COMEN Share with the World

COMEN

Digitally signed by Furculiță Andrei
Date: 2022.12.28 11:03:43 EET
Reason: MoldSign Signature
Location: Moldova

H12 Electrocardiograph

CE 1639

Shenzhen Comen Medical Instruments Co., Ltd. P/N：EN-H12-8P-20200302-V1.2

Add: No.2 of FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, China.
Tel:+86-755-2640 8879 400-700-9488 Fax:+86-755-2643 1232 Website: en.comen.com E-mail: info@szcomen.com

Getting Smaller but Stronger

The development of the Internet has revolutionized all industries, including computers, mobile phones, watches and glasses, and even affected to medical devices.

The concept of miniaturization has been thriving, and it is the frontier trend that Comen has been following in the footsteps of the world so as to create the H12 high-end 12-channel electrocardiogram machine.

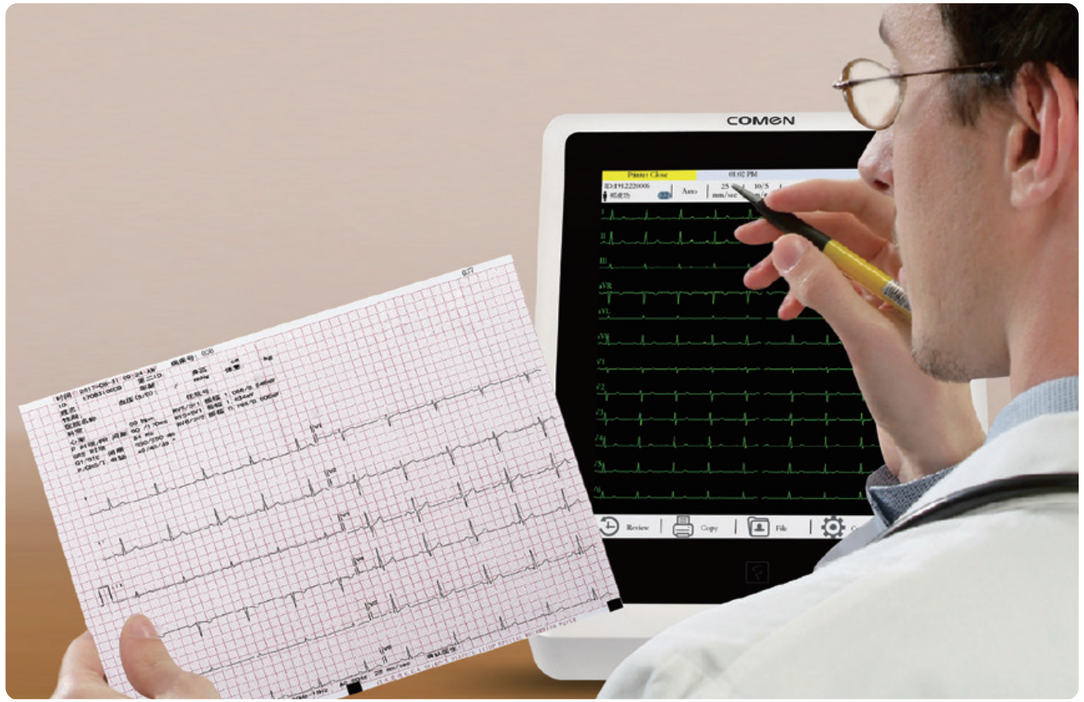
We believe that the smaller and more exquisite electrocardiogram machine, should not only has good looking design but also perfect performance. It should integrate excellent outlook and function well. To this end, we are reinventing ourselves from the inside out and innovating completely, adhering to the thought of exquisite design, precise measurement,and perfect performance to make H12 more practical and aesthetically pleasing than previous products.

Compact, flexible, intuitive design

Continuous refine of H12 makes it more compact, more delicate and more practical.

Accurate measurement

High precision digital filtering technology eliminates baseline drift and other disturbances, providing real and accurate ECG waveforms.

