Medecom
communicating imaging

Med Diag

Diagnostic Workstation for Digital Radiology

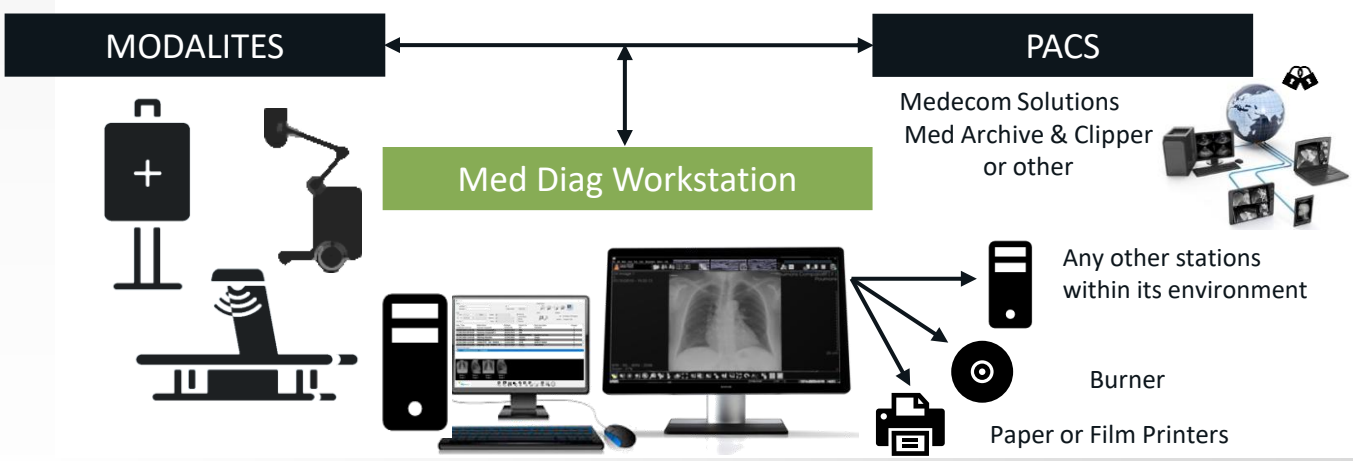
Features

- ✓ **Multimodality** on a single solution :
  - **CR & DR**
  - **Display of static or dynamic images: ultrasound, angiography, fluoroscopy**
  - **Mutli-slice images**
- ✓ **Manufacturer independent**, display exams regardless of the brand of the modality. The ability to automatically adapt the images to different manufacturers optimizes the reading of exams.
- ✓ **Viewing current and prior exams** makes it easier to direct compare exams
- ✓ **Numerous measurement tools and wide range of tools dedicated by displayed modality are available** such as pan, zoom, video inversion, high-performance image processing
- ✓ **Indexing pathological images to facilitate the safeguarding and export of images of interest**: these images are made available for illustration use or for case studies
- ✓ **SR report module** offers management of templates displayed automatically according to the exams performed and the user
- ✓ **Customized printing** by advanced configuration

How does the Med Diag optimize the Workflow?

Compliant to DICOM & HL7 standards, and thanks to dedicated tools available for the different viewed modalities, Med Diag has been developed to easily communicate with the acquisition workstations, to PACS and other printers defined by specific configuration.

Workflow Optimization



Medecom is a privately owned company established in 2000. Medecom has over 5 000 installations in 70 countries through a strong distributor network & OEM agreements.

Med Diag

Diagnostic Workstation for Digital Radiology

Med Diag workstation in its environment

☑ **Quick and easy**
User-friendly access to exams

☑ **color screen** dedicated to view the exam list

☑ **Mouse configurated** for quick and easy access to all functionalities available

☑ **High-resolution** diagnostic display that meets medical standards

Digital Radiology Display & Stitching Module

Med Diag does more than just display Bone/Lung images. This workstation can also **display any other modality (optional for mammography or 3D images).**

Functionalities allow to display tools dedicated to the selected modality.

Access to simple and complex measures is facilitated

- ✓ Hip dysplasia
- ✓ Meary
- ✓ Cardio Thoracic Index
- ✓ Hip/ Column deviation
- ✓ Occipital Axis
- ✓ Hallus valgus
- ✓ Coxometry
- ✓ TA-GT (Patellar translation)
- ✓ Angles
- ✓ Gonometry

Image treatments can be applied. These processes can be configured according to the type of exams and user preferences.

Access to a **wide range of predefined or customizable** print templates guide and enable the printing of exams and reports.

The **stitching module** allows the reconstruction of images of the lower limbs or the spine and the realization of Cobb angles or Gonometry measurements. The measurements can be saved and printed.

Archiving system

Medecom offers a secure archiving system: Med Archive with a capacity adapted to the needs.

The installation of Med Diag and Med Archive facilitates pre-fetching and auto-fetching for the comparison of exams.

Recommended hardware configuration

- ✓ Operation System: Professional Windows 10 or 11 (64 bits)
- ✓ Disk space requirements: 1 Gb for the software
- ✓ Technical features:
  - 16 Gb of RAM
  - 512 MB MIN graphics card compatible to OpenGL 3.2

Indications for use

CE 1639 FDA

The Med Diag software is a Class IIa medical device.

Notified Body SGS : CE 1639 - Manufacturer : Medecom

Please always consult the complete User Manual before use and read all instructions carefully to ensure the correct use of your medical device.

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EU Quality Management System Certificate FR25/00000027

The management system of

MED.E.COM s.a.r.l.

31 rue du Père Gwenaël – 29470 Plougastel-Daoulas, France

SRN Number: FR-MF-000003036

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 29 January 2025 until 20 January 2030 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 20 July 2029

Issue 2. Certified since 20 January 2025

Authorised by
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EU Quality Management System Certificate FR25/00000027, continued

MED.E.COM s.a.r.l.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa devices:
MDA0315; MDS1010

MEDXR software intended for acquisition, processing, display and communication of radiographic images, for diagnosis by a healthcare professional. Model: Med X-Ray.
[Basic UDI-DI: 3665587ACQUISITION00001YU]

MEDWS software intended for processing, advanced visualization, and communication of radiographic images, for diagnosis by a healthcare professional. Models: MedMammo; MedView; MedDiag.
[Basic UDI-DI: 3665587DIAGNOSIS0000001LD]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - FR/MD/238551 - S2A 7.2 + CTC
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: Correction of SRN Number

Certificate FR12/01144

The management system of

MED.E.COM s.a.r.l. trading as MEDECOM

31 rue du Père Gwenaël – 29470 Plougastel-Daoulas, France

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and development, production, sales and servicing of software solutions for digital radiology.

This certificate is valid from 28 June 2024 until 28 June 2027 and remains valid subject to satisfactory surveillance audits.
Issue 9. Certified since 29 June 2012

Authorised by
Jonathan Hall
Global Head - Certification Services

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