



**MedDream**  
**USER MANUAL**  
**version 7.7.0**  
**(MedDream video viewing and converting**  
**functionalities v4.4.0)**

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Specifications due to technical developments are subject to change. This user`s manual is not subject to the revision service. Please contact the manufacturer or authorized dealer to request the latest edition of the manual.

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## 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 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 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.



**WARNING!** Software usage not by intended use may cause patient death, potential injury or serious health impairment, requiring professional medical intervention.

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**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](mailto: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](http://www.softneta.com)).

Name, Surname: Raimundas Mikalauskas

Tel. +370 630 06808

Mail: [dpo@softneta.com](mailto: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](mailto: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](http://www.softneta.lt) / [www.softneta.com](http://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 is 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](mailto:support@softneta.com). Paper version of User Manual will be sent not later than in 72 hours after receiving Your request (to the address You specify).

## Questions

Please visit our 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.

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

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

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**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.

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

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Additional Symbols:



Tick box



Search



Export




















Forward








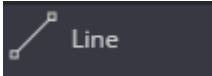

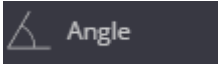


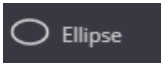

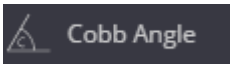

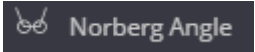



View icon



Ascending/Descending

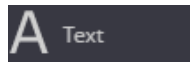
|   |                                   |
|---|-----------------------------------|
|    | System menu                       |
|    | Language menu                     |
|    | Windowing function                |
|    | Patient history                   |
|    | Windowing                         |
|    | Synchronize windowing             |
|    | Invert                            |
|    | Zoom                              |
|  | Pan                               |
|  | Channels                          |
|  | Scroll                            |
|  | Magnifier                         |
|  | Layout                            |
|  | Multi image                       |
|  | Reset                             |
|  | MPR (multi-planar reconstruction) |
|  | Reference line                    |

|   |                              |
|---|------------------------------|
|    | Crosshair                    |
|    | Rotate                       |
|    | DICOM                        |
|    | Link                         |
|    | Automatic link               |
|    | Manual link                  |
|    | Measure                      |
|   | Line                         |
|  | Polyline                     |
|  | Angle                        |
|  | Area                         |
|  | Volume                       |
|  | Ellipse                      |
|  | Velocity Time Integral (VTI) |
|  | Cobb Angle                   |
|  | Tibial Plateau Angle         |
|  | Norberg Angle                |
|  | Verbal Heart Scale           |

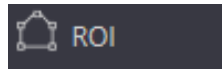




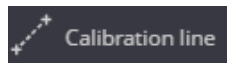
Cardiothoracic ratio



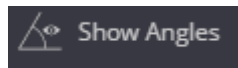
Text annotations



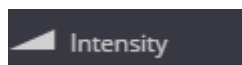
Region of interest



Calibration line



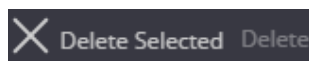
Show Angles



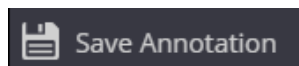
Intensity



Delete all measurements



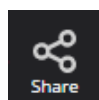
Delete selected measurements



Save annotation



Key objects



Share files via DICOM Library



Live share



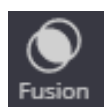
Start live share



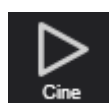
Stop live share



Copy live share link



Fusion



Cine mode



Series



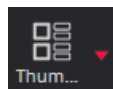
Plugins



Full Screen



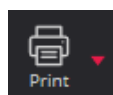
Theme



Thumbnails



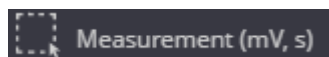
Preload series



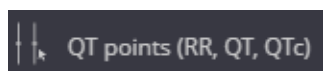
Print



Hanging protocols



Measurement



QT points



HR



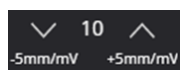
QRS Axis



Filter



Change horizontal scale (mm per second)



Change vertical scale (mm per mV)



ECG view scrollbar



Pause



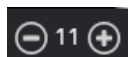
Play



Previous Instance



Next Instance



Frame rate in multi-frame



Stop playback



Volume on



Volume off



Create report



Open/Edit report



Paste to report



Download



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



Study and patient information are selected from scheduled modality workload



Try run task again



Stop running task



Rollback the task. This button will appear on failed “CONVERT JPG/VIDEO to DICOM” task. Allow user to return all DICOM files to images or video for more study changes



Delete task



send DICOM C-ECHO and verify basic connectivity by DICOM protocol



Activate source profile - display video input source streaming window in application include on startup



Update or change source profile settings



Delete source profile



Reload all active sources



Add new source profile



Can copy full stream address



Download VLC media player format playlist file, that contains the same stream address



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



Manufacturer

## 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

| Number   | Requirements   |
|--|--|
| EN ISO 13485:2016                                  | Medical devices - Quality management systems - Requirements for regulatory purposes  |
| EN ISO 14971:2019                                  | Medical devices – Application of risk management to medical devices  |
| IEC 82304-1:2016                                   | Health software – Part 1: General requirements for product safety  |
| EN 62304:2006 +A1:2015                             | Medical device software - Software life-cycle processes CONSOLIDATED EDITION   |
| EN 62304:2006/AC:2008<br>EN 62366-1:2015           | Medical devices - Application of usability engineering to medical devices  |
| EN ISO 15223-1:2016<br>(corrected version 2017-03) | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements   |
| EN ISO 12052:2017                                  | Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management (ISO 12052:2006)   |
| EN ISO 14155:2020                                  | Clinical investigation of medical devices for human subjects - Good clinical practice  |
| EN 1041:2008 +A1:2013                              | Information supplied by the manufacturer with medical devices  |
| IEC 82079-1:2019                                   | Preparation of information for use (instructions for use) of products  |
| 93/42/EEB<br><br>ENTR/F/3/PBE/<br>D(2009)19003     | Directive concerning medical devices<br><br>Interpretative document of the commission's services<br><br>Implementation of directive 2007/47/EC amending directives 90/385/EEC, 93/42/EEC and 98/8/EC   |
| 2017/745   | Directive concerning medical devices<br><br>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 |
| GHTF/SG1/N055:2009                                 | Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer   |
| GHTF/SG1/N063:2011                                 | Summary Technical Documentation (STED) for Demonstrating conformity to the Essential Principles  |
| GHTF/SG1/N055:2009                                 | Guidelines MDD: GHTF/SG1/N055:2009 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer  |
| MDCG 2020-8  | Clinical Investigation and Evaluation: Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies (EC)  |

|                                      |   |
|--------------------------------------|---|
| MDCG 2020-7                          | Clinical Investigation and Evaluation: Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies (EC)  |
| MDCG 2020-10/1                       | Clinical Investigation and Evaluation: Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745 (EC)   |
| MDCG 2020-10/2                       | Clinical Investigation and Evaluation: Clinical Investigation Summary Safety Report Form v1.0 (EC)  |
| MDCG 2020-6                          | 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) |
| MDCG 2020-1                          | Clinical Investigation and Evaluation: Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software (EC)  |
| MDCG 2020-5                          | Clinical Investigation and Evaluation: Clinical Evaluation – Equivalence. A guide for manufacturers and notified bodies (EC)  |
| IMDRF MDCE WG/N56 FINAL:2019 (IMDRF) | Clinical Investigation and Evaluation: Clinical Evaluation  |
| IMDRF MDCE WG/N57 FINAL:2019 (IMDRF) | Clinical Investigation and Evaluation: Clinical Investigation   |
| IMDRF MDCE WG/N55 FINAL:2019 (IMDRF) | Clinical Investigation and Evaluation: Clinical Evidence  |
| MDCG 2019-11                         | Software: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR (EC)   |
| SaMD WG/N41:2017                     | Software as a Medical Device (SaMD): Clinical Evaluation  |
| IMDRF/GRRP WG/N52 FINAL:2019 (IMDRF) | Labelling: Principles of Labelling  |
| MDCG 2018-5                          | UDI: UDI Assignment to Medical Device Software (EC)   |
| MDCG 2018-6                          | 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)                                    |
| IMDRF/UDI WG/N48 FINAL: 2019 (IMDRF) | UDI: UDI system   |
| IMDRF/UDI WG/N7 FINAL:2013 (IMDRF)   | UDI: UDI Guidance   |
| MDCG 2019-7                          | PRRC. Guidance on Article 15 of the Medical Device Regulation (MDR) and<br><br>in vitro Diagnostic Device Regulation (IVDR) regarding a ‘person responsible for regulatory compliance’ (PRRC) (EC)                              |
| MDCG 2019-16                         | Guidance on Cybersecurity for medical devices   |

|                                  |  |
|----------------------------------|--|
| MDCG 2020-3                      | 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           |
| 2014/30/EU                       | Directive 2014/30/EU, Electromagnetic Compatibility (EMC)  |
| GFTF/SG3/N99-10:2004 (Edition 2) | Quality Management Systems – Process Validation Guidance   |
| 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 Rev8               | MEDDEV 2.12-1 rev 8 on a medical devices vigilance system. Additional guidance on MEDDEV 2.12/1 rev 8  |
| 0.30.16-PROD                     | 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 801               | U.S. FDA Medical Device Regulation: 21 C.F.R. Part 801 et seq. (Labeling)  |
| 21 C.F.R. Part 803               | U.S. FDA Medical Device Regulation: 21 C.F.R. Part 803 (The Medical Device Reporting (MDR))  |
| 21 C.F.R. section 814.9.         | U.S. FDA MAF Regulation: 21 C.F.R. section 814.9. (Medical Device Master File)   |
| 21 C.F.R. section 814.9.         | U.S. FDA 510(k) Regulation: 21 C.F.R. section 814.9. (Premarket approval of medical devices)   |
| 21 C.F.R. Part 820               | U.S. FDA Medical Device Regulation: 21 C.F.R. Part 820 (Quality System regulation)   |
| 78 Fed. Reg. 58785, 58785-58828  | UDI-GUDID Regulations: 78 Fed. Reg. 58785, 58785-58828 (Unique Device Identification System)   |
| 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   |



|   |  |
|---|--|
| IMDRF/CYBER WG/N60FINAL:2020 (IMDRF)  | Cybersecurity: Principles and Practices for Medical Device Cybersecurity   |
| 45 C. F. R. Part 160, subparts A and E of part 164                                    | 45 C.F.R. Part 160 (Public Welfare: The HIPAA Privacy Rule)  |
| 45 C. F. R. Part 160, subparts A and C of part 164                                    | 45 C.F.R. Part 160 (Public Welfare: The Security Rule)   |
| Guidance on the provisions in the HIPAA Security Rule.1 (45 C.F.R. §§ 164.302 – 318.) | Guidance on Risk Analysis Requirements under the HIPAA Security Rule   |
| -   | 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  |
| 2015 m. rugsėjo 17 d. Nr. XII-1938  | Biomedicininų tyrimų etikos įstatymas / Biomedical Research Ethics Law   |
| 2016 m. sausio 15 d. Nr. V-4  | Įsakymas dėl prašymo išduoti leidimą atlikti biomedicininį tyrimą, paraiškos biomedicininiam tyrimui, biomedicininio tyrimo etinio vertinimo anketos pavyzdinių formų patvirtinimo / Order on the biomedical research forms approval: for of request for permission to implement biomedical research; biomedical research ethical evaluation form.           |
| 2017 m. gegužės 5 d. Nr. T1-683   | Įsakymas dėl Valstybinės akreditavimo sveikatos priežiūros veiklai tarnybos prie Sveikatos apsaugos ministerijos generalinio direktoriaus 2004 m. rugpjūčio 5 d. įsakymo nr. T1-136 „Dėl pranešimų apie neatitinkančius reikalavimų medicinos prietaisus (budra) pateikimo tvarkos aprašo patvirtinimo“ pakeitimo / Order on the changes in vigilance system |
| Nr. T1-564, 2016-0412   | Įsakymas „Dėl laisvos prekybos pažymėjimų išdavimo medicinos priemonėms (prietaisams) tvarkos aprašo patvirtinimo“ / Order “On Approval of the Description of the Procedure for Issuing Free Trade Certificates for Medical Devices”   |
| Nr. T1-568, 2016-04-13  | Dėl teikiamų rinkai medicinos prietaisų registravimo tvarkos aprašo patvirtinimo pakeitimo / Amendment of the approval of the description of the procedure for registration of medical devices placed on the market  |
| 2019-01-01 redakcija  | <a href="#">LR asmens duomenų teisinės apsaugos įstatymas</a> / Law on Legal Protection of Personal Data of the Republic of Lithuania  |
| 1T-63(1.12.E)   | <b>Duomenų subjekto teisių įgyvendinimo pavyzdinės taisyklės.</b> 2018-07-09 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-63(1.12.E) / Model rules for the exercise of the rights of the data subject. Order of the Director of the State Data Protection Inspectorate on July 9, 2018.   |

|               |  |
|---------------|--|
| 1T-68(1.12.E) | <b>Leidimų perduoti asmens duomenis į trečiąsias valstybes ar tarptautinėms organizacijoms išdavimo tvarkos aprašas. 2018-07-18 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-68(1.12.E) / Description of the procedure for the issuance of permits for the transfer of personal data to third countries or international organizations. Order of the Director of the State Data Protection Inspectorate, 2018-07-18.</b>  |
| 1T-72(1.12.E) | Pranešimo apie asmens duomenų saugumo pažeidimą pateikimo Valstybinei duomenų apsaugos inspekcijai tvarkos aprašas. 2018-07-27 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-72(1.12.E). / Description of the Procedure for Submitting a Report on the Infringement of Personal Data Security to the State Data Protection Inspectorate. July 27, 2018 Order of the Director of the State Data Protection Inspectorate.  |
| 1T-73(1.12.E) | Duomenų subjekto teisių gauti informaciją, susipažinti su asmens duomenimis, reikalauti ištaisyti ar ištrinti asmens duomenis ir apriboti 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. |

