КЫРГЫЗ РЕСПУБЛИКАСЫНЫН ВИЦЕ-ПРЕМЬЕР-МИНИСТРИ

ВИЦЕ-ПРЕМЬЕР-МИНИСТР КЫРГЫЗСКОЙ РЕСПУБЛИКИ

№20-24157 2020-ж.г. «22» 06.

Минздрав – С.Т.Абдикаримову

Для информации.

А.Ж.Исмаилова

КЫРГЫЗ РЕСПУБЛИКАСЫНЫН ӨКМӨТҮНҮН АППАРАТЫ ПРАВИТЕЛЬСТВА КЫРГЫЗСКОЙ РЕСПУБЛИКИ
КАНЦЕЛЯРИЯСЫ №3 КАНЦЕЛЯРИЯ

Кыргыз Республикасынын Саламаттык сактоо министрлигинин Иш каалздары жана укуктуруу иштери белуму
Отдел делопроизводства и организационной работы Министерства здравоохранения Кыргызской Республики
кириш вход. № 1607
на б. тиркеме б. л. прилож. л.
«22» 06 2020 ж.г.

Зав. отделом У.Мамаканов

Исполнитель Н.Аднаева Тел. 960355

2020/99326045/31373568

Türkiye Cumhuriyeti Büyükelçiliği, Kırgız Dışişleri Bakanlığına saygılarını sunar ve Türkiye Cumhuriyeti'nin ilk yerli ve milli üst düzey yoğun bakım ventilatörü olan "Biyosis / Biyovent Solunum Cihazı"na ilişkin olarak aşağıda kayıtlı hususları bildirmekten şeref duyar.

Türkiye Cumhuriyeti Sağlık Bakanlığı ile Sanayi ve Teknoloji Bakanlığı'nın koordinasyonunda Türk teknoloji ve savunma sanayii firmalarında görevli mühendisler ve uzman doktorlar tarafından 5 yıllık AR-GE çabasıyla geliştirilen Türkiye Cumhuriyeti'nin ilk yerli ve milli üst düzey yoğun bakım ventilatörü "Biyosis / Biyovent Solunum Cihazı"nın tanıtım broşürü ilişikte sunulmaktadır.

Farklı coğrafyalara ihracatı yapılan mezkûr cihaz ayrıca Türkiye Cumhuriyeti'ndeki Şehir ve Pandemi Hastanelerinde COVID-19 pandemisi nedeniyle tedavi gören hastaların entübasyonunda kullanılmaktadır. Hem yaşlı hem de erişkin hastalar için kullanımı uygun ve bakım maliyetleri düşük olan, 2 yıl firma garantisi ve 3 yıl opsiyonel ilave garanti uzaması bulunan "Biyosis / Biyovent Solunum Cihazı" UDEM ve ISO sertifikalı sahip olup, sözkonusu kalite sertifikaları, deney raporu ve laboratuvar sonuçlarıyla birlikte ekte sunulmaktadır.

Sağlık Bakanlığı'nın ilgili kuruluşu olarak faaliyet gösteren Uluslararası Sağlık Hizmetleri (USHAŞ) A.Ş. tarafından yurtdışı satışı gerçekleştirilen "Biyosis / Biyovent Solunum Cihazı" hakkında ilave bilgi ve satış işlemine dair detaylar USHAŞ Direktörü Uluç İçöz'den (e-posta: uluc.icoz@saglik.gov.tr, telefon: +90 505 274 9103) temin edilebilecektir.

Büyükelçilik, keyfiyetin ve ekli tanıtım broşürünün Kırgız Cumhuriyeti'ndeki ilgili makamlara iletilmesi hususunda saygıdeğer Bakanlığın tavassutlarını rica eder.

Türkiye Cumhuriyeti Büyükelçiliği bu vesileyle, Kırgız Dışişleri Bakanlığına en derin saygılarını yineler.

Bişkek, 9 Haziran 2020

T.C. BİŞKEK BÜYÜKELÇİLİĞİ 1967

Ek: Tk.

Kırgız Cumhuriyeti Dışişleri Bakanlığı
Cc. Kırgız Cumhuriyeti Sosyal İşlerden Sorumlu Başbakan Yardımcılığı
Kırgız Cumhuriyeti Sağlık Bakanlığı
BİŞKEK

Кыргыз Республикасынын Өкмөтүнүн Аппаратынын Канцеляриясы
Канцелярия Аппарата Правительства Кыргызской Республики
кирүүчү вход № 24157
16 б. тиркеме 16 б.
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«16» 06 2020 ж.

Неофициальный перевод

2020/99326045/31373568

Посольство Республики Турция выражает своё уважение Министерству Иностранных Дел Кыргызской Республики и имеет честь сообщить нижеследующую информацию относительно аппаратов ИВЛ "Biyosis/Biyovent", которые являются первыми отечественными и национальными аппаратами интенсивной терапии высокого уровня Республики Турция.

В приложении приводится информационная брошюра относительно первых в Турции отечественных и национальных аппаратов интенсивной терапии высокого уровня ИВЛ "Biyosis/Biyovent", которые были разработаны в результате 5 летних исследований и разработок инженеров и специалистов, работающих в компаниях турецкой технологической и оборонной промышленности под координацией Министерства Здравоохранения и Министерства Промышленности и Технологий Республики Турция.

