewing functionalities .......................................................................................... 26
MedDream viewing functionalities .................................................................................................... 26
MedDream viewing functionalities minimal hardware requirements .................................................. 23
Minimal MedDream video viewing and converting functionalities hardware requirements ............ 24
Minimal PACS functionalities hardware requirements ....................................................................... 25
Minimal SendToPACS functionalities hardware requirements .......................................................... 25

P
Personal data security breach .......................................................................................................... 5
Product customization ......................................................................................................................... 20
Product installation ........................................................................................................................... 23
Product labeling ................................................................................................................................. 20

Q
Questions ......................................................................................................................................... 6

S
Serious incidents reporting .............................................................................................................. 5
Short product description .................................................................................................................. 18
Summary of clinical evaluation report ............................................................................................... 11

W
Warnings regarding residual risks .................................................................................................. 16
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