

CE₂₁₉₅ ISO 13485 **SZUTEST**

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About us

Introduction:

Dahian Pezeshki Pishro is a professional manufacturer of medical devices in the field of Electrocardiographs. Our company was founded in 2008 with the goal of offering highquality, economical and trustable products for medical care and continues improving. Years of expertise researching, developing and manufacturing electrocardiograph provides the ideal background for satisfying market needs. Dahian's dedication to technological leadership, precision manufacturing and uncompromised customer support ensures quality products and service our customers can expect. Our products meet the requirements of MDD/93/42/EEC and CE.

Products:

The company currently has designed and produced the following products:

- YASHAM 1260 (12 channels electrocardiograph)
- YASHAM 635 (6 channels electrocardiograph)
- YASHAM 310 (3 channels electrocardiograph)
- YASHAM 110 (one channel electrocardiograph)
- ECG Viewer (software PC based ECG viewer)

The company hopes by employing specialists, support clients and give best service to them at highest level.

International Certificates:

- EN ISO 13485 : 2012 Issued by QS, 2017 2020.
- CE mark by Kiwa-Meyer in 2017 for Electrocardiographs.

Dahian Pezeshki Pishro company now has the highest percentage of Electrocardiograph market share in Iran and Plans to increase its exports in other countries.



Technical Data of YASHAM 635







Technical Data for ECG:

Patient input circuit: Fully floating an isolated, defibrillation protected Monitor Display:

- -12-channel display or Rhythm
- -Heart Rate
- -Sensitivity: 2.5,5,10,20 mm/mV or Automatic
- -Filter status (Notch, Low-pass, Drift, EMG)

Insufficient electrode contact (Lead - Off Detection)

Leads: 12 Simultaneous standard leads Chart Printout speed: 6.25/12.5/25/50 mm/s

Sensitivities: 2.5/5/10/20mm/mV, either automatically adjusted or manually selected

Automatic or Manual lead programs:

- -1/3/6-channel presentations of 12 simultaneously or Real time recorded leads
- -1+long Lead/3+long/Rhythm

Data record:

- Patient Data (name, age, height, weight), User ID
- Listing of all ECG recording condition (Data, Time, Filter)

Measurement program: ECG measurement results (intervals, amplitudes, electrical axes)

- -Calibration voltage: 1mV±3%
- -Basic ECG Measurement over 12 leads and interpretation

Recording track: 2/3/4/6-channel presentation optimal positioning on width of 110 mm

Filter: Low pass filter: 25,35,75 or 150 Hz, Drift: baseline stabilizer, Notch: 50/60 Hz, EMG Filter

ECG amplifier:

Simultaneous recording of all 9 active electrode signals (=12 leads)

Sampling frequency: 1000 Hz

Pacemaker Detection/Rejection: ±2 -±700mV/0.1ms -2ms

System:

Dimensions: 350x284x65mm, approx.2.0 kg

Built- in Monitor: 95x53 mm effective display area 480x272 dots resolution On-screen Status Indictors: power source, Battery status, (date,) time Control panel and key board: User-friendly keys, LED indictor, Touchscreen Power Supply Requirements: 90-240V,50/60Hz; stand-alone operation with

Built-in rechargeable Li-ion battery, integrated power supply unit

Battery Capacity: 10 hours of normal use

Power consumption: Max 30 VA

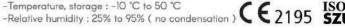
Frequency range of digital recording system: 0.05 - 150 Hz (IEC/AHA)

Chart Paper: Thermo-sensitive, 110 mm wide

Printing Process :High-resolution thermal head printer, Vertical resolution 8 dost/mm Memory: Possibility to save up to 100 Resting ECG Measurements internally

Environmental conditions:

- -Temperature, operations: 10 °C to 40 °C
- -Temperature, storage : -10 °C to 50 °C



Standards:

Safety: IEC (EN) 60601-1; IEC (EN) 60601-1-2 (EMC)

Performance: ANSI/AAMI EC11

Protection class: I according to IEC 60601-1 (with internal power supply)

Applied part: CF according to IEC (EN) 60601-1

Hardware options: Equipment trolley

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6 Channels Electrocardiograph



Technical Data of YASHAM 310





Technical Data:

Patient input circuit: Fully floating an isolated, defibrillation protected class I, Type CF (based on IEC 60601-1)

Monitor Display:

- -12 channel display or Rhythm
- -Heart Rate
- -Sensitivity: 2.5,5,10,20 mm/mV or Automatic
- -Filter status (Notch , Low-pass , Drift , EMG)

Leads: 12 Simultaneous standard leads Recording speed: 6.25/12.5/25/50mm/s

Sensitivities: 2.5/5/10/20mm/mV

Recording:

1 channel, $\overline{2}$ channel, 3 channel, 1 channel + 1 long lead , 2 channel + 1 long lead rhythm

Recording Data:

Patient Data: name, age, height, weight, User ID, Gender, blood type, heart rate

List of all ECG recording condition (date , time , filter , speed)

Recording Mode and Format:

Auto 1 , Auto 1+1, Auto 2, Auto 2+1, Auto 3, Manual 1 , Manual 1+1 , Manual 2 Manual 2+1 , Manual 3, Rhythm

Low-Pass Filter:

25 (F1) or 35 (F2) or 75 (F3) or 150 Hz (F4)

ECG Amplifier:

Simultaneous recording of 12 leads Sampling frequency: 1000 Hz

System:

Dimensions: 260x210x65mm, approx. 1.8 kg

Built- in Monitor: 110x65mm effective display area, 800x480 dots resolution

On-Screen Status Indictors: power source, Battery status, date, time

Power Supply Requirements: 100-240V.50/60Hz

Stand-alone operation with Built-in rechargeable Li-ion battery Polymer,

integrated power supply unit

Battery Capacity: 8 hours of normal use Chart Paper: Thermo-sensitive, 63 mm wide

Printing Process: High-resolution thermal head printer, Vertical resolution

8 dots/mm

Environmental conditions:

Temperature, operating : 10 °C to 40 °C
Temperature, storage : -10 °C to 50 °C

Relative humidity: 25% to 95% (no condensation)



Standards:

Safety: IEC (EN) 60601-1; IEC (EN) 60601-1-2 (EMC)

Performance: IEC (EN) 60601-2-25

Software: EN62304

Protection class: I according to IEC 60601-1 (with internal power supply)

Applied part: CF according to IEC 60601-1

Optional Interface:

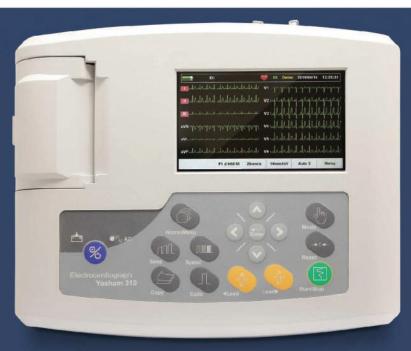
USB HOST (FS/HS Speed -5Vdc-MAX, 500 mA) USB DEVICE (FS/HS Speed -5Vdc-MAX, 500 mA)

SD CARD

USB HOST: for upgrading firmware by qualified operator.
USB device: for transferring data to PC or any host device.
SD Card: for saving recorded ECG signal data on SD card.

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Technical Data of YASHAM 110

Technical Data:

Patient input circuit: Fully floating on isolated, defibrillation protected class I, Type CF (based on IEC 60601-1)

Monitor Display:

- -12-channel display or Rhythm
- -Heart Rate
- -Sensitivity: 2.5,5,10,20 mm/mV or Automatic
- -Filter status (Notch , Low-pass , Drift , EMG)

Recording Mode and Format: 1 channel (manual and auto mode)

+ Rhythm mode

Recording Data:

Patient Data : name , age , height , weight , User ID , Gender , blood type ,

heart rate

List of all ECG recording conditions (data, time, filter, speed)

Recording Mode and Format:

Auto, Manual, Rhythm

Low pass Filter: 25,35,75, or 150 Hz

ECG Amplifier:

Simultaneous recording of 12 leads Sampling frequency: 1000 Hz

System:

Dimensions: 60 Hx245Lx92M, approx. 0.5 kg (Net weight)
On-Screen Status Indictors: power source, Battery status, date, time
AC Power input for Charger: 100-240 VAC, 1-0.4A, 50/60 Hz

Stand-alone operation with Built-in rechargeable Li-ion battery Battery Capacity: 5 hours of normal use (Monitoring)

Chart Paper: Thermo-sensitive. 50 mm wide

Printing Process: High-resolution thermal head printer, 8 dots/mm

Environmental conditions:

Temperature, operations : 10 °C to 40 °C Temperature, storage : -10 °C to 50 °C

Relative humidity: 25% to 95% (no condensation)

Standards:

Safety: IEC (EN) 60601-1, IEC (EN) 60601-1-2 (EMC) Performance: IEC (EN) 60601-2-25, ANSI/AAMI ECI1

Software: EN62304, IEC (EN) 60601-1-4 Applied part: CF according to IEC (EN) 60601-1













Optional Interface:

USB OTG: for upgrading firmware by qualified operation and for

transferring data to PC or any host device.