Также данный аппарат, который экспортируется в разные страны, используется при интубации пациентов, получающих лечение в Городских и Эпидемиологических Больницах Турции, в связи с пандемией COVID-19. Аппарат ИВЛ «Biyosis/Biyovent», который подходит как для пожилых, так и для взрослых пациентов и имеет низкие затраты на техническое обслуживание, 2-годичную гарантию от фирмы и 3-летнее дополнительное продление гарантии, сертифицирован Международным Сертификационным Центром/UDEM и Международной Организацией по Стандартизации/ISO, и эти сертификаты качества представлены в приложении вместе с протоколом испытаний и лабораторными результатами.

Дополнительную информацию об аппарате ИВЛ «Biyosis/Biyovent», продажу за границу которой осуществляет компания "Улусларарасы Саглык Хизметлери (USHAŞ) Аноним Ширкети", являющаяся соответствующим учреждением Министерства Здравоохранения Республики Турция, и подробную информацию о процессе продажи можно получить у Директора USHAŞ господина Улуч Ичёз (адрес электронной почты uluc.icoz@saglik.gov.tr, телефон +90 505 274 9103).

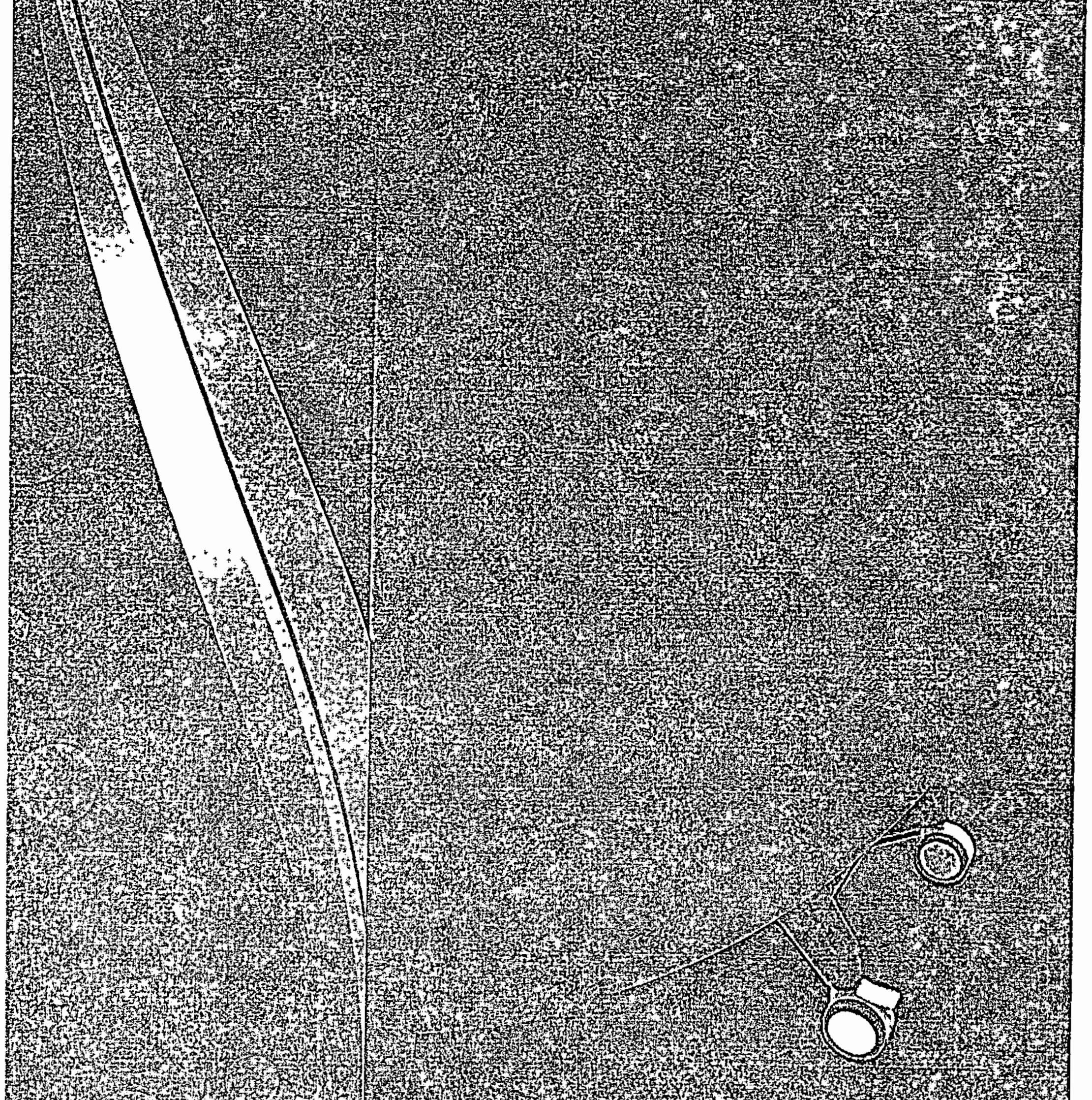
Посольство просит уважаемое Министерство оказать содействие в передаче вышеуказанной информации с приложенными брошюрами в соответствующие и компетентные инстанции Кыргызской Республики.

Посольство Республики Турция пользуется случаем, чтобы возобновить Министерству Иностранных Дел Кыргызской Республики уверения в своем весьма высоком уважении.