## Warnings regarding residual risks

| No | Hazard                        | Warning/ Caution/ Note   |
|----|-------------------------------|--|
| 1  | Illegal access                | <p><b>WARNING!</b> If integrated Viewer is used, the login window may be disabled in configuration.</p> <p><b>NOTE.</b> Remote hospital DICOM archive and DICOM modality worklist server settings can be the same or not – depends on hospital infrastructure. Recommended to consult to your DICOM archive or worklist server administrator.</p>  |
| 2  | Inadequate filtration process | <p><b>WARNING!</b> It is not possible to search for Ideographic and Phonetic versions of patient names. The search is performed only against the basic version (Alphabetic), even if the image contains the other two versions and the PACS supports them.</p> <p><b>WARNING!</b> One date interval value can be picked at a time. The ends of picked interval are displayed in the date fields on the left of the interval pick list. The fields are empty if no specific interval (<b>Any</b>) is picked.</p> <p><b>WARNING!</b> The search according the picked <b>modalities</b> is performed automatically on any change in pick list.</p> <p><b>WARNING!</b> The default selection on search window open is <b>All</b> and filtering by modality is not performed.</p> <p><b>WARNING!</b> Patient history search is performed according to the Patient ID. Contact your system administrator, if multiple patients ID are displayed.</p> <p><b>WARNING!</b> The mobile mode has the following search limitations comparing to desktop version: search according accession number and source AE title is not allowed; search according custom date interval is not allowed; the customization of modalities pick list and search according custom modality is not allowed.</p> <p><b>CAUTION!</b> Please fill all fields correctly to identify patient and avoid editing patient with already existing studies.</p> |
| 3  | Incorrect configuration       | <p><b>WARNING!</b> If integrated Viewer is used, the search window may be disabled in configuration.</p> <p><b>WARNING!</b> The first image opens, if AutoOpen First Image conditions are met (see description in Settings).</p> <p><b>WARNING!</b> In case the first study image should be opened according to Settings, the image is opened in the first (top right) viewport and only if this viewport is empty.</p> <p><b>WARNING!</b> The patient's history icon is visible only if the viewing patient's history is allowed by system configuration, and the user rights.</p> <p><b>WARNING!</b> Key objects functionality may be disabled in configuration.</p> <p><b>WARNING! Share files via DICOM Library</b> function should be enabled and the required parameters should be set in configuration.</p> <p><b>WARNING! Forward</b> function should be enabled and the required parameters (list of forward destination machines) should be set in configuration.</p>  |

|   |  |  |
|---|--|--|
|   |  | <p><b>WARNING! Export</b> function should be enabled and the required parameters (path to DICOMDIR viewer and size of ISO archive) should be set in configuration.</p> <p><b>WARNING! LiveShare</b> function should be enabled in configuration, and sockets connection to MedDream server from host's and guests' workplace should be allowed.</p> <p><b>WARNING!</b> The media sizes may be supplemented or replaced with other values by system administrator.</p> <p><b>WARNING!</b> The viewer may be included in ISO archive, if the appropriate viewer software is provided and system administrator configures to enclose it in export archive.</p> <p><b>CAUTION!</b> To display correct DICOM modality worklist search result, please see Network settings and adjust correct worklist character set and wildcard options.</p> <p><b>NOTE.</b> To record multiple signal inputs with pedals, do not forget to change source profile ENABLE RECORDING KEYS option in Recording settings. To setup pedals keys – see General settings.</p> <p><b>CAUTION!</b> Try to set the same character set for the patient studies, try open one the same study and look for DICOM tag “<i>Specific Character Set</i>“(0008, 0005).</p> <p>Some PACS, during study import, will update patient name from DICOM file with different encoding – may lead to display incorrect patient name in the DICOM viewer (this will not change/damage any DIOCM files – just database record).</p> <p><b>CAUTION!</b> 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.</p> <p>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.</p> <p><b>NOTE.</b> GUI validates and checks available recording device option combination by DICOM TRANSFER SYNTAX option.</p> <p>Requires to ensure, that PACS supports transfer syntax(ask PACS administrator or see PACS DICOM conformance statement document) and recorder DICOM files will be accepted by PACS</p> <p>Some options can be updated in C:\MedDreamStation\recorder\configurationSettings.json, but during re-installation – will be overridden.</p> <p><b>CAUTION!</b> Registration requires internet access to <a href="https://lic.softneta.com">https://lic.softneta.com</a>.</p> |
| 4 | 3rd party libraries / internal components work incorrectly / not available | <p><b>WARNING!</b> The section described how to open the studies in Viewer window from the Search results list in Search window. For a description of opening studies in mobile mode, see the Opening studies in MedDream Mobile mode section. If Viewer is used in an integrated solution, the window is opened by an integrating information system, such as a hospital information system or a patient portal.</p>  |

|   |                                 |   |
|---|---------------------------------|---|
|   |                                 | <p><b>WARNING!</b> Annotation saving is implemented according to DICOM standard. The function is available only if the used study storage provides DICOM saving functionality.</p> <p><b>WARNING!</b> Key object saving is implemented according to DICOM standard. The function is available only if the used study storage provides DICOM saving functionality.</p> <p><b>WARNING!</b> Live sharing is dedicated for images. Multiframe, video, ECG, PDF, SR documents is not supposed to be live shared.</p> <p><b>WARNING!</b> 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.</p> <p><b>NOTE.</b> See more details in section Selecting patient from DICOM modality worklist.</p> <p><b>NOTE.</b> Some pedals producing different signal key combination on longer press. It is recommended to consult with active personal about pedal pressing habits (how long and how they press on snapshot or video recording buttons).</p> <p><b>NOTE.</b> If profile has DIRECTSHOW enabled – all STREAM options will not be possible.</p> <p><b>CAUTION!</b> On Windows OS it is recommended to have at least more than 2GB free space to function properly.</p>  |
| 5 | Component / function is missing | <p><b>WARNING!</b> The tools in <b>Measure</b> button menu may vary depending on license type, active image type and system settings:</p> <ul style="list-style-type: none"> <li>• <b>Measure</b> button is not displayed for structure reports (SR).</li> <li>• ECG studies has different set of Measure tools (see <b>Error! Reference source not found.</b>).</li> <li>• <b>Cobb Angle</b>, <b>TPA</b>, <b>Norberg Angle</b>, and <b>VHS</b> measuring is intended for veterinary usage. By default settings these tools are not shown in Measure menu for other than VET license types.</li> <li>• <b>VTI</b> measuring is applicable and displayed only for US modality.</li> </ul> <p><b>WARNING!</b> Access to Export, Forward, and Settings functionality may be not allowed either by Settings, or by user rights.</p> <p><b>WARNING!</b> Systems menu options may be disabled in Settings. The Settings option may also be not allowed by user rights.</p> <p><b>WARNING!</b> Annotations functionality may be disabled in configuration.</p> <p><b>WARNING!</b> The <b>Register</b> button is visible only if user has administrator right granted by user rights and Settings menu is enabled in system settings.</p> <p><b>WARNING!</b> License registration is required for legal software use. The license registration function is accessible only for users having administrator rights.</p> <p><b>CAUTION!</b> Please ensure, that video recording is not active.</p> <p><b>WARNING!</b> In order to ensure successful VS work, the settings must be modified only by the system administrator.</p> <p><b>CAUTION!</b> When connecting pedal and keyboard, review SNAPSHOT or PLAY/STOP KEY settings and try to avoid pressing configured keys.</p> |

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| 6 | Software problem<br>usage | <p><b>WARNING!</b> We recommend upgrade PC or reduce video quality, if it does not match minimal requirements for recording, playing and streaming at the same time.</p> <p><b>WARNING!</b> Quick series images preview cannot be done for CT, PT, or MR series, if not displaying thumbnails is configured. Use scrollbar cursor dragging in viewport for quick series images preview.</p> <p><b>WARNING!</b> It is not possible to sort and filter the patient's history list if working in mobile mode.</p> <p><b>WARNING!</b> The internet connection and access to license server should be ensured for successful license registration.</p> <p><b>WARNING!</b> 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.</p> <p><b>WARNING!</b> The localization tools are mainly used for CT, MR and PT studies, that contains several series taken in several planes.</p> <p><b>WARNING!</b> Note, that MedDream cannot guarantee that the manual series linking displays the images of the same patient and at the corresponding position.</p> <p><b>WARNING!</b> VTI measuring tool is applicable only for the images of "US" modality with visible blood velocity profile.</p> <p><b>WARNING!</b> TPA, Norberg Angle, and VHS measuring is intended for veterinary usage. By default settings these tools are not shown in Measure menu for other than VET license types.</p> <p><b>WARNING!</b> Saved Annotations can only be viewed.</p> <p><b>WARNING!</b> If Key object image is opened from thumbnail, Key object filter is not activated. To activate the filter, expand the key object menu by clicking the key object icon on the right of the image, and click the filter menu.</p> <p><b>WARNING!</b> Windowing, Pan and Zoom functions are available during cine mode (see pages 19-20 on Manipulating and analyzing images).</p> <p><b>WARNING!</b> Forward and Export functions are not available in Search window if working in mobile mode.</p> <p><b>WARNING!</b> JPEG/MP4/pdf and TIFF/MP4/pdf formats are disabled in the following conditions:</p> <ul style="list-style-type: none"> <li>- At least one study contains object of SR or ECG type, if study export (<b>Save study</b>) is selected.</li> <li>- The active series contains object of SR or ECG type, if series export (<b>Save active series</b>) is selected.</li> <li>- The active image is SR or ECG type, if image export (<b>Save active image/video</b>) is selected.</li> </ul> <p><b>WARNING!</b> <b>Save active image/video</b> and <b>Save active series</b> scopes are enabled only for active study export from Viewer window.</p> <p><b>WARNING!</b> The size limits for one attachment file and one-time upload package, that are defined in system configuration, cannot be exceeded.</p> <p><b>WARNING!</b> In Hanging protocol alpha version, the setting <b>Do not fetch metadata for these modalities</b> can only be modified in settings file. Note that for large-scale studies (for example CT, MRI) it is recommended not to use metadata due to long loading time.</p> |
|---|---------------------------|--|

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|---|---|--|
|   |   | <p><b>WARNING!</b> Note, that browser's zoom function changes resolution and the software may automatically switch to mobile mode.</p> <p><b>WARNING!</b> Forward and Export functions are not available in Search results window if working in mobile mode.</p> <p><b>WARNING!</b> Software usage not by intended use may cause patient death, potential injury or serious health impairment, requiring professional medical intervention.</p> <p><b>NOTE.</b> During conversion to DICOM – user will not be able to open this study. User can stop the task and roll back to image and video. After roll back task is completed – can open study for editing in CURRENT STUDY window. After conversion complete – can open study in DICOM VIEWER window.</p> <p><b>NOTE.</b> If cannot see any devices or some is missing – please check connection cables to the device. If problem persist - check Windows OS device list, if all drivers installed properly.</p> <p><b>NOTE.</b> If parameter DELETE IF DISK SPACE IF LOWER THAN (GB) TO 5GB and MINIMUM MAKE FREE DISK SPACE (GB) value is 2.1GB – auto deletion expected result will be 7.1GB disk free space.</p>                |
| 7 | Vulnerability of e-PHI (electronic personal health information) | <p><b>WARNING!</b> Running MedDream software on shared user's account can lead to unauthorised access to patient's medical data.</p> <p><b>WARNING!</b> For proper forward functioning the forward destination should be properly configured and the device should support DICOM saving functionality.</p> <p><b>CAUTION!</b> Incorrectly installed software could cause inconvenience to medical professionals using the software and disruption of the medical professional activities.</p> <p><b>CAUTION!</b> 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.</p> <p><b>CAUTION!</b> The system does not anonymize the content of shared images and entered message. You take responsibility for sensitive data in shared information.</p> <p><b>WARNING!</b> 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.</p> |
| 8 | Measurements inaccurate   | <p><b>WARNING!</b> 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.</p> <p><b>WARNING!</b> Note, that measuring functions in MedDream is approximate.</p>   |

## 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.
- 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

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.

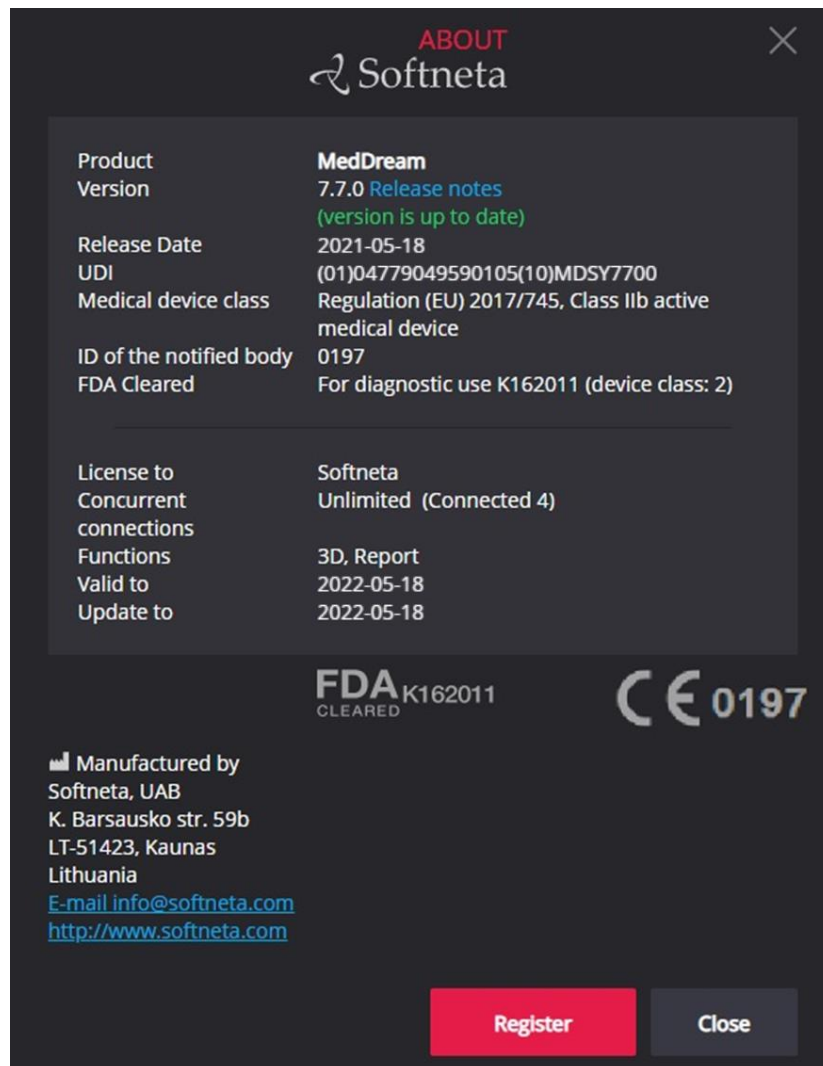
System appearance, and availability of tools may be also customized by changing the settings. See the detail functionalities description and description of Settings in annexes of this document.

## Product labeling

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

- Product name.
- Product version.
- Release date.
- Unique Device Identification number (UID).
- Certification information: Medical device class, ID of the notified body, and FDA cleared mark.
- Contacts of product manufacturer.

- Licensing information: organization that owns the license of current product installation, and dates, until the current license is valid and will receive updates.



See the detail description of About window and how to access it in annexes of this document.

## License agreement and registration



**WARNING!** 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.



**WARNING!** 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

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.

