DigiMedX DigiMedX FP DigiMedX HR

(with MegXsoft acquisition software)

User Manual



WARNING

X-RAY EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATOR UNLESS MEASURES OF PROTECTION ARE STRICTLY OBSERVED.

Though this equipment is built to the highest standards of electrical and mechanical safety, the useful X-ray becomes a source of danger when used by unauthorized or unqualified operators. Excessive exposure to X-radiation causes damage to human tissue.

Therefore, adequate precautions must be taken to prevent unauthorized or unqualified persons from operating this equipment or exposing themselves or others to its radiation.

Before operation, persons qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in the Annals Number 26 of the ICRP, and with applicable national standards.

TABLE OF CONTENTS

WA	VARNING				
TAI	BLE OF CONTENTS	3			
1.	HOW TO USE THIS MANUAL	6			
2.	DIGIMEDX PRESENTATION	7			
2.1	Introduction	7			
2.2	Benefits of a Full Digital Equipment	8			
3.	SPECIFICATION	10			
3.1	Features	10			
	3.1.1 Digital Detector				
	3.1.2 X-ray Generator	10			
	3.1.3 Tubes				
	3.1.4 Stand				
	3.1.5 Image processing				
	3.1.6 Collimator				
	3.1.8 Options				
	3.1.9 Service				
3.2	Manufacturer	13			
3.3					
3.4	Product Identification	13			
3.5	Power Supply	15			
3.6					
3.7	Compliance Standards - Electromagnetic Compatibility	18			
3.8	Radioprotection	19			
4.	WARNINGS	24			
4.1	Warning Symbols	24			
4.2	Protection against X-ray Radiations				
4.3	X-ray Beam Quality				

9.	CONTROLS AND COMMANDS DESCRIPTION	53
9.1	Management Tab	53
	9.1.1 Patient	
	9.1.2 Save	56
	9.1.3 Send	56
	9.1.4 Bitmap/Jpeg/Dicom	56
	9.1.5 Print	59
	9.1.6 Close	59
	9.1.7 Tools	59
	9.1.8 Information	59
9.2	Generator Tab	60
	9.2.1 Anatomical programs	60
	9.2.2 X-ray parameters	
	9.2.3 Acquisition	
	9.2.4 Commands	64
9.3	Treatment Tab	64
	9.3.1 Treatment Type	65
	9.3.2 Grey levels	66
	9.3.3 Min-max	
	9.3.4 Gamma	
	9.3.5 Edge Enhancement	
	9.3.6 Filter	
	9.3.7 Setup locking	
	9.3.8 Image manipulation	
	9.3.9 Cropping	
	9.5.10Commanus	/ <i>L</i>
10.	MAINTENANCE	73
10.1	General Aspects	73
	Tube Preheating	74
	Batteries Maintenance	
	Regular Installation Checks	
	Cleaning	
	S	
11.	APPENDIXES	77
11.1	Glossary	77
	Warning Messages	
	Error Messages	
	List of Function Keys	
11.5	Dicom Viewer	79

HOW TO USE THIS MANUAL 1.

This user manual is divided in different chapters. Each of these chapters provides information dedicated to a user or a function. So, according to his needs, the user can go directly to the chapter that will help him.

These chapters are:

- 1. How to Use this Manual: this introductory chapter.
- 2. <u>DigiMedX Presentation</u>: quick description of this equipment advantages.
- 3. Specification: all equipment technical specification.
- 4. Warnings: all precautions to know and keep in mind when using this equipment.
- <u>5. System Powering</u>: how to start and stop DigiMedX.
- 6. Acquisition with a Film Cassette: how to use DigiMedX with a cassette instead of the built-in digital detector.
- 7. X-ray Examination Setup: how to properly prepare the system for a good quality image acquisition.
- 8. Image Acquisition Software: how to configure and use MegXsoft, the software installed on DigiMedX.
- 9. Controls and Commands Description: how to configure the software.
- <u>10. Maintenance</u>: a list of commonly used terms with a short description.
- 11. Appendixes: additional information.

Before installing DigiMedX for the first time, the user should read the chapters 3, 4, 5, and 9.

Before using DigiMedX, a new user should read the chapters 2, 4, 5, 7, and 8.

2. DIGIMEDX PRESENTATION

2.1 Introduction

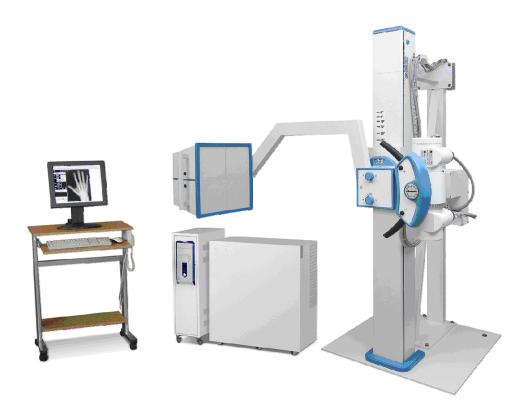
DigiMedX is a complete economic radiographic equipment. It uses DDR –Direct Digital Radiological– image acquisition and covers 95% of conventional X-ray examinations.

