



Engineering and trading Ltd.
H-1087. Budapest, Könyves Kálmán str. 76.
Fone/Fax : 36-1-333-33-49, 36-1-333-47-45

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Electronic version

Monfreeze
series of medical picture storage devices
Instructions manual

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APPENDIX

MANUFACTURER'S STATEMENT

7.1. Érvényes fejezetek jegyzéke

	Verzió	Kiadás dátuma
Contents	2.5	2001-04-09
General	2.3	2001-04-09
Specification	2.0	2000-01-15
Operating instructions	2.4	2000-06-17

1. GENERAL

1.1. Purpose of the device

As a result of the rapid development and popularization of picture generating means (X-ray equipment, ultrasound devices, endoscopy), the volume of various pictures generated in the medical diagnostics increased. The storage and rapid retrieval of the high volume of picture data and their visualization during the process of diagnosis offers an indispensable assistance to the physician performing the diagnosis. The recent types of picture generating means are provided with connection facilities to devices used for storing and archiving the data; nevertheless, picture storage devices can be connected to older devices as well (using a custom-made configuration).

The Monfreeze picture storage device is suitable to be connected to picture generating devices by using the interfaces provided for this purpose or, in case of older devices, even without interfaces of this kind. Due to the operating principle of the picture storage device, the picture transferred can be “frozen” in any standard or closed loop TV system without the need of any special alteration in the TV chain. The picture digitizer is an equipment suitable to store the last picture or those selected. It is capable of recording the pictures from various picture generators according to the diagnostic needs of biological processes, and to transfer them to the computer without any distortion.

The storage rate of the picture storage device ranges from the stationary individual picture to the motion pictures of 25 pictures/s according to the TV standard. It is technically possible to record the biologic processes in real time (e.g. examinations with filling-up, swallowing processes).

1.2. Picture generating means

Basically, the picture quality is determined by the quality of the picture generating device. High-quality stored picture can only be obtained from high-quality live picture (generated by a high-quality picture generating device).

The device can also be connected to cameras provided with CCD or Vidicon which eliminates the need for replacing the TV chain as a whole.

It also enables the analogue signals to be converted into digital signals.

Due to its operating principle, the picture storage device enables the transferred picture or pictures to be “frozen” in any black/white or colour, standard or high-resolution closed-loop TV system without the need of any special alteration in the TV chain.

1.3. Configuration Stages

The picture storage system is available in several configuration stages as follows:

1.3.1. Use only for storing pictures

Storing the last picture or up to 200 pictures until the equipment is switched off.

Its advantages are:

Improvement in the efficiency of diagnosis

Protecting both the patient and the physician from the risks of the diagnostic procedure

Increasing the efficiency of medical treatment

In case that several pictures are stored, the possibility of repeated evaluation following the examination.

1.3.2. DICOM 3.0 output

The picture storage equipment is capable of carry out DICOM 3.0 communication at a standardized UTP output of standard 10 or 100 Mbps rate. See the Conformance Statement.

1.3.3. Archiving, picture processing

In order to facilitate the handling and the subsequent retrieval of picture data, the picture processing and the use of new diagnostic methods offered by the technical development require the picture information to be compressed or archived.

1. Identifying the patient and the picture:

Each picture shall contain

the name of patient,

the patient's date of birth,

social insurance ID number (TAJ with Hungarian initials)

date of shooting the picture.

2. For the purpose of identification, it is also possible to add text to the pictures automatically. The above data can be retrieved from any selected picture.

When selecting the picture archiving system, it is indispensable to specify its user environment and the intended purpose.

1.4. Manufacturer's Statement

Manufacturer: **MEDIMON Kft.**
Address: H-1087 Budapest
Könyves Kálmán krt. 76.
EU representative: **Gábor Lengyel**
Name: Diatron mestechnik Ges.m.b.H.
Address: Ameisgasse 49-51/2
A-1141 Wien
Phone: 00 43 19148500

The manufacturer declares that the product indicated below:

Product designation: Monfreeze series of medical picture storage-, digitizer-
and archiving devices
Type designation: Monfreeze

The product is in conformity with the guidelines and norms listed below:

Electric safety:	MSZ EN 60601
EMC:	MSZ EN 55011 MSZ EN 50082-1 MSZ EN 61000-4-2
Shock protection:	I.B class
Protection:	MSZ IEC 529, IP20
Classification:	93/42/Eec II.B
Product standard:	IEC 601-1
No. of ORKI Quality Certificate	1005/99
No. of MEEI* Compliance Certificate	M0043E011
CE certification number	TÜV-A-MT-1-00/Q019
Annex II of directive 93/42/ECC on MDD	
EN ISO 9001 EN 46001	TÜV-A-M 20 105 9860

*) MEEI = Hungarian initials for the Hungarian Institute for Electrotechnical Control

NOTIFIED BODY

TÜV ÖSTERREICH
Akkreditierte Zertifizierungsstelle für Medizinprodukte
A-1230 Wien, Deutschstrbe 10.
Notified Body Nr.: 0408

1.5. Product Identification:

The type of Monfreeze medical picture storage device can be deduced from the type number according to the table below. The type number is indicated on the label on the rear side of the picture storage device (Fig. I/1).