## Minimal client side requirements

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

| Parameter                 | Requirements  |
|---------------------------|---|
| <b>Desktop Web HTML5</b>  |   |
| Operating system          | Windows 10 (32/64 bit),<br>Mac OS X 10.9+   |
| Web Browsers              | Chrome 74+, Firefox 74+, Safari 10+, Microsoft Edge 85+                                   |
| CPU                       | Modern x86/x64 Consumer CPU<br>(5th generation Intel i3 2 core CPU or better)             |
| RAM*                      | 4+ GB of RAM,<br>256+ MB of VRAM  |
| HDD                       | 10 GB   |
| Network Bandwidth**       | >=2 Mbit/s for X-Ray,<br>>=8 Mbit/s for CT, MRI   |
| <b>Mobile iOS Web</b>     |   |
| Operating system          | iOS 9+  |
| Web Browsers              | iOS 9+ Safari, Chrome   |
| CPU                       | iPhone 6+, iPad Air+  |
| RAM*                      | 1 GB  |
| HDD                       | 2 GB  |
| Network Bandwidth**       | >=1 Mbit/s for X-Ray,<br>>= 4 Mbit/s for CT, MRI  |
| <b>Mobile Android Web</b> |   |
| Operating system          | Android 6+  |
| Web Browsers              | Android 6+ Chrome   |
| CPU                       | ARMv7 processor with vector FPU, minimum 550MHz, OpenGL ES 2.0, H.264 and AAC HW decoders |
| RAM*                      | 1 GB  |
| HDD                       | 2 GB  |
| Network Bandwidth**       | >=1 Mbit/s for X-Ray,<br>>= 4 Mbit/s for CT, MRI  |

\* for CT, MRI, PET-CT client side MPR/MIP rendering:

- 64bit CPU and 64 bit operating system;
- Graphic board with  $\geq 1$  GB video memory;
- 8 GB of RAM to open more than 800 images;
- 12 GB of RAM to open more than 1500 images;
- 16 GB of RAM to open more than 3000 images (cardiac or functional imaging, MG Tomosynthesis).

\* for MG Mammography:

- 64-bit CPU and 64 bit operating system;
- Graphic board with  $\geq 1$  GB video memory;
- 12 GB of RAM.

\* for MG Tomosynthesis:

- 64-bit CPU and 64 bit operating system;
- Graphic board with  $\geq 1$  GB video memory;
- 16 GB of RAM.

\*\*Network bandwidth will directly affect image open speed.



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

**NOTE!** See Install Manual for MedDream viewing functionalities server system requirements.

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

| Parameter                            | Requirements  |
|--------------------------------------|---|
| Processor                            | Intel® Core™ i5 or i7<br>When using FHD streaming, recording and playing at the same time:<br>4 threads, 4 GHz or 8 threads, 1.8 GHZ.<br><br>Using intel media SDK (reduce CPU consumption), requires 3rd Generation (or later) Intel® Core™, selected Intel® Celeron™, Intel® Pentium™ and Intel® Atom® processors with integrated graphics supporting Intel® Quick Sync Video |
| Memory                               | 4 GB RAM  |
| Hard drive                           | SDD 500 GB (SATA)<br>depends on usage workflow, can be $\geq 256$ , GB, ~7 days requires 56 GB  |
| Onboard graphics                     | Intel® HD Graphics  |
| Network Interface                    | 1000 Mbit/s   |
| Screen resolution                    | 1920x1080 pixels (lower resolution not supported)   |
| Supports following operating systems | Windows 7/8/10 (32 and 64 bit)  |



We recommend upgrade PC or reduce video quality, if it does not match minimal requirements for recording, playing and streaming at the same time.

If you faced with such a problem, please contact Softneta UAB Customer support – e-mail [support@softneta.com](mailto:support@softneta.com) and we will help you resolve it.

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## 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.

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 Viewer: 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).

To verify the MedDream Video viewing and converting functionalities, perform the following steps:

- Use your usual way to connect to MedDream and open: 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, otherwise check user manual chapter „Recording settings“;
- 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“;
- After patient is created or selected from worklist try to record video. If having problem, check chapter „Recording settings“, otherwise contact system administrator or [support@softneta.com](mailto:support@softneta.com)

## IT security measures

The “Security considerations” section in the Install Manual provides detail recommendations, how to install and configure the MedDream software 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 have on time security patches and updates, required antivirus software, firewalls and other protection means.
- Use MedDream shutdown function, after finishing your work.



**WARNING!** Running MedDream software on shared user’s account can lead to unauthorised access to patient’s medical data.

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- 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.
- 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:
  - do not expose the password to other persons;
  - do not allow the browser to save the password.
- 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.



**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 bug’s, 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.

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## MedDream video viewing and converting functionalities

### Selecting patient

The user can select the patient from:

- WORKLIST – select scheduled modality worklist from DICOM worklist server (to setup worklist server - see 7.1.2 Network settings).
- PATIENT – manually fill/update patient information.
- LOCAL – select from VS existing patients.



Figure 1. Select patient for recording video.

### Selecting patient from DICOM modality worklist

Select WORKLIST window in main menu:

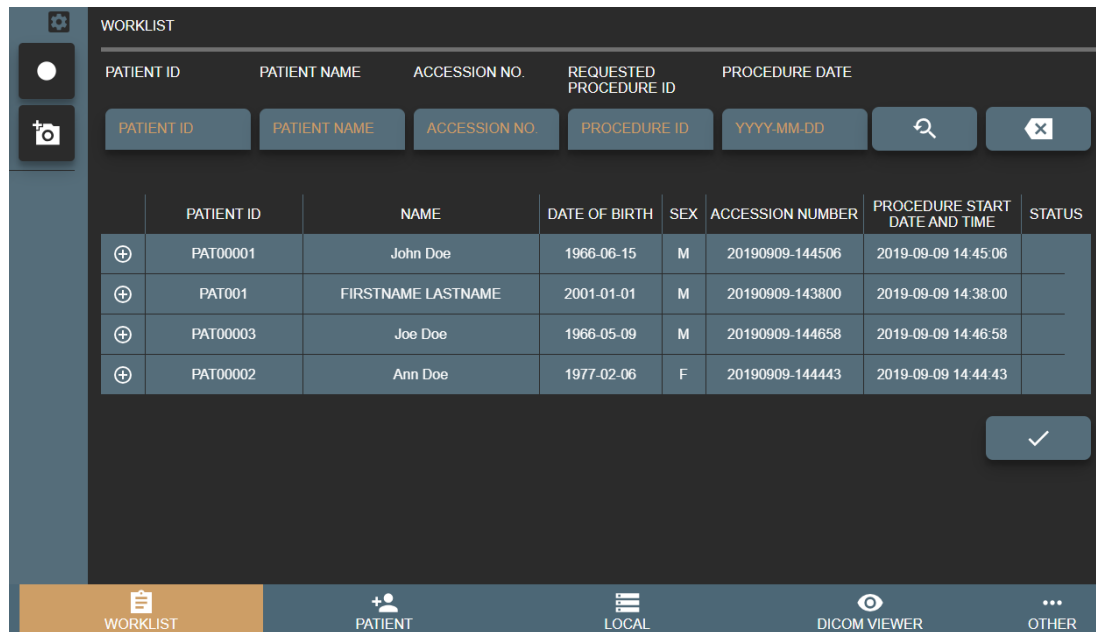


Figure 2. Patient from Worklist.

The search can be performed by:

- Patient ID
- Patient Name
- Accession Nr.
- Procedure ID – modality worklist scheduled procedure id.
- Procedure Date – modality worklist scheduled procedure start date.



To display correct DICOM modality worklist search result, please see Network settings and adjust correct worklist character set and wildcard options.

To display more detailed information – press button 

The screenshot shows a 'Worklist details' window with the following information:

|                                     |   |
|-------------------------------------|---|
| Study accession number              | 20190909-144506                                   |
| Patient name                        |   |
| Family name                         | Doe   |
| Given name                          | John  |
| Patient id                          | PAT00001  |
| Patient birth date                  | 1966-06-15  |
| Patient sex                         | M   |
| Study uid                           | 1.2.826.0.1.3680043.2.737.24567.2019.9.9.14.46.11 |
| Scheduled procedure step sequence   |   |
| Modality                            | OT  |
| Scheduled station aetitle           | VSTATION  |
| Scheduled procedure step start date | 2019-09-09  |
| Scheduled procedure step start time | 14:45:06  |

At the bottom of the window, there is a red button with a white 'X' icon.

Figure 3. Patient information from Worklist.


The same information can be accessed via CURRENT STUDY window patient information.

The screenshot shows a 'PATIENT DATA' window with the following information:

| ID       | NAME     | BIRTHDATE  | ACCESSION NUMBER | DESCRIPTION |
|----------|----------|------------|------------------|-------------|
| PAT00001 | John Doe | 1966-06-15 | 20190909-144506  |             |

At the bottom right of the window, there are two buttons: a blue button with a white plus icon and a blue button with a white pencil icon.

Figure 4. Patient information from Current study.

Select worklist item with required patient (will highlight in orange) and press button . Confirm your action.



The screenshot shows a 'Create new study' dialog box with the following information:

Create study and patient from worklist?

ID: PAT00001  
Name: John Doe  
Date of birth: 1966-06-15  
Gender: M

At the bottom of the dialog box, there are two buttons: a green button with a white checkmark icon and a red button with a white 'X' icon.

Figure 5. Create new study from worklist.

Column STATUS can have icon -  - which indicates, that worklist item study already created on VS. In this case, by selecting and pressing button  - system will open existing study with the same worklist information.



## Create new patient

Create patient by pressing PATIENT button in main menu:

Figure 6. Selecting patient from Worklist.



It is recommended to look for existing patient in LOCAL archive, see 1.3 Select patient from local storage.

Fill form fields:

1. Patient ID - max 64 characters, if left empty – will generate automatically from current date and time;
2. First Name – max 64 characters, patient first name;
3. Last Name - max 64 characters, last patient name;
4. Sex – patient sex options of male/female/other.
5. Date of Birth - patient birth date in format YYYY-MM-DD (e.g. 1985-01-10).
6. Description - max 64 characters for short study description.



Please fill all fields correctly to identify patient and avoid editing patient with already existing studies.

In the end, press button  to create new study with patient.

If patient ID already exist but other data is different – VS will open conformation window to select one of the options:

- Update existing patient with data? – will update patients data and create new study,
- Select existing patient? – will create new study with existing patient,

- Create new patient? – will create patient with new patient ID (will add extra random number to added patient ID) and create new study.

Figure 7. Enter/Select existing patient from form.


## Select patient from local storage

VS creates patients and studies on local machine that can be accessed by pressing LOCAL button in main menu.

| PATIENT ID        | NAME      | DATE OF BIRTH | SEX |
|-------------------|-----------|---------------|-----|
| 20190910095347858 |           |               |     |
| 20190910085229544 |           |               |     |
| PAT00001          | John Doe  | 1966-06-15    | M   |
| TEST              | TEST TEST | 2011-01-01    | M   |

Figure 8. Select patient from Local archive.

Search result is combination of patients and its studies (patient list, where you can expand and see patient studies). To get exact patient or study in search result - fill search field with patient ID, name, accession number, study description, study id or study UID. DATE field will allow search patients studies with desired study date (see more on section 3. Search for patients and studies).

To create empty study - select row with patient information and press the button . Confirm the action.

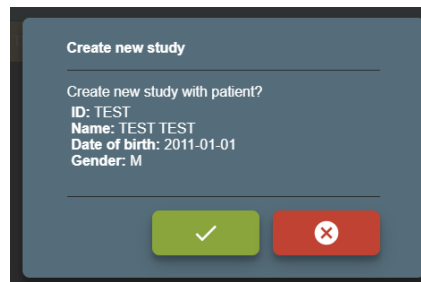




Figure 9. Select patient to create study.

## Updating patient data

User can start recording process without filling or selecting patient in CURRENT STUDY window. It will automatically generate patient ID from current date and time. If the study recording is completed or will be closed for today (will review records on other day) - recommended not to forget and update/select correct patient.



Please ensure, that video recording is not active.

Expand patient information section by pressing on it or on button , and press edit button .

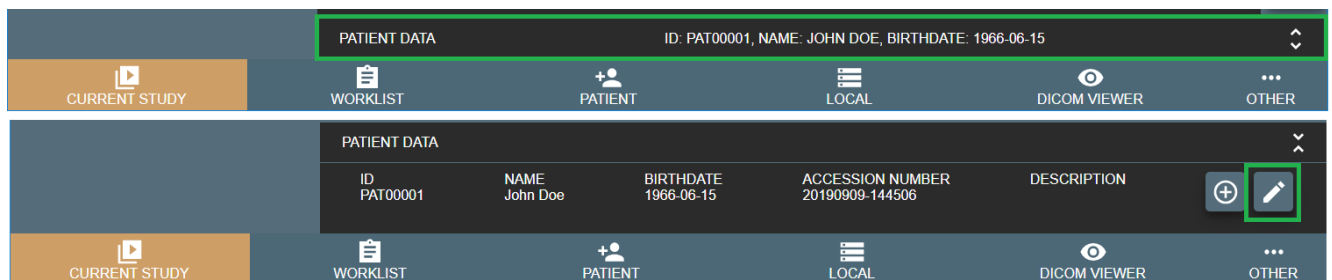


Figure 10. Expanding patient data information and possibility to update patient data.

Will appear dialog with options, how to update or replace patient data:

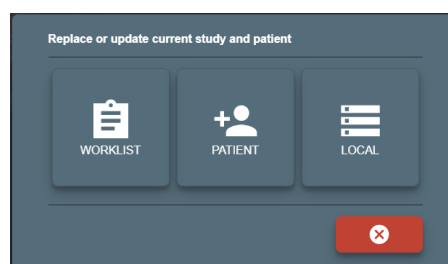


Figure 11. Updating patient data.

User can select from where to take patient data: WORKLIST, PATIENT or LOCAL

**WORKLIST** – will open WORKLIST window to select and replace patient and update study data from remote worklist server. After selecting – will ask to confirm patient replace:

The dialog box is titled "Update patient and study". It contains the question "Replace patient and study data with worklist?". Below this, it shows two sections: "Current" and "From worklist".

| Field         | Current          | From worklist |
|---------------|------------------|---------------|
| ID            | PAT333           | PAT00001      |
| Name          | Name last name   | John Doe      |
| Date of birth | 1955-02-03       | 1966-06-15    |
| Gender        | M                | M             |
| Description   | Some description |               |

At the bottom, there are two buttons: a green button with a white checkmark and a red button with a white 'X'.

Figure 12. Confirming patient update from worklist.

**PATIENT** – will open PATIENT window to manually update patient form.

If updated patient is different patient with the same patient ID – will open confirmation window:

- Update existing patient with data?
- Select existing patient?
- Create new patient ?



See more details in section 1.1 Selecting patient from DICOM modality worklist.

If study and patient was created from worklist – changing patient data, will lose worklist information (will generate new study UID).

After changes – will ask to confirm:

The dialog box is titled "Update patient and study". It contains the question "Update patient and study data?". Below this, it shows two sections: "Current" and "Updated".

| Field         | Current        | Updated             |
|---------------|----------------|---------------------|
| ID            | PAT333         | PAT333              |
| Name          | Name last name | Name TEST last name |
| Date of birth | 1955-02-03     | 1955-02-03          |
| Gender        | M              | M                   |
| Description   |                | Some description    |

At the bottom, there are two buttons: a green button with a white checkmark and a red button with a white 'X'.

Figure 13. Confirming patient update from form.