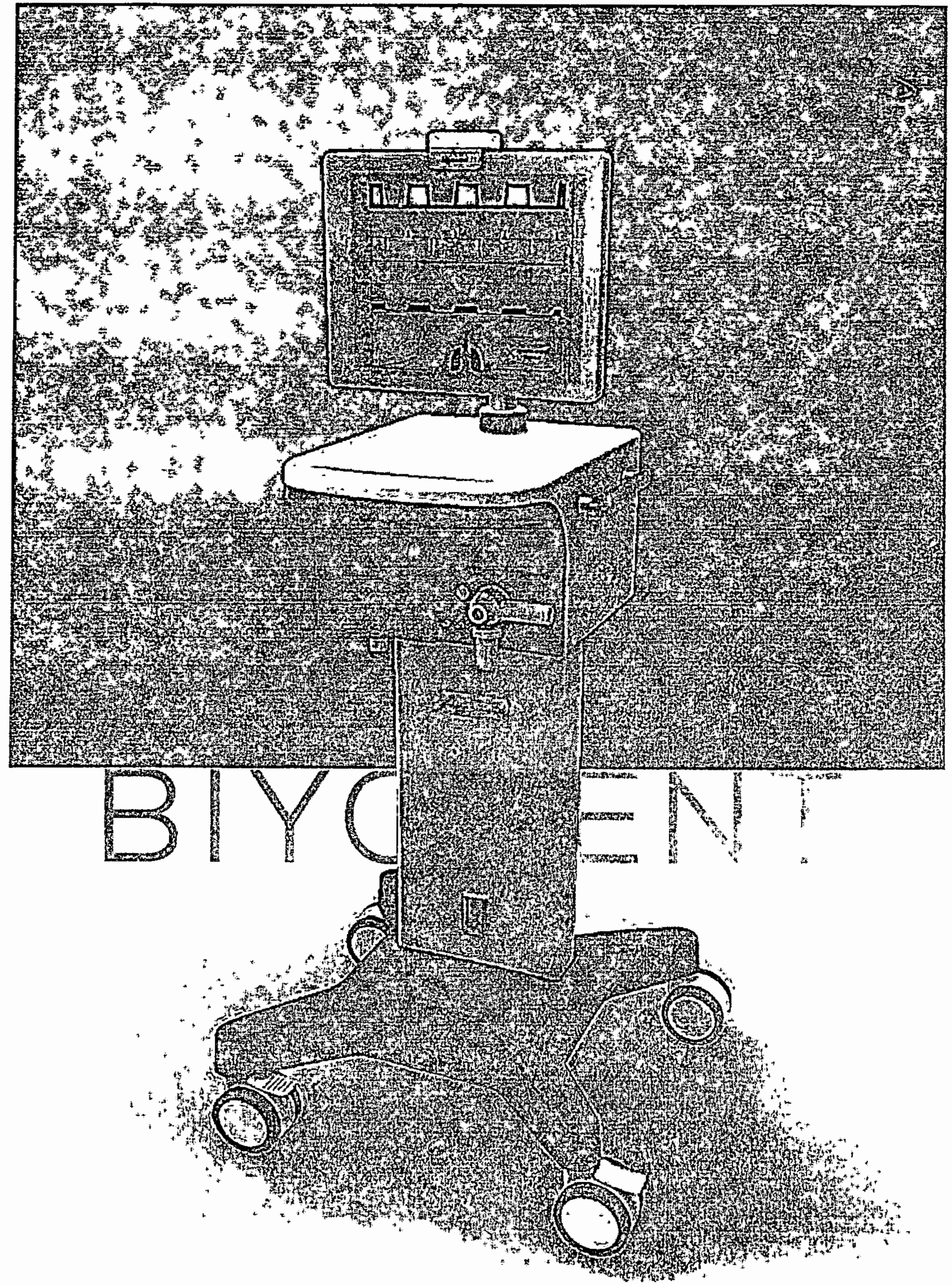
Бишкек, 9 июня 2020 года

Министерство Иностранных Дел Кыргызской Республики
Копии: Вице-Премьер-Министру по Социальным Вопросам
в Министерство Здравоохранения КР
БИШКЕК

BIYOVENT
THE FIRST INTENSIVE CARE
MECHANICAL VENTILATOR
OF TURKEY



biosys
MİLLİ MEDİKAL SİSTEMLER



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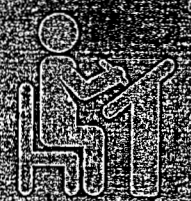
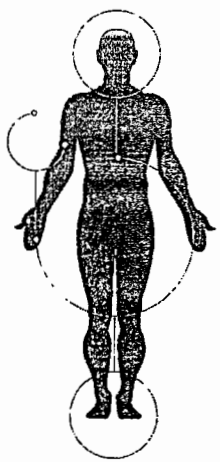
Made In Türkiye



Biyovent is produced with the support of the Republic of Turkey Ministry of Industry and Technology, The Scientific and Technological Research Council of Turkey and Bilkent Cyberpark after a five-year research and development process.
The five-year design is verified and manufactured with the cooperation of engineers of defense industry and doctors who are experts at respiratory physiology.



BIYOVENT
THE FIRST HIGH LEVEL INTENSIVE CARE MECHANICAL VENTILATOR OF TURKEY

DESIGNED AND PRODUCED FOR INTENSIVE CARE AND REANIMATION UNITS.

- Modern and ergonomic lines.
- User-friendly interface.
- Perfect performance.
- Traditional and innovative operating modes.
- Compatible with pediatric and adult patients.
- Low cost and maintenance.