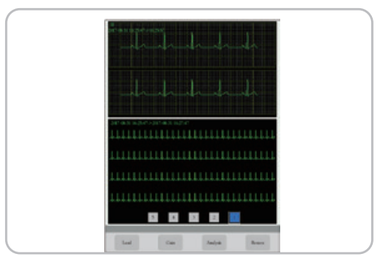


- 12-lead ECG acquisition, amplification and recording simultaneously
- Polarization voltage≥ ±650mV, CMRR≥105dB, Time Constant≥5S and 24bits A/D conversion allows powerful anti-defibrillation ability and accurate collection of ECG waveforms
- First using Cabrera Leads mode help accurate definition and calculating frontal plane axis of myocardial ischemia and Myocardial infarction, improve determinant of infarction artery, fatalness evaluation, etc.
- Support HRV analysis and rhythmic R-R analysis
- Pacemaker detection

Perfect performance

- Hand writing input of patients information;
- Support ECG data management software, HL7 protocol, DICOM Worklist.
  Doctor can view ECG waveform report from computer directly
- Patient case management help easy search, transmit, print and view patients information .
- Standby and automatic wake-up as well as timing shutdown support;
- USB disk to input & output ECG data.
- Intelligent charging mode, both slow charging and fast charging available.
  Charging mode matches with working mode to reduce heat and protect components.

Scanner available allows for quick inputting of the patients information.



600 seconds of 12-lead waveforms review;
10 seconds 12-leads waveforms recording.

Amplification of Leads status map to show whether the ECG leads are connected well.

More efficient printing systems

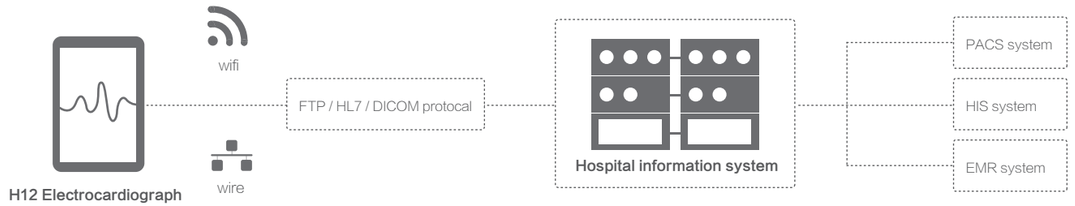
- Automatic measurement of ECG waveform, automatic measurement of report output,support a variety of record formats;
- Various recording format: 12×1, 12×1+1T, 6×2, 6×2+1R, 3×4, 3×4+1R, 3×4+3R;
- Recording mode: one key printing, extend printing and normal printing
- Intellectualized Cali-Rec™ recording calibration system solves the problem of ECG paper jam, paper deflection completely

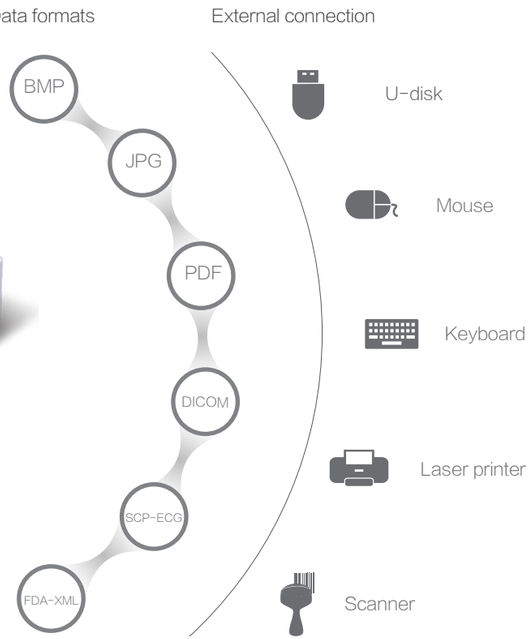
Powerful data storage

- 600 seconds 12-lead waveforms review
- 10000 ECGs internal memory；support formats DAT, BMP, JPG, PDF, DICOM, FDA-XML, SCP
- Support patients’ name and ID number search.