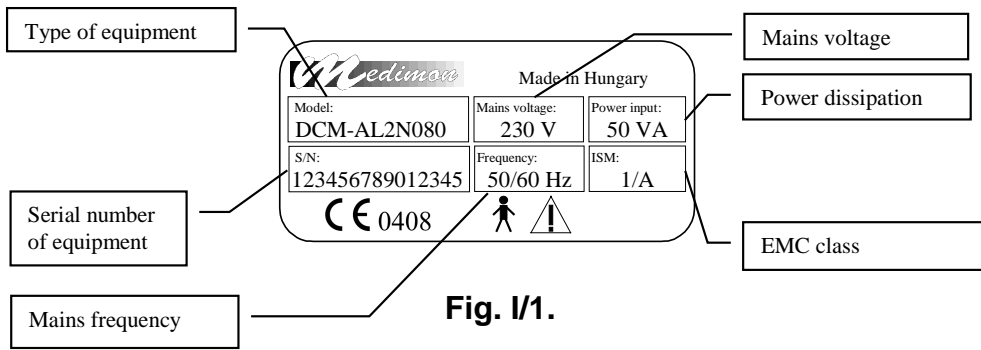


Fig. I/1.

Main type		No. of bits		Resolution		Outputs		Pulse mode		No. of pictures
DCM	Picture storage device with DICOM 3.0 output	A	10 bits	L	Normal resolution	1	One-monitor design	N	Standard equipment	Max. number of pictures that can be stored indicated by three characters (e.g: 090). equipment for storing only the last picture is indicated by 001
				H	High resolution	2	Dual-monitor design	I	Pulse-mode equipment	
				S	Special resolution: e.g. CT, MR					

Based on the above, the type designation **DCM-AH1N180** represents an equipment of 10-bit high resolution, provided with DICOM 3.0 output, suitable to store 180 pictures, operating in standard (other than pulse-) mode.

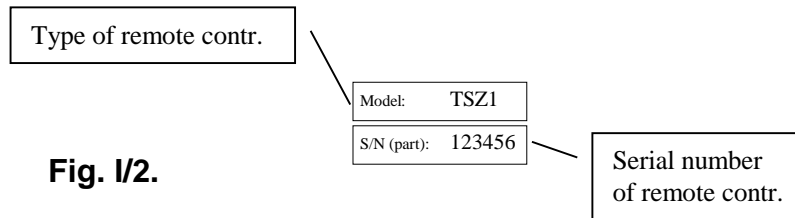


Fig. I/2.

The remote controller associated with the equipment is also provided with label. Its interpretation is indicated in the above Figure I/2.

1.6. Symbols used

EXPLOSION HAZARD!



This equipment is not qualified for use in narcotic gas environment or in other hazardous environment. Use of inflammable material for its cleaning may also involve risk.

ATTENTION!



This symbol marks the important technical descriptions, hazardous situations, safety regulations and information of high importance.

SPECIAL PERSON!



Activity marked with this symbol is allowed to be performed only by persons trained and authorized by the manufacturer.

1.7. Manufacturer's notes

It is of assistance to your work if you are familiar with the use and operation of the device. Therefore, read the Instruction manual carefully.



The manufacturer warrants for its equipment if it was put into service and is used properly. Any improper use results in damage and the termination of warranty.

Should you detect any anomaly in the operation of the device or the device is failed, the X-ray examination can be continued in a traditional way with the picture storage switched off until the remedy of failure.



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The computer connected to the device shall be of design in conformity with the safety regulations relating to the medical devices. The compliance shall be certified! In respect of dielectric strength, the remaining parts of the network shall meet the specification relating to the medical equipment!

The device inserted into the system shall be connected to the protective earthing network established for the equipment!

The mains plug connector forms part of a multi-function unit which also includes the mains switch and the fuse holder.

According to the manufacturer's specification, two glass-tube type 5x20 fuses of T 315 mA rating shall be used. In case of fuse replacement, take care that the proper fuse in the proper position is used.

The fuse rating is shown in the label with the cover of fuse holder folded down.

1.8. Possibility of expanding and improving the equipment:

The expansion starting from the simple device suitable to be used for storing the last picture up to archiving and the networked system can also be performed progressively in several stages.

Possibility of expansion:

- from the storage of “last picture” (1 picture) up to 200 pictures
- DICOM 3.0 communication possibility
- entering the stored pictures into the computer
- networking of self-dependent storage- and archiving systems.

2. SPECIFICATION:

2.1. Designation of the device

MONFREEZE series of medical picture storage-, digitizing and picture archiving devices.

2.2. Protection

IP20 according to the Hungarian Standard MSZ 806/1-76.

2.3.Shock protection

Class I.B according to the Hungarian Standard MSZ EN60601-1:1995.

2.4 Related standards

Electric safety:	MSZ EN 60601
EMC:	MSZ EN 55011
Shock protection:	I.B class
Protection:	MSZ 80661-76, IP20
Classification	93/42/Eec II.B
Product standard:	IEC 601-1

2.5. Power supply

Supply voltage:	230 V 50/60 Hz
Max. power dissipation	50 VA
Mains fuse	2x 315mAT
Type of protection	B
Shock protection class:	I.

2.6. Video parameters

Rated input signal:	1 V p-p/75 ohm
Rated output signal:	1 V p-p/75 ohm
Resolution:	625/525 lines x8 bits, 1249/1049 lines x8 bits 625/525 lines x10 bits, 1249/1049 lines x10 bits
Video system:	Monochrome baseband 625 or 1249 lines 50 Hz, 525 or 1049 lines 60 Hz

2.7. Control

AC or DC 12-24 V.

2.8. Method of storage

Displaying the last full picture.

Storage capacity: 4 MB - 320 MB

2.9. Temperature range:

During operation: 0 - +35°C

During storage and transport -20 - +50°C

2.10. Dimensions

Picture storage device: 341x280x137 mm

Remote controller: 45x85x16,5 mm

2.11. Mass

Picture storage device: 4,8 Kg

Remote controller with 10 m of
cable: 0,4 Kg

At the lower left corner, the user information is displayed.


The device shall be operated by means of the remote controller (Fig. III/1.).

The keys of remote controller have several functions depending on the operating mode of the device.


3.1. Basic mode

In its basic mode, the equipment functions as follows:

3.1.1. During X-raying:

At the upper right corner, the symbol  (live picture) appears. On depressing the **REC** key on the remote controller, the picture displayed on the X-ray monitor is recorded with the actual index number and, then, the index number is incremented by one automatically.

If the Cinema mode is selected (**Cine xx F/S** is shown at the upper right corner), by holding the **REC** key depressed, moving pictures are recorded from the actual index number at a speed set in the menu (chapter 3.2).

When the X-raying is terminated, the picture displayed last is recorded with the actual index number. If the automatic increment is enabled (the symbol  appears at the upper right corner), the counter is incremented on each storage function until the maximum index number is reached.

If the character display flashes during the process of screening then the number of images in the image store has reached the maximum storage capacity. In this case additional pictures can only be taken by overwriting existing images. If the system has an attached archiving device, the images can be transferred before they are overwritten.

3.1.2. With X-raying switched off:

By using the arrows **Up** and **Down**, it is possible to move between the stored pictures forwards and backwards. Holding either of the keys depressed, the index number continuously increases and decreases, respectively. Depressing the two keys simultaneously resets the counter to its initial position (picture No. 1).

In case of equipment with DICOM 3.0 output, depressing the **Menu** key causes the waiting list to appear. See chapter 3.3 and the operating instructions of software for further information.

In case of picture storage device provided with DICOM 3.0 output, the **Send** key shall be used to send the actual picture to the pre-configured DICOM 3.0 server.

The Cinema mode can be switched on and off by depressing the **Cine** key for a short time (< 1sec). If switched on, the speed set in the menu appears at the upper corner of the screen.

With the Cinema mode switched on, depressing the **Cine** key again for more than 1 s starts the playback continuously between the picture No. 1 and that of the maximum index number.

In Cinema mode, the speed of playback can be increased or decreased by depressing the key + or - .

3.2. Two monitor system

The two monitor system different of the standard single last image holder.

The first monitor (OUT1) the last image holder. The second monitor (OUT2) store image with **REC** key. In standard position the second monitor storing images the actual index number. If the automatic increment is enabled (the symbol Δ appears at the upper right corner), the counter is incremented on each storage function until the maximum index number is reached.

During X-raying **Send** key archiving the first monitor images. If the X-ray is switched off, the **Send** key archiving the second monitor images to the PC.