**LOCAL** – will open LOCAL window to select patient from local archive.

If study and patient was created from worklist – changing patient, will lose worklist information (will generate new study UID). After change – will ask to confirm:

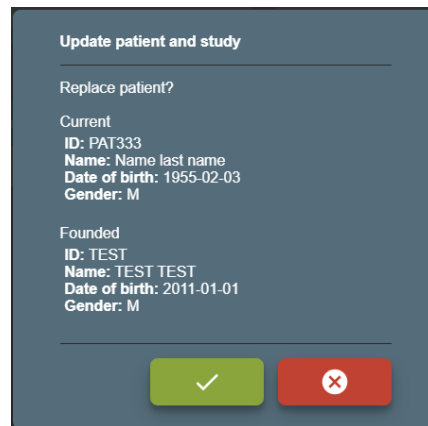


Figure 14. Confirming that patient update from local storage.

## Recording study

New study can be recorded by pressing CURRENT STUDY button in main menu. If user select patient or just start recording by pressing pedals - will open CURRENT STUDY window.

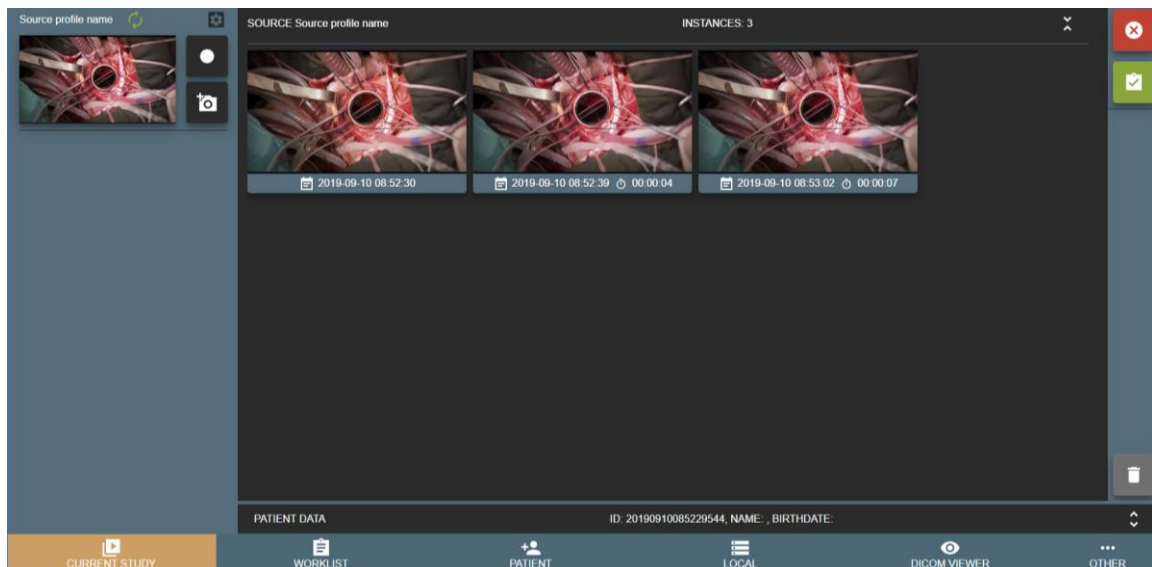







Figure 15. Recording study.

Left side of VS software reserved for multiple input signals streaming windows (max 4 sources for 1920x1080 current design) and right side is for study records.

VS software is designed to record every input signal into separate series. Series description will be input signal source profile name – to identify device input for every series. For other situations, then input signal stream window is reloaded or study was opened to continue recording – will cause to create another separate series for every input source signal.

- To take a snapshot/photo - press button  (can take a snapshot while recording).

- To start recording - press start button  and button becomes red , and will blink , indicating that recording started.
- To stop recording - press recording button  and button becomes :

Images thumbnails can be seen after snapshot is done and displays just date and time under thumbnail (Figure 19). Video thumbnail can be seen just after video is done and adds video duration under thumbnail (Figure 18).



Figure 16. Recorded video.



Figure 17. Recorded image.

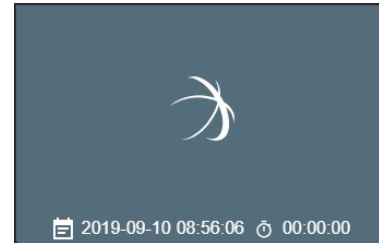


Figure 18. Recording video.



To record multiple signal inputs with pedals, do not forget to change source profile **ENABLE RECORDING KEYS** option in Recording settings. To setup pedals keys – see General settings.

During recording, user can expand input signal streaming window by pressing on the window. To minimize – press again on the window.

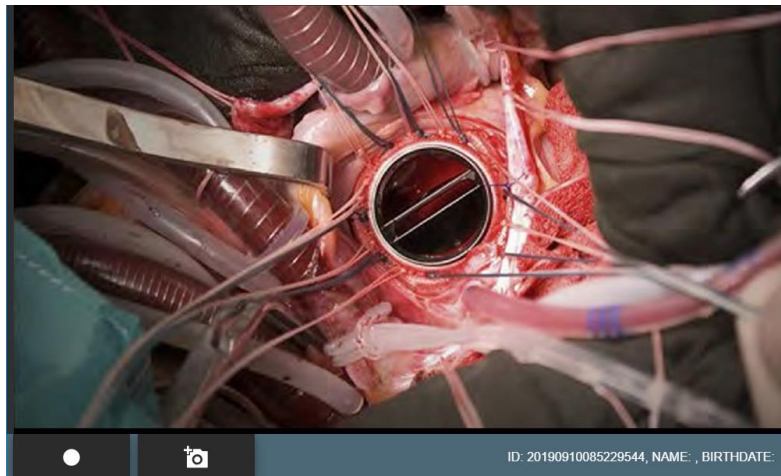



Figure 19. Maximized recording window.

To expand video or image - press on the recorded video or image thumbnail. To minimize – press on button  in the bottom right corner.

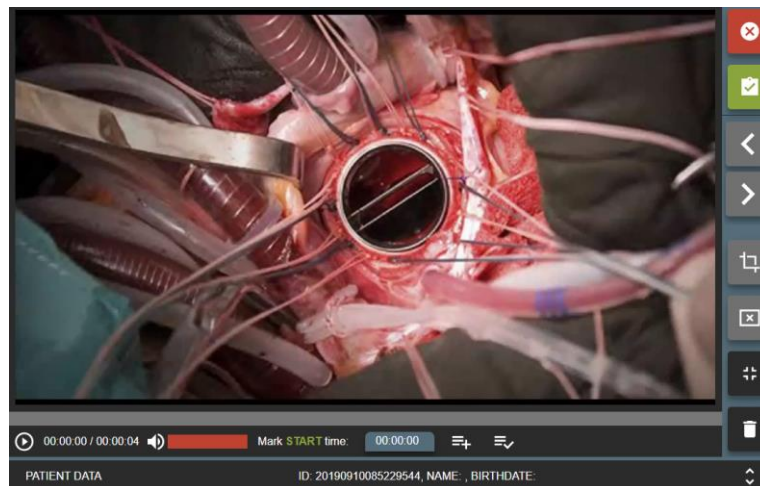


Figure 20. Maximized video.

Images or completed video can be deleted by pressing button  and confirming delete action.

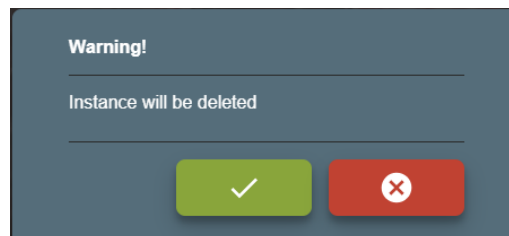



Figure 21. Deleting selected image/video.

To delete multiple images or video – press (to select) on thumbnail bottom (date and time bar) and press button .

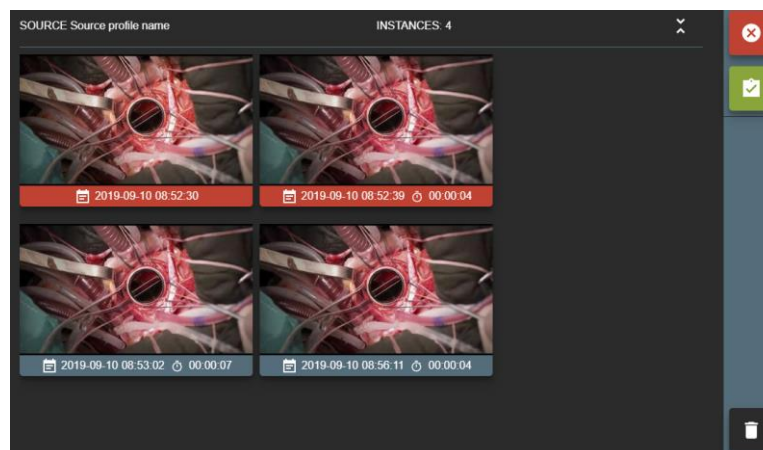
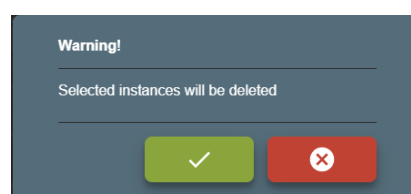

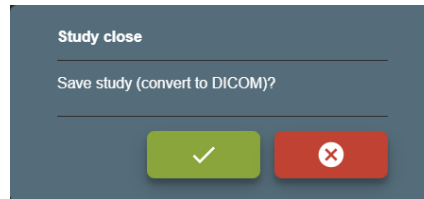


Figure 22. Selected multiple image/video.



*Figure 23. Delete multiple image/video.***Saving recorded study:**

Then recording completed (bad images or video was deleted or video trimmed) and patient data is correct – press save button  and confirm action to complete study.


*Figure 24. Close study and complete.*

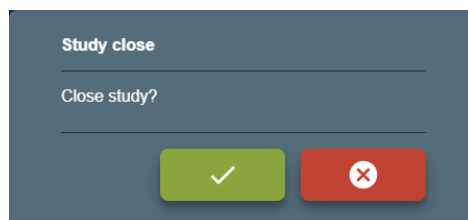
User will be redirected to TASKS window and can see information about saved and send study: files will be converted to DICOM format. After study is completed (converted to DICOM) – will try to send to hospital PACS (requires to setup remote DICOM archive in Network settings).



During conversion to DICOM – user will not be able to open this study. User can stop the task and roll back to image and video. After roll back task is completed – can open study for editing in CURRENT STUDY window.

After conversion complete – can open study in DICOM VIEWER window.


If user press close button  and confirm action - study will be closed (no conversion to DICOM). This is not recommended action, but in quick situations, where need to start new patient recording and previous study requires review/edit – press the button and confirm study close.

*Figure 25. Close study.*



## Search for patients and studies

Open search by pressing LOCAL button in main menu. Search result will be patients list with studies

(expand patient record by pressing button  and see studies). To get exact patient or study in search result, you can fill search field with patient ID, name, accession number, study description, study id and study UID. DATE field will allow search patients studies with desired study date. Search can be made by exact, partial word fragment or by several criteria's separated by space.

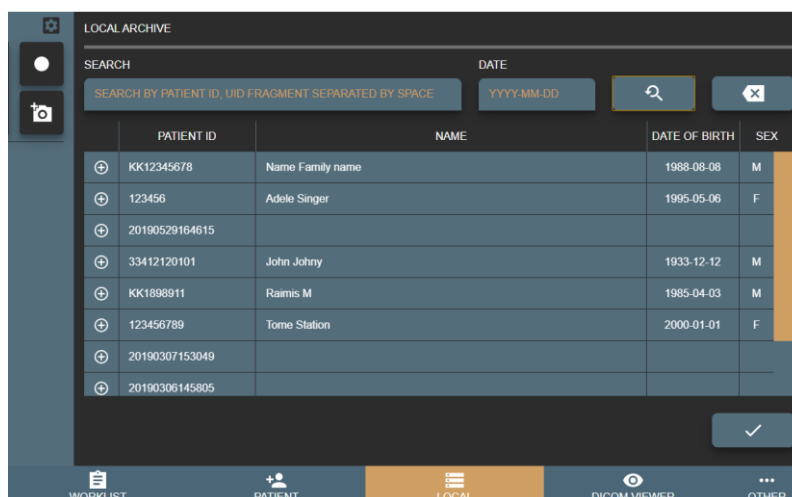


Figure 26. Searching patient in Local storages.

## Indication icons on select patient and his studies

There are multiple icons indicating the status of the study and other processes:

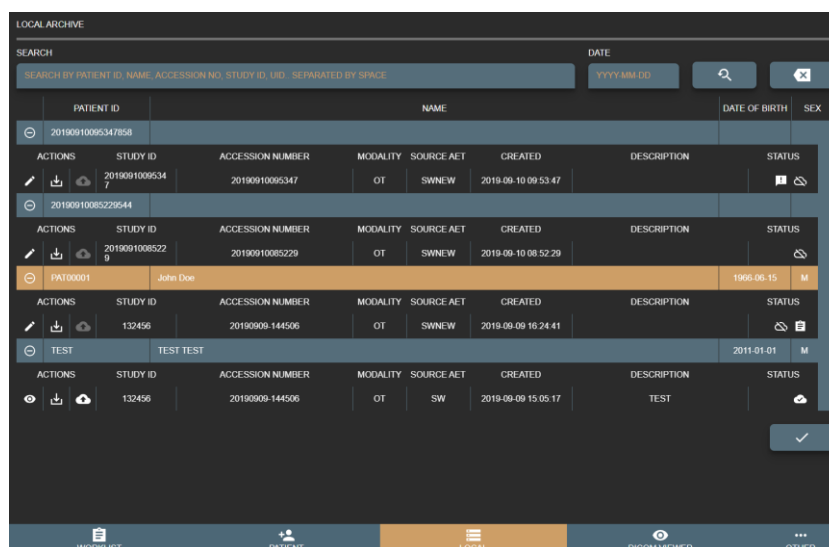


Figure 27. Patient study list.



Button to open not saved (not converted to DICOM format) study in CURRENT STUDY window for more changes.



Button to open already saved (converted to DICOM format) study in DICOM VIEWER window.



Button to export the study to local or external drive.



Button to forward study to hospital PACS (requires to setup remote DICOM archive in Network settings).



New study in the list, not reviewed.



Study is not stored in hospital PACS.



Study is stored in hospital PACS.




Study and patient information are selected from scheduled modality worklist.

## Trim video

This function is to cut good video parts and combine into new shorter video file. For example, if video recording started before patient comes into operating room or finished when operating room starts cleaning after surgery – user can remove these video parts. Can edit completed video and return to original as many times as you like. If video trim completed and saved - will override original video.

Main idea is to select desired scenes/video chunks of times (make time list) and combine into one video.

