Anexa 1

ECOGRAF DEDICAT EXAMINARILOR CARDIOLOGICE

CARACTERISTICI TEHNICE SOLICITATE	CARACTERISTICI TEHNICE OFERTATE MODEL: **Versana Premier (GE Healthcare)**
UNITATEA DE BAZA	**UNITATEA DE BAZA**
Minim 3 porturi de sonda active	4 porturi de sonda active
Sistem de blocare a celor 4 roti	Sistem de blocare a celor 4 roti
Ecograful sa dispuna de spatiu pentru periferice	Ecograful sa dispuna de spatiu pentru periferice
Suport pentru tubul de gel	Suport pentru tubul de gel
Maner pentru deplasarea cu usurinta a echipamentului	Maner pentru deplasarea cu usurinta a echipamentului
Posibilitate de atasare a unui incalzitor de gel	Posibilitate de atasare a unui incalzitor de gel
HDD minim 500 GB	HDD 500 GB
Zgomot generat maxim 40 dB	Zgomot generat 36 dB
Putere consumata (cu tot cu periferice) max 650VA	Putere consumata (cu tot cu periferice) 450VA
Monitor	**Monitor**
Diagonala min 21 inch	Diagonala 21,5 inch
Tehnologie LED sau superior	Tehnologie LED sau superior
Rezolutie Full HD (1920 x 1080)	Rezolutie Full HD (1920 x 1080)
16.7 M culori	16.7 M culori
Posibilitate de reglare a luminozitatii	Posibilitate de reglare a luminozitatii
Monitorul trebuie sa fie fixat pe un brat articulat care sa permita :	Monitorul trebuie sa fie fixat pe un brat articulat care sa permita :
- Rotire pe orizontala ±160 grade	- Rotire pe orizontala 170 grade
- Rotire pe verticala +25/-70 grade	- Rotire pe verticala +25/-90 grade
- Reglarea inaltimii min 18 cm	- Reglarea inaltimii 18 cm
Panou de control	**Panou de control**
Minim 4 taste configurabile de catre utilizator	9 taste configurabile de catre utilizator
Minim 5 suporturi pentru sonde	6 suporturi pentru sonde
Inaltime reglabila pe minim 18 cm	Inaltime reglabila pe 18 cm
Pentru simplificarea fluxului de lucru, ecograful trebuie sa dispuna de ecran tactil	Pentru simplificarea fluxului de lucru, ecograful dispune de ecran tactil
Ecran tactil	**Ecran tactil**
Tehnologie LED	Tehnologie Ultra-hight resolution LED
Diagonala minim 10 inch	Diagonala 10 inch
Rezolutie minim 1280 x 800	Rezolutie minim 1280 x 800
Tastatura alfa-numerica disponibila pe ecranul tactil	Tastatura alfa-numerica disponibila pe ecranul tactil
Ecran tactil de tip capacitiv	Ecran tactil de tip capacitiv
Aplicatii disponibile pe echipament	**Aplicatii disponibile pe echipament**
Abdomen	Abdomen
Cardiologie	Cardiologie
Ginecologie	Ginecologie

Musculoscheletal	Musculoscheletal
Obstetrica	Obstetrica
Pediatrie	Pediatrie
Parti moi	Parti moi
Urologie	Urologie
Vascular	Vascular
Preseturi standard	**Preseturi standard**
Abdomen	Abdomen
Cord adult	Cord adult
Adnexa	Adnexa
Aorta	Aorta
Arc aortic	Arc aortic
Arterial	Arterial
Vezica urinara	Vezica urinara
Intestine	Intestine
San	San
Carotida	Carotida
Penetrare	Penetrare
Cord fetal	Cord fetal
Cap (neonatologie)	Cap (neonatologie)
Translucenta nucala	Translucenta nucala
Abdomen pediatrie	Abdomen pediatrie
Cord pediatrie	Cord pediatrie
Sold pediatrie	Sold pediatrie
Prostata	Prostata
Renal	Renal
Tiroida	Tiroida
Testicul	Testicul
Doppler transcranial	Doppler transcranial
Uter	Uter
Venos	Venos
OB Trim 1	OB Trim 1
OB Trim 2	OB Trim 2
OB Trim 3	OB Trim 3
Moduri de operare	**Moduri de operare**
2D	2D
Doppler color	Doppler color
Doppler pulsat	Doppler pulsat
Doppler continuu	Doppler continuu
Power Doppler	Power Doppler
Power Doppler directional	Power Doppler directional
M	M
M anatomic	M anatomic
Single/Dual/Quad	Single/Dual/Quad
3D	3D
4D	4D
STIC (Spatio Temporal Image Correlation)	STIC (Spatio Temporal Image Correlation)
Doppler color tisular	Doppler color tisular
Doppler pulsat tisular	Doppler pulsat tisular

Elastografie	Elastografie
Imagine panoramica	Imagine panoramica
Imagine trapezoidala	Imagine trapezoidala
Mod de lucru ce usureaza vizualizarea acului de biopsie si a traiectoriei acestuia	Mod de lucru ce usureaza vizualizarea acului de biopsie si a traiectoriei acestuia
Transductori	**Transductori**
Echipamentul sa fie compatibil cu :	Echipamentul este compatibil cu :
Sonde liniare in gama totala de frecventa minim 3-16 MHz	Sonde liniare in gama totala de frecventa 3-18 MHz
Sonde convexe in gama totala de frecventa minim 2-8 MHz	Sonde convexe in gama totala de frecventa 1.5-10 MHz
Sonde micro-convexe in gama totala de frecventa minim 4-9 MHz	Sonde micro-convexe in gama totala de frecventa 3,5-10 MHz
Sonde endocavitare in gama totala de frecventa minim 4-9 MHz	Sonde endocavitare in gama totala de frecventa minim 3,5-10 MHz
Sonde phased array in gama totala de frecventa minim 2-4 MHz	Sonde phased array in gama totala de frecventa 2-4 MHz
Sonde abdominale volumetrice in gama totala de frecventa minim 4-8 MHz	Sonde abdominale volumetrice in gama totala de frecventa 3-5 MHz
Sonde endocavitare volumetrice in gama totala de frecventa minim 5-9 MHz	Sonde endocavitare volumetrice in gama totala de frecventa minim 5-9 MHz
Sonda creion de 2 MHz	Sonda creion de 2 MHz
Caracteristici standard ale echipamentului	**Caracteristici standard ale echipamentului**
Formator de unde digital	Formator de unde digital
Gama totala de frecventa acoperita min 2-16 MHz	Gama totala de frecventa acoperita 1,7-18 MHz
Minim 570 000 canale de procesare	Minim 570 000 canale de procesare
Adancime de scanare min 2-38 cm	Adancime de scanare 0-38 cm
Minim 4 focare	8 focare
Soft de imbunatatire a imaginii 2D si 3D/4D prin intarirea contururilor si reducerea artefactelor	Soft de imbunatatire a imaginii 2D si 3D/4D prin intarirea contururilor si reducerea artefactelor
- Reglabil in 5 trepte	- Reglabil in 5 trepte
Minim 256 tonuri de gri	256 tonuri de gri
Gama dinamica minim 256 dB	Gama dinamica 224 dB
Sistemul sa atinga un frame rate de minim 950 fps	Sistemul sa atinga un frame rate de 1774 fps
Posibilitate de inversare a imaginii	Posibilitate de inversare a imaginii
- Sus/jos	- Sus/jos
- Stanga/dreapta	- Stanga/dreapta
Rotire a imaginii cu 90/180/270 grade	Rotire a imaginii cu 0/90/180/270 grade
Mod de compunere a frecventelor reglabil in minim 3 pasi	Mod de compunere a frecventelor reglabil in minim 3 pasi
Memorie CINE min 45000 frame-uri	Memorie CINE min 45000 frame-uri
CINE Loop minim 14000 linii	CINE Loop minim 14000 linii
Optimizare automata a imaginii in scala de gri prin apasarea unui singur buton	Optimizare automata a imaginii in scala de gri prin apasarea unui singur buton
Timp de pornire a sistemului max 180 sec	Timp de pornire a sistemului 180 sec
Minim 30 preseturi personalizabile de catre utilizator	Minim 30 preseturi personalizabile de catre utilizator
Baza de date pacienti	Baza de date pacienti
Posibilitate de editare a meniului de pe ecranul tactil	Posibilitate de editare a meniului de pe ecranul

	tactil
Softuri disponibile optional pe sistem	**Softuri disponibile optional pe sistem**
4D	4D
Softuri de prelucrare a volumului	Softuri de prelucrare a volumului
- Vizualizare a volumului in slice-uri 2D cu grosime reglabila	- Vizualizare a volumului in slice-uri 2D cu grosime reglabila
- Vizualizare a unei sectiuni in volum definita dupa orice plan trasat de catre utilizator	- Vizualizare a unei sectiuni in volum definita dupa orice plan trasat de catre utilizator
Masurare automata a intimei medii	Masurare automata a intimei medii
DICOM 3.0	DICOM 3.0
Elastografie de tip strain pentru parti moi	Elastografie de tip strain pentru parti moi
Modul de exportare a imaginilor pe smartphone prin intermediul unei aplicatii disponibile pentru Android si IOS	Modul de exportare a imaginilor pe smartphone prin intermediul unei aplicatii disponibile pentru Android si IOS
Mod de lucru ce usureaza vizualizarea acului de biopsie si a traiectoriei acestuia	Mod de lucru ce usureaza vizualizarea acului de biopsie si a traiectoriei acestuia
Panoramic	Panoramic
Masuratoare semi-automata a translucentei nucale	Masuratoare semi-automata a translucentei nucale
Masuratoare automata a foliculilor ovarieni dintr-o achizitie 3D a ovarului	Masuratoare automata a foliculilor ovarieni dintr-o achizitie 3D a ovarului
Mod de reconstructie realista a tesuturilor in 3D/4D	Mod de reconstructie realista a tesuturilor in 3D/4D
STIC (Spatio Temporal Image Correlation)	STIC (Spatio Temporal Image Correlation)
Strain (cardiologie)	Strain (cardiologie)
Modul 2D	**Modul 2D**
Steer 2D minim 5 unghiuri	Steer 2D minim 5 unghiuri
Chroma minim 11 harti	Chroma minim 11 harti
Afisare in mod dual 2D si Doppler Color in timp real	Afisare in mod dual 2D si Doppler Color in timp real
Minim 5 frecvente selectabile	Minim 5 frecvente selectabile
Minim 12 harti de gri	Minim 12 harti de gri
Mod de lucru cu armonice fundamentale	Mod de lucru cu armonice fundamentale
Mod de lucru cu armonice cu inversie de faza	Mod de lucru cu armonice cu inversie de faza
Posibilitate de reglare a densitatii de linii minim 3 pasi	Posibilitate de reglare a densitatii de linii minim 3 pasi
Soft de reducere a artefactelor si intarire a contururilor	Soft de reducere a artefactelor si intarire a contururilor
- Reglabil in minim 5 pasi	- Reglabil in minim 5 pasi
Compunere spatiala	Compunere spatiala
- Reglabila in minim 3 pasi	- Reglabila in minim 3 pasi
Imagine trapezoidala	Imagine trapezoidala
Reglare a unghiului de scanare minim 40-100%	Reglare a unghiului de scanare 40-100%
Zoom	Zoom
- Read zoom de minim 8 ori	- Read zoom de 8 ori
- Write zoom	- Write zoom
Modul M	**Modul M**
Minim 11 harti	11 harti

Posibilitate de reglare a vitezei de baleiere (sweep speed)	Posibilitate de reglare a vitezei de baleiere (sweep speed)
Mod M anatomic	Mod M anatomic
Modul Doppler Color	**Modul Doppler Color**
Minim 12 harti de culoare	14 harti de culoare
Posibilitate de reglare a sensibilitatii	Posibilitate de reglare a sensibilitatii
Hide color : on/off	Hide color : on/off
Gama PRF minim 0.1 KHz – 19.5 KHz	Gama PRF minim 0.1 KHz – 19.5 KHz
Inclinarea ferestrei doppler cu minim ±30 grade	Inclinarea ferestrei doppler cu minim ±30 grade
Filtru de perete reglabil in minim 4 pasi	Filtru de perete reglabil in minim 4 pasi
Modul Doppler pulsat	**Modul Doppler pulsat**
Calcul automat pentru PSV, EDV, TAPV, RI, PI, S/D, TAMV, D/S, Max Pressure Gradient, Mean Pressure Gradient, VTI, Peak A	Calcul automat pentru PSV, EDV, TAPV, RI, PI, S/D, TAMV, D/S, Max Pressure Gradient, Mean Pressure Gradient, VTI, Peak A
Harti de culoare minim 11	Harti de culoare 11
Gama PRF minim 1-22.5 kHz	Gama PRF minim 0.3-27.9 kHz
Optimizare automata a spectrului prin ajustarea baseline-ului si reglarea PRF-ului prin apasarea unui singur buton	Optimizare automata a spectrului prin ajustarea baseline-ului si reglarea PRF-ului prin apasarea unui singur buton
Reglare a dimensiunii portii minim 0.5 – 25 mm	Reglare a dimensiunii portii 0.5 – 25 mm
Corectie automata a unghiului de insonatie la 60 grade	Corectie automata a unghiului de insonatie la 60 grade
Modul Doppler Continuu	**Modul Doppler Continuu**
Gama PRF minim 2-57 kHz	Gama PRF 2-57 kHz
Modul Power Doppler	**Modul Power Doppler**
Minim 12 harti de culoare	12 harti de culoare
Hide color	Hide color
Inversare a hartii de culoare (Power Doppler Directional)	Inversare a hartii de culoare (Power Doppler Directional)
Filtru de perete reglabil in minim 4 pasi	Filtru de perete reglabil in minim 4 pasi
Gama PRF minim 0.1 KHz – 19.5 KHz	Gama PRF 0.1 KHz – 19.5 KHz
Inclinarea ferestrei doppler cu minim ±30 grade	Inclinarea ferestrei doppler cu minim ±30 grade
Modul 3D/4D	**Modul 3D/4D**
Vizualizare tomografica a volumului in slice-uri 2D de grosime reglabila	Vizualizare tomografica a volumului in slice-uri 2D de grosime reglabila
Calcul automat al dimensiunilor foliculilor pornind de la o achizitie 3D a ovarului	Calcul automat al dimensiunilor foliculilor pornind de la o achizitie 3D a ovarului
Soft de reconstructie realista a tesuturilor	Soft de reconstructie realista a tesuturilor
- Posibilitate de reglare a unghiului de iluminare	- Posibilitate de reglare a unghiului de iluminare
- Posibilitate de reglare a culorii tesutului	- Posibilitate de reglare a culorii tesutului
Unelte de prelucrare a volumului (stergere, decupare pentru inlaturarea artefactelor sau a structurilor inutile)	Unelte de prelucrare a volumului (stergere, decupare pentru inlaturarea artefactelor sau a structurilor inutile)
ROI Curve – posibilitate de curbare a boxului pentru reconstructia 3D/4D in zone cu putin lichid amniotic)	ROI Curve – posibilitate de curbare a boxului pentru reconstructia 3D/4D in zone cu putin lichid amniotic)
Posibilitate de reglare a unghiului de reconstructie pentru scurtarea timpului de achizitie	Posibilitate de reglare a unghiului de reconstructie pentru scurtarea timpului de

	achizitie
Elastografie	**Elastografie**
Echipamentul trebuie sa dispuna de software de elastografie de tip strain pe sonda liniara si endocavitara	Echipamentul trebuie sa dispuna de software de elastografie de tip strain pe sonda liniara si endocavitara
Modul elastografic sa fie realizabil fara compresia utilizatorului pentru mai multa acuratete si reproductibilitate a examinarii	Modul elastografic sa fie realizabil fara compresia utilizatorului pentru mai multa acuratete si reproductibilitate a examinarii
Softul de elastografie sa dispuna de un indicator de calitate a achizitiei in timp real	Softul de elastografie sa dispuna de un indicator de calitate a achizitiei in timp real
Minim 5 harti de culoare selectabile	Minim 5 harti de culoare selectabile
Afisare in mod dual	Afisare in mod dual
Reglare a transparentei hartii de culoare	Reglare a transparentei hartii de culoare
Inversare a hartii de culoare	Inversare a hartii de culoare
A. CONFIGURATIE DE LIVRARE	**B. CONFIGURATIE DE LIVRARE**
1.Unitatea de baza incluzand minim cerintele tehnice de la punctul A.	**1.Unitatea de baza incluzand minim cerintele tehnice de la punctul A.**
2. Transductor phased array multifrecventa	**2. Transductor phased array multifrecventa**
- gama de frecventa in intervalul minim 2-4 MHz	- gama de frecventa in intervalul minim 2-4 MHz
- minim 60 elemente	- minim 60 elemente
- unghi de scanare minim 90°	- unghi de scanare minim 90°
- aplicatii: abdomen, cardiac, vascular, pediatric	- aplicatii: abdomen, cardiac, vascular, pediatric
3. Transductor Liniar multifrecventa	**3. Transductor Liniar multifrecventa**
- gama de frecventa in intervalul minim 3-16 MHz	- gama de frecventa in intervalul minim 3-16 MHz
- minim 192 elemente	- minim 192 elemente
- camp de scanare minim 35 mm	- camp de scanare minim 35 mm
- aplicatii: pediatrie, musculoscheletal, parti moi, vascular	- aplicatii: pediatrie, musculoscheletal, parti moi, vascular
- Posibilitate de atasare a unui ghid de biopsie	- Posibilitate de atasare a unui ghid de biopsie
4. Transductor Convex multifrecventa	**4. Transductor Convex multifrecventa**
- gama de frecventa in intervalul minim 2-8 MHz	- gama de frecventa in intervalul minim 2-8 MHz
- minim 190 elemente	- minim 190 elemente
- unghi de scanare minim 55°	- unghi de scanare minim 55°
- aplicatii: abdomen, obstetrica, ginecologie	- aplicatii: abdomen, obstetrica, ginecologie
- Posibilitate de atasare a unui ghid de biopsie	- Posibilitate de atasare a unui ghid de biopsie
5. Pachet cardiologie compus din: - doppler continuu - masuratori cardiace	**5. Pachet cardiologie** compus din: - doppler continuu - masuratori cardiace
6. Soft de reducere a artefactelor si intarire a contururilor pentru imbunatatirea imaginii 2D	**6. Soft de reducere a artefactelor si intarire a contururilor pentru imbunatatirea imaginii 2D**
7. Soft de compunere spatiala pentru rezolutie superioara in modul 2D	**7. Soft de compunere spatiala pentru rezolutie superioara in modul 2D**
8. Videoprinter alb-negru digital	**8. Videoprinter alb-negru digital**
CONDIȚII DE SERVICE ȘI GARANȚIE	**CONDIȚII DE SERVICE ȘI GARANȚIE**

Perioada de garanţie: minim 24 luni de la data recepţiei finale	Perioada de garanţie: minim 24 luni de la data recepţiei finale
Termen de interventie – maxim 72 de ore de la primirea notificarii	Termen de interventie – maxim 72 de ore de la primirea notificarii
Transportul, montarea şi punerea în funcţiune se realizează de către furnizor, costul acestor operaţii fiind incluse în preţ	Transportul, montarea şi punerea în funcţiune se realizează de către furnizor, costul acestor operaţii fiind incluse în preţ
Personal calificat pentru instruire personal utilizator si punere in funcţiune	Personal calificat pentru instruire personal utilizator si punere in funcţiune
SERVICE POSTGARANTIE	**SERVICE POSTGARANTIE**
Perioada minima: 7 ani pe baza de contract şi asigurare piese de schimb şi consumabile	Perioada minima: 7 ani pe baza de contract şi asigurare piese de schimb şi consumabile
Timp maxim de interventie: 96 ore, la sediul beneficiarului	Timp maxim de interventie: 96 ore, la sediul beneficiarului

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60116081 0001

Report No.: 15094929 004

Manufacturer:

GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60110059 0001

Expiry Date: 2021-05-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

X. Ren

Effective Date: 2017-01-03

Date: 2017-01-03

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60116081 0001
Report No.: 15094929 004

Manufacturer:
GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

Manufacture of Ultrasound Diagnostic Systems

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Storage of Ultrasound Diagnostic Systems

Notified Body

X. Ren

Date: 2017-01-03

TÜVRheinland®

Doc. 1/1, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60116081 0001
Report No.: 15094929 005

Manufacturer:
GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle S. Liu

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-MLD" S.R.L. Nr.6 REPUBLICA MOLDOVA, MUN. CHIŞINĂU

Date: 2017-12-20

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China**

has established and applies a quality management system for medical devices for the following scope:

**Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products and additional sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-12-20
Certificate Registration No.:	SX 60123505 0001
An audit was performed. Report No.:	15094484 005
This Certificate is valid until:	2020-06-30

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-12-20

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel. +49 221 806-1371 Fax +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60123505 0001
Report No.: 15094484 005

Organization:
GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Scope:

Products:
- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:
GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

Manufacture and Distribution of Ultrasound Diagnostic Systems

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech Development Zone, Jiangsu 214028, P.R.China

Storage and Distribution of Ultrasound Diagnostic Systems and Probes, Anesthesia Devices, Bone Densitometry Systems, ECG Module

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle

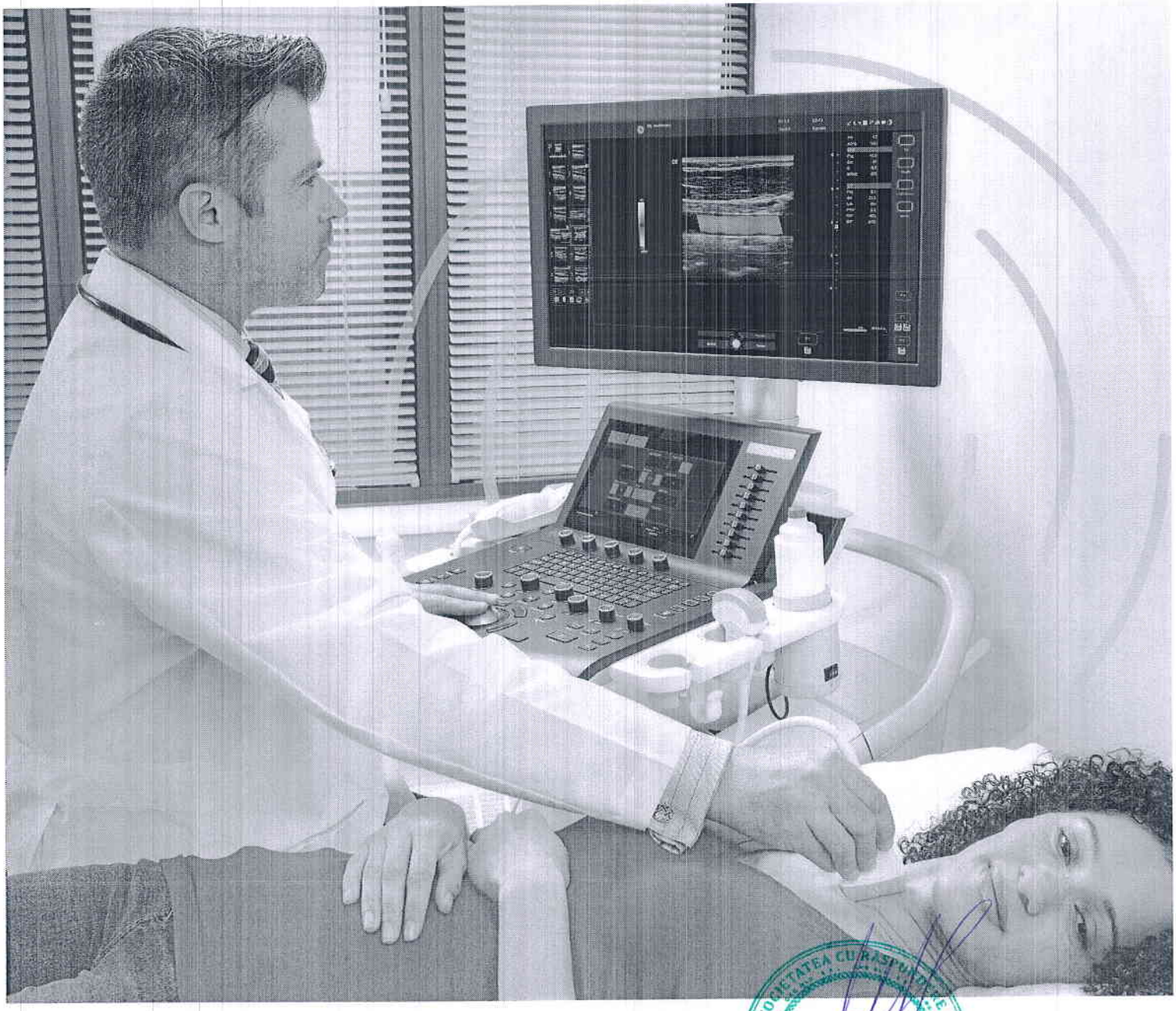
SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-MLD" IDNO 1003600117582 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

S. Liu

Date: 2017-12-20

Versana Premier™

Care with Confidence



gehealthcare.com

Premier

Productive.
und designed for peace of mind.

und system can help you deliver high-quality, personalized care,
busy day. This innovative system is well suited for general practice
ters, community health clinics, and other facilities offering basic
cover abdominal, OB/GYN, cardiac, urology, vascular and

linical features let you provide quick and comfortable exams,
gnose a broad range of conditions.

tivity tools

support

na users

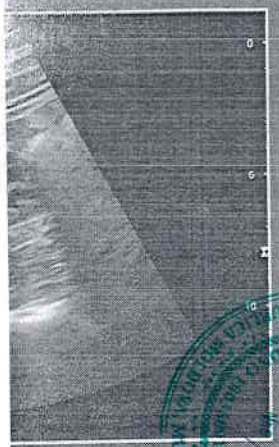
- Simple maintenance; easy troubleshooting and repair
- InSite™ service technology† for fast remote diagnostics and repairs

you can trust

levels of excellence

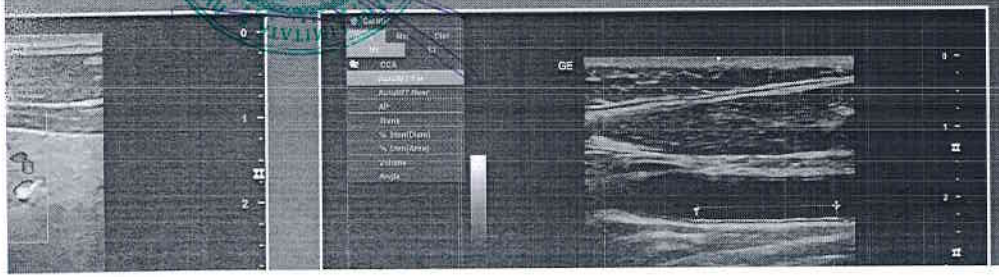
technology

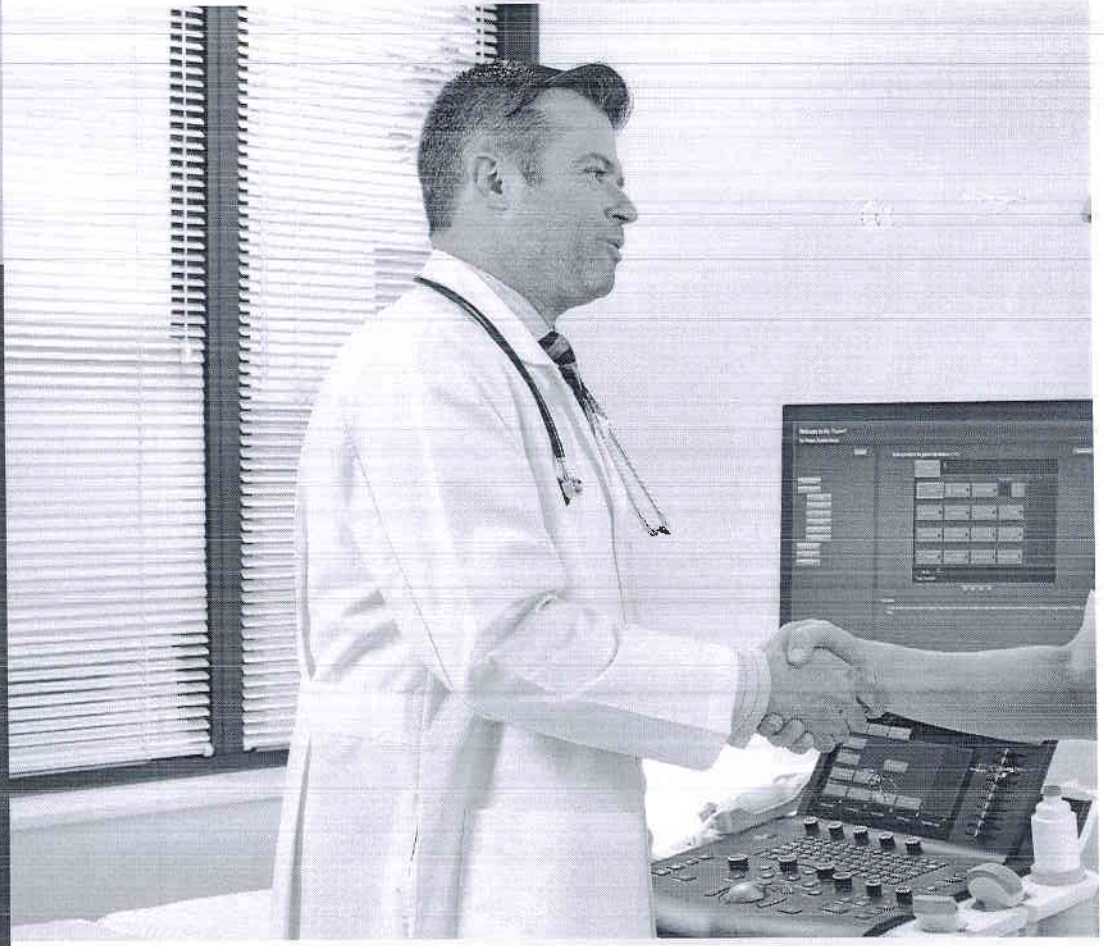
ding imaging power and clarity to boost diagnostic confidence. It helps you see ues, and delineate structure boundaries. You'll enjoy proven functionalities found



ture borders clearly.

Sensitive B-Flow™ and B-Flow color imaging to analyze blood flow, diagnose vessel-wall irregularities and stenosis, and more.





+ Decades of GE Healthcare heritage at your serv

Invest in Versana Premier and benefit from vast GE ultrasound exp with you, your practice, and your patients in mind to meet your clir connectivity needs.

cal education, and financing to fit your budget

nple to use

cations help you diagnose a wide spectrum of patient conditions. Intuitive
ow. The system boots up quickly and operates quietly. It is compact to fit small
ven rooms.

Whizz dynamic image tuning continuously optimizes the image as you scan, even as you move from one organ or area to another

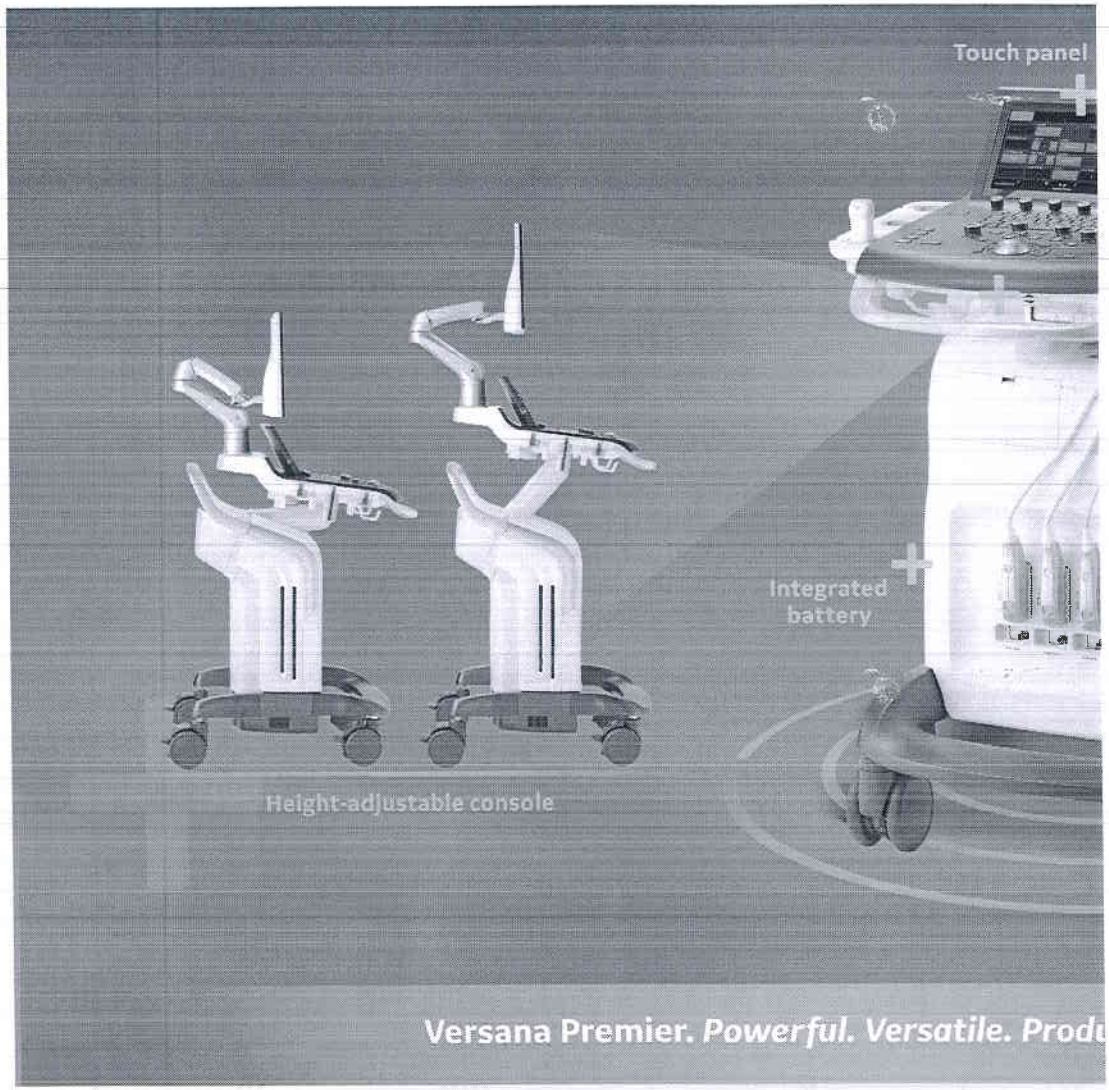
Use *3D volume* imaging for rich anatomical views

Take *automated measurements* of bladder volume, cysts or masses, IMT thickness, fetal characteristics and more

Overlay *voice comments* on images for playback when reviewing exams

Use *battery power* to move the system from room to room without powering down

Network options let use the cloud[1] to share images with for consultation[2]



+ Sharp
- stay

- Scan C illustra
- My Trai care, se
- Web-b
- Local fa

An opportunity **for growth**

Ultrasound to serve you well today and set your course for the future.

+ Experience the strength of the GE Healthcare family

Your support team is fully trained & GE Healthcare qualified, deeply experienced, and close by.

- Expert support during and after purchase
- In-depth product instruction
- Remote or on-site technical, clinical and network support

+ Customized solutions and path to growth

Help your practice grow with Versana Premier. You can select a basic package, with the option to add more probes and software. Or let GE experts help select another system to suit your needs.

+ Versana Club: Learn. Network. Share.

The Versana Club gives you access to member resources members that can help expand your ultrasound knowledge and improve your practice. It's a place to share images with your peers from around the world.

You'll also enjoy:

- Educational offerings
- Web-based video tutorials
- Information on Versana family service solutions and products
- Up-to-date content on ultrasound and patient care
- Notices of regional ultrasound events and other news
- Access to the broader family of GE ultrasound user clubs

Versana Premier. Care with Confidence.

Powerful. Versatile. Productive. World-class ultrasound designed for peace-of-mind.

[‡] Local educational offerings may vary according to regions. Please check with your local GE representative.
[*] Option may not be available in all countries.
[1] Requires internet connection; may not be available in all countries.
[2] Image sharing to mobile devices via Bluetooth available in some countries
[3] Financing options vary from country to country. Please check with your local GE representative.

Products mentioned in this material may be subject to government regulation and may not be available in all countries. Please check with your local Sales Representative. Shipment and the effective sale in certain countries can only occur if the product is approved. Final product configuration and features may differ from the ones represented here and may not be available in every country. Check with your local GE representative for details.

Imagination at work

JB59804XX

Anexa 2 Specificaţii tehnice pentru Analizator biochimic automat , sistem Inchis

Cerinţe generale

Cerinţele electrice ale sistemului:		
	Toate componentele echipamentului electric se vor conecta la priză prin fişă de reţea de tip F "Schuko"	DA
	Electricitate: 220 Volţi monofazic	DA
	Frecvenţa 50 Hertz	DA
Condiţiile fizice şi de mediu:	Temperatura mediului min -20 max +40oC	DA
	Umiditatea 30-100%	DA
Variaţia tensiunii de reţea:	Echipamentul trebuie să funcţioneze satisfăcător de la -12.5% la +8% din tensiunea nominală a reţelei de 220 Volţi.	DA
	Echipamentul nu trebuie să fie distrus la variaţii de -21% pînă la +12.5% din tensiunea nominală a reţelei de 220 Volţi.	DA
Interferenţa electromagnetică (EMI)	Performanţa dispozitivului nu trebuie să fie afectată de EMI radiată sau indusă de liniile de alimentare ale altor dispozitive.	DA
Calitatea construcţiei	Echipamentul nu trebuie să aibă margini ascuţite.	DA
	Toate componentele echipamentului trebuie să fie bine fixate.	DA
	Echipamentul trebuie să fie sigur şi să asigure o protecţie adecvată contra părţilor în mişcare şi a părţilor aflate sub tensiune electrică.	DA
	Echipamentul trebuie să fie construit din materiale durabile şi să reziste la utilizare şi curăţire tipică.	DA
	Întrerupătoarele, butoanele şi alte componente de comandă trebuie să fie proiectate pentru o utilizare intensivă.	DA
	Terminalele mecanice, electrice şi pneumatice precum şi conectoarele, jacurile, articulaţiile trebuie proiectate astfel încît să prevină pătrunderea lichidelor, conectarea incorectă şi folosirea inadecvată a conectoarelor.	DA
	Conexiunile trebuie să fie sigure şi să reziste la deconectări accidentale şi după caz să menţină sterilitatea.	DA
Etichetarea:	Tot echipamentul furnizat va purtamarcajul CE.	DA
	Etichetele şi marcajele trebuie să fie clare şi lizibile.	DA
	Etichetele şi marcajele trebuie să fi suficient de durabile încît să reziste la curăţarea de rutină şi uzura normală.	DA
	Legenda adecvată de avertizări trebuie să fie plasată pe dispozitiv.	DA

Cerinţele specifice

PARAMETRI	SPECIFICAŢIE	**SPECIFICAŢIE OFERTATA ProM (Elitech Group/Olanda)**
Certificat CE,ISO 9001	DA	DA
Tip „bench top"	DA	DA
Greutate	DA	DA
Compartiment reactive/probe	Posibilitatea de procesare nu mai putin de 120 seruri concomitent	Posibilitatea de procesare nu mai putin de 86 seruri concomitent
Sistem de racire al reactivelor	Nu mai sus de 15°C	DA
Teste/oră	Nu mai puţin de 200teste /oră	DA
Tip probe analizate	Plazma	DA
	Urina	DA
	Ser	DA
Compartiment reactive	Posibilitatea de utilizare - nu mai puţin de 50 de reactivi plasaţi concomitent .	Posibilitatea de utilizare - 64 de reactivi plasaţi concomitent .
Compartiment preparare/dozare	Dozare reactiv: 10÷440 mcL ,cu pas 0.126mcL Dozare ser: 3÷40 mcL;cu pas 0.126 mcL Viteza de dispensare : nu mai putin de 880 mcl/sec	Dozare reactiv: 10÷440 mcL ,cu pas 0.126mcL Dozare ser: 3÷40 mcL;cu pas 0.126 mcL Viteza de dispensare : nu mai putin de 880 mcl/sec
Compartiment de reacţie/citire al probelor	Rotor cu 100-120 de cuve de unică folosinţă de reacţie/citire,volum de reacţie 200-800mcL,lungimea optică 6mm ,37°C	Rotor cu 56 de cuve de multipla folosinţă de reacţie/citire,volum de reacţie 200-800mcL,lungimea optică 6mm ,37°C
Număr de probe se pot programa pe aparat (la o listă de lucru)	Nu mai puţin de 120 seruri plasate concomitent	DA
Mecanizm de protectie	Detectie verticala a obstacolului, cu oprirea analizatorului (protectia de obstructie a acului dozator)	DA
Consum de apa didtilată	Mai puţin de 0,5L pe ora Analizorul nu va necesita conectare la sursa de apă externă	DA
Diluţie automată a probelor	DA	DA
Autoverificare	DA	DA
Marcare valori anormale	DA	DA
Afişare rezultate	Calculator extern	DA
Cititor al codului de bare	OPTIONAL	DA

Sistem	Analizator automat sistem deschis, cu procesarea testelor mono si bireagente. Ofertantul este obligat sa nu includa sistemul optional la nivel de soft in timpul exploatarii aparatului. Complet automat, acces aleatoriu, discret	DA
Exportul datelor	DA	DA
Teste programate	Da	DA
Interffaţa computer	Bidirecţional ,	DA
Teste difinite de utilizator	DA	DA
Metode de testare	Punct final	DA
	Cinetic	DA
	Timp fix	DA
	Turbodimetrie	DA
	Diferenţial	DA
	Bicromatic	DA
	Diferenţial cu blank de probă	DA
Teste de bază	Creatinina	DA
	Ureia	DA
	Proteina totală	DA
	Albumina	DA
	Acid uric	DA
	Colesterol	DA
	Trigliceride	DA
	Glucoza	DA
	Bilirubin total şi direct	DA
	Kaliu	DA
	Natriu	DA
	Calciu	DA
	Fosfor anorganic	DA
	Clor	DA
	Calciu	DA
	Magneziu	DA
	Fier	DA
	ALT	DA
	AST	DA
	Fosfataza alcalină	DA

	Lipaza	DA
	Amilaza	DA
	Gama GTP	DA
	Creatin Kinaza	DA
	Lactat dehidrogenaza	DA
	Colesterol HDL	DA
	Microalbumina	DA
	s.a.	DA
Tip reagent	Lichid	DA
Rezultate stocate (memorate)	Minimum 100 000	DA
Întrerupere temporară a lucrului	Posibilitate de a întrerupe lucru temporar datorită unor factori externi (lipsa ser, lipsa reactiv, lipsa apa, bidon reziduri plin)	DA
Sistem optic	Filtre cu gama între 340-670nm, 8 filtre,reversie optică Citire bicromatica sustinuta de orice protocol "end point", "diff mode", "cinetic", "fixe time"	DA
Rezoluţie	0,0001 Abs	DA
Interval de măsurare	0÷2.5 Abs ,conversat la10mm	DA
Sursa lumină	Lampă cu halogen	DA
Sistema operationala Licenţiată	Windows XPori mai performantă	DA
Alimentare electrică	220V (50/60Hz)	DA
Calculator	COM port (RS-232)	DA
	PENTIUM 4/ 2000MHz/1Mb/800MHz	DA
	RAM 1024 MB	DA
	HDD 256GB 7200rpm	DA
	DVD ROM+CD-RW IDE/, tastatură, mouse	DA
	LCD 17 "	DA
Sistem UPS	220v ,2000VA, AVR	DA
Printer	Laser A4, min 1200x600dpi,20ppm,USB Alb/negru	DA
Putere consumata	Mai putin de 300VA	DA
		DA
REAGENTI:	În set se va oferi reagenţii pentru un ciclu de lucru (indicaţi lista şi cantitatea)	DA

CERINȚELE PENTRU ASISTENȚĂ

Piese	Indicaţi perioada în care piesele de schimb pentru echipamentul oferit vor fi disponibile.	10 ani
Termen de garanţie	Nu mai puţin de 3 ani, indiferent de distribuitorul de reagenţi	2 ani
Service ingineri certificaţi de producător	DA	DA
Autorizaţia producătorului pentru deservirea tehnică a utilajului oferit	DA	DA
Întreţinerea profilactică	O descriere a întreţinerii profilactice necesară pentru echipamentul oferit, inclusiv frecvenţa.	Conform documentatiei de exploatare
Documente şi manuale.	Tot echipamentul trebuie să fie livrat cu copii ale instrucţiunilor de utilizare şi întreţinere în limba de stat sau rusa	DA

CERINȚE OBLIGATORII

Certificat CE, ISO	DA
Autorizare de la producător	DA

ELITech Distribution
13-15 rue Jean Jaurès
92800 Puteaux - France
Tél : +33 (0)1 41 45 07 13
Fax : +33 (0)1 41 45 07 14
www.elitechgroup.com

ELITechGroup
ELITECH DISTRIBUTION

Puteaux, 29 March 2017

Letter of Authorization

To whom it may concern:

ELITech Distribution, a company of the ELITech Group distributing laboratory diagnostic products with headquarters at 13-15 rue Jean Jaurès, 92800 Puteaux – France, hereby confirms that the company **GBG-MLD SRL**, located at Mun. Chisinau, Str. Tighina 65 of. 607, MD-2001 - Moldova (the "Company"), is authorized to market the products as listed below (the "Products"), in Moldova (the "Territory"):

All products manufactured by ELITech Clinical Systems SAS
All products manufactured by ELITechGroup B.V.

Company hereby accepts (i) to market and promote Products in Territory as per the provisions set out hereunder and (ii) to be subject to General Conditions of Sales of ELITech Distribution.

Company is not entitled to assign nor transfer, totally or partially, its respective rights and obligations arising out of this Letter of Authorization, and particularly, it is not entitled to market Products through the intermediary of a sub-distributor and/or an affiliate without the prior written consent of ELITech Distribution.

This Letter of Authorization is (i) valid for a period of three (3) years unless terminated with a written notice by the issuer, (ii) subject to the signing of the Regulatory and Quality assurance Agreement signed by the above-mentioned company and ELITech Clinical Systems SAS and ELITechGroup B.V. on 29 March 2017 and (iii) governed by and construed in accordance with French law.

"GBG-MLD" S.R.L. IDNO 1003600107582 REPUBLICA MOLDOVA, MUN. CHISINAU

The President
ELITech Group S.A.S.
Represented by Romain Bergeaud

ELITECH DISTRIBUTION
Société par actions simplifiée
au capital de 500 000 Euros
Siège social : 13-15, rue Jean Jaurès
92800 PUTEAUX
RCS NANTERRE 538 673 716
Tél. : +33 1 41 45 07 13 - Fax : +33 1 41 45 07 14

Declaration of Conformity

We: **ELITechGroup B.V.**
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

declare under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices ("IVD Directive")
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS2 Directive")

It is certified that this product is registered in accordance with the requirements of above mentioned EU Directives and carries the CE marking.

Product	**Clinical chemistry analyzer, automated**
Model	**Selectra ProM**
Reference numbers	**6003-400** (Break-in number from 17-7503)
GTIN	**03661540600302**
GMDN code	**56678**
Accessories	**See Annex**

Product classification
As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure
In accordance with:

- Annex III of the IVD Directive
- Article 4 of the RoHS2 Directive

Spankeren, January 2018

Maurice Verdaasdonk
Managing Director

Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control and laboratory used – Part 2-010: particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements	
	IEC 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

Declaration of Conformity

Annex – List of IVD accessories

EGBV PART NUMBER	DESCRIPTION
3201-019	Precision Test Solution

Lot. 3 Analizator hematologic, automat (5 diff), cu sistem de tip închis		
Descriere	Analizator hematologic automat (5 diff) cu sistem de reactivi de tip închis destinat analizei componenței sanguine	**Analizator hematologic automat (5 diff) cu sistem de reactivi de tip închis destinat analizei componenței sanguine, Model Cell-Dyn Emerald OT-22 (Aboott, SUA)**
Parametru	**Specificaţia**	**Specificaţia ofertata Cell-Dyn Emerald OT-22**
Tip sistem	închis	închis
Metode de măsurare	impendansmetrică	leucocitara: flow-citometrie cu laser care permite citire optica pe toate cele 3 linii celulare WBC, RBC si PLT de la prima procesare a hemoleucogramei
	fotometrică	fotometrică - Sistemul are tehnologie flow cytometrie de rezolutie inalta si Multi-Angle Polarized Scatter Separation (MAPSS) pentru diferentierea celulelor albe si masurarea numarului de cellule rosii si trombocite.
	optică (5 diff)	optică (5 diff)
Procedura de curăţire	automată	automată
Parametri determinați și calculați:	WBC	WBC
	RBC	RBC
	Hgb	Hgb
	Hct	Hct
	MCV	MCV
	MCH	MCH
	MCHC	MCHC
	PLT	PLT
	LYM #	LYM #
	MON#	MON#
	NEU#	NEU#
	BAS#	BAS#
	EOS#	EOS#
	LYM%	LYM%
	MON%	MON%
	NEU%	NEU%
	BAS%	BAS%
	EOS%	EOS%
	RDW	RDW
	PDW	PDW
	MPV	MPV

	P-LCC	P-LCC
	P-LCR	P-LCR
	LIC%	LIC%
	LIC#	LIC#
	ALY%	ALY%
	ALY#	ALY#
	PLT Clumps#	PLT Clumps#
	PLT Clumps%	PLT Clumps%
	Lip#	Lip#
	Lip%	Lip%
	NRBC#	NRBC#
	NRBC%	NRBC%
	Blast#	Blast#
	Blast%	Blast%
	PCT	PCT
Capacitate (probe/oră)	≥ 60	Viteza de lucru: aprox 84 HLG/ora
Diluarea	automată	Sistemul asigura masurarea corecta a tuturor parametrilor , a numarului de celule albe si in prezenta eritrocitelor rezistente la liza RRBC precum si a celulelor albe fragile FWBC (ex. Leucemie) prin 3 moduri de lucru, cu dilitia automata a probelor.
Afişaj	grafic	Posibilitatea vizualizarii a 9 scattergrame diferite- color, Capacitate stocare: 10.000 de rezultate & grafice
Introducerea datelor	manual	Posibilitate de introducere informatii complete pentru pacient, posibilitate de a genera lista de lucru pacienti atat manual cat si prin scanare de cod de bare.
Interfaţa PC	da	Sistemul are calculator propriu si posiblitate legare in retea de calculatoare, interfata bidirectionala RS 232
Afişarea histogramelor	da	Sistemul are posibilitatea vizualizarii a 9 scattergrame diferite- color, Capacitate stocare: 10.000 de rezultate & grafice
Stocarea datelor	da	Aparatul are o capacitate minima de stocare de minimum 10,000 de date de pacient

Calibrarea	automată	automată- Operatorul poate face calibrare pentru toti parametrii masurabili cu sange integral sau sange de calibrare comercial urmand pasii de calibrare indicati de soft, automat si maual Program autocalibrare- ghid on line
	manuală	manuală
Grafice	RBC (repartizarea eritrocitelor după volum)	RBC (repartizarea eritrocitelor după volum)
	PLT (repartizarea trombocitelor	PLT (repartizarea trombocitelor după volum)
Scatergrame	WBC - 5 diff	Aparatul are masurare volumetrica,- metoda de referinta ICSH pentru masurarea celulelor, pentru WBC, PLT si RBC pentru a asigura precizia rezultatelor cu Posibilitatea vizualizarii a 9 scattergrame diferite- color
Afişarea pe ecran a tuturor datelor-	histograme	histograme
	rezultate	rezultate
	grafice	grafice
	rezultate din arhivă	rezultate din arhivă
	date de servis	date de servis
Monitorizarea datelor pacientului	nume pacient	nume pacient
	ID pacient	ID pacient
	sex	sex
	vîrsta	vîrsta
Monitorizarea reactivelor	numărul lotului	numărul lotului
	data expirării	data expirării
	volumul rămas	volumul rămas
Afişarea rezultatelor pe imprimantă	Parametri determinaţi şi calculaţi	Parametri determinaţi şi calculaţi
	histograme pe parametrii de bază- RBC, WBC, PLT	histograme pe parametrii de bază- RBC, WBC, PLT
	date despre pacient	date despre pacient
Indicatori de avertizare	da	da
Control al calităţii	≥ 3 nivele	Managementul controalelor de calitate (grafice Levey-Jenings, regulile Westgard, moving average)- 3 nivele de control plus control inclus/ sau dedicate pentru reticulocite
	Construirea tabelelor şi graficelor Levey-Janings	Construirea tabelelor şi graficelor Levey-Janings
Memorie internă	> 200000 pacienţi	200000 pacienţi
Alimentarea	220 V, 50 Hz	220 V, 50 Hz
	Vas pentru deşeuri	Vas pentru deşeuri
	tuburi pentru reagenţi	tuburi pentru reagenţi