Micro SD: for saving recorded ECG signal data on Micro SD card



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YASHAM 1260

Technical Data of YASHAM 1260:

Technical Data:

Patient input circuit: Fully floating and isolated, defibrillation protected Class I, Type CF (based on IEC 60601-1)

Monitor Display:

- -12 channel signal of Leads or Rhythm of selected Lead
- -Heart Rate
- -Sensitivity
- -Print Speed
- -Print Mode
- -Filter status (Notch, Low-pass, Drift, EMG)
- -Date & Time
- -Patient Info.
- -Power situation

Leads: 12 simultaneous Standard leads

Recording Speed: 6.25/12.5/25/50 mm/s

Sensitivities: 2.5/5/10/20 mm/mV

Recording Mode: 6+3/12/6 channel presentations of 12 simultaneously recorded leads or Rhythm

Data Record:

- -Patient data (name, age, height, weight, User ID, Gender, blood type, heart rate(
- -Listing of all ECG recording conditions (date, time, filter, speed)
- -Measurement Results
- -Interpretation Results
- -Lead Axis



Yasham 1260

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YASHAM 1260

Fiters:

-High cut Filter: 25 or 35 or 75 or 150 Hz -EMG Filter: Adaptive Low-Pass Filter -High-Pass filter: 0.05 or 0.5 Hz (Drift)

-HUM Filter: 50 or 60 Hz (Auto Detect & Adaptive)

Signal Processing:

-12 leads Simultaneous Amplifier -Sampling frequency: 1000 Hz

-LSB < 0.5µV

-Time Constant: 3.2 sec.

Pace detection:

-1 to 700mV

-0.1 to 2 ms

-from4 independent Lead (1.11, 1,V4)

System:

Dimensions: 350*285*85(104)mm, approx. 5 kg

Built-In Monitor: 222*125 mm,10.1 inchl(Diagonal), effective

display area, 1024*600 dots resolution

On-Screen Status Indicators: power source, Battery status,

date, time

Power Supply Requirements: 90-264V, 50/60Hz

Stand-alone operation with Built-in rechargeable Li-ion bat-

tery, integrated power supply unit

Battery Capacity: 4 hours of normal use

Chart Paper: Thermo-sensitive, 210-216 mm wide

Printing Process: High-resolution thermal head printer

Printing Resolution:

8 dots/mm Vertical

40 dots/mm Horizontal @25mm/s

Environmental conditions:

Temperature, operating: 10°C to 40°C Temperature, storage: -10°C to 50°C

Relative humidity: 25% to 95% (no condensation)



Standards:

Safety: IEC (EN) 60601-1, IEC (EN) 60601-1-2(EMC)

Performance: IEC (EN) 60601-2-25

Software: EN62304

Protection class: I according to IEC 60601-1(with internal power supply)

Applied part: CF according to IEC 60601-1

Optional Interface:

USB HOST (FS/HS Speed -5Vdc-MAX. 500 mA)

USB DEVICE (FS/HS Speed -5Vdc-MAX, 500 mA)

LAN (RJ-45) (10/100 M/B - UDP/TCP/IP)

WiFi

USB Host: for upgrading firmware by qualified operator.

USB Device: for transferring data to PC or any host device.

LAN (RJ-45): This port is used in order to communicate with central server or hub for data transfer.

One can use this port for communicating with hospital PACS system.

PACS: Picture Archiving and Communication System

WiFi: is used in the place which wiring is not possible. This method is used

for transferring data from device to sever of reference PC.

One can use this method for communicating with hospital PACS system.

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ECG Viwer



Using ECG Viewer developed by Dahian Pezeshki Pishro Company, ECG data is acquired by connecting YASHAM 310 or YASHAM 110 to PC and in addition to displaying signals on monitor, recording is performed by the printer connected to PC.

Capabilities:

- · Connecting ECG device to PC through USB port
- •Recording 12-lead ECG on A4 paper in Sync mode (in JPEG or PDF format)
- •Recording in Auto 4, Auto 6, Auto 6+1 and Rhythm modes
- Displaying patient profile and physician's name in the top of the record including: (Name, ID, Gender, Weight, Height, Blood, Age, Physician Name)
- Displaying specification of recorded leads in the top of the record including: (Gain, Filter, Speed, Rec Time, Rhythm Lead, Rec Mode, Rec Type, Heart Rate, Time/Date)
- Displaying 12-lead ECG signals simultaneously and rhythm signal is separated page
- · Capability of filtering signals
- Capability of storing patient profile in addition to received signal data file in database on PC and creating backup of database in selectable time intervals in software
- Capability of saving patient signal files on USB flash memory
- Capability of searching patient in database, deleting selected patient or displaying saved signals of each patient in offline mode
- · Capability of patient monitoring in 15 minutes

Minimum Requirements:

- ·Standard 15-inch or 17-inch or similar-sized monitors
- •1 Giga byte RAM
- ·Windows 7 or later versions
- · Processor IGHz or faster
- NET Framework version 4.5.2
- · 4.5 Giga byte Hard
- VGA with following specification:
 - √ 512 Mega byte RAM (DDR2/DDR3/DDR4) which including Share Memory
 - → Supporting OpenGL 2.0 and supporting Full 3D in maximum resolution
 - ✓Updated VGA driver
- · Standard laser printer



ECG Viwer

Required softwares:

- ✓Microsoft .NET Framework 4.5.2
- √Access Database Engine
- ✓Microsoft Office 2010 or newer version
- √FastStone Image Viewer
- √Adobe Acrobat Reader

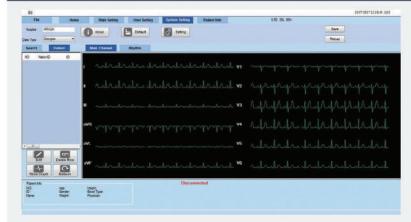
USB Port Specification:

√Type A Male to Type B Male cable with 1.5 meters length (for YASHAM 310) USB OTG cable (for YASHAM 110)

Specifications of drawing signals:

- ✓ Signal sensitivities of 2.5, 5, 10, 20 mm/mV or automatic gain
- ✓ Digital filters: Drift filter, EMG filter, HUM filter and Low-pass filter.
- → Displaying heart icon with beep sound at the top of the page
- ✓ Recording speeds: 6.25, 12.5, 25, 50 mm/sec







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ELIZ 1400

Safety

Class: IIa, Internally-powered

Applied Part Protection: Type CF (based on IEC 60601-1)

Functional

Resolution: 16 bit

Download interface: USB 2.0 or micro SD card reader

Sample rate: 200 Hz (for each channel)

Frequency response: 0.05 Hz to 40 Hz, @ -3 dB, +0.4dB

Signal verification: LCD at hook-up

Pacemaker detection: On (According to IEC 60601-2-47)

Input Impedance: $>10 M\Omega$

Battery

Battery type: AA 1.5V Alkaline Recording time: Up to 2 days

Physical

Dimensions: 69 x 79 x22 mm Weight incl. batteries: 100 g Enclosure: Molded plastic Operating position: Vertical

Electrical

Gain settings: 0,5X, 1X and 2X

Connector: 19 pin

Patient cable: 5 electrodes

Environmental

Operating temperature: 0 ° C to +45 ° C Non-operating temperature: -20 ° C to +60 ° C

Operating humidity: ≤ 80%

Non-operating humidity: 5 % to 95 %



Waveform: Restilinear Bifaic Waveform

Patient Impedance Range: 10 ohm to 300 ohm

Energy Selection by User: Yes

Shock Advisory System: Yes

Charge Time: Less than 10 sec

Shock Delivery: Via multifunction pads

Feedback for CPR: Yes

Waveform Modification: Yes

Output Energy Levels: 50J, 70J, 85J, 120J, 150J, 200J

ECG Monitoring & ECG Monitorng Cable: Yes

Shock Alowance: if the shock advisory system advises defibrillation

Data Transfer: Bluetooth 2.0

CPR Coaching: Yes

Self-Tets: Yes

Energy Protocol: Increase energy after every shock or only after lower energy shock was unsuccessful

Output Energy Accuracy: +- 10% into 50 Ohm +15% into 25 to 100 Ohm

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