ECG Information solution proposal

- Support wire/wireless networking
- Support connection with U disk, SD card, mouse, keyboard, scanner, laser printer
- Support BMP / JPG / PDF / DICOM / SCP-ECG / FDA-XML format reporting
- Support ECG data management software, HL7 / FTP / DICOM protocal allow connection with hospital HIS、EMR、PACS system. Doctor can view ECG waveform and diagnosis report from computer directly





广东外办

21009953 2100005320

土耳其 1 /2 (SH) Y

深圳市科曼医疗设备有限公司

深圳国立商事认证中心

证 明 书

CERTIFICATE

中国国际贸易促进委员会暨中国国际商会

China Council for the Promotion of International Trade is China Chamber of International Commerce

00002838

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证 明 书
CERTIFICATE

号码 No. 214403A0/024833

兹证明：在所附声明上的深圳市科曼医疗设备有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. on the annexed DECLARATION is genuine.

China Council for the Promotion of International Trade
商事证明专用章
CCPIT

授权签字：
Authorized Signature: LIU JUN

日期：2021年04月26日
(Date: Apr. 26, 2021)

证书查询网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

认字第21009953号

兹证明前面文书上中国国际贸易促进委员会商事证明专用章CCPIT（24）的印章和授权签字人 刘俊 的签字属实。

中华人民共和国外交部（440）
二〇二一年四月二十八日 广州

00783376

中华人民共和国外交部（440）

T.C.
GUANCO BAŞKONSOLOSLUĞU
İşbu belge üzerindeki imza ve mührün
Guangdong Dışişleri Ofisi'ne
ait bulunduğu, metne şamil olmamak
üzere onaylanır.

Selçuk ALKAN
Muavin Konsolos
Vice Consul

T.C. BAŞKONSOLOSLUĞU GUANCO 1923

No: 30/4/2021/400

Tarife: 5/III/3a

Harç: 124 Yuan

Makbuz No: 28708424

ÖZBAY TERCÜME BÜROSU OFFICE

SHENZHEN COMEN MEDICAL INSTRUMENTS CO.,LTD
Add:No.2 of FIYTA Timepiece Building, Nanhuan Avenue,
Gongming sub-district, Guangming District, Shenzhen, P.R China.
Tel: +86-755-26408879 Fax: +86-755-26431232
www.szcomen.com info@szcomen.com

声明
Declaration

兹证明我公司确已经取得 SGS 所颁发的 CE 证书；
WE HEREBY CERTIFY THAT WE HAS ACQUIRED CE CERTIFICATE, WHICH IS ISSUED BY SGS;

证书编号：CN19/41057
CERTIFICATE REGISTRATION NO: CN19/41057

颁发时间：2021-03-22
DATE OF ISSUE: 2021-03-22

有效期至：2023-02-05
VALID UNITIL: 2023-02-05

证书影印件如下页，且此影印件与原件相符。
THE FOLLOWING PAGE IS A PIECE OF THE CERTIFICATE AND THE PHOTOCOPIER IS IN CONFORMITY WITH THE ORIGINAL.

Mac 汪胜飞/Turkey General Manager 土耳其总经理
Authorized Signature

深圳市科曼医疗设备有限公司
SHENZHEN COMEN MEDICAL INSTRUMENTS CO.,LTD.
2021 年 04 月 21 日
April 21th, 2021

ÖZERAY TERCÜME BÜROSU
ÖZERAY TRANSLATION OFFICE
NOTER YEMİNLİ TERCÜME

EC Certificate Full Quality Assurance System: Certificate CN19/41057

The management system of

Shenzhen Comen Medical Instruments Co., Ltd.

Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 22 March 2021 until 05 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 30 April 2015.

Certification is based on reports numbered CN/SZX 50010

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

EC Declaration of Conformity

Manufacturer:
Shenzhen Comen Medical Instruments Co.,Ltd
Address:
Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China.

Whose Single Authorized Representative:
Lotus NL B.V.
Address:
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, declare at our sole responsibility that following products

Product name	Model
Electrocardiograph	CM300, CM300A, CM1200, CM1200A, CM1200B,H3, H12, H12A
Vital Signs Monitor	NC3, NC3A, NC3B, OPUS i3, NC5, NC5A
Infrared Ear thermometer	IRT10, IRT10A
Anesthetic Gas Scavenging System	AGSS-L, AGSS-H
Ceiling Pendant	D5, D7, D6, D8, D9, D9A, D9B
Sequential Compression System	SCD600
Phototherapy Unit	BL70, BL70A, BL70B
Defibrillator monitor	S8, S6, S5, S3

meet the provisions of Directive 93/42/EEC.

Those medical devices have been assigned to class IIa according to rules of the Directive 93/42/EEC (The rule for each device are shown in the following annex I). It bears the mark

CE 1639

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) of Directive 93/42/EEC.

Compliance of the designated product with the Annex II (excluding Section 4) of Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS Belgium NV
SGS House Noorderlaan
87 2030 Antwerp Belgium
Certificate No.: CN19/41057
Issue date: 2021.03.22
Expiry date: 2023.02.05

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Shenzhen Comen Medical Instruments Co.,Ltd
Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China.

Shenzhen, 2021.4.28
Place, date

Duan Cong, Management Representative
Legally binding signature, Function

Shenzhen Comen Medical Instruments Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

- Electrocardiograph (Model: CM300, CM300A, CM1200, CM1200A,CM1200B, H3, H12, H12A)
- Multi-parameter Patient Monitor for vital physiological parameters (Model: C30, C50, C70, C80, C86, C90, C500, C800, C860, NC19, NC19A, Datalys 750, Datalys 770, Datalys 780, Datalys 790, STAR8000, STAR8000A,STAR8000B, STAR8000C, STAR8000D, STAR8000E, STAR8000H, NC8, NC10, NC12, C100A, NC8A, NC10A, NC12A, C90A, C30A, C70A, STAR8000F, OPUS I8, OPUS I10, OPUS I10 Expert, OPUS I12, OPUS I12 pro, OPUS I15, K12 pro, K12A pro, K15 pro, K15A pro, K18 pro, K18A pro, K22 pro, K22A pro, K1, K1A)
- Fetal & Maternal Monitor for vital physiological parameters (Model: STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)
- Specialized Fetal & Maternal Monitor for monitoring or measurement of fetal heart rate, fetal movement, uterine pressure, ECG, CO2, NIBP, SpO2, body temperature, respiration, pulse/pulse frequency (Model: C20, C26, C29, C22, C22A, C21, C21A, C10, C11)
- Specialized Cardiovascular Monitor for processing, displaying and recording the patient's electrocardiogram and for vital physiological parameters (Model: C100, C100B)
- Central Monitoring System Software for intensively monitoring vital physiological parameters from patient monitoring system (Model: STAR8800)
- Vital Signs Monitor for routine check of NIBP, SpO2, Temperature and Pulse rate (Model: NC3, NC3A, NC3B, OPUS I3, NC5A)
- Vital Signs Monitor for routine check of NIBP, SpO2, ECG,Temperature and Pulse rate (Model: NC5)
- Specialized Neonatal Monitor for vital physiological parameters (Model: C60, C66, C68, Datalys 760)
- Infrared Ear thermometer (Model: IRT10, IRT10A)
- Anaesthetic Gas Scavenging System (Model: AGSS-L, AGSS-H)
- Ceiling Pendant (Model: D5, D7, D6, D8, D9, D9A, D9B)
- T piece Infant Resuscitation System (model: BQ70, BQ70A)
- Anaesthesia Machine (Model: AX-400A, AX-500A, AX-700A, AX-800, AX-900, AX-900A, AX-400, AX-500, AX-600, AX-700)
- Infant Radiant Warmer (Model: BQ80, BQ80A)
- Catheter-positioning guiding system (Model: U8, U8A)
- Syringe Pump (Model: M300, M500)
- Infant Phototherapy equipment (Model: BL70, BL70A, BL70B)
- Temperature Control System for management patient body temperature and vital physiological parameters Monitor (Model: P3, P6)
- Sequential Compression System for prevention of deep vein thrombosis and pulmonary embolism (Model: SCD600)
- Defibrillator Monitor (Model: S8, S6, S5, S3)

Sterility aspect only Restricted to the Aspect of manufacture concerned with securing and maintaining sterile conditions:

- Sterile disposable laryngoscope blade (Model: CVL-2-1, CVL-3-1)
- Sterile disposable electrode with extension wire used for Catheter-positioning guiding system (Model: 98ME01AC019)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.