

ergoline



Operation Manual
ELMD-4
Reha-Converter incl. 9" Monitor

Art-Nr: 475.197 - ELMD4 ♦ Version: 05/02

Operation Manual for ELMD-4 Reha Converter with 9"-Monitor

Printed in Germany

We reserve the right of modifications due to technical development at any time and without prior notice.

Reprinting, translation and copying in any form - also in parts - is only permitted after prior written consent by the manufacturer.

This Operation Manual is not registered for automatic update in case of possible alterations.

Information regarding the latest version is available from the manufacturer.

ergoline GmbH
Lindenstraße 5
D-72475 Bitz
Tel.: +49 (0) 7431 98 94 - 0
Fax: +49 (0) 7431 98 94 - 127
e-mail: info@ergoline.com
internet: <http://www.ergoline.com>



EU Declaration of Conformity



according to the Low Voltage Directive 73/23/EEC and the Amendment Directive 93/68/EEC

For the following equipment:

Product : Mono Monitor

Type Designation/Trademark : VM-9AF, VM-9SF

Manufacturer's Name : Taiwan Video System Corp.

Manufacturer's Address : No. 26, Lane 316, Chung Shan S. Road,
Yung Kang Siang, Tainan 710, Taiwan, R.O.C.

Is herewith confirmed to comply with the requirements set out in the Council Directive 73/23/EEC for electrical equipment used within certain voltage limits and the Amendment Directive 93/68/EEC. For the evaluation of the compliance with this Directives, the following standards were applied :

 EN 60 950:1988/A1:1990/A2:1991

 ZH 1/618/10.80

Responsible for making this declaration is the :

Manufacturer Authorized representative established within the EU

Authorized representative established within the EU (if applicable):

Company Name : ARX Technology Trading GmbH

Company Address : Lessingstr. 2-10
21629 Neu Wulmstorf, Germany

Person responsible for making this declaration

Name, Surname : Albert Sun

Position/Title : General Manager

 Hamburg

(Place)

 15.11.1999

(Date)

~~ARX Technology Trading GmbH~~

~~Lessingstr. 2-10
21629 Neu Wulmstorf
Tel: 048 734 6330
Fax: 048 701 7440~~

(Company stamp and signature)

EG-Konformitätserklärung

Für das folgend bezeichnete Erzeugnis

Produkt: **REHA Converter**

wird hiermit bestätigt, daß es folgenden einschlägigen Bestimmungen entspricht:

EG-Richtlinie 73/23 EWG in Verbindung mit Richtlinie 93/68 EWG

Zur Beurteilung des Erzeugnisses wurden folgende Normen und normative Bestimmungen herangezogen:

EN 55011 (1997) und	„Funkentstörung von elektrischen Betriebsmitteln und Anlagen, Grenzwerte und Meßverfahren für Funkentstörungen von industriellen, wissenschaftlichen und medizinischen Hochfrequenzgeräten (ISM-Geräten)“
EN 61000-4-5 (1996) Störfestigkeit	„Elektromagnetische Verträglichkeit – gegen Stossspannungen (Surge)“
EN 61000-4-2 (1996) Störfestigkeit	„Elektromagnetische Verträglichkeit – gegen die Entladung statischer Elektrizität (ESD)“
EN 61000-4-3 (1996) Störfestigkeit	„Elektromagnetische Verträglichkeit – gegen hochfrequente elektromagnetische Felder.“
EN 61000-4-4 (1996) Störfestigkeit	„Elektromagnetische Verträglichkeit – gegen schnelle transiente Störgrößen (Burst).“

Das Qualitätssicherungssystem der Fa. ergoline GmbH ist von der TÜV Product Service GmbH, gemäß den Darlegungsmodellen EN ISO 9002/1994 und EN 46002/1996, sowie gemäß 93/42/EWG Anh.V, (CE0123) zertifiziert.

ergoline GmbH
Lindenstraße 5
D-72475 Bitz
Tel: 0049-7431-9894-0
Fax: 0049-7431-9894-127



Bitz, den 01.01.2002

Vertreter der Geschäftsleitung
für das Qualitätssicherungssystem

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Declaration of Conformity for Reha-Converter
Declaration of Conformity for 9" MDA-Monitor

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General Description

The 4 channel surveillance monitor **ELMD-4** is designed for ECG monitoring of patients on training ergometer. The monitor system consists of the **Reha-Converter** and of a **9" MDA computer monitor** for display of the ECG curves.

Usually, the monitor is interfaced via a connecting cable with up to 4 ergometers. The cable can be used to transmit the signals of up to 4 input channels.

From each patient, the 1 channel ECG is displayed. Furthermore, the heart rate is continuously calculated from each ECG signal and displayed as numerical value on screen.

1. Introduction

Within this Operation Manual, important comments to ensure the safety and to avoid potential damage are labelled with the following symbols:



Warning !

Describes a potentially dangerous situation.

Failure to comply may lead to death or serious injuries, or may cause damage to the equipment or to the environment.



Important !

Application hints to achieve an optimal application of the device and further helpful information.

This Operation Manual is an **integral part of the device** and has to be available at the equipment at any time.

This Operation Manual is designed by the manufacturer according to his best knowledge and experience in the construction, production and operation of the device.

The Operation Manual may be extended via special statements by the operating company, e.g. for supervision and obligatory registrations, internal maintenance plans, testing intervals.

1.1 Comments by the Manufacturer for the User

As the user, you are responsible for :

- the professional application as directed via expert personnel which has been instructed for the correct operation of the equipment,
- compliance to the safety relevant information and maintenance comments,
- compliance to the safety regulations, safety comments as well as the precautions in respect to vocational safety and accident prevention,
- the technical instruction of the operating personnel at the device and for having taken notice of the Operation Manual,
- the Operation Manual being accessible for the operating personnel.



Regarding the **Product Relevant Regulations** applying to the operation of the monitor **ELMD-4**, please refer to the respective Declarations of Conformity for the **Reha-Converter** as well as 9" MDA Monitor (product: **Mono Monitor**) as enclosed in this Operation Manual.

1.2 Warranty Regulation

***ergoline* GmbH is only responsible for the safety and reliability of this device, if:**

- all revisions, enhancements, repairs and service to the device are carried out by *ergoline* authorized personnel, e.g. an *ergoline* dealer,
- ambient electrical service where the device is installed conforms to IEC 601-1 and
- the device is operated in accordance with the Operation Manual.

2. Safety Notices

2.1 Safety

Complying to the safety comments protects from potential injuries and prevents improper application of the ergometer. Each operator of this monitor ELMD-4 as well as personnel which is in charge of installation, maintenance, examination or repair of this device, must have read and fully understood the contents of this Operation Manual prior to operating the unit or doing any work on this device.

Special attention is required at sections labelled with additional symbols .

2.2 Intended Use

The surveillance monitor **ELMD-4** is only to be used for ECG monitoring of patients during rehabilitation training controlled and monitored via the rehab system **ergosoft plus**.

2.3 Basic Safety Comments



This device must only be operated in perfect working order in technical respect.

Despite the precautions, the operation of this device may involve certain risk or danger, especially in case of

- improper application or,
- application is not as directed.

*There is the hazard of injuries or of property damage, in case of nonconformance to the Operation Manual, especially to the **Safety Notes**.*



It is necessary to ensure that no dangerous ground currents occur as a result of attaching the monitor ELMD-4 to other devices. Device specifications of this device are in the appendix to this manual. Direct your questions to your dealer or to *ergoline's* service department. Especially at the coupling of several devices to a measurement system it has to be taken care that proper grounding is achieved via a single power supply, e.g. wall socket.



The monitor ELMD-4 should only be operated where electrical requirements meet IEC 601-1.



This device is not suitable for use in rooms or areas where there is danger of explosion.



Always observe accident prevention precautions when operating this device.



This unit may only be operated for therapy purposes under the supervision of qualified personnel.

2.4 Normative Notices

2.4.1 Notice for EMC (electromagnetic compatibility)

- The EMC test was done with an interference level of 3 V/m. The device should not be used in areas with a higher level.
- The device should not be used beside a high voltage system.
- To connect the device with other devices it is only allowed to use special shielded cables provided by ergoline.
- Strong transmitting equipment may not be operated in the immediate vicinity of this device.
- Electromagnetic interferences will appear first by an instable value of the heart rate in the display. If the value changes without reason, this may be caused by an electromagnetic interference.

2.5 Requirements for Operating Personnel

The operating personnel of this device has to :

- be properly instructed and trained regarding the operation of the monitor,
- have full command regarding the handling of the device,
- be aware of the relevant safety requirements for the operation of such devices, and act accordingly (see Chap. „**Introduction**“),
- be informed regarding additional regulations, e.g. safety regulations,
- be informed regarding potential hazard and risk arising from the operation of such devices.

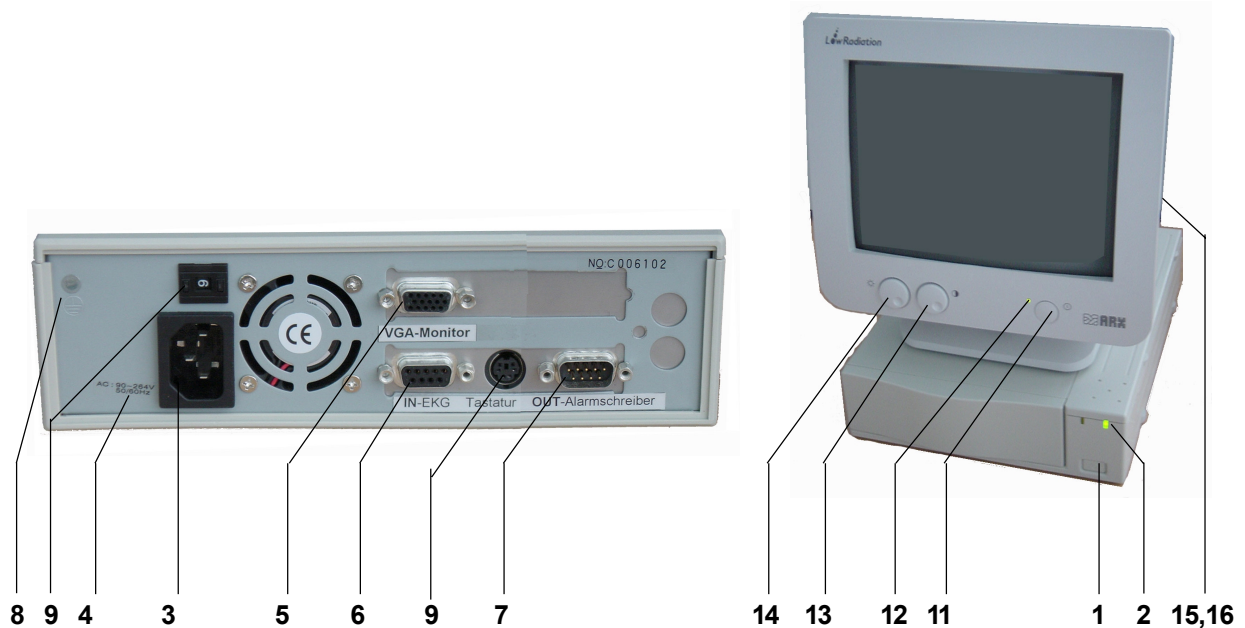
2.6 Maintenance

The surveillance monitor **ELMD-4** does not require any specific maintenance. Alterations to the monitors measurement capabilities are cause for re-certification. These inspections are to be performed by an ergoline authorized service technician.

3. Putting into Operation

Check the mains fuse at the respective work station prior to putting the device into operation. **Maximal fuse value: 16A**

3.1 Operating Elements and Connections



Operating elements and connections at Reha-Converter:

- 1 On/Off switch for Reha Converter
- 2 LED indicating ON/OFF status; green light if 'On'
- 3 socket for mains connection
- 4 label indicating power supply specifications
- 5 output socket for monitor
- 6 input socket for ECG signal (up to four 1-channel ECG's)
- 7 output socket for connection to alarm recorder ergorec-8
- 8 provided for additional grounding
- 9 not used

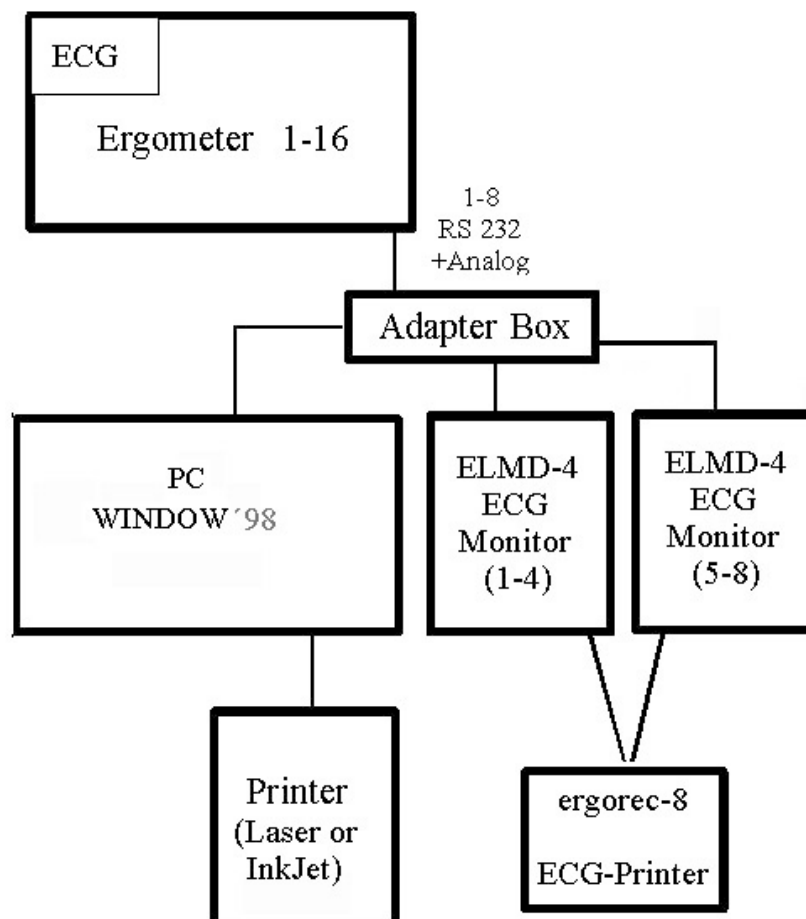
Operating elements and connections at display monitor:

- 11 On/Off switch for Monitor
- 12 LED indicating ON/OFF status; green light if 'On'
- 13 control knob to adjust the display contrast
- 14 control knob to adjust the display brightness
- 15 mains cable
- 16 (ECG) signal cable for connection to socket '5' at Reha Converter

3.2 Installation

- Place the Reha Converter and the 9" MDA monitor at the place provided.
- Connect the signal cable ('16') of the MDA monitor to socket "VGA-Monitor" ('5') at the Reha Converter.
- Connect cable from the adapter box to socket "IN EKG" ('6') at the Reha Converter.
- Connect cable to the alarm recorder ergorec-8 to socket "OUT-Alarmschreiber" ('7') at the Reha Converter.
- Connect both the mains cable of the Reha Converter and the 9" MDA monitor to input sockets 230 V (electrical requirements meet IEC 601-1).
- It is recommended to have the connection of the monitors be done by a service technician authorized by ergoline. Only use the original cables as delivered by ergoline.
- Take care that proper grounding is achieved.
- Switch on the device with the mains switch.

Comment: The monitor ELMD-4 should only be operated where electrical requirements meet IEC 601-1.
The connections between the monitor, the alarm recorder and the ergometer must only be done by a service technician authorized by ergoline.



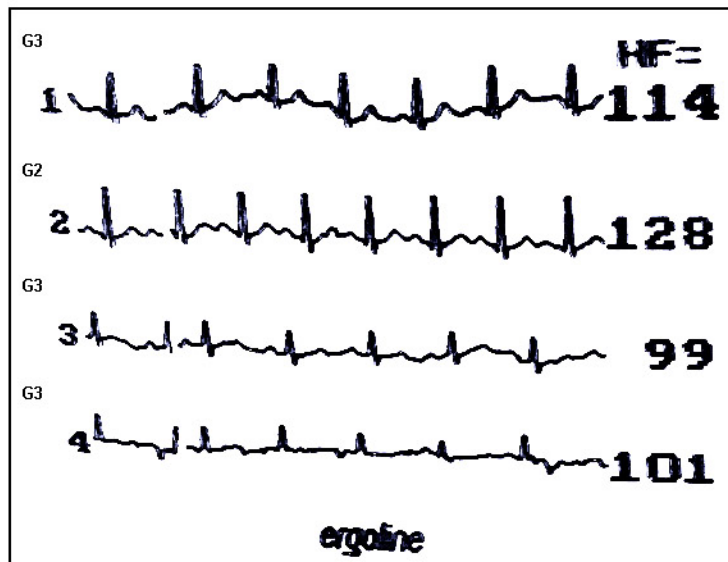
4. Operation and ECG Display

The display of the ECG traces is automatically adjusted.

The calculated heart rate is displayed on the right hand side of each ECG trace, i.e. HF = 114 beats per minute.

The current gain setting (G1, G2 or G3) is indicated on the left hand side of each ECG trace.

The brightness and the contrast of the display can be adjusted with knobs '14' and '13' (see chap. 3.1).



4 Channel Surveillance Monitor ELMD-4

Annex: Technical Data

Display

TTL Video	MDA Computer monitor
Resolution	720 x 348 pixel non-interlaced
Display	ECG trace
horizontal	6,5 sec at 25 mm/sec with 9" screen
vertical	1mV/cm with 9" screen
Heart rate	
digital display	40 ... 180 bpm
Averaging	average out of 8 RR intervals
Update of signal	at end of line
QRS tone	acoustic converter integrated
ECG input	4 x bipolar, 2 V input level
	AC coupling
	time constant 0,6 sec
Input sensitivity	low 0,5 / 1,0 / 2,0 V
Amplifier adjustment	automatic in 3 steps
Safety	according to IEC EN 60601-1
Protecting class	I according to DIN VDE 0750 (IEC 601-1)
Voltage supply	230 V, 50 Hz
Power consumption	approx. 300 mA
Dimensions (W x H x D)	265 x 66 x 250 mm
Weight	1,5 kg incl. mains cable

Input and outputs:

9 pin SUB-D plug (output)

PIN	signal
1	channel 1
2	channel 2
3	channel 3
4	channel 4
9	GND for channel 1-4

9 lead D-SUB socket (input)

PIN	Signal
1	channel 1
2	channel 2
3	channel 3
4	channel 4
9	GND for channel 1-4

Mains cable input for 230 V / 50 Hz