Biyovent
Respiratory Therapy Equipment

Ergonomic Design

- Design with smooth and modern lines
- Right/left and up/down angled, 15 inches, high resolution full touch screen monitor
- Touch-operated rapid access keys
- Top section detachable from support legs
- User-friendly expiration valve
- Protective carrying handles
- Shock-absorbing and impact resistant wheels
- External humidification support

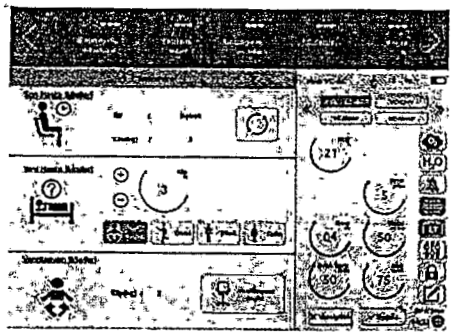
Smart Safety System and User-friendly Interface

- Smart alarm identification and alarm silence (2min)
- Gradual auditory and visual alarm
- Adjustable apnea time and apnea backup mode (5-60 sec.)
- Automatic bilateral apne ventilation mode
- 2 minute supply of oxygen (O2 suction)
- Stand-by mode
- Leak and trigger compensation
- Automatic tube compensation
- Comparative measurement of sensors and automatic calibration (when turning on the device and on request)
- Oxygen sensor
- Monitoring the trend of a patient for 1 week
- Logging the system for 6 weeks
- 2 hour internal battery
- 8 hour optional battery
- 5 ms valve response time
- 100 mbar emergency valve
- 50 mbar automatic expiration evacuation
- IP 21 impermeability
- Low air and oxygen pressure detection
- Automatic change of source
- Software update
- Working with a medical compressor
- Display of loss of main power and level of battery
- Display of technical failure, fan failure and connection loss alarm

Economic Solutions

- 100 % made in Türkiye
- Minimum maintenance cost
- Reusable expiration valve
- 2 years warranty + 3 years optional warranty extension
- Quick and qualitative technical service

Pediatric and Adult — One Machine Compatible with All Patients



Biyovent can support all female & male and pediatric & adult patients.

It can deliver up to 150 breaths and go down to 20 cc low Vtidal.

It can calculate the values of patient elastance and compliance fast and precisely.

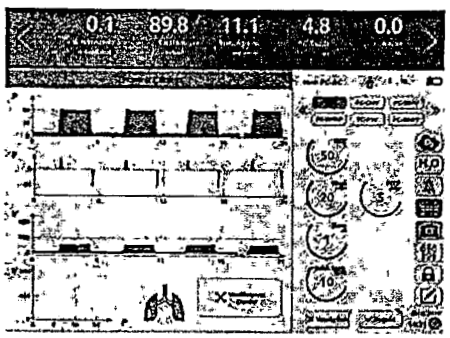
It can automatically calibrates itself when it is turned on.

Automatic tube compensation.

It provides leak compensation up to 80 % .

Inspiration hold and expiration hold in 1-60 sec. intervals.

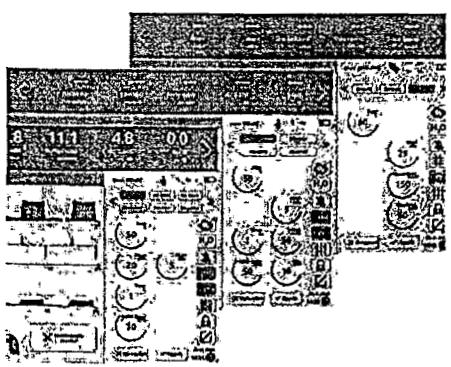
Advanced Adaptive Control — Biyovent uses advanced adaptive control algorithms. It responds in milliseconds.



Biyovent has Nasal Cpap and High Flow Oxygen Therapy modes.

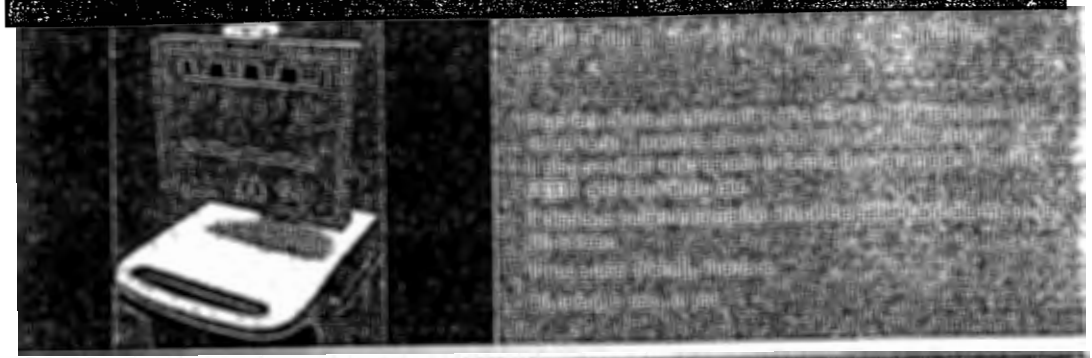
Biyovent has an integrated nebulizer system.