DigiMedX has been analysed by WHO –World Health Organisation– and complies with their WHO/DIL/00.1 Rev 1 standard requirements.

In collaboration with 20 medical radiological centres all around the world, WHO studies the optimal design for a radiological stand. DigiMedX follows this design and brings the additional benefits of a digital image acquisition easy process. So any conventional exposure can be done on a patient in a standing, sitting or lying position. Optional accessories are available for geometrical magnification.

DigiMedX generator is battery operated. So it can be used in area where the power supply is not efficient or not available all the time. A main $4\,A$ main supply at $230\,VAC$ is enough to power the complete system. It could also be supplied by a small power group of $1.5\,kVA$.

The tube stand with its swivel arm is very easy to use. The movements are well balanced and the arm is locked in place by electromagnetic brakes. A additional safety detector avoids accidental collision of the image detector with the floor during rotation and translation movements.



DigiMedX equipment

DigiMedX is made of several parts: ■ The stand including: ☐ The swivel arm: rotating and up/down positioning system. ☐ The X-ray generator. ☐ The image acquisition detector (CCD or flat panel). ■ The generator cabinet including: □ The high-voltage generator. ☐ The backup batteries. ■ The computer cabinet including: ☐ The control computer. \Box The optional UPS.

■ The user interface including:

☐ The computer screen, keyboard and mouse.

☐ The remote acquisition switch.

BENEFITS OF A FULL DIGITAL EQUIPMENT 2.2

DigiMedX is digital equipment that does not require any consumable. No film, chemicals, chemicals disposal or dark room is required.

This makes the X-ray image acquisition much easier to handle and to process. It is also much faster as no time consuming film processing is required. And last but not least the equipment operation is much cheaper as there is almost no additional operational cost.

The digital acquired images can be stored and, at any time, transferred, viewed, processed or printed on any computer running a DICOM viewer. They can be printed either on standard paper or on radiology films.

Benefits of DigiMedX compared with film technology

- Immediate visualization of the radiography (about 10s).
- No operator displacement as all processing is done on DigiMedX.
- Opportunity to quickly analyse the images and to appropriately react according to the result.
- No need for several cassettes for multiple exams on a patient.
- Fewer images needed to get a diagnosis and therefore less exposure for the patient.
- More patients treated in less time.
- X-ray dose reduced for the patient and the user.
- Easy storage of acquired images on a digital support.

Benefits of DigiMedX interface

- User-friendly system with one computer controlling both generator and imaging system.
- Large latitude of settings.
- Interpretable images in a wider range of kV and mAs than film.
- Interpretable results for almost any image.
- Automatic image processing to improve the diagnostic.
- Easy and quick image processing.

3. SPECIFICATION

3.1 FEATURES

3.1.1 Digital Detector

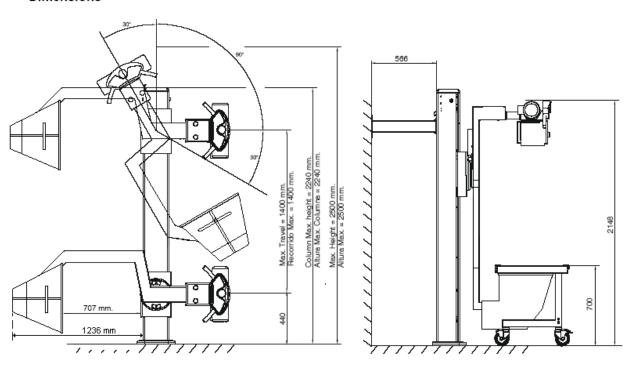
For DigiMedX	For DigiMedX FP	For DigiMedX HR
Based on a very sensitive	Based on a very sensitive	Based on a very sensitive
16-bit CCD, giving a wide	14-bit flat panel, giving a wide	16-bit CCD, giving a wide
contrast range.	contrast range.	contrast range.
400 by 400 mm entrance	430 by 430 mm entrance	400 by 400 mm entrance
detector, no geometrical	detector, no geometrical image	detector, no geometrical
image distortion.	distortion.	image distortion.
 1024by 1024 pixels. Image acquisition time less than 10 s. Certified by WHO – World Health Organization. 	 ■ 3072 by 3072 pixels, with 140µm by 140 µm pixels. ■ Image acquisition time less than 10 s. ■ Certified by WHO – World Health Organization. 	 2848 by 2848 pixels. Image acquisition time less than 15 s. Certified by WHO – World Health Organization.

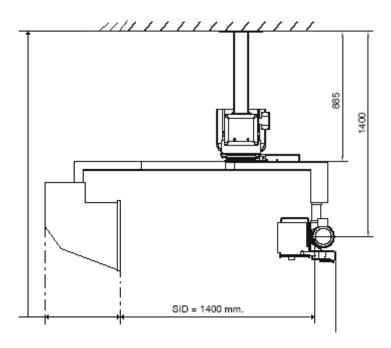
3.1.2 X-ray Generator

- 32 kW 500 mA at 0.1 s, high frequency inverter.
- Use power supply line 230 V +/- 10 %, 10 A.
- Maximum power :
 - $\hfill\Box$ 400 mA at 80 kVp.
 - \square 320 mA at 100 kVp.
 - \square 250 mA at 125 kVp.
- Parameters can be memorized and recalled by physiological menu.
- X-ray tube with anode rotation and anode capacity of 150 kJ (thermal overload protection by microprocessor).
- X-ray tube with double focus of 0.3 and 1.0 mm.
- All generator parameters are monitored by microprocessor for high reliability performance.
- Manual collimator with light centring.
- Battery powered by 90 lead batteries with a 9-Ah capacity.

3.6 MECHANICAL SPECIFICATION

Dimensions





DigiMedX mechanical dimensions

A second screen appears with configuration automatic tests. If all tests are ok, this screen disappears after a few seconds, once all tests are passed.



MegXsoft starting screen and temperature control

During start-up process, the imager must be cooled down to its operating temperature. This starting screen displays current camera temperature and cooling progress.

- 1 If an image must be acquired in a hurry, the cooling down process may be bypassed by clicking on **Cancel** button then on **Close** button that will replace it. In such a case, image quality might not be optimum.
- 1 The cool down process does not take place with DigiMedX FP and HR.

Once initialisation process is complete without error, the system is ready and MegXsoft user interface is automatically started.

If errors occur during initialisation as illustrated in next picture, a brief explanation of these errors is displayed. Nevertheless, the application can be started by clicking the **Enter** button.

Dialog box description

In this dialog box, the following information are entered and recorded:

- **Patients list** Selection list of the patient whose parameters are being modified and/or opened.
- **Exams list** Selection list of the exams whose parameters are being modified and/or opened.
- **Filters** List only patients whose name and/or reference start with entered value. Filtering is done immediately at entering time. Example: entering "sa" in filter left field will reduce list first to names starting with "s" then to names starting with "sa".
- Patient information:
 - □ **Name** (mandatory) Enter patient first and last name.
 - □ **Reference** Patient reference number. This field is automatically filled with a unique unchangeable number.
 - ☐ **Gender** Select patient sex: **M** (masculine), **F** (feminine) or **O** (other).
 - ☐ **Birthdate** Enter patient birth date.
 - □ **Comment** Enter a comment about this patient.
- Exam information:
 - □ **Date** (mandatory) Select the date of the exam.
 - □ **Reference** Exam reference number. This field is automatically filled with a unique unchangeable number.
 - □ **Anatomical program** Select a pre-programmed anatomical exam from the rich proposed list. See section 9.2.1 <u>Anatomical programs</u> for further information.
 - □ **Comment** Enter a comment about this exam.

Dialog box usage

- To open an exam:
 - □ Choose patient then exam in the lists.
 - □ Click on **Open** button.
 - □ If an anatomical program has been selected, X-ray constants are retrieved from it and automatically send to generator.
- To add a new patient or exam:
 - ☐ Click on corresponding ⚠️ Add button on left side of information pane.
 - □ Configure parameters according to requested usage.
 - □ Save the new settings using **Ok** button or discard them using **Cancel** button.
- To modify patient or exam:
 - ☐ Choose patient and exam in the lists.
 - □ Configure parameters according to requested usage.
 - □ Save new settings using **Ok** button or discard them using **Cancel** button.
- To delete patient or exam:
 - □ Choose patient and exam in the lists.
 - □ Click on corresponding Delete button on left side of information pane. A patient and/or an exam cannot be deleted while it is selected and active.
 - □ Confirm delete in displayed confirmation box using **Yes** button.
- *Please note that some basic information is mandatory.*

10. MAINTENANCE

10.1 GENERAL ASPECTS

The following table summarizes who must perform the maintenance jobs for the equipment maintenance.

Who	Action	Maintenance job	When	Documentation
Field engineer from local supplier	check	 cable mechanical motions and brakes stand control buttons stand movement safety user interface X-ray parameters image quality 	once a year	Service Manual
	cleaning	all equipment parts		
User	check	mechanical partstube preheatingbatteries	every 2 weeks and as often as needed	
	cleaning	coversfloor under the equipmentmonitor screens		



DigiMedX is sophisticated equipment and requires proper care and maintenance. The applied maintenance has a direct impact on its performance and longevity. It is the responsibility of the user to take good care of the equipment and to apply the maintenance program.



In case of problem, all components (generator, housing, X-ray tube, cables, collimator, computer, screen, detector...) must be replaced by a model of the same brand and specification as the original. All part replacement must be done in agreement with he manufacturer.



All maintenance job must be performed by people with the appropriate education and training.