Sending back from the PC to the monitor always on the second monitor.

3.3. Menu

With the **Menu** key depressed for at least 1 s, the menu used for setting the functions appears at the center of the screen. The menu items vary depending on the configuration!

The actual menu item is indicated by the „>” cursor. For moving between the menu items, the keys **Up** and **Down** shall be used. By using the keys + and – the values of menu items can be changed.

The **REC** key is used to store the value of a menu item as default setting.

Use the **Menu** key to exit the menu.

- **AUTOMATIC INCREMENT YES NO**

If switched on, the counter is incremented on each storage function until the maximum index number is reached.

If the counter is switched off, the actual picture is overwritten when a new picture is stored.

- **FILM SPEED**

The speed of recording and playback can be selected as follows: 1-2-4-8-12-25 picture/sec (50 Hz).

- **INTENSITY OF TEXT DISPLAYED**

The intensity of characters can be increased and decreased, respectively, between the specified limits.

- **CLEARING THE SCREEN**

Clears all the texts displayed on the screen.

- **PULSE FREQUENCY 0,5;1;2;3;4;5 s/pulse**

In case of pulse control, the active pulses appear at time intervals corresponding to the value displayed.

- **PULSE ENABLE YES NO**

In pulse enable mode, the Cinema mode is disabled.



- **SERVICE SETTINGS**

Accessible only if the Setup jumper exists. Depress **REC** to select the menu.

The sub-menu includes.

- **HALF-PICTURE INTERCHANGE**

„+” and. „-”, the result is shown in the screen

- **KARAKTER OFFSET**

Moves all the characters in vertical direction.

- **POSITION OF IDENTIFIERS**

Moves the ID character set (user name) in vertical direction.

- **USER IDENTIFIERS**

Depressing the **REC** key sets the first character position, use the – key to move in the alphabet; depress **REC** at the appropriate character. Depress the keys ☹☹ to close after the last character is entered. Take care when entering as no correction is possible. If error is made start it again from the beginning.!

- **SERIAL CONNECTION (ON)**

After depressing the **REC** key, the program of the picture storage equipment can be changed. This also requires a special computer program. Exit the function is possible only by switching the equipment off and on.

- **PICTURE POSITION**

You can modify the digitalizing raster start point with + - keys.

- **VIDEO SYSTEM**

You can modify the video system frequency. (50 – 60 Hz)

After this setting, you must restart the device.

- **VIDEO LEVEL**

Menu item to assist in setting the device. The number appearing below it indicates the video output level. Set the gain so as the video level with picture content falls between 200 and 255 (the maximum value) (see chapter 5).

- **PROGRAM VERSIONS**

Two numbers appear here: the first one represents the FPGA program version number and the second one is the version number of the microcontroller program.

- **ID**

This 10-digit ID number is the individual internak identifier of the device. It differs from the serial number. If DICOM is sent, it is contained in the picture header for future identification.

3.4. Patient selection in case of picture storage of DICOM system

On switching the picture storage device ON, the message “**PLEASE SELECT A PATIENT**” appears at the upper left corner of the screen.

On depressing the “*menu*” key, the list of patients waiting for consultation appears on the monitor. The actual patient is indicated by the „>” cursor. For moving in the list, the keys – and + shall be used. Depressing the **REC** key selects the patient desired.

When a patient is selected, the message “**ARE YOU SURE TO SELECT A NEW PATIENT?- YES, NO**” appears. Answering “Yes” clears the pictures of the previous patient from the picture storage and the name of the new patient appears at the upper left corner.



Caution: The patient’s pictures not sent to the computer are definitely deleted when selecting a new patient.

Then, another question appears: “**CAN THE PREVIOUS PATIENT BE CLEARED FROM THE LIST? YES, NO**”. The answer “Yes” clears the patient’s name from the waiting list.

3.5. DICOM SETUP menu



This menu is available only in the case of picture storage of DICOM 3.0 system and is accessible only if the Setup jumper exists. On depressing the keys **Cine** and **Menu** simultaneously for more than 1 second, this menu appears.

This menu serves for setting the pictures transferred.

The actual menu item is indicated by the „>” cursor. For moving between the menu items the **Up** and **Down** keys shall be used. Using the + and – keys changes the values of menu items. At the upper right corner of the menu field, the version number of program responsible for DICOM communication is shown.

Use the **Menu** key to exit themenu.

- **TEXT OFFSET**

Moves the entries in the patients’ list vertically.

- **PICTURE OFFSET**

Sets the vertical offset of the picture transferred.

- **PICTURE LENGTH**

Sets the length of the picture transferred.

- **HALF-PICTURE ORDER 00, 01**

The result is shown in the picture transferred.