To trim video, follow steps bellow:

- Press on selected video thumbnail and open video.
- Manually select in the progress bar or write the start time of the video and press button :

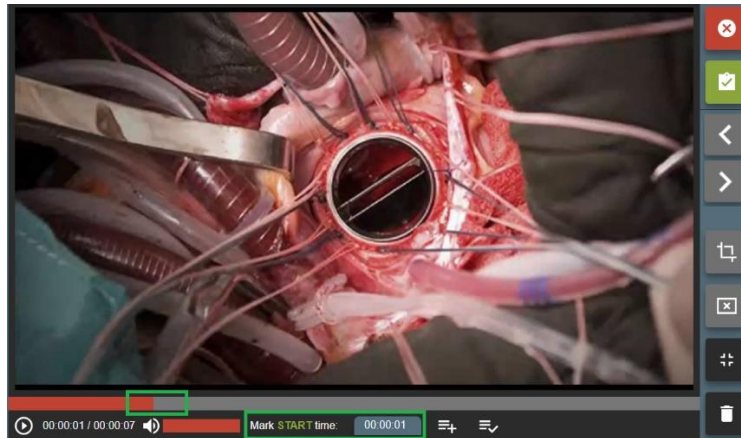


Figure 28. Trim start time.

- Then select in the progress bar or write the end time of the video and press :

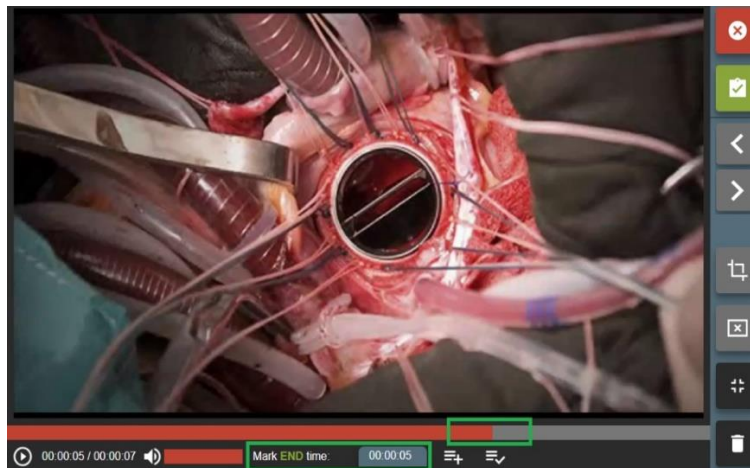


Figure 29. Trim end time.

- Will display times of video from where start and where to end video cut in the right upper corner:

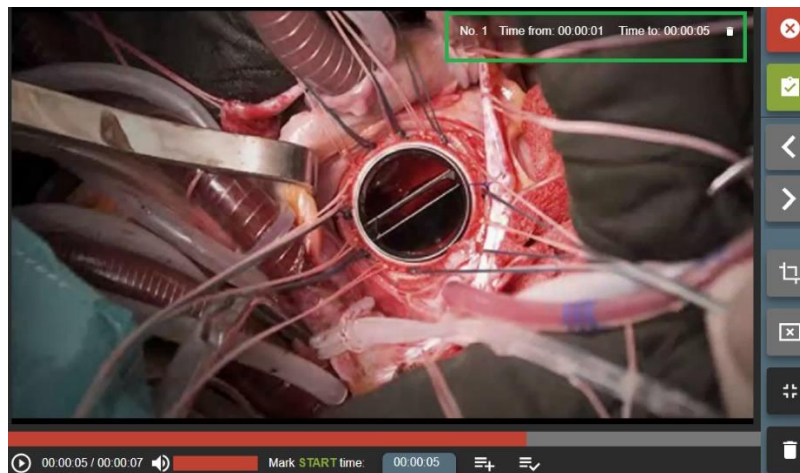



Figure 30. Trim time interval.

- Time periods can be updated, deleted or added more.
- To trim video – press button  and confirm video time pieces:

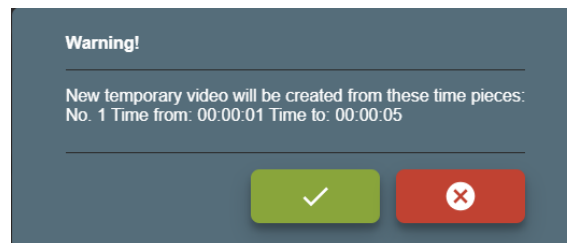



Figure 31. Make trim.

After a few seconds (depends on system load) will combine new temporary video. You can review video and see if all been done correctly. If some parts are missing – press cancel button  to remove temporary video and go back to original.



Video cut time error is +/- 1s (depends on video frame rate and frames on particular time).

- To save new video and replace original – press button .



Figure 32. Save or cancel modified video.

## DICOM Viewer

VS has integrated DICOM viewer and can view saved (converted to DICOM) or received from hospital PACS studies in DICOM VIEWER window.

Find patient study from LOCAL window and press button 

|         |  |  |          |                  |          |            |                     |             |            |   |
|---------|--|--|----------|------------------|----------|------------|---------------------|-------------|------------|---|
|         |  |  | TEST     | TEST TEST        |          |            |                     |             | 2011-01-01 | M |
| ACTIONS |  |  | STUDY ID | ACCESSION NUMBER | MODALITY | SOURCE AET | CREATED             | DESCRIPTION | STATUS     |   |
|         |  |  | 132456   | 20190909-144506  | OT       | SW         | 2019-09-09 15:05:17 | TEST        |            |   |

## Tasks

Tasks represents VS process actions, that can be done in background.

**Services:** In menu “Other ->Settings-> Storage -> Services” administrator can stop/start services.

VS uses services:

- STUDY TO DICOM SERVICE STATUS – responsible to save (convert to DICOM) studies, recommended always ensure, that this service is running.
- STUDY TO DICOM ROLLBACK SERVICE STATUS – responsible to convert back DICOM files to image and video format. This service is used to convert back DICOM files, because conversion fails or study needs more changes.
- FORWARD STUDY TO DICOM ARCHIVE SERVICE STATUS - responsible to send saved studies to remote PACS,
- EXPORT STUDY SERVICE STATUS - responsible to export study to external storage.

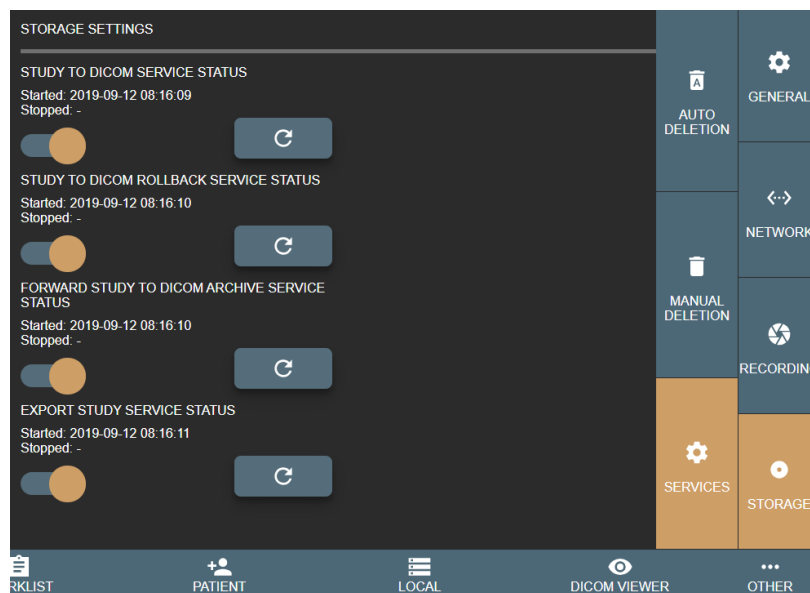


Figure 35. Services settings.

Each Service status can be checked by pressing refresh button .

**TASKS:** In menu “Others -> Task” user/administrator can check each study saving process and find their status. Task list is divided in 3 categories:

- NEW/STARTED – started or pending tasks.
- STOPPED – stopped tasks. User can try to load again later.
- COMPLETED – successfully finished tasks. All completed tasks without errors, will be deleted after 1 hour.






| TASKS   |  |  |   |
|---|--|--|---|
| NEW/STARTED   |  |  |   |
| <b>Send DICOM to remote DICOM archive (PACS)</b> Patient: ID: TEST, Name: TEST TEST<br>Started: - Stopped: - Completed: - Completed files: 0/0  |  |  |    |
| STOPPED   |  |  |   |
| <b>Send DICOM to remote DICOM archive (PACS)</b> Patient: ID: TEST, Name: TEST TEST<br>Started: 2019-09-10 10:24:38 Stopped: 2019-09-10 10:24:39 Completed: - Completed files: 0/3<br>Messages:<br>Failed to establish association: Connection refused: connect |  |  |   |
| COMPLETED   |  |  |   |
| <b>Send DICOM to remote DICOM archive (PACS)</b> Patient: ID: TEST, Name: TEST TEST<br>Started: 2019-09-10 10:07:57 Stopped: - Completed: 2019-09-10 10:07:57 Completed files: 3/3  |  |  |    |
| <b>Convert JPG/VIDEO to DICOM</b> Patient: ID: TEST, Name: TEST TEST<br>Started: 2019-09-10 10:07:56 Stopped: - Completed: 2019-09-10 10:07:57 Completed files: 3/3   |  |  |    |

Figure 36. Task list.

Buttons explanations:



Try run task again.



Stop running task.



Rollback the task. This button will appear on failed “CONVERT JPG/VIDEO to DICOM” task. Allow user to return all DICOM files to images or video for more study changes.



Delete task.

Tasks lists are refreshed automatically.

## Settings

MedDream Video viewing and converting functionalities may be customised via settings.

Customization possibilities:

Custom video settings.

Multi languages support: English, Lithuanian, Russian other languages by request.

Additional foot pedal support.

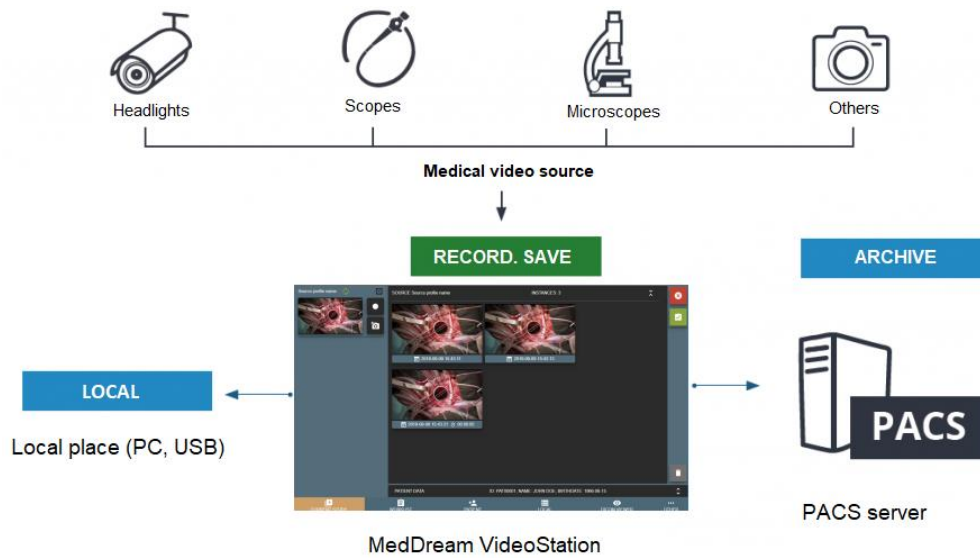
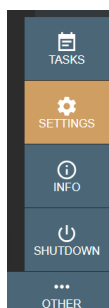


Figure 37. Connection diagram.

VS settings located in OTHER > SETTINGS of main menu.



In order to ensure successful VS work, the settings must be modified only by the system administrator.



Picture 38. SETTINGS menu item in OTHER expandable menu.

Settings are grouped in the following groups: GENERAL, NETWORK, RECORDING and STORAGE.



## General settings



Figure 39. VS general settings.

In GENERAL settings you can modify the following options:

- MODALITY – set DICOM modality attribute for studies without modality worklist. By default, after installation, recorded files modality will be set to OT. Can be changed according study type and we recommend choosing one of these modalities: <http://www.dicomlibrary.com/dicom/modality/>.
- SNAPSHOT KEY – pedal signal keys combinations to make image.
- PLAY/STOP KEY – pedal signal keys combinations to start or stop video recording.
- KEY BINDING LISTENER – function for retrieving the pedal signal keys.

Default, SNAPSHOT KEY and PLAY/STOP KEY are set, but it is recommended to review and update key combinations for every pedal. It is possible to add multiple key combinations (all pedals) for snapshot or video recording as long as they do not conflict with pressing habits.







Some pedals producing different signal key combination on longer press. It is recommended to consult with active personal about pedal pressing habits (how long and how they press on snapshot or video recording buttons).



When connecting pedal and keyboard, review SNAPSHOT or PLAY/STOP KEY settings and try to avoid pressing configured keys.

How to change or update key combinations:

- Press the button,  and it will change to  indicating, that started listening key press.
- Press the pedal button and will see KEY BINDING LISTENER will display key combination.
- Add key combination to SNAPSHOT or PLAY/STOP KEY by pressing  button. To remove previous key combination - press .

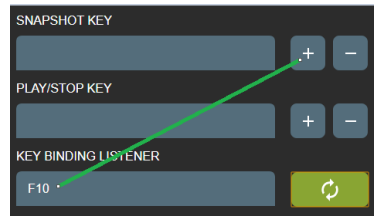


Figure 40. Shortcuts for recording and image making.

- User can add several possible keyboard combinations.

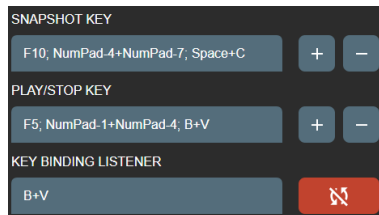




Figure 41. Shortcuts for recording and image making.

- After complete press button  to turn off key listener – will change to .
- After settings update, navigate to recording settings and change device profile key option (Recording settings > ENABLE RECORDING KEYS).
- 
- EXTERNAL KEYBOARD – enable to use physical keyboard connected to PC or windows keyboard on screen. Default is to use keyboard on screen due touch screen monitor, but sometimes monitor is hanged very high and cannot be controlled by hand. For this requires to connect mouse and keyboard.
- ON EXIT – ALSO SHUT DOWN PC - shut down PC after exiting the VS program. By default, this option is set to no. It may take some time (~3 - 20s) to stop process (complete recordings and shut down services).
- LOG FILE LOCATION - displays the location of log files.
- SYSTEM LOGGING – set logging level to None, Error, Info or Debug of all actions. The default, and recommended is turning on logs to Error level to identify system bugs or hazard situations. Log file can be viewed with text editor.
- CHARSET – set DICOM character set (0008, 0005) for studies to be encoded. For now, there is 3 common character sets: ISO\_IR 100 (Latin1), ISO\_IR 144 (Cyrillic) or ISO\_IR 192 (UTF-8). To support most of the characters – use ISO\_IR 192. But it is recommended to consult to your PACS administrator.



Try to set the same character set for the patient studies, try open one the same study and look for DICOM tag “*Specific Character Set*“(0008, 0005). Some PACS, during study import, will update patient name from DICOM file with different encoding – may lead to display incorrect patient name in the DICOM viewer (this will not change/damage any DIOCM files – just database record).