Accesorii	tuburi pentru spălare	tuburi pentru spălare
	Calculator extern sau integrat, dacă este necesară prezența lui pentru buna funcționare a analizorului	Sistemul are calculator propriu si posiblitate legare in retea de calculatoare, interfata bidirectionala RS 232
Limba de comunicare	rom/rus	rom/rus

Abbott Products Romania S.R.L.
Green Court Bucharest
Gara Herastrau 4C
Corp B, etaj 2, sector 2
Bucuresti, Romania

C.U.I. RO 15910608
R.C.: J40/15462/18.11.2003
Capital Social: 595002 lei
Banca: Citibank
IBAN: RO22CITI0000007245850043

Tel. +40-21-529 30 00
Fax. +40-21-529 30 01

AUTORIZARE

Catre: IMSP SR Rezina
LP: 21007317

Noi, ABBOTT PRODUCTS ROMANIA SRL, reprezentant autorizat in Romania (Strada Gara Herastrau, numarul 4C, sector 2, Bucuresti, inreg. la MEC sub nr. 1069/22) al companiei Abbott Laboratories, producator de instrumente de hematologie Cell-Dyn Emerald 22, biochimie Architect c4000, precum si de reactivi, controale, calibratori si consumabile pentru acestea, avand capacitatile de productie in SUA, Abbott Park 60064, Illinois,Santa Clara California, Germania –Wiesbaden, Marea Britanie- Dartford, autorizam prin prezenta pe furnizorul **Global Biomarketing Group – Moldova SRL**, sa oferteze in licitatie si sa livreze produsele mai sus mentionate, la IMSP SR Rezina. Prin prezenta, garantam calitatea si performantele produselor oferite si autorizam pe **Global Biomarketing Group – Moldova SRL** sa asigure, pentru produsele respective, indeplinirea obligatiilor care decurg din contractul de furnizare.
Aceasta autorizare s-a eliberat pentru a servi la licitatia LP nr21007317, cod CPV 33100000-1, anuntata in 30.05.2019, avand ca si autoritate contractanta- IMSP SR Rezina.

Data completarii:
27.05.2019

Producator:

ABBOTT PRODUCTS ROMANIA SRL

Customer Experience Manager,
Camelia Pirvulescu

ABBOTT PRODUCTS ROMANIA S.R.L. BUCURESTI

SOCIETATEA CU RASPUNDERE LIMITATA "GBG-MLD" REPUBLICA MOLDOVA, MUN. CHISINAU

Abbott
Promise for Life

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Stefan Dumitras

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

CELL-DYN EMERALD 18/22+22AL, Service & Application

November 5th-9th, 2018

Gustavo Rodriguez/ Srinivasan Gopalan

TRAINER NAME

ABBOTT DIAGNOSTICS

TRAINER SIGNATURE

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim

Abbott

Abbott

Declaration of Conformity

Certificate Identification: SC-09H39

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	**Names and Description of Devices**	Classification
09H39-01	35476	CELL-DYN Emerald Instrument	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 C2 Diagnostics, Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
Harmonized Standards	Listed in the Technical Documentation

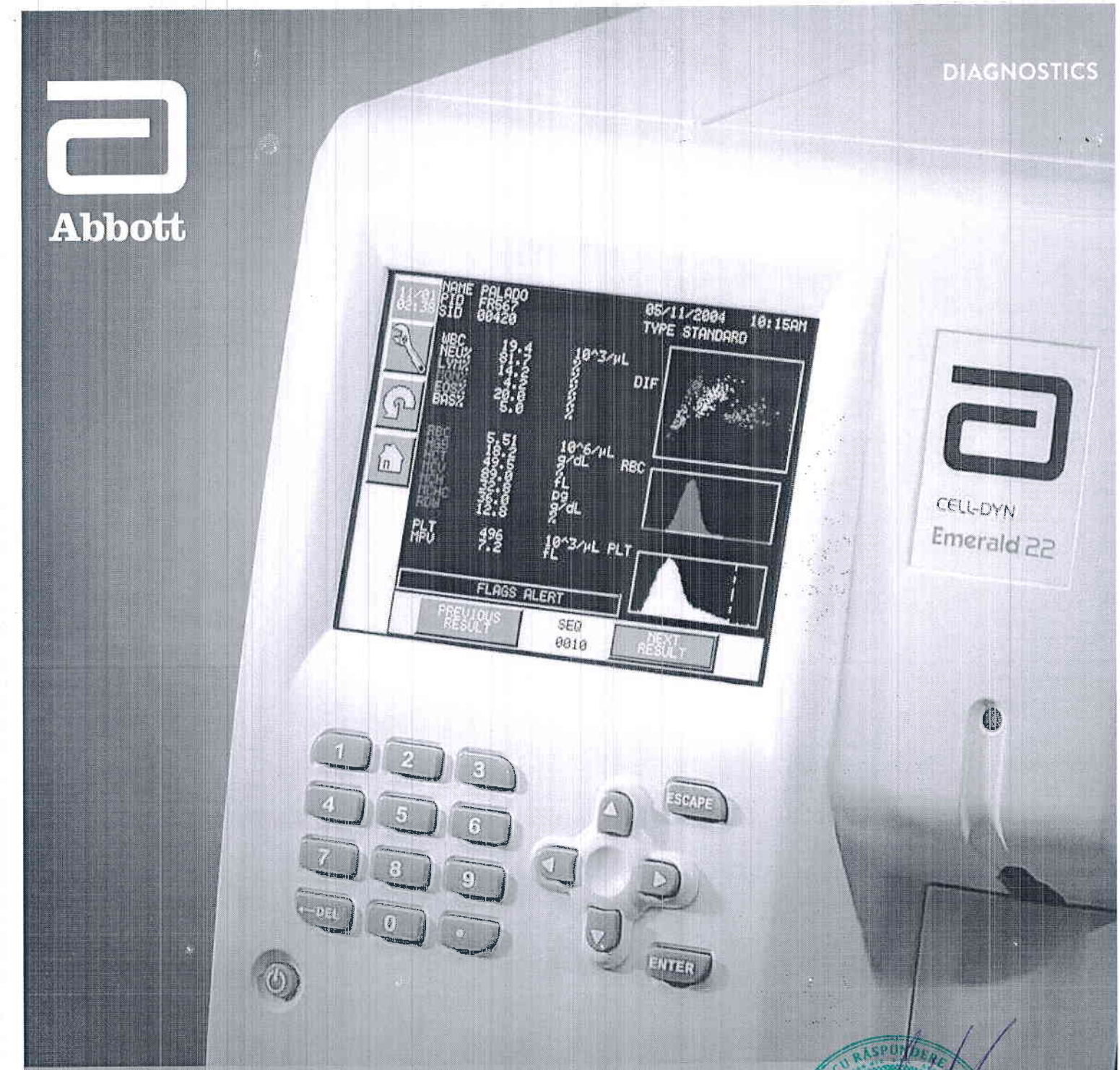
We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Kevin Richardson	Full Name:	Rosemarie Lulu
Position:	Manager, Supplier Quality	Position:	Regulatory Affairs Project Manager
Date of Approval:	29 JUNE 2016	Date of Approval:	28 JUNE 2016
Date Issued:	JUN 29 2016	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 (Feb 26, 2015)	Effective (Date or Lot Number):	JUL 01 2016

Abbott

DIAGNOSTICS



CELL-DYN Emerald 22

The Information You Need
The Size You Want

CHOOSE TRANSFORMATION

Packed with Results

FULL PERFORMANCE SOLUTION FOR SMALLER LABORATORIES

COMPACT DESIGN

Conserving valuable laboratory workspace with a small footprint and only 2 reagents plus on-board cleaner

EASE OF USE

- Decreasing manual entry errors and increasing compliance by use of barcoded reagents
- Reducing hands-on time with touch-free scheduled daily maintenance, startup and shutdown

FLEXIBLE USER INTERFACE

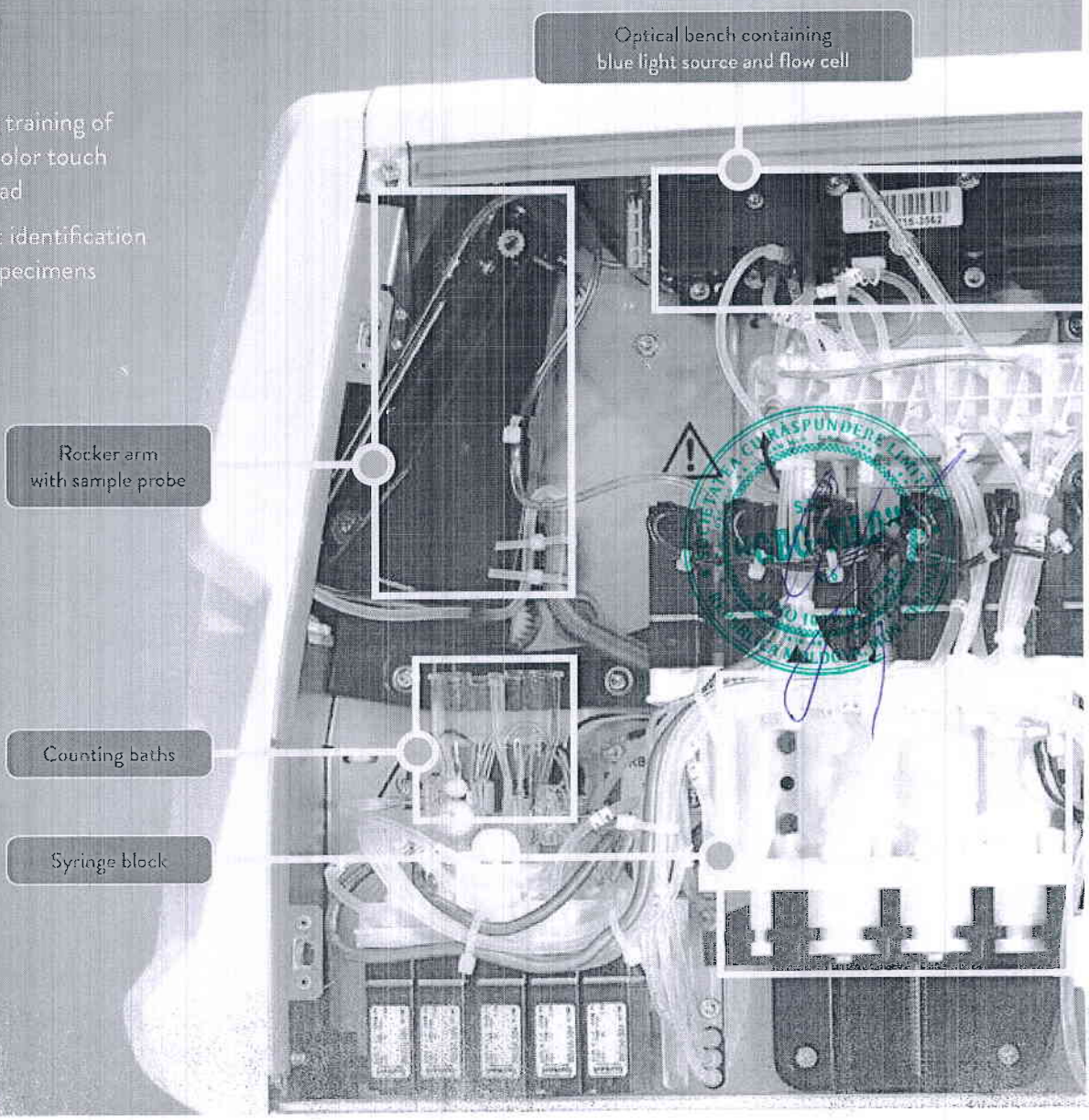
- Improving use and easing training of software functions with color touch screen and numeric keypad
- Providing positive patient identification with barcode reader for specimens

RELIABILITY

Helping you keep your commitments

OPTICAL 5-PART DIFFERENTIAL

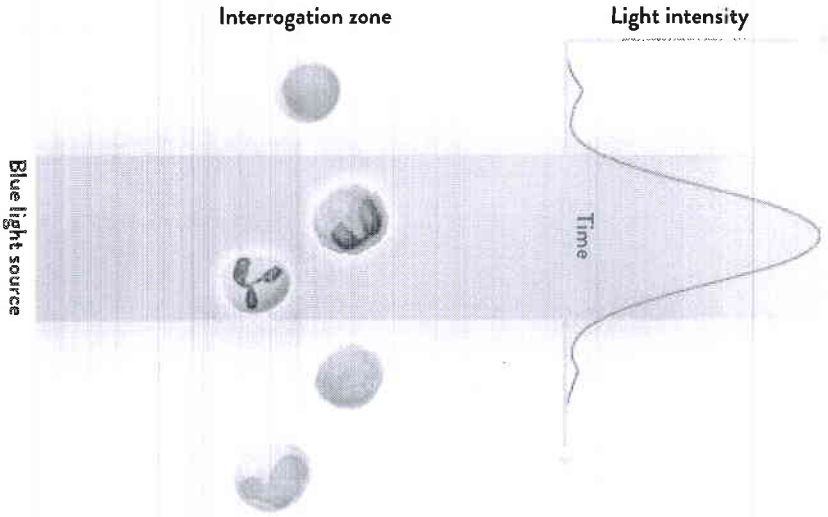
Delivering comprehensive results for your doctors and patients



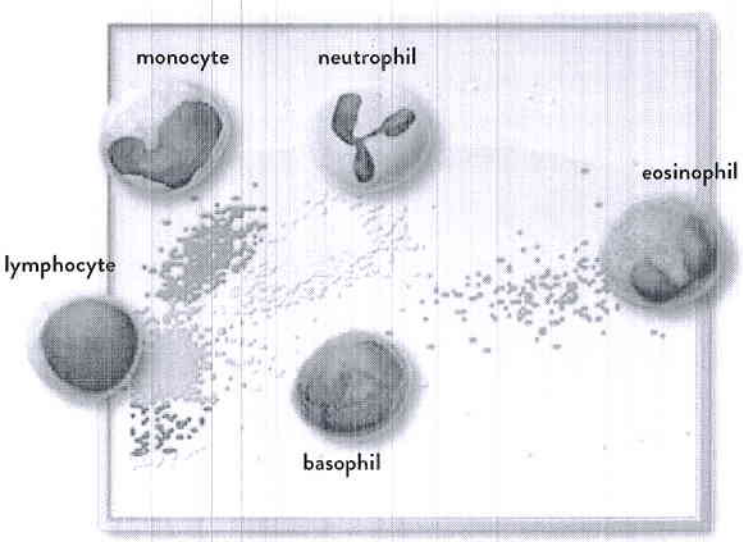
True Optical 5-Part Differential System

CELL-DYN Emerald 22 uses UNI-FLOW technology, which includes a cyanide- and formaldehyde-free Lyse, flow cell, and optical bench. The Lyse destroys the red blood cell stroma and stabilizes the white blood cells, while it creates a chromagen for hemoglobin measurement using the same dilution.

For each cell entering the optical detection area in the interrogation zone, two pulses are generated – Axial Light Loss and Forward Side Scatter measurement. The five-part differential is obtained by scattergram analysis after action of the Lyse, with no dyes, stains, or special channel measurements.



Enhanced Scattering Efficiency



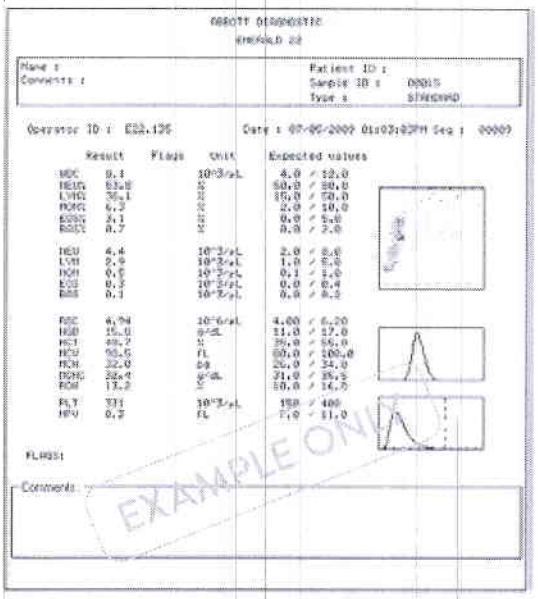
The cluster separation is enhanced with the low wavelength (455 nm) blue solid state LED. This wavelength enhances differentiation of intracellular contents, improving the identification and separation of eosinophils and monocytes from neutrophils.

The unique flow cell design, enhanced LED light source, and simple optical bench provide a true five-part differential in a small, easy-to-use, and reliable analyzer.

CELL-DYN
Emerald 22

CELL-DYN Emerald 22 Specifications

PATIENT REPORT EXAMPLE



PARAMETERS

White Cells	Red Cells	Platelets
WBC	RBC	PLT
NEUT # %	HGB	MPV
LYM # %	HCT	
MONO # %	MCV	
EOS # %	MCH	
BASO # %	MCHC	
	RDW	

CELL-DYN EMERALD 22 REAGENTS

Reagent Description	List Number
CELL-DYN Emerald 22 Easy Cleaner	09H60-01
CELL-DYN Emerald 22 Lyse	09H61-01
CELL-DYN Emerald 22 Diluent	09H62-01

CELL-DYN EMERALD 22 CONTROLS AND CALIBRATORS

Calibrator/Control	List Number
CELL-DYN 22 Plus Calibrator	09H73-01
CELL-DYN 22 Plus Control Full-Pack (12 tubes)	09H72-01
CELL-DYN 22 Plus Control Half Pack (6 tubes)	09H72-02

TECHNOLOGY & OPTICAL METHODS

- Optical Flow Cytometry technology
- Electrical impedance
- Absorption spectrophotometry
- Electronic valves
- Cyanide-free lyse reagent
- LCD color touch screen
- RS232 and TCP/IP LIS interface
- USB ports

THROUGHPUT

- 45 samples per hour

SAMPLE SIZE

- ~28µL

SPECIMEN DATA MANAGEMENT

- Search by date or sequence number
- Flagging for patient limit sets
- Flagging for panic values
- 1,000 records with histograms on internal memory
- Up to 300,000 records USB external data storage
- Programmable patient limits
- Programmable report units
- Standard barcode reader (reads code 128, code 39, and interleaved 2 of 5)

QUALITY CONTROL

- 6 control files
- 100 runs per file
- Levey-Jennings graphs
- Upload/download control information

DEMOGRAPHICS

- Sequence number
- Alphanumeric specimen ID
- Date and time analyzed
- Patient name
- CBC with or without 5-part WBC differential
- Flagging and alerts

DISPERSIONAL DATA ALERT

- Operator-defined patient limits for high and panic values
- System-defined limits for reportable range and analytical measurement range
- Suspect parameter flags caused by interfering substances or sample abnormalities
- Suspect parameter flags generated when WBC data indicates possible presence of an abnormal population

STANDARDS & SAFETY COMPLIANCE

- UL 61010-1
- CAN/CSA-C22.2 No. 61010-1
- IEC 61010-1
- IEC 61326-1
- IEC 61326-2-6
- FCC part.15
- CE Mark
- ETL Mark

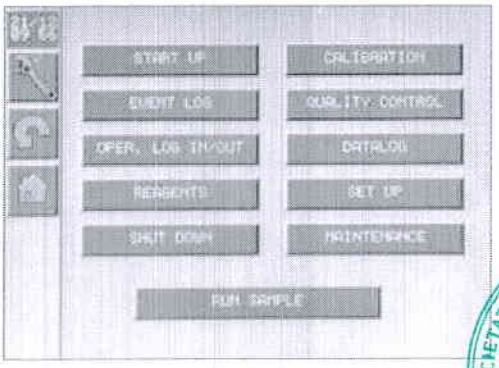
PERIPHERAL DEVICES

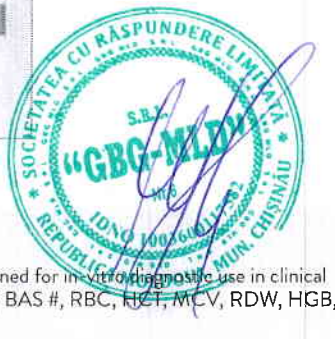
- Inkjet printer
- USB thumb drive
- Handheld barcode scanner

PHYSICAL DIMENSIONS

- Height 13.8" (35cm)
- Width 9.8" (25cm)
- Depth 13.8" (35cm)
- Weight ~ 24.2lbs (11kg) (without on-board reagents)

MAIN MENU





See Operations Manual for warnings, precautions, and limitations for proper use of the instrument.

Intended Use: The CELL-DYN Emerald 22 System is a quantitative multi-parameter automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories for the following parameters: WBC, LYM%, LYM #, MON%, MON #, NEU%, NEU #, EOS%, EOS #, BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K2 EDTA anti-coagulated blood.

The CELL-DYN Emerald 22 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

www.abbottdiagnostics.com
1-877-4ABBOTT

Abbott

Anexa 4 Coagulometru semiautomat			
Descriere	Coagulometru semiautomat destinat pentru testarea mostrelor preluate de la pacienţi pentru determinarea factorilor de coagulare a sîngelui.		
Parametrul		**Specificația**	**Specificația ofertata C-2 (Helena Bioscience, Marea**
Configurația	**Capacitatea sistemului**	≥ 2 probe simultan	2 probe simultan
Termostat integrat	**Poziții**	≥20	20
Memorare	**control calitate**	≥30	30
Tip măsurare		optică	Photo-Optic
Tip probă	**plasmă**	da	da
Teste	**APTT**	da	da
	FIB	da	da
	PT	da	da
	TT	da	da
Data management	**Display**	LCD sau LED	LCD
	Imprimantă integrată	da	da

emitel
meet the expert !

CERTIFICATE

Certificate Number
PR 08 08 0022 003

Date of Issue
28 August 2008

Expiration Date
NONE

Test Report Number/s
E-0022-2619-00 MG
S-0022-2128-01 BT
S-0022-2128-02 BT

Product Description
Coagulometer

Page
1 of 1

Holder of Certificate :
Helena Laboratories (UK) ltd trading as
Helena Biosciences Europe
Queensway South, Team Valley Trading Estate, Gateshead, Tyne & Wear, NE11 9SD, United Kingdom

Manufacturer :
Helena Laboratories (UK) ltd trading as
Helena Biosciences Europe
Queensway South, Team Valley Trading Estate, Gateshead, Tyne & Wear, NE11 9SD, United Kingdom

Type/Model Name/s: Helena C-1, C-2, C-4

Directive/s: **2004/108/EC**
2006/95/EC

Standard/s:
EN 61326-1:2006
EN 61000-3-2:2000
EN 61000-3-2:2006
EN 61000-3-3:1995+A1:2001+A2:2005
EN 61010-1:2001 (2nd Edition)
EN 61010-2-101:2002 (1st Edition)

The certificate is issued after testing of the named product/s and/or audit of the technical documentation and confirms that the tested product complies with the essential protection requirements of the mentioned directives on a voluntary basis.

2008-08-28
Date

Signature

CE After preparation of the necessary technical documentation as well as the conformity declaration the required marking can be affixed to the product. Other relevant directives have to be observed. See also notes overleaf.

emitel AG
Ohmstrasse 1
94342 Strasskirchen
GERMANY
+ 49 (0) 9424 9482-0
+ 49 (0) 9424 9482-640
www.emitel.de
germany@emitel.de

Training certificate

helena
Biosciences Europe

This is to certify that

Sergeu Sorokovice

from

IM Global Biomarketing Group

has received training on the following:

Electrophoresis products: SAS-1/2

Haemostasis products: C-series, AC-4, ~~AggRAM and reagents~~

Service training: AC-4

Signed:

Helena Biosciences Europe (UK) • Helena Biosciences Europe (UK) • helena Biosciences Europe

Date: 31st October - 4th November 2011

Tel +44 (0)191 482 8440 info@helena-biosciences.com Queensway South, Team Valley Trading Estate,
Fax +44 (0)191 482 8442 techsupport hs@helena-biosciences.com Gateshead, Tyne and Wear, NE11 0SD, United Kingdom

www.helena-biosciences.com

Anexa 5

Specificație tehnică

Model: 9100c NXT + Monitor B40, Producător: GE Healthcare, Țara: China

Specificație tehnică solicitată	Specificație tehnică propusă
MAȘINĂ DE ANESTEZIE 2 •Evaporator SEV,ISO •Monotir 10,Model-Vizor 10 1 c)Analizator de gaze,Model-Irma AX- 1 Parametri tehnici: 1.Minute volum – de la 0 pînă la 30 L/min (MV) 2.Volum inspirator – de la 0 pînă la 2000ml (vt) 3.FR de la 0 pînă la 100 r/min Regimuri de lucru VCV;PCV;SIMV; Manual Mode.	**DA** MAȘINĂ DE ANESTEZIE •Evaporator SEV,ISO – Seria TEC •Monitor GE B40 1 c)**DA** Analizator de gaze, E-SCAIO Parametri tehnici: 1.**DA** Minute volum – de la 0 pînă la 60 L/min (MV) 2.**DA** Volum inspirator – de la 0 pînă la 2000ml (vt) 3.**DA** FR de la 0 pînă la 99r/min – batai pe minută **DA** Regimuri de lucru VCV;PCV;SIMV; **DA** Manual Mode.

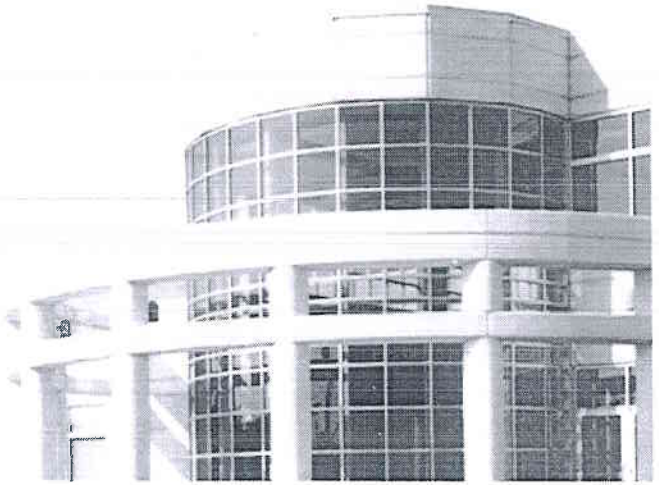
CERTIFICATE OF ACHIEVEMENT

PRESENTED TO: **Stefan DUMITAS**

GBG Moldova

IN RECOGNITION OF HAVING COMPLETED THE PRESCRIBED COURSE OF STUDY FOR

9100C training



16.02.2017

Trainer

Training & Education Manager

GE imagination at work

*This certificate is valid for two years starting from the date of issue

CERTIFICATE OF ACHIEVEMENT

PRESENTED TO: **Stefan DUMITRAS**

GBG Moldova

IN RECOGNITION OF HAVING COMPLETED THE PRESCRIBED COURSE OF STUDY FOR

Full service training CARESTATION 600 series

12.06.2017

Trainer

GE Medical Systems Information Technologies GmbH
Munzinger Str. 3-5 • 79111 Freiburg
Tel. 0761 4543-0 • Fax 0761 4543-233

imagination at work

Training & Education Manager

*This certificate is valid for two years starting from the date of issue

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60109676 0001

Report No.: 31591873 001

Manufacturer:
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
PO Box 7550
MADISON WI 53707-7550
USA

Products:
Anesthesia and Vaporizer Systems,
Ventilators and Patient Circuits (single use)

Expiry Date: 2021-04-19

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-04-26

Date: 2016-04-26

Notified Body

TÜV Rheinland LGA Products GmbH

Jürgen Welte

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197

Technical Specifications

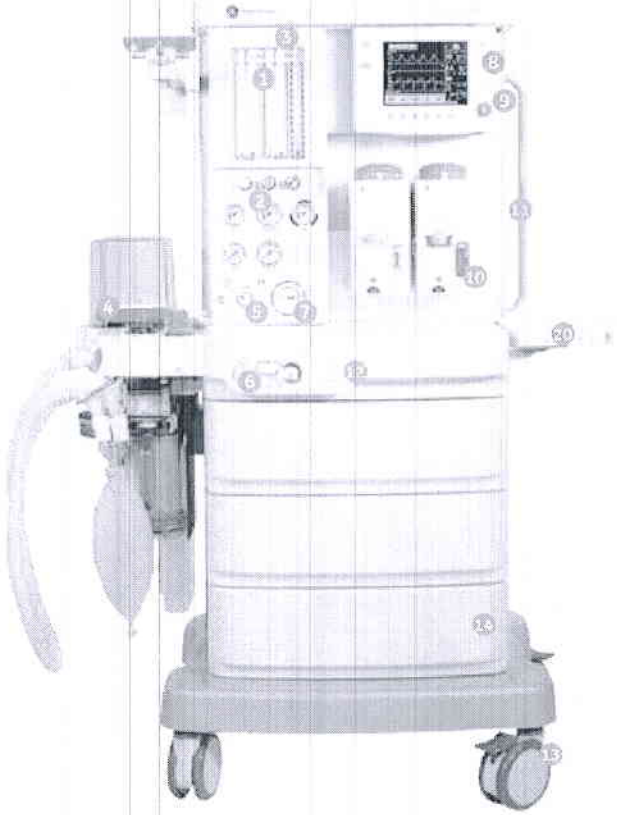
9100c *NXT*

The anesthesia workstation that gives you peace of mind

Precise
Enables you to effectively deliver anesthesia and foster seamless recovery

Versatile
Scalable across a wide range of patient groups and surgical procedures

Dependable
Based on GE/Datex Ohmeda's legacy of 100+ years of innovation and trust



1. Flowhead assembly
2. Pipeline & cylinder pressure gauge
3. Task light
4. Breathing circuit with CO_2 bypass
5. System switch
6. ACGO port and switch
7. PAW gauge
8. 7.5in(diagonal) display for 2 waveforms
9. USB for SW update + RS 232 (15 pin)
10. Selectatec manifold & vaporizers
11. Ergonomic handle
12. Oxygen flush
13. Wheel caster & brake
14. Storage space
15. Auxiliary power and switch
16. Pipeline connections
17. Cylinder yoke option
18. Hose hooks
19. Scavenging system
20. Flip-up shelf

Physical specifications

Dimensions:
Height: 145 cm/ 57.1 in
Width: 87 cm/ 34.2 in
Depth: 67.4 cm/ 26.5 in
Weight: approximately 140 kg/ 308 lbs

Top shelf:
Weight limit: 25Kg/55 lbs
Width: 60.6cm/23.2 in
Depth: 35.2cm/13.9 in

Work surface:
Height from floor: 83.9cm/33 in
Width: 53.5 cm/ 21 in
Depth: 46cm/ 18.1 in

Folding side shelf (optional):
Weight: limit: 12kg/25lbs
Width: 27.7cm/10.91in
Depth: 36.6cm/14.41in

DIN rail:
Side of machine (rail height) 116.35cm/45.8

Drawers (internal dimensions):
Height: 35.9cm/14.1 in
Width: 43.1cm/16.9 in
Depth: 11.2cm/4.4 in

Casters:
Diameter: 12.5 cm/5 in
Brakes: Individual locking

Ventilator operating specifications

[illegible] operating modes:
[illegible] with Apnea backup

Minute volume range:
[illegible] Volume Control mode

Incremental settings:
20 to 100 mL (increments of 5 mL)
100 to 300 mL (increments of 10 mL)
300 to 1,000 mL (increments of 25 mL)
1000 to 1,500 mL (increments of 50 mL)

Pressure ($P_{inspired}$) range:
5 to 50 cm H_2O (increments of 1 cm H_2O)

Pressure (P_{peak}) range:
10 to 99 cm H_2O (increments of 1 cm H_2O)

Rate:
4 to 99 bpm (increments of 1 bpm)
2 to 60 bpm (increments of 1 bpm)
(SIMV, PSVPro™)

Inspiratory/expiratory ratio:
2:1 to 1:6

Inspiratory pause:
Off, 5% to 60% with increments of 5%

Trigger window:
5% to 80% or 4 seconds, whichever is less, increments of 5%

Flow trigger:
0.2 to 10 L/min with increments of
0.2 L/min for volumes < 1 L/min; and
0.5 L/min for volumes ≥ 1 L/min.

Positive End Expiratory Pressure (PEEP)

Type: Integrated, electronically controlled

Range:
OFF, 4 to 25 cm H_2O (increments of 1 cm H_2O)

Ventilator performance

Pressure range at inlet:
280 kPa to 600 kPa/ 41 psig to 87 psig

Peak gas flow:
120 SLPM + fresh gas flow

Flow valve range:
0 to 102 SLPM
Fresh gas flow compensation

Ventilator monitoring

Loops: P-V, F-V loops
Waveforms - Pressure, Flow

Expiratory minute volume range:
0 to 60 L/min (increments of 0.1L/min)

Expiratory tidal volume range:
0 to 2,000 mL (increments of 1 mL)

O_2%:
10 to 100% (increments of 1%)

Peak pressure:
0 to 120 cm H_2O (increments of 1 cm H_2O)

Mean pressure:
0 to 120 cm H_2O (increments of 1 cm H_2O)

PEEP pressure:
0 to 120 cm H2O (increments of 1 cm H2O)

Waveforms sweep
0 to 20 seconds

Ventilator accuracy

Delivery/monitoring accuracy

Volume delivery[1]:
<=300ml tidal volume - +/-12ml or +/-12% of setting, whichever is greater
>300ml tidal volume - +/-10% of setting

Pressure delivery:
±10% or ±3 cm H_2O (whichever is greater)

PEEP delivery:
±5% or ±1.5 cm H_2O (whichever is greater)

Volume monitoring[1]:
<300ml tidal volume - +/-12ml or +/-12% of reading, whichever is greater
> =300ml tidal volume - +/-10% of reading

Pressure monitoring:
±5% or ±2.4 cm H_2O (whichever is greater)

Alarm Setting

Tidal volume (TV_{exp}):
Low: 5 to 800 mL (<10mL: increments of 5mL; >10mL: increments of 10mL)
High: 100 to 1800 mL (increments of 10 mL)

Minute volume (MV_{exp}):
Low: 0.1 to 15 L/min (increments of 0.1 L/min)
High: 3 to 40 L/min (increments of 1 L/min)

Inspired oxygen (FiO_2):
Low: 20 to 70% (increments of 1%)
High: 40 to 100% (increments of 1%)

Apnea alarm:
No breaths >5mL in Apnea delay time set.
Apnea delay time range: 10 to 30 seconds (increment in steps of 1 second)

Low airway pressure:
1 to 20 cm H_2O (increments of 1 cm H_2O)

P_{peak} high:
10 to 99 cm H_2O (increments of 1 cm H_2O)

Sustained airway pressure:
PAWs (PEEP Setting + 10cm H_2O) for 15 seconds

Sub atmospheric pressure:
Paw < -10 cm H_2O

Alarm Pause

Mute duration:
110 seconds

Ventilator components

Flow sensor

Type:
Variable orifice flow sensor

Dimensions:
22 mm OD and 15 mm ID

Oxygen Sensor

Type:
Galvanic fuel cell

Life Cycle:
Approximately 12 months (Dependent on usage)

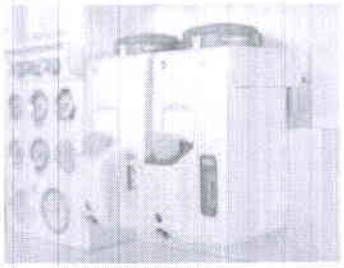
Anaesthetic agent delivery

Delivery

Vaporizers: Tec 7

Number of positions: 2

Mounting:
Tool-free installation Selectatec® manifold interlocks and isolates vaporizers



Electrical specifications

Leakage current

100/120 V: < 500µA

220/240 V: < 500µA

Power and battery backup

Power input:
100-120 Vac, 50/60 Hz
220-240 Vac, 50/60 Hz

Backup power:
Demonstrated battery backup time under typical operating conditions is 90 minutes when fully charged

Battery type:
Internal rechargeable sealed lead acid

Power cord:
Length: 5 m
Rating: 90 to 240 Vac
Current capacity: 10 A for 220-240 Vac and 15 A for 100-120 Vac

Communication ports

USB 2.0 for upgrade, RS-232 (15-pin)

Circuit breaker/fuse

Supply voltage:
100-120 or 220-240 Vac +/- 10% at 50 or 60 Hz

Inlet circuit breakers:
100-120 Vac - 15 A
220-240 Vac - 8 A

Outlet circuit breakers:
100-120 Vac - (2) 2A (1) 3A
220-240 Vac - (2) 1A (1) 2A

System leakage current limit - do not exceed:
IEC rated systems (): less than 500µamps for the system and all systems connected to electrical outlets

Resistance to ground:
less than 0.2 Ω

Pneumatic specifications

Auxiliary common gas outlet

Connector: ISO 22 mm OD and 15 mm ID

Gas supply

Pipeline input range:
280 kPa to 600 kPa/41 psi to 87 psi

Pipeline connections:
DISS - Male; S90- 116 (French Air Liquide); BSPP 1/4, BSPP 3/8 (Scandinavian); or NIST (ISO 5359). All fittings available for O_2, Air, and N_2O

Cylinder input[3]:
Pin indexed in accordance with CGA-V-1; contains input filter and check valve

Primary regulator diaphragm minimum burst pressure:
2,758 kPa/400 psig

Primary regulator nominal output:
Pin indexed: The primary regulator is set to pressure less than 345 kPa (50 psi).

O_2 controls

Method:
Proportionate decrease of N_2O with reduction in O_2 flow
N_2O cutoff with loss of O_2 pressure

Supply failure alarm:
Range: 207kPa+/-14kPa
Sounds at maximum volume every 10 seconds

O_2 flush range:
25 to 75 L/min

Flowmeters

O_2 ranges:
0.1 to 1.0 L/min and
1.2 to 10.0 L/min

N_2O ranges:
0.1 to 1.0 L/min and
1.2 to 10.0 L/min

Air range:
0.1 to 10.0 L/min

Hypoxic guard system

Type:
Mechanical gear

Range:
Provides a nominal minimum 21% concentration of oxygen in O_2/N_2O mixture

Environmental specifications

System operation

Temperature:
10° to 40°C/50° to 104°F

Humidity:
15 to 95% relative humidity, noncondensing

Altitude:
440 to 3,565 m/500 to 800 mmHg

Oxygen cell operation:
15° to 40°C/59° to 104°F

System storage

Temperature:
-25° to 65°C/ -13° to 149°F

Humidity:
10 to 95% relative humidity, noncondensing

Altitude:
440 to 5,860 m/375 to 800 mmHg

Oxygen cell storage:
-15° to 50°C/5° to 122°F 10 to 95% relative humidity 500 to 800 mmHg

Electromagnetic compatibility

Immunity:
Complies with all requirements of EN/IEC

Emissions:
CISPR 11 group I class B

Approvals:
EN/IEC 60601-1, EN/IEC 60601-1-2, ISO 80601-2-13

Breathing circuit specifications

Operational modes

Breathing Circuit (Circle Mode only), ACGO

Carbon dioxide absorbent canister

Absorbent capacity: 1200mL

Integrated expiratory limb water reservoir

Ports and connectors

Exhalation: 22 mm OD ISO 15 mm ID taper

Inhalation: 22 mm OD ISO 15 mm ID taper

Bag port: 22 mm OD

Pressure gauge

Scale range: -2 to 10 kPa/-20 to 100 cm H_2O

Begin/Ventilator switch

Type: Bi-stable

Control:
Controls ventilator and direction of breathing gas within the circuit

Integrated Adjustable Pressure Limiting (APL) valve

Range: 1 to 70 cm H_2O

Tactile knob indication at:
30 cm H_2O and above

Adjustment range of rotations:
1 to 30 cm H_2O (0 to 230°)
30 to 70 cm H_2O (230 to 320°)

Materials

All materials in contact with exhaled patient gases are autoclavable, except flow sensors and O_2 cell.

All materials in contact with patient gas are free of natural rubber latex

Breathing circuit parameters

Mechanical mode:
Automatically compensates for compression losses within the absorber and bellows assembly

Circuit volume:
2.6 L Vent Mode (including absorber)
2.1 L Bag Mode

Anesthetic gas scavenging

All scavenging
Positive pressure relief:
10 cmH_2O

Passive scavenging
Negative pressure relief:
0.3 cmH_2O Outlet

Passive outlet connector:
30 mm male taper ISO

Active scavenging

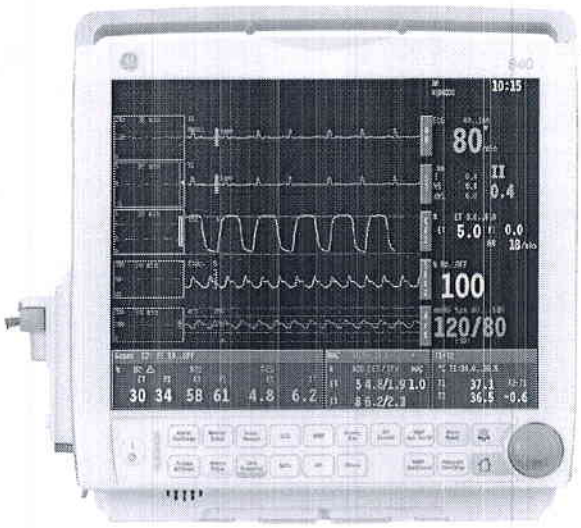
Disposal system type	Outlet connector	Hospital waste gas disposal system requirements
Adjustable flow, high vacuum	DISS EVAC	285mmHg(12 inHg) minimum at 38 L/min flow
High flow, low vacuum	BSI 30 mm threaded (BS6834)	25mmHg(1 inHg) minimum at 100 L/min flow
Low flow, high vacuum	DISS EVAC	285mmHg(12 inHg) minimum at 36 L/min flow
Low flow, low vacuum	12.7 mm barb	6 L/min flow
Low flow, low vacuum	25 mm barb	6 L/min flow
Low flow, low vacuum	30 mm ISO male	40 L/min flow

DOC 3975644

GE Healthcare

B40 Patient Monitor

Affordable clinical excellence



Patients with acute, life-threatening conditions need the best possible care. The B40 Monitor from GE Healthcare provides a continuous flow of quality information to enhance clinical decision-making for adult, pediatric and neonatal[1] patients in various care areas.

Advanced clinical parameters

The B40 Monitor is designed with advanced measurement technologies for accurate and reliable patient monitoring:

- EK-Pro arrhythmia analysis
- DINAMAP* SuperSTAT non-invasive blood pressure
- TruSignal* enhanced SpO_2 saturation monitoring other options available: Nellcor® OxiMax® SpO_2 and Masimo® SET® SpO_2 algorithms
- Datex-Ohmeda* gas technology to support non-invasive monitoring in anesthesia and critical care areas
- Entropy* monitoring that provides information on the patient's central nervous system during general anesthesia[1]
- Comprehensive package of neonatal[1] measurements

Performance and reliability

With its streamlined design, the portable B40 Monitor fits into crowded spaces and is easily moved to different care areas as needed. The system's rugged design stands up to harsh environments and the everyday wear-and-tear of busy care areas. It will provide the performance and accuracy that you expect of GE equipment–so you can provide the care that your patients expect.

Ease of use for fast decision-making

The B40 Monitor makes it easy to acquire accurate patient data to support timely decision-making:

- 12.1" crystal-clear monitor displays up to six waveforms simultaneously
- Intuitive menus and one-button access to commonly used functions
- 72-hour trend display with graphical and numerical data to review patient progress
- HL7 direct output and connectivity with the CARESCAPE* Gateway enables communications to EMR systems
- Capability to work in CARESCAPE Network and S/5 Network environments

[1] Impedance respiration is intended for use with only adult and pediatric patients in United States, Guam, Puerto Rico, Saint Croix, Saint Thomas and Canada. CO_2 measurement through E-miniC Module is intended for use with patients weighing over 5kg (11 lb) only. Entropy is intended for use with adult and pediatric patients older than 2 years.

Technical specifications

Display

Size	12.1 in (diagonal)
Resolution	800 x 600 pixels (SVGA)
Number of traces	Up to 6
Display layout and colors	User-configurable
Controls	Trim Knob* control and hard keys (standard)

Parameters and modules

Parameters	Modules[3]
ECG	Configured hemodynamic module
Resp	
SpO_2	
NIBP	
Temp	
2 channel InvBP	
Entropy	E-Entropy[3]
Sidestream CO_2	E-miniC[3]
Sidestream CO_2, O_2 and N_2O	E-sCO[3]
Sidestream CO_2, O_2 agents and N_20	E-sCAiO[3] N-CAiO[3,4]

NOTE: The monitor also is compatible with the E-sCOV and E-sCAiOV modules without Spirometry function.

NOTE: When monitoring neonatal[5] or other patients that have high respiration rate or low tidal volume, the E-sCO or E-sCAiO Modules shall be used within the limits of respiration rates and tidal volumes to ensure specified measurement accuracy.

ECG

Leads available	3-lead configuration: I, II, III 5-lead configuration: I, II, III, aVR, aVL, aVF and V
Sweep speed	12.5, 25 or 50mm/s
Gain range	0.2 to 5.0 cm/mV
Heart rate accuracy	30 to 300 bpm, ±5% or ±5 bpm, whichever is greater
Bandwidth	
50/60 Hz power supply	Monitor: 0.5 to 40 Hz ST: 0.05 to 40 Hz Diagnostic: 0.05 to 150 Hz
Pacemaker detection	Range: 2 to 700 mV Pulse width: 0.5 to 2 ms
Arrhythmia analysis	Asystole, bradycardia, tachycardia, ventricular fibrillation, ventricular tachycardia
ST segment analysis	Numeric range: -9 to +9 mm (-0.9 to +0.9 mV) Accuracy: ±0.2mm or ±10%, whichever is greater, within the measurement range of -8mm to +8mm Numeric resolution: 0.1 mm (0.01 mV) ST Trends: Up to 72 h

Impedance respiration[1]

Range	Adult/pediatric: 4 to 120 resp/min Neonate[5]: 4 to 180 resp/min
Accuracy	±5% or ±5 resp/min, whichever is greater
Gain range	0.1 to 5 cm/Ohm

SpO_2

TruSignal SpO_2

Measurement range

Pulse oximetry	1 to 100%
Pulse rate	30 to 250 bpm

Measurement accuracy

Saturation	Without motion-adult/pediatric Finger sensor: 70 to 100% ±2% Ear sensor: 70 to 100% ±3% Without motion-neonate[5]: 70 to 100% ±3% With motion-adult/pediatric/ neonate[5]: 70 to 100% ±3% Low perfusion-adult/pediatric: 70 to 100% ±3% (1~69% unspecified)
Pulse Rate	Without motion: ±2 bpm (Adult/Pediatric/Neonatal[5]) With motion: ±3 bpm (Adult/Pediatric/Neonatal[5]) Low Perfusion: ±5 bpm (Adult/Pediatric)

Nellcor OxiMax

Measurement range

Pulse oximetry	1 to 100%
Pulse rate	20 to 250 bpm

[1] Refer to B40 User's Guide for more information.

[4] Not compatible with monitor software version VSP-B_1.05 or earlier.

[5] Impedance respiration is intended for use with only adult and pediatric patients in United States, Guam, Puerto Rico, Saint Croix, Saint Thomas and Canada. CO_2 measurement through E-miniC Module is intended for use with patients weighing over 5kg (11 lb) only. Entropy is intended for use with adult and pediatric patients older then 2 years.

Measurement accuracy

Saturation	Adult: 70 to 100% ±2% Neo: 70 to 100% ±3% Low perfusion: 70 to 100% ±2%
Pulse Rate	±3 bpm

Masimo SET

Measurement range

Pulse oximetry	1 to 100%
Pulse rate	25 to 240 bpm

Measurement accuracy

Saturation	Without motion-adult/pediatric: 70 to 100% ±2% Without motion-neonate[6]: 70 to 100% ±3% With motion-adult/pediatric/neonate[6]: 70 to 100% ±3% Low perfusion: 70 to 100% ±2% (0~69% unspecified)
Pulse rate	Without motion: ±3 bpm With motion: ±5 bpm

NIBP

Measurement technique	Oscillometric with step deflation
Modes	Manual, automatic and stat

NIBP Measurement ranges

Systolic	Adult/Pediatric: 30 to 290 mmHg Neonate[1]: 30 to 140 mmHg
MAP	Adult/Pediatric: 20 to 260 mmHg Neonate[1]: 20 to 125 mmHg
Diastolic	Adult/Pediatric: 10 to 220 mmHg Neonate[1]: 10 to 110 mmHg
Accuracy	Meets AAMI SP10
Default initial inflation pressure	Adult/Pediatric: 135 ±15 mmHg Neonate[1]: 100 ±15 mmHg
Maximum determination time	Adult/Pediatric: 2 min Neonate[1]: 85 s
Over pressure monitor	Adult/Pediatric: 300 ±6 to 330 mmHg Neonate[1]: 150 ±3 to 165 mmHg

Invasive blood pressure

Measurement range	-40 to 320 mmHg (-5.3 to 42.7 kPa)
Measurement accuracy	±5% or ±2 mmHg, whichever is greater
Frequency response	4 to 22 Hz
Transducer sensitivity	5 µV/V/mmHg

Temperature

Numerical display	T1, T2, T2-T1
Measurement range	10 to 45°C (50 to 113°F)
Measurement accuracy	±0.1°C without probe
Display resolution	±0.1°C at 25 to 45°C with reusable probes
Probe	YSI probes recommended by GE Healthcare

Networking

Compatibility	CARESCAPE Network and S/5 Network

I/O connectors

RS-232 computer serial output, Defibrillation synch, Nurse call

Mounting

GCX compatible

Integrated carrying handle

Paper Recorder

Method	Thermal dot array
Horizontal resolutions	24 dots/mm (600 dpi)
Vertical resolution	8 dots/mm (200 dpi)
Waveforms	Selectable 1, 2, or 3 waveforms
Numerics	HR, SpO_2, NIBP, IBP1, IBP2, ETCO2, T1, T2, Resp, O2, AA
Tabular trend printout	HR, NIBP, IBP1, IBP2, T1, T2, Et/FiCO2, RR, Et/Fi O2, Et/Fi AA
Graphical trend printout	HR, ST, IBP1, IBP2, NIBP, SpO_2, Pleth, CO_2, N_2O, O2, AA, Resp, T1+T2, Entropy
Paper width	50 mm, printing width 48 mm
Paper speed	1, 6.25, 12.5, 25 mm/s

Printing

Network laser printer supported in S/5 network.

[5]Impedance respiration is intended for use with only adult and pediatric patients in United States, Guam, Puerto Rico, Saint Croix, Saint Thomas and Canada. CO_2 measurement through E-miniC Module is intended for use with patients weighing over 5kg (11 lb) only. Entropy is intended for use with adult and pediatric patients older than 2 years.

Performance specifications

Alarms

Priority	High, Medium, Low and Message
Notification	Audible and visual
Setting	Default and individual
Visual alarm notification	Red, yellow, cyan Audio silence message General alarm message
Audio pause	2 min
Adjustment	Central alarm display and adjustment page
Trending	10 min graphical trends referenced to set alarm limits

Trends

Graphical	All parameters, selectable time scales from 20 min to 72 h
Numerical	All parameters, every 5 min sampling or after NIBP determination
Snapshot	Up to 10 snapshots Manual or alarm triggered
OCRG trend	Real time or snapshot Neonate mode only
Trend cursor	In both graphical and numerical trends
Minitrends	5 or 30 min minitrends can be displayed for a continuous historical view

Environmental specifications

Operating conditions

Temperature	5 to 40°C (41 to 104°F)
Relative humidity	20 to 90% noncondensing
Atmospheric pressure	700 to 1060 hPa (525 to 795 mmHg)

Storage and transport conditions

Temperature	-20 to 60°C (-4 to 140°F)
Relative humidity	10 to 90% noncondensing
Atmospheric pressure	700 to 1060 hPa (525 to 795 mmHg)

Power specifications

AC input	100 to 240V ±10%, 50/60 Hz, 150VA
Protection	Class I
Battery	Exchangeable lithium-ion, 2 pcs max
Charging time	2 h per battery pack
Run time	Up to 4.5 h; 2 h to 90% per battery pack

Physical specifications

Dimensions (H x W x D)	Without extension rack: 31 x 31 x 16 cm (12.2 x 12.2 x 6.3 in) With extension rack: 31 x 35 x 18 cm (12.2 x 13.8 x 7 in)
Weight	<=7kg (15 lb)
Ingress protection	IP21

Warranty

One year.

Certifications

IEC 60601-1 passed

CE marking according to Council Directive 93/42/EEC concerning medical devices amended by 2007/47/EC