- **SET DATE YYYY.MM.DD. HH.MM.**

Setting the clock of image holder

Setting list. Year, month, day, hour, minute.

The arrow shows you the active position.

Modification: + -

REC (Enter) button you can store and step forward to the next position.

If without pushing **REC** button you move up or down, you keep the earlier position.

- **EXIT**



Stops the program responsible for DICOM communication. The program can be re-started only if the system is switched on again. If the program is stopped, an FTP server starts. This enables the DICOM program to be set – and updated if necessary - by means of the appropriate computer program.

3.5.1. Setting and updating the DICOM program



The DICOM setting of picture storage can be set by means of a program running under **Windows 95/98** or **Windows NT 4**. Insert the attached disc into the floppy drive. For starting, the **Run** menu item in the Windows **Start** menu shall be used. Key in: **a:\digitset.exe**. After starting, the **Login to digitizer** window appears. Enter the IP address of the picture storage device in the **IP** field. The IP address of the picture storage device is factory-configured to 192.9.200.9 and the network mask to 255.255.255.0. The **User** field shall be used to specify the user name while the password shall be entered in the **Password** field.



The user password and user name are as follows:

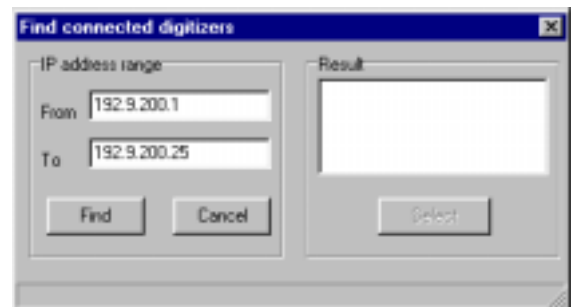
User	x
Password	x

Then, click the **Login** key.



Attention! For connection, the network mask of computer shall agree with that of the picture storage. The picture storage shall be switched on and the FTP server started by using the End of Program menu item of DICOM setup menu.

If you do not know the IP address of picture storage device, try to find it by depressing the **Find** key. Key the start and end of the range of search in the fields **From** and **To**. The IP addresses of picture storage devices found are displayed in the **Result** field. Select (click) the appropriate one from among those that appear and, then, use the **Select** key to copy it into the **IP** field in the **Login to digitizer** window.





Due to network Timeouts, the search may take a long time; therefore, avoid to specify too large range for search.

If the connection is established, the **Connect to digitizer** window showing the current settings appears.

The uppermost field serves for updating the program responsible for the DICOM 3.0 communication. In the **Upgrade software** field the access path to the new program shall be specified. Use the **Send** key to perform the updating.

In the **Digitizer** field, the network parameters and DICOM parameters of the picture storage device can be set. These parameters are:

New IP IP address of picture storage

Port DICOM port address of picture storage

DICOM Name DICOM identifier of picture storage

Hostname network identifier of picture storage

Netmask network mask of the picture storage

Under the DICOM Server, the parameters of the receiving DICOM server can be modified

IP IP address of the server

Port address of DICOM port of the server

DICOM Name DICOM identifier of the server

By using the **Set** key, the settings can be actualized. To exit the program without actualizing the settings, use the **Cancel** key.



Having the settings performed, the picture storage shall be restarted!

Manufacturer's Statement

Manufacturer: MEDIMON Kft.
Address: H-1087 Budapest
Könyves Kálmán krt. 76.
EU representative: Gábor Lengyel
Name: Diatron mestechnik Ges.m.b.H.
Address: Ameisgasse 49-51/2
A-1141 Wien
Phone: 00 43 19148500

The manufacturer declares that the product indicated below:

Product designation: Medigit series of medical picture storage-,
digitizer- and archiving devices
Tyoe designation: Medigit

The product is in conformity with the guidelines and norms listed below:

Electric safety:	MSZ EN 60601
EMC:	MSZ EN 55011
	MSZ EN 50082-1
	MSZ EN 61000-4-2
Shock protection:	I.B
Protection:	MSZ IEC 529, IP20
Classification:	93/42/Eec II.B
Product standard:	IEC 601-1
No. of ORKI Quality Certificate	1005/99
No. of MEEI* Compliance Certificate	M0263E030
CE certification number	TÜV-A MT-1/00/Q0192

*) MEEI = Hungarian initials for the Hungarian Institute for Electrotechnical Control

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TÜV ÖSTERREICH
Akkreditierte Zertifizierungsstelle für Medizinprodukte
Notified Body Nr. 0408
A-1230 Wien, Deutschstrbe 10.

László Tamási

Managing Director