Once all settings are set, double check and press save the button



## Network settings

Network settings are grouped into three groups:

- LOCAL - network settings of local VS receiver, which handles received DICOM files (studies).
- REMOTE - network settings for hospital remote PACS. This allows to send saved studies to hospital PACS.
- WORKLIST - network settings for DICOM modality worklist server connection. This enables to search scheduled DICOM modality worklist (scheduled patient procedures).





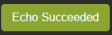
Remote hospital DICOM archive and DICOM modality worklist server settings can be the same or not – depends on hospital infrastructure. It is recommended to consult your DICOM archive or worklist server administrator.


## Local settings

Figure 42. Local VS settings.

In LOCAL settings of the NETWORK group you can view and modify VS DICOM file receiver options:

- AET TITLE – max 16 Latin1 characters. Requires to ask your administrator for this entity title to identify VS PC.
- HOST OR IP ADDRESS – VS PC host or IP address. It is recommended to set IP address for faster network lookup. For receiver it is recommended to leave 127.0.0.1 local IP address.
- PORT – max 65535 number. DICOM protocol mostly use 104 or 11112 ports that should not be reserved by OS process. Recommended to consult administrator. For receiver it is recommended to leave 104 port as it is.
- DICOM RECEIVER SERVICE STATUS – will show receiver status (start/stop date and time). Also, you can turn off receiver and refresh the status:
  - Press  to refresh the status info.

- Press  to check the receiver status: DICOM C-ECHO will be send to verify basic connectivity by DICOM protocol. In case of success, the  message will appear.

Once all settings are set, double check and press save button .

## Remote settings

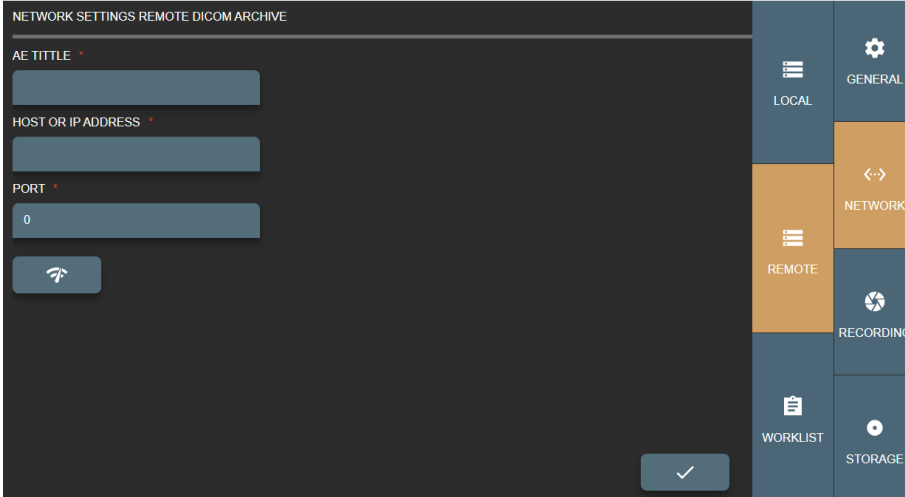




Figure 43. Remote DICOM archive settings.


In REMOTE settings of the NETWORK group you can view and modify options to connect remote hospital PACS:

- AE TITLE – max 16 Latin1 characters. Requires to ask your administrator for this entity title to identify remote PACS.
- HOST OR IP ADDRESS – PACS host or IP address. It is recommended to set IP address for faster network lookup.
- PORT – max 65535 number. DICOM protocol mostly use 104 or 11112 ports. Recommended to consult administrator.

Press  to check the remote PACS status: DICOM C-ECHO will be send to verify basic connectivity by DICOM protocol. In case of success, the  message will appear.



Sending DICOM studies from VS to DICOM archive typically requires LOCAL VS AE TITLE to be registered on remote DICOM archive.


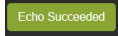
Once all settings are set, double check and press save button .

## Worklist settings

Figure 44. Worklist settings.

In WORKLIST settings of the NETWORK group you can view and modify the following options:

- MODALITY – set modality attribute to fetch from the hospital's Worklist server. By default, after installation, worklist modality will be set to OT.
- SCHEDULED AE TITLE – set the AE TITLE to fetch from the hospital's Worklist server.
- AET TITLE – max 16 Latin1 characters. Requires to ask your administrator for this entity title to identify DICOM modality worklist server.
- HOST OR IP ADDRESS – worklist server host or IP address. It is recommended to set IP address for faster network lookup.
- PORT – max 65535 number. DICOM protocol mostly use 104 or 11112 ports. Recommended to consult administrator.
- CHARSET – setup encoding for worklist results. Result comes in DICOM standard and most results do not define encoding – need to be set and tested manually.
- WORKLIST WILDCARD – add wild card symbol “\*” on search parameters. Some worklist servers do not support this, for example on patient ID or accession number and requires to search exact patient ID or accession number. Recommended to consult with administrator (typically this information can be found in worklist server or PACS conformance statement document).

Status checking control. Press  to check the remote DICOM archive status: DICOM C-ECHO will be send to verify basic connectivity by DICOM protocol. In case of success, the  message will appear.



Receiving modalities worklist typically requires LOCAL VS AE TITLE to be registered on hospital's Worklist server.

Once all settings are set, double check and press save button



## Recording settings

Recording settings are used for configuring video input sources. It allows define several configurations for one input source, naming each configuration as profile. Recording settings window display all the configured profiles.

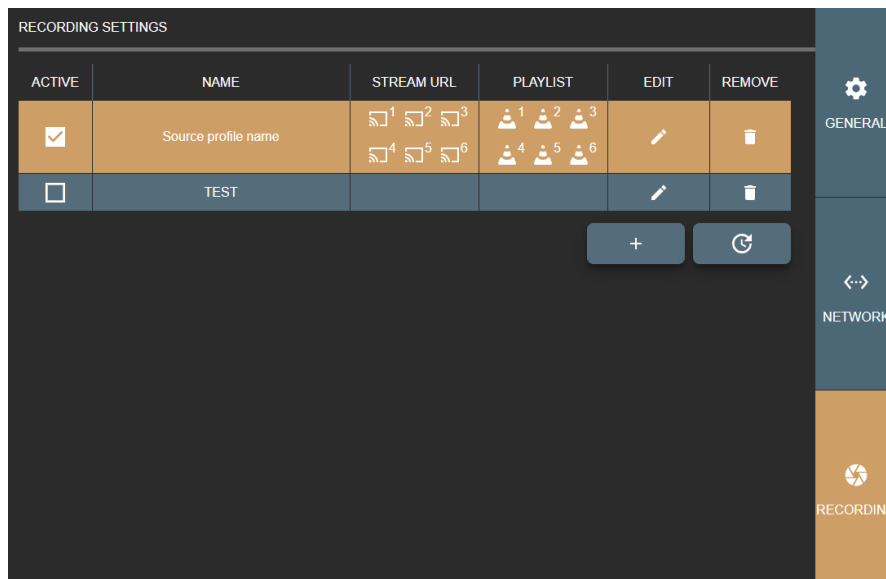


Figure 45. Recording settings window with list of configured input source profiles.

The following actions are allowed in input source list of recording settings window:



Activate source profile. After application start, will start active devices



Update or change source profile settings.



Delete source profile. If source is active – requires to stop source.



Reload all active sources.



Add new source profile.



Copy full stream address.



Download VLC media player format playlist file, that contains the same stream address.



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.

Clicking the update  or add new  controls in the profiles list, opens the RECORDING PROFILE SETTINGS window to configure the recording profile.

Also, there is direct access to recording profile settings from near stream window - settings button:

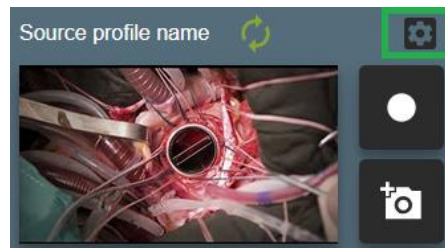


Figure 46. Fast entering into profile settings.

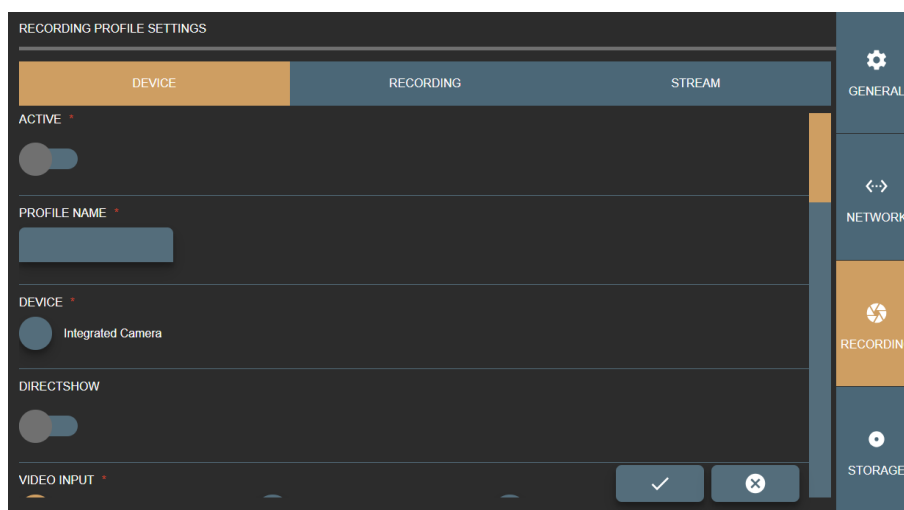


Figure 47. Device window of the Recording profile settings.

Recording profile settings are grouped into three groups:

- **DEVICE** - contains input source options. Affects preview window, signal type.
- **RECORDING** - contains recording process setup and configuration options. For recording. Recommended select the same resolution and frame rate as in **DEVICE** options.
- **STREAM** - contains streaming set available when **DIRECTSHOW** disabled.

GUI validates and checks available recording device option **combination** by DICOM TRANSFER SYNTAX option.



Requires to ensure, that PACS supports transfer syntax(ask PACS administrator or see PACS DICOM conformance statement document) and recorder DICOM files will be accepted by PACS

Some options can be updated in  
C:\MedDreamStation\recorder\configurationSettings.json, but during re-installation – will be overridden.

## Device settings

In DEVICE window of the RECORDING PROFILE SETTINGS you can view and modify options:

- **ACTIVE** – enable or disable recording device profile.
- **PROFILE NAME** – enter or edit name for the profile. Each input source profile is identified by profile name. If user enters the already existing profile name, the system will overwrite the existing input source profile data. In order to create a new profile, enter different unique profile name.
- **DEVICE** – select found video devices, like camera or video capture board.



If cannot see any devices or some is missing – please check connection cables to the device. If problem persist - check Windows OS device list, if all drivers installed properly.

- **DIRECTSHOW** - enables getting input device signal through Windows OS DirectShow API. Disabled by default. VS application is using YUAN video capture board SDK API and can access capture board signal with lowest latency compared to DirectShow.

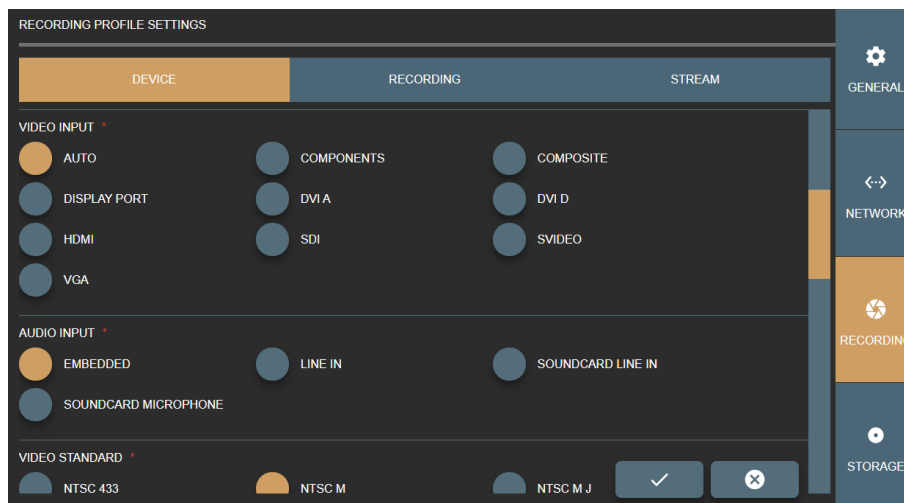


Figure 48. Specifying video and audio inputs in the Recording profile Device settings.

- **VIDEO INPUT** – specify the type of video input. The default selection is AUTO, and system tries to find capture board signal. But it's recommended to consult with VS PC administrator about capture board input type and select the correct one.
- **AUDIO INPUT** – specify, how to get audio signal. This option depends on device input or device itself. For example, default selection EMBEDDED should work with simple USB camera with microphone array, or device with HDMI video input (audio should come by the same cable).

With other audio capture boards or other audio input device signals, it is required to see and setup WINDOWS OS audio devices or redirect audio signal to capture board. This situation is a little bit tricky and requires testing to configure input signal environment properly.



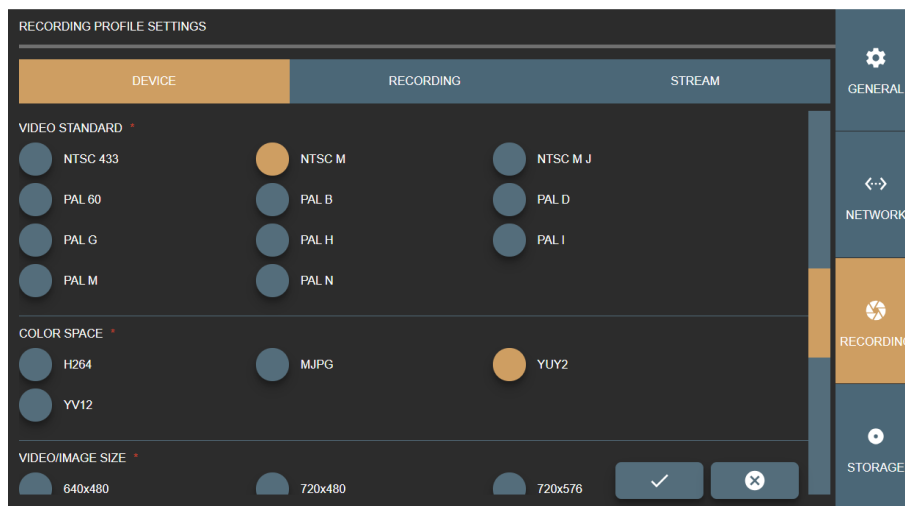


Figure 49. Specifying video standard and color space in the Recording profile Device settings.

- VIDEO STANDARD – specify standard for the analog video signal, if creating profile for analog input device.

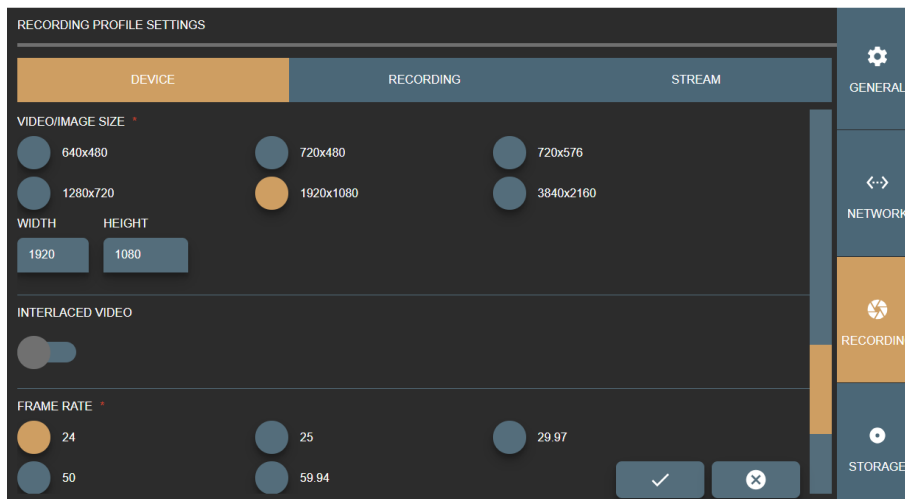


Figure 50. Specifying video and image attributes in the Recording profile Device settings.

- Specify other attributes of the video output of the profile:
  - COLOR SPACE - select color space.
  - VIDEO/IMAGE SIZE – select or fill video or image resolution.

VS software will try to scale medical device output signal to match settings. It is recommended to select close enough or the same resolution for medical device output signal to ensure best quality. Use WIDTH and HEIGHT entry controls to adjust the selected size or enter the custom size.

- INTERLACED VIDEO – set if video signal is interlaced.
- FRAME RATE – set wanted frame rate.



Figure 51. Display calibration options in the Recording profile Device settings.

- DISPLAY CALIBRATION – enhance video for better view.

## Recording settings

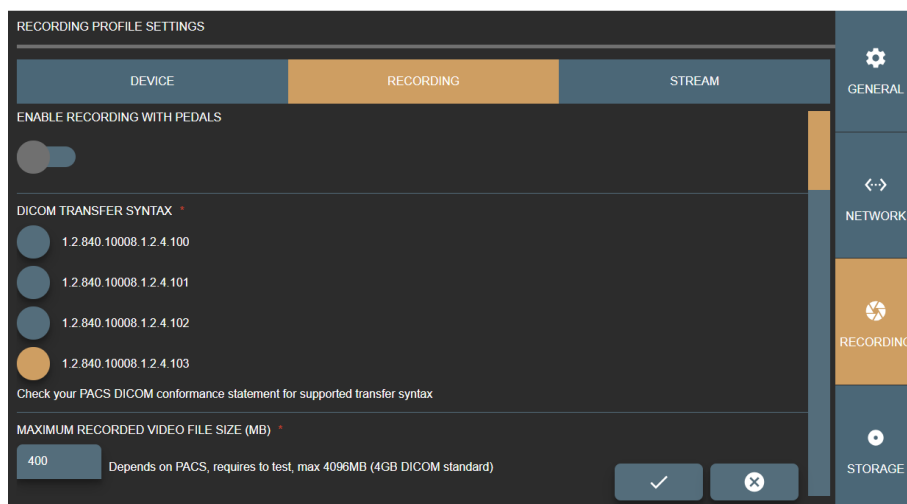


Figure 52. Recording and video output options in the Recording profile Recording settings.

In RECORDING window of the RECORDING PROFILE SETTINGS, you can view and modify the following options:

- ENABLE RECORDING KEYS – enable to control profile source recording with pedals (see pedal setup description in General settings on page 49).
- DICOM TRANSFER SYNTAX – select the transfer syntax for DICOM file:
  - 1.2.840.10008.1.2.4.100 and 1.2.840.10008.1.2.4.100 - MPEG2 video with strict combination options for older medical devices.
  - 1.2.840.10008.1.2.4.102 and 1.2.840.10008.1.2.4.101 - MPEG2 video for older medical devices.
  - 1.2.840.10008.1.2.4.102 and 1.2.840.10008.1.2.4.102 - MPEG-4 video options for most of devices.

- 1.2.840.10008.1.2.4.102 and 1.2.840.10008.1.2.4.103 - MPEG-4 video with strict combination options.

It is important to select DICOM transfer syntax according hospital PACS. Some archives are very old and do not support some of transfer syntax. Recommend to consult with administrator (see DICOM archive conformance statement document).

- MAXIMUM RECORDED VIDEO FILE SIZE (MB) – enter the maximum allowed size for recorded video. The maximum value according to DICOM standard is 4096Mb, but it may depend on PACS (how big files can be accepted) and requires testing.
- VIDEO/IMAGE SIZE – select resolution.

VS software will try to scale medical device output signal to match settings. It is recommended to select close enough or the same resolution for medical device output signal to ensure best quality.

RECORDING PROFILE SETTINGS

DEVICE RECORDING STREAM

ENCODER

AMD VCE INTEL MEDIA SDK NVIDIA CUDA

NVIDIA NVENC SOFTWARE

ENCODER FORMAT

H264

VIDEO/IMAGE SIZE

1280x720 1920x1080

ENCODING PROFILE

HIGH

ENCODING PROFILE LEVEL

41

ENCODING MODE

CBR VBR

ENCODING BIT RATE

8388608 For CBR, 8\*1024\*1024 = 8388608 = 8Mbps

ENCODING COMPLEXITY

0 0 - best speed for low resources, 6 - best quality

ENCODING GROUP OF PICTURES(GOP)

48 Max 255, recommended 'frame rate' \* 2 (every 2s), 0 - auto

QUANTIZER MIN, MAX

17 28 0 - best quality, 51 - worst quality, recommended 17-28

FRAME RATE

24 25 29.97

AUDIO ENCODER FORMAT

✓ ✕

Figure 53. Video encoding options in the Recording profile Recording settings.

- ASPECT RATIO X,Y – set aspect ratio by resolution or manually change values, that ensure square pixel aspect ratio.

- ALLOW DOWN SCALE – set restriction to re-scale image/video. Recommended leave as it is, but in some cases it allows ensure original resolution as device signal resolution or expand to fit DICOM standard.
- ENCODER – define, what PC resources are used during video compression. The default option is SOFTWARE, and the CPU is used for video compression. If your system supports GPU video processing and is properly configured, select the other following option: ADM VCE, INTEL MEDIA SDK (requires install Intel media SDK), NVIDIA CUDA, NVIDIA NVENC.
- Customize video compression by setting the parameters:
  - ENCODER FORMAT – set available encode format.
  - ENCODING PROFILE – set available encoding profile.
  - ENCODING PROFILE LEVEL – set available encoding profile level.
  - ENCODING MODE – set available encoding mode.
  - ENCODING QUALITY – enter the value from 0 for the worst quality to 10000 for the best quality encoding for VBR encoding mode. The default value is 8500.
  - ENCODING BIT RATE – enter bit rate value for CBR encoding mode. The higher bit rate means the higher quality. Default value is 8388608 (what equals to 8Mbps).
  - ENCODING COMPLEXITY – enter the values from 0 for the best speed to 6 for the best quality.
  - ENCODING GROUP OF PICTURES (GOP) – enter values from 0 up to 255. 0 is for auto selection. The recommended value is frame rate multiplied by 2.
  - QUANTIZER – enter MIN and MAX values from 0 for the best quality to 51 for the worst quality. The default and recommended values are from MIN 17 to MAX 28.



Figure 54. Audio encoding options in the Recording profile Recording settings.

- Customize audio encoding and compression by setting the parameters:
  - AUDIO ENCODER FORMAT – set available format.
  - AUDIO CHANNELS – set available channels.
  - AUDIO BITS – set available bits.

- AUDIO FREQUENCY – set available frequency.
- AUDIO BIT RATE – enter bit rate value. The higher bit rate means the higher quality.
- AUDIO VOLUME – enter audio volume from 0 to 100 percent. The default value is 100 percent.

## Stream settings

To view and edit the streaming settings for the profile, select the STREAM menu in RECORDING settings.



If profile has DIRECTSHOW enabled in DEVICE settings, streaming is not possible and the STREAM settings menu is not available.

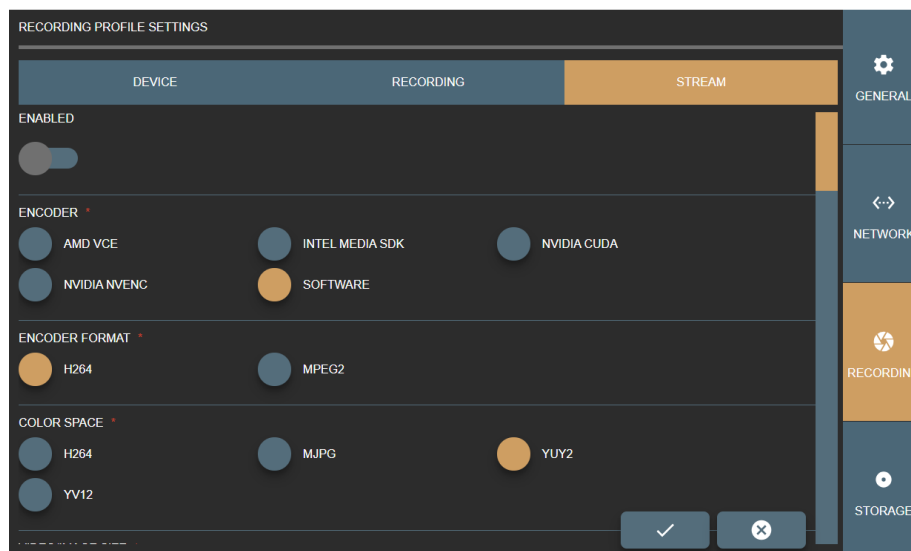


Figure 55. Video encoding options in the Recording profile Stream settings.

In STREAM window of the RECORDING PROFILE SETTINGS you can view and modify the following options:

- ENABLED – enable or disable input source signal to stream by RTSP protocol via network for the profile.
- ENCODER – define, what PC resources are used during stream compression. The default option is SOFTWARE, and the CPU is used for video compression. If your system supports GPU video processing and is properly configured, select the other option from following: ADM VCE, INTEL MEDIA SDK (requires install Intel media SDK), NVIDIA CUDA, NVIDIA NVENC.
- ENCODER FORMAT – set available format for stream output.
- COLOR SPACE – set available color space for the stream output.

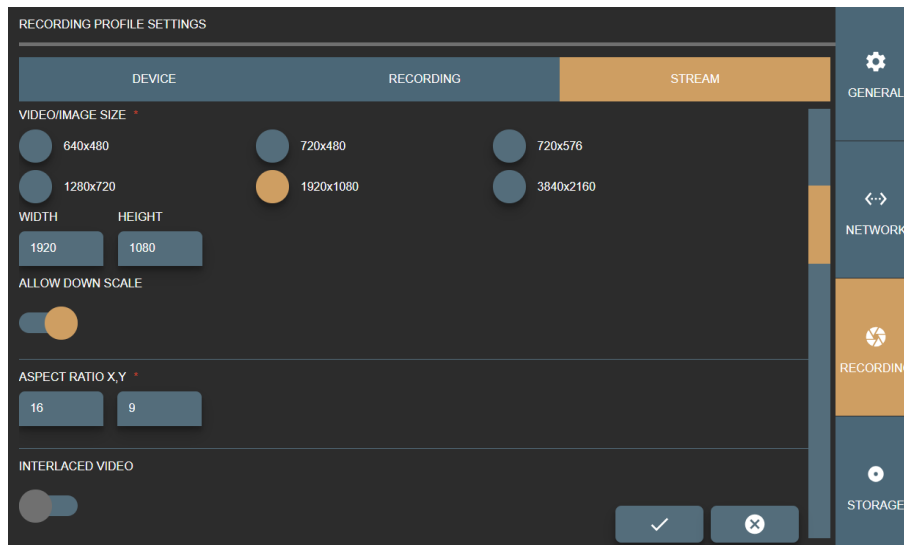


Figure 56. Stream output options in the Recording profile Stream settings.

- VIDEO/IMAGE SIZE – set available video resolution.

It is recommended to select close enough or the same resolution for medical device output signal to ensure best quality. Use WIDTH and HEIGHT entry controls to adjust the selected size or enter the custom size: the controls are automatically filled with values of the selected option.
- ALLOW DOWN SCALE – set restriction to re-scale image/video. Recommended leave as it is, but in some cases it allows ensure original resolution as device signal resolution or expand to fit DICOM standard.
- ASPECT RATIO X,Y – set aspect ratio by resolution or manually change values.
- INTERLACED VIDEO – enables interlace. The default value is disabled.

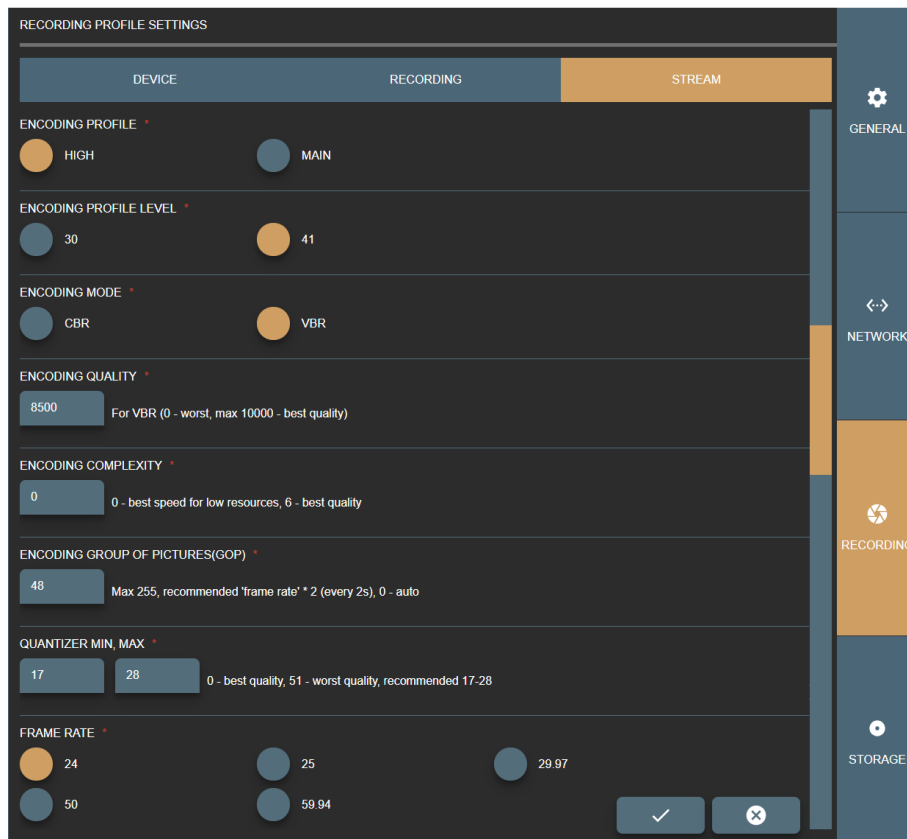


Figure 57. Stream video compression options in the Recording profile Stream settings.

- Customize stream video compression by setting the parameters:
  - ENCODING PROFILE – set available encoding profile.
  - ENCODING PROFILE LEVEL – set available encoding profile level.
  - ENCODING MODE – set available encoding mode.
  - ENCODING QUALITY – enter the value from 0 for the worst quality to 10000 for the best quality encoding for VBR encoding mode. The default value is 8500.
  - ENCODING BIT RATE – enter bit rate value for CBR encoding mode. The higher bit rate means the higher quality. Default value is 8388608 (what equals to 8Mbps).
  - ENCODING COMPLEXITY – enter the values from 0 for the best speed to 6 for the best quality.
  - ENCODING GROUP OF PICTURES (GOP) – enter values from 0 up to 255. 0 is for auto selection. The recommended value is frame rate multiplied by 2.
  - QUANTIZER – enter MIN and MAX values from 0 for the best quality to 51 for the worst quality. The default and recommended values are from MIN 17 to MAX 28.
  - FRAME RATE – set available frame rate.

RECORDING PROFILE SETTINGS

DEVICE RECORDING **STREAM**

AUDIO ENCODER FORMAT \*  
☒ AAC ☐ MP3

AUDIO CHANNELS \*  
☐ 1 ☒ 2

AUDIO BITS \*  
☒ 16 ☐ 20 ☐ 24

AUDIO FREQUENCY \*  
☐ 32000 ☐ 44100 ☒ 48000

AUDIO BIT RATE \*  
 128\*1024 = 131072 = 128kbps, max MPEG2 384kbps, H246 496kbps

AUDIO VOLUME \*

GENERAL NETWORK **RECORDING** STORAGE

✓ ✗

Figure 58. Stream audio options in the Recording profile Stream settings.

- Customize stream audio encoding and compression by setting the parameters:
  - AUDIO ENCODER FORMAT – set available format.
  - AUDIO CHANNELS – set available channels.
  - AUDIO BITS – set available bits.
  - AUDIO FREQUENCY – set available audio frequency.
  - AUDIO BIT RATE – enter bit rate value. The higher bit rate means the higher quality. Default value is 131072.
  - AUDIO VOLUME – enter audio volume from 0 to 100 percent. The default value is 100 percent.

RECORDING PROFILE SETTINGS

DEVICE RECORDING **STREAM**

USER NAME \*

USER PASSWORD \*

PORT \*

GENERAL NETWORK **RECORDING** STORAGE

✓ ✗

Figure 59. Real Time Streaming Protocol (RTSP) options in the Recording profile Stream settings.

- STREAM USER NAME and PASSWORD – enter RTSP stream security option.
- STREAM PORT – enter free RTSP stream port number. For multiple profiles with stream enabled – set different port numbers. It is recommended to consult with network administrator for avoiding conflict with other streams.

Press save button  to create or update profile.



Or press cancel button  to discard the changes.

## Storage settings

Customize Storage settings to manage disc space and services. Storage settings are grouped into three groups:

- AUTO DELETION – setup space monitoring to delete old studies.
- MANUAL DELETION - manual delete studies.
- SERVICES – handle system services(turn off/on, view status).

## Auto deletion settings

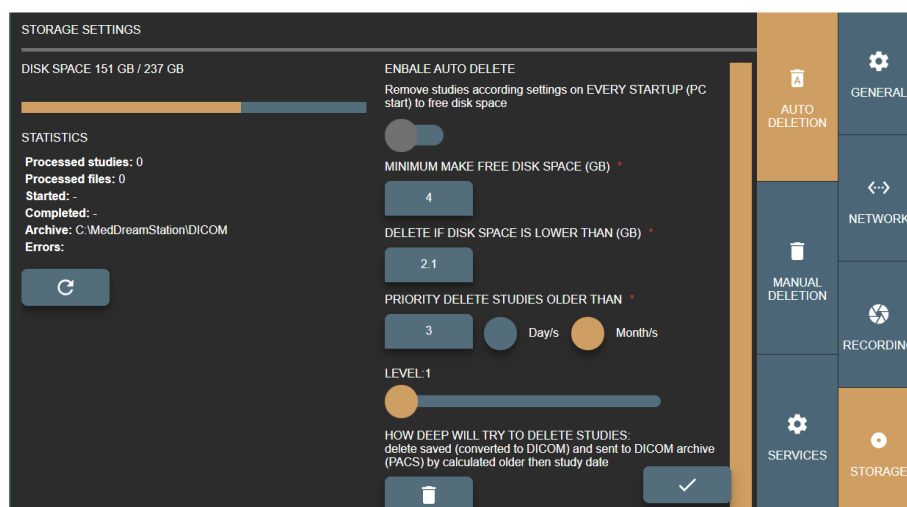



Figure 60. Auto deletion page in Storage settings.

Auto delete main idea is to free space on VS application startup (on computer startup starting application).



On Windows OS it is recommended to have at least more than 2GB free space to function properly.

On the left side of the Auto Deletion page you can see the information about disk space, archive location, and statistics of the last auto deletion process. Statistics can be updated by pressing refresh button .

On the right side of the Auto Deletion page you can set the following settings for automatic deletion process:

- ENABLE AUTO DELETE – turn on auto delete.
- MINIMUM MAKE FREE DISK SPACE (GB) – specify how much space to make free.
- DELETE IF DISK SPACE IS LOWER THAN (GB) – specify required empty disk space, when to trigger auto delete function at VS application startup (on computer startup).



If parameter DELETE IF DISK SPACE IS LOWER THAN (GB) is set to 5GB and MINIMUM MAKE FREE DISK SPACE (GB) value is 2.1GB – auto deletion expected result will be 7.1GB disk free space.

- PRIORITY DELETE OLDER THAN – specify how old studies should be deleted from current date in days or months.
- LEVEL – specify the condition for how deep the system should try to delete studies. Auto delete process have number of steps to free space by finding studies and removing them to meet desired free space (MINIMUM MAKE FREE DISK SPACE (GB)). The following levels are allowed:
  1. delete saved (converted to DICOM) and sent to DICOM archive (PACS) by calculated older than study date,
  2. delete saved (converted to DICOM) and sent to DICOM archive (PACS),
  3. delete received studies by calculated older than study date,
  4. delete received studies,
  5. delete saved (converted to DICOM) and NOT sent to DICOM archive (PACS) by calculated older than study date,
  6. delete saved (converted to DICOM) and NOT sent to DICOM archive (PACS),
  7. delete NOT saved (not converted to DICOM) by calculated older than study date,
  8. delete NOT saved (not converted to DICOM),
  9. delete by calculated older than study date,
  10. delete any.

Save changes by pressing button



To start auto delete manually – press on button



(requires to activate ENABLE AUTO DELETE).

## Manual deletion

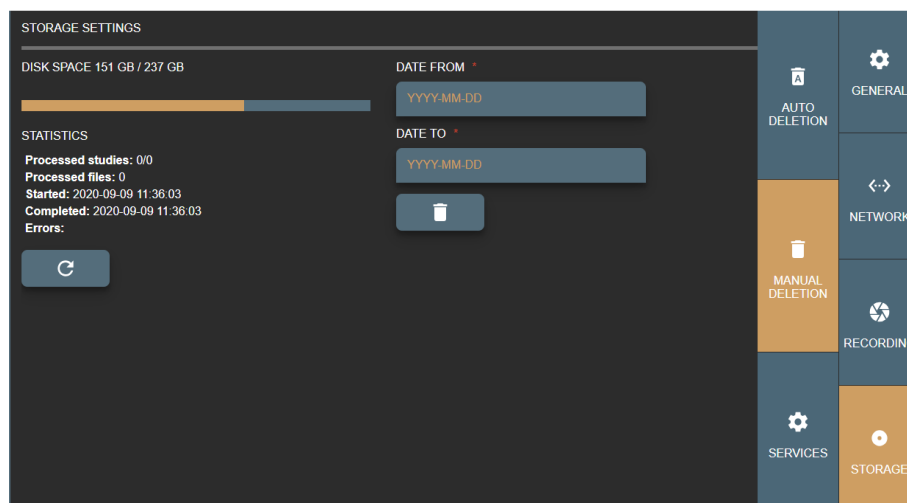



Figure 61. Manual deletion page in Storage settings.

Manual deletion main idea to delete all studies that is created between date range. To delete the studies, apply the following steps:

- In DATE FROM field enter the start date, when studies were created.
- In DATE TO field enter the end date, when studies were created.
- When dates are entered, press delete  button.

On the left side of the Manual Deleting page you can see the information about disk space, and statistics of the manual deletion process. Statistics can be updated by pressing refresh button



## Services

In Services page you can see the status of system services.

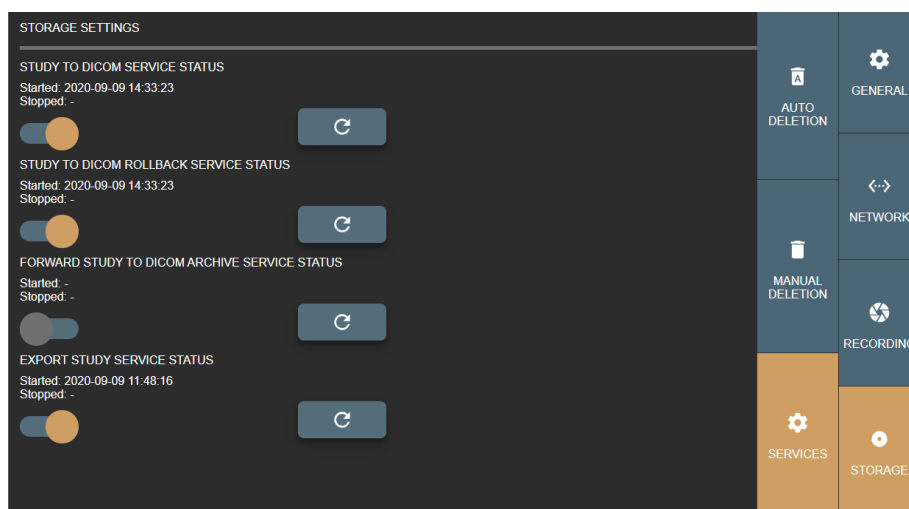


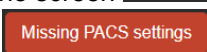


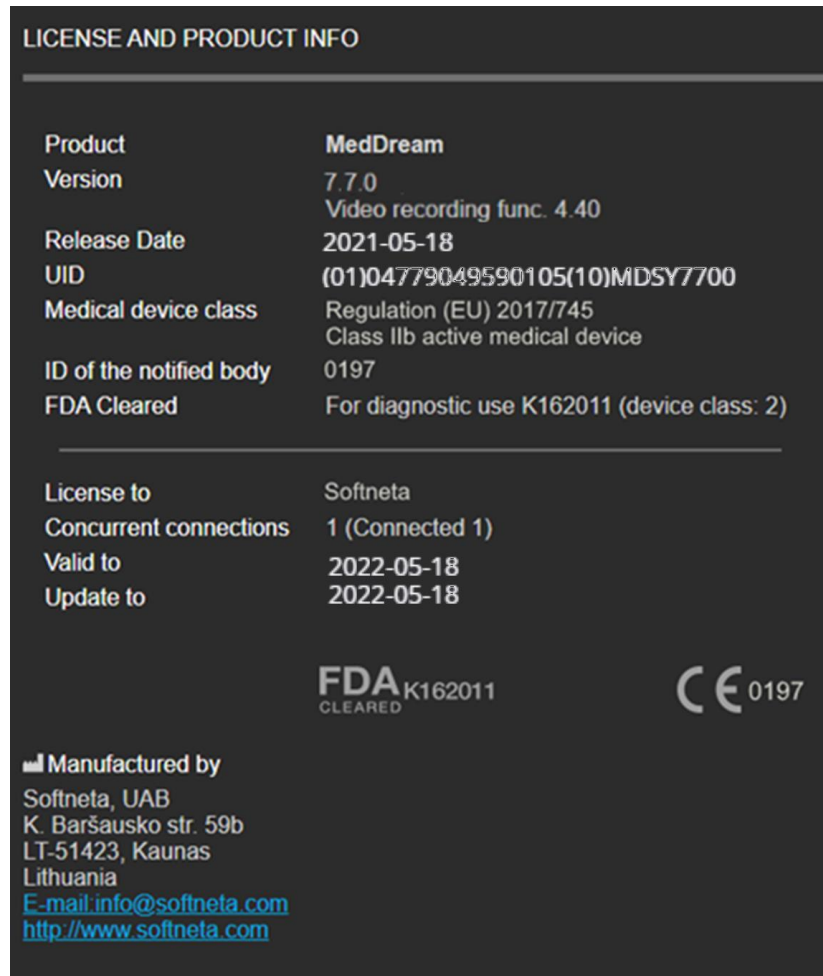
Figure 62. Services page in Storage settings.

Service can be started/stopped by clicking on/off control . The service status is automatically updated, and the information message is displayed on the screen . If the status cannot be changed, the error message is displayed on the screen . In such cases you should fix an error (for example, go to the network settings and enter the settings for DICOM archive), and then try to start the service.

Service status information can also be updated by pressing refresh button .

## About VS and license

Information about the product is displayed on the left side of the License and product info window.



**LICENSE AND PRODUCT INFO**

|                         |   |
|-------------------------|---|
| Product                 | MedDream  |
| Version                 | 7.7.0<br>Video recording func. 4.40                         |
| Release Date            | 2021-05-18  |
| UID                     | (01)04779049590105(10)MDSY7700                              |
| Medical device class    | Regulation (EU) 2017/745<br>Class IIb active medical device |
| ID of the notified body | 0197  |
| FDA Cleared             | For diagnostic use K162011 (device class: 2)                |

|                        |                 |
|------------------------|-----------------|
| License to             | Softneta        |
| Concurrent connections | 1 (Connected 1) |
| Valid to               | 2022-05-18      |
| Update to              | 2022-05-18      |

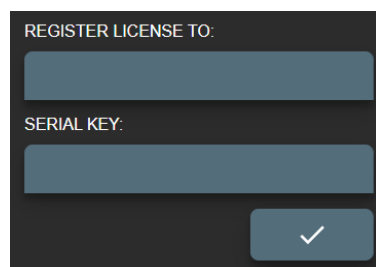
**FDA** K162011  
CLEARED

**CE** 0197

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<http://www.softneta.com>

Figure 63. About product.

To register or update the license, use the license registration form on the right side of the License and product info window:



REGISTER LICENSE TO:

SERIAL KEY:

Figure 64. License registration form.

- In REGISTER LICENSE TO field enter the organization or end user name.
- In SERIAL KEY field enter the serial key, that you have got from software provider.

Press registration button





Registration requires internet access to <https://lic.softneta.com>.

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FDA cleared

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