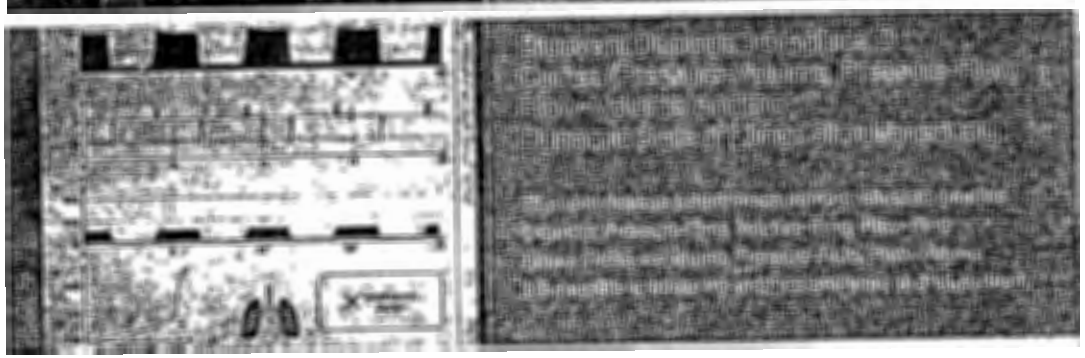
Advanced Adaptive Control — Biyovent works both in traditional and innovative modes.

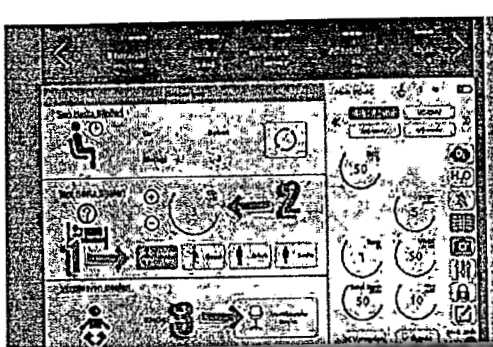


Pressure Controlled Modes:	Volume Controlled Modes:	Spontaneous and Smart Modes:
P-ACV	V-ACV	SPN-PS
P-SIMV+PS	V-ACV(PRVC)	SPN-VS
P-CMV	V-CMV	
P-PSV	V-SIMV+PS	
P-Bilevel	V-SIMV(PRVC)+PS	
APRV		

Interface of Biyovent and Features of Software

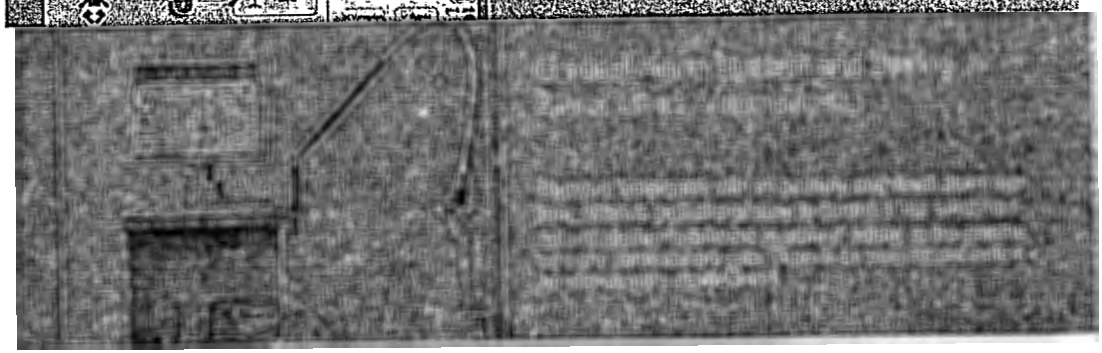


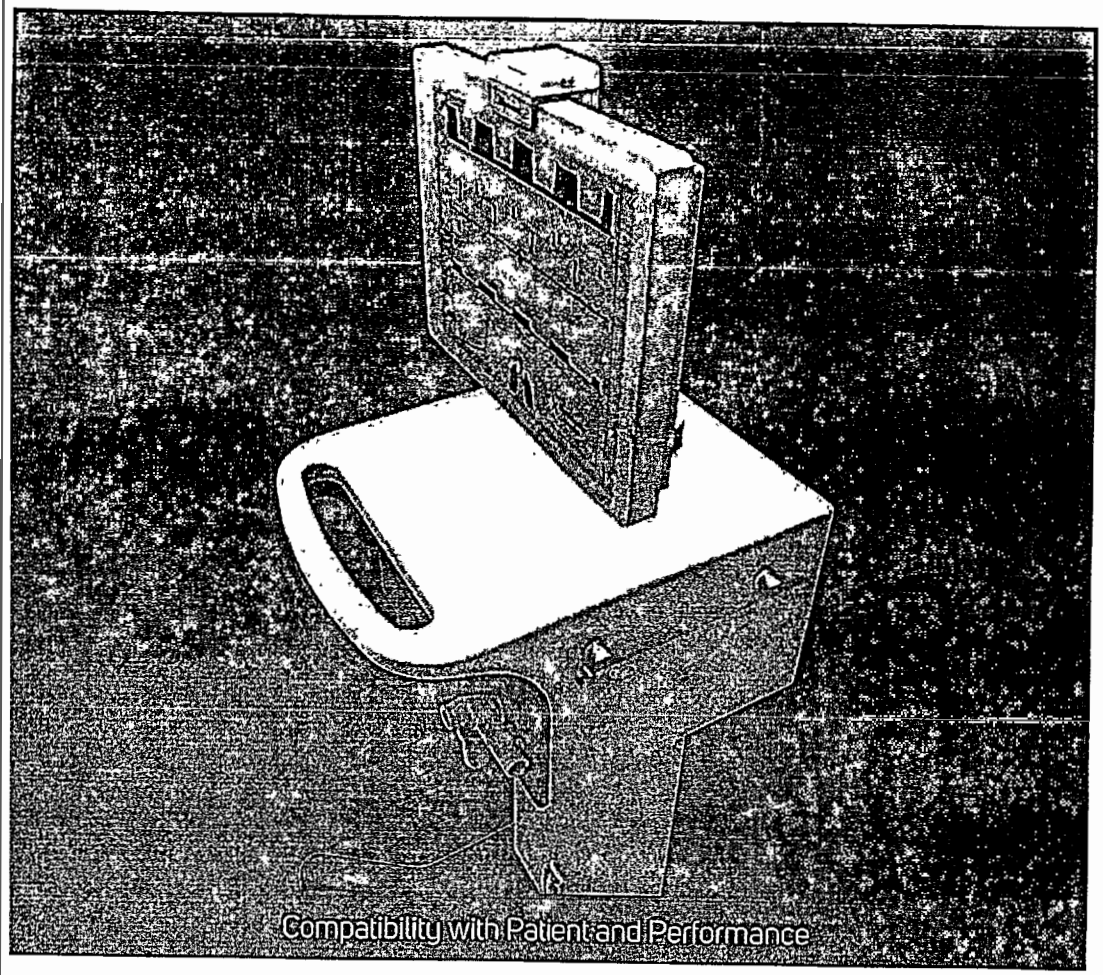


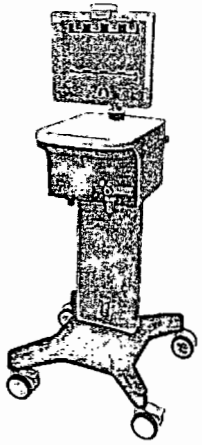


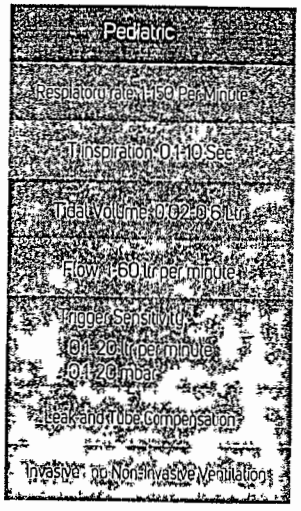
Just Identify the Patient, let Biyovent do the rest...

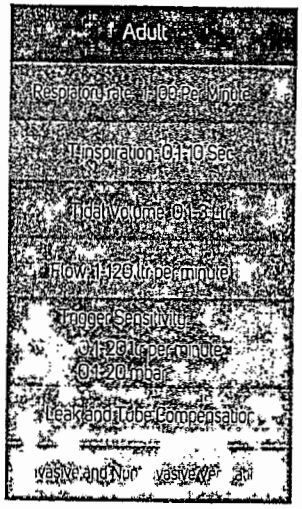
Biyovent has trigger compensation feature.







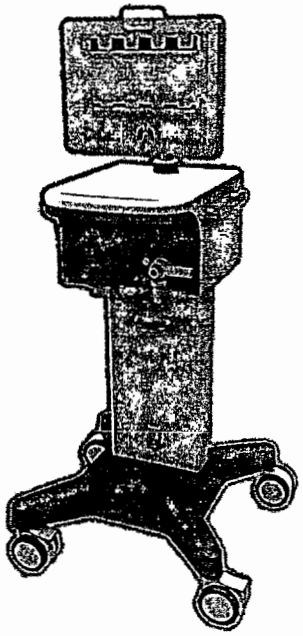




Technical Features of Biyovent

Types of Patients:

Padiatric and Adult



Modes of Ventilation

P-ACV	Pressure Controlled, Assisted Ventilation
P-SIMV+PS	Pressure Controlled, Synchronized Mandatory Ventilation With Pressure Support
P-PSV	Pressure Controlled, Ventilation With Pressure Support
P-BILEVEL	Pressure Controlled, Two-Level Ventilation
P-CMV	Pressure Controlled, Continuous Mandatory Ventilation
APRV	Airway Pressure Release Ventilation
V-ACV	Volume Controlled, Assisted Ventilation
V-ACV(PRVC)	Volume targeted, Pressure Controlled, Assisted Ventilation
V-CMV	Volume controlled, Continuous Mandatory Ventilation
V-SIMV+PS	Volume controlled, Synchronized Mandatory Ventilation With Pressure Support
V-SIMV(PRVC)+PS	Volume Targeted, Pressure Controlled, Synchronized Mandatory Ventilation With Pressure Support
SPN-PS	Spontaneous Ventilation With Pressure Support
SPN-VS	Spontaneous Ventilation With Volume Support
nCPAP	Nasal CPAP Mode

High Flow Oxygen Therapy Mode, 2-120 ltr/min

Spontaneous Breath Indicator

Working Features

Inspiration pressure	2-100 mBar
Inspiration Time	0.1-10 sec
Peep Pressure	1-50 mBar
Respiratory rate	(p): 1-150/min (a): 1-100/min
Tidal Volume	(p): 20-600 mL (a): 100-3000 mL
Flow Rate	(p): 1-60 lt/min (a): 1-120 lt/min
O2 Mixture	21-100%
Spontaneous Pressure Support	0-100 mBar
I/E rate	1:10(x60*)-10:1

(p): pediatric (a): adult

Detailed Features

Apnea Time	5-60 sec, Bilateral Apnea Ventilation
Apnea Mode	P-CMV, V-CMV
Flow Trigger	0.1-20 lt/min
Pressure Trigger Termination	0.1-20 mBar
Termination Of Inspiration	0-80%
Tramp	0.1-5 sec
Automatic Tube Compensation	0-80%
Automatic Leak Compensation	0-80%
Trigger Compensation	On-Off
Inspiration Pause	1-60 sec
Expiration Pause	1-60 sec
Internal (Integrated) Nebulizer	1-20 Lt/min
O2 Support	2 min

Displayed Data on screen

P Peak	Measurement of Peak Pressure Inspiration
P Peep	Measurement of PEEP
P Plateau	Masurement of Plateau Pressure Inspiration
P Average	Masurement of Average pressure
F Inspiration	Inspiration Flow
F Expiration	Expiration Flow
MVe	Volume Measurement
SpnMVe	Spontaneous Minute Volume Measurement
SpnMVe/MVe	Spontaneous Volume Per Minute / Volume Ratio Per Minute
V Tidal	Tidal Volume
FIO2	Oxygen Ratio
Respiratory rate	Number of Breaths Per Minute
Spontaneous respiratory rate	Spontaneous Number of Breaths Per Minute
T Inspiration	Inspiration Time
T Exspiration	Exspiration Time
I/E	Inspiration and Expiration Time Ratio
R Airway	Airway Resistance Measurement
C Static	Static Compilance Measurement
C Dynamic	Dynamic Compilance Measurement
Elastance	Elastance Measurement
RC Constant	Rc Time Constant Measurement
WOB	Energy Spent During Inspiration
WOB/Lt	Energy Spent During Inspiration / Volume
V Resudial	Resudial volume at the end of breathing
V Expiration	Exspiration Tidal Volume
V Ads	Anatomic Dead Space Measurement
AutoPeep	Trapped Air Pressure After Respiration Occlusion
P0.1	Pressure Measurement Per 100 milli Seconds
RSBI	Rapid Shallow Breathing İndex
PTP	Negative Pressure x Negative Pressure Time
FTP	Negative Flow x Negative Flow Time
P NIF	Negative Inspiration Pressure Force
MVsp%	Spontaneous Ratio to Mandatory Minute Volume
Leak Rate	Leak Volume Rate
Leak Volume	Leak Volume After Respiration Cycle

Alarm Feautures

Auditory and Visual Alarm and Recording
Two-Minute Alarm Silence
Inspiration Pressure Lower Limit / Upper Limit
Tidal Volume Lower Limit / Upper Limit
Speed of Respiration Lower Limit / Upper Limit
Volume Per Minute Lower Limit / Upper Limit
I/E Ratio Lower Limit / Upper Limit
FIO2 Lower Limit / Upper Limit
Apnea Time Upper Limit
Leak Upper Limit

Graphic Features

Pressure Time Graphic
Flow Time Graphic
Volume Time Graphic
Pressure-Volume, Pressure-Flow, Volume-Flow Cycles

Patient Records and Logging

Last 3 Days Record of Ventilation Value Trend and Graphical Representation.
Information Storage With The Capauty of 2000 Record Alarm and Ventilation Alarm.

Electrical Features

Battery Time	2 Hours + 8 Hours Optional
Mains Voltage Power	180 - 264 VAC
Consumption	47-63 Hz 100W

Features of The Source of Pressure

02 Pressure 2.5 - 7 Bar Central System / Tube
Air Pressure 2.5 - 7 Bar Central System / Tube
Automatic Change and Alarm Display When The Source Is Consumed
Working With a Medical Compressor or Regulator

Size and Weight

Lenght	150cm
Depth	44cm
Width	42cm
Weight	55kg
Monitor Movement	Left and Right 150°

Up and Down 15°
15 inch Full Touch Screen Monitor
Pendant and Column Mounting

Digital Interfaces

4 USB, 2 COM, 2 Ethernet

Comparison of Modes

Biosys	Puritan Bennett	Dräger	GE	Hamilton	Maquet	Mindray
P-ACV	A/C: PC	PC-AC	PCV	PCV	PC	P-AC
P-SIMV+PS	SIMV: PC	PC-SIMV	SIMV-PC	PSIMV+	SIMV-PC+PS	P-SIMV
PPSV	PS	SPN-CPAP/PS	CPAP/PSV	Spont	PS	PSV
P-Bilevel	BiLevel	PC-BIPAP	BiLevel	DuoPAP	Bi Vent	DuoLevel
APRV	APRV	PC-APRV	APRV	APRV	Bi Vent APRV	APRV
V-ACV	A/C: VC	VC-AC	VCV	(S)CMV	VC	V-AC
VACV(PRVC)	A/C: VC+	Autoflow	PCV+VG	APV/SIMV+	PRVC+	PRVC
V-CMV	A/C: VC	VC-CMV	VCV	CMV	VC	V-AC
V-SIMV+PS	SIMV: VC+	SVG-SIMV	SIMV-VC+	SIMV	SIMV-VC+PS	V-SIMV
V-SIMV(PRVC)+PS	VC+	VC-SIMV+ Autoflow	SIMV-PCVG	APV/SIMV+	SIMV-PRVC+PS	PRVC
SPN-PS	APS	SPN-CPAP/PS	CPAP	Spont	PS/CPAP	-
SPN-VS	VS	SPN-CPAP/VS	-	-	VS	-

- +PS(Pressure Support) feature supports the breathing efforts with pressure.
- PRVC(Pressure Regulated Volume Control) feature provides pressure control for volume target.

biosys
MİLLİ MEDİKAL SİSTEMLER

Bilkent Üniversitesi, Cyberpark A303C, Çankaya, Ankara/Türkiye, 06800

www.biosys.com.tr
info@biosys.com.tr

UDEM

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Biosys Biyomedikal Mühendislik San. ve Tic. Ltd. Şti.
Company Address	: Ankara Teknoloji Bölgesi Cyberpark No:4/A Cyberplaza A Blok 3.Kat No:A 303 Bilkent Çankaya ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non-Sterile Intensive Care Ventilator - Class IIb
GMDN	: 47244
Certificate Number	: M.2020.106.13453
Report Number	: MD.4068.IB
Initial Assessment Date	: 14.02.2020
Registration Date	: 30.03.2020
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM APPROVED 2282

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design examination certificate is required for placing the Class II devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile condition, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
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UDEM

Lvt
Test Laboratuvarları

LVT Test Laboratuvarları Ltd. Şti.
www.lvt.com.tr
Saray Modern Keresteciler Sanayi Sitesi 4.Cadde No:9 Kazan / ANKARA
Tel: 0 312 815 13 25-26 Faks: 0 312 815 13 27

DENEY RAPORU
Test Report

AB-0341-T
20-1129-R0-N1-1
04-20

Müşteri *Client*	:	BİOSYS BİYOMEDİKAL MÜH. SAN. ve TİC. LTD. ŞTİ.
Adres *Address*	:	ANKARA TEKNOLOJİ GELİŞTİRME BÖLGESİ CYBERPLAZA 4/A CYBERPARK A303/C ÇANKAYA / ANKARA
İmalatçı *Manufacturer*	:	BİOSYS BİYOMEDİKAL MÜH. SAN. ve TİC. LTD. ŞTİ.
Deney Numunesi *Test Sample*	:	BİYOVENT
Marka *Trade Mark*	:	BİOSYS
Deney Metodu *Test Method*	:	TS EN 60601-1:2009+A1:2014+AC:2011+A12:2015+A1/AC:2014 (IEC 60601-1:2005/AMD1:2012/COR1:2014)
Deney Tarihi *Date of Test*	:	16.04.2020 – 28.04.2020
Toplam Sayfa Sayısı *Total Number of Pages*	:	193
Basım Tarihi *Date of Issue*	:	29.04.2020

Deney laboratuvarı olarak faaliyet gösteren LVT Test Laboratuvarları Ltd. Şti. TÜRKAK'tan AB-0341-T numarası ile IEC/ISO TS EN 17025:2017 standardına göre akredite edilmiştir.
LVT Test Laboratuvarları Ltd. Şti. accredited by TÜRKAK under registration number AB-0341-T for IEC/ISO 17025:2017 as test laboratory.

Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınması konusunda Avrupa Akreditasyon Birliği (EA) ile Çok Taraflı Anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanıma anlaşmasını imzalamıştır.
The Turkish Accreditation Agency (TÜRKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreements (MLA) and to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the recognition of test reports.

Deney ve/veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (talep halinde) ve deney metotları, bu raporun tanımlayıcı kısmı olan takip eden sayfalarda verilmiştir.
The test and / or measurements results, the uncertainties (if required) with confidence probability and test methods are given on the following pages which are part of this report.

Mühür *Seal*	Deney Sorumlusu *Person in Charge of Test*	Laboratuvar Müdürü *Head of Testing Laboratory*
	Afa Gürül ARSLANLI	Cahit GÖKSEL

Rapor listelerini karekodla kontrol edebilirsiniz.
You can check the report details via QR code.

İçindekiler
Contents

FRT.61/Rev06/0220
Evrakın elektronik imzalı suretine http://e-belge.saglik.gov.tr adresinden 8695fe10-a133-4757-818d-4281bd5ed2ec kodu ile erişebilirsiniz.
Bu belge 5070 sayılı elektronik imza kanuna göre güvenli elektronik imza ile imzalanmıştır.

1. Numunelerin Tanımı / *Definition of the Samples* : Solunum Cihazı / *Ventilator*

1.1 Biyovent (20-1129-R0-N1)

Numune Kabul Tarihi / *Date of Receive*		:	16.04.2020
Numune Seri No / *Serial No*		:	400003
Tip / *Type*		:	Biyovent
Kutup Sayısı / *Number of Poles*		:	Monophase
Beyan Gerilimi / *Rated Voltage*	U_n	:	220 V AC
Beyan Akımı / *Rated Current*	I_n	:	0.5 A
Beyan Frekans / *Rated Frequency*	f_n	:	50 Hz
Beyan Koruma Derecesi / *Rated Degree of Protection*	IP	:	20
Numune Boyutları / *Dimensions of the Sample*	mm	:	150*58*58
Numune Ağırlığı / *Weight of the Sample*	kg	:	55
Sınıf / *Class*		:	Class I and Internally powered ME equipment.
Cihaz – Malzeme Listesi / *Device – Component List*		:	See table 8.10

2. Deney Sonuçları / *Test Results* : Deney sonuçları, müşteri tarafından laboratuvara teslim edilen ve sadece deneyi yapılan numuneye aittir. / *The test results only belong to the tested sample(s) delivered to the laboratory by client.*

Numune / *Sample*	Uygulanan Deney / *Applied Test*	Sonuç / *Result*
Biyovent	TS EN 60601-1:2009+A1:2014+AC:2011 +A12:2015+A1/AC:2014. IEC 60601-1:2005/AMD1:2012/COR1:2014	OLUMLU / *Passed*

3. Çevre Şartları / *Environmental Conditions*

3.1 Ortam Sıcaklığı / *Ambient Temperature* : (21±3) °C

3.2 Ortam Nemi / *Ambient Moisture* : (37±3) %Rh

4. Deney Metodundan Sapma, Ekleme ve Çıkarmalar / *Deviations, Additions & Cutbacks from the Test Method* : Deneyler standart deney metoduna göre uygulanmıştır. / *Tests were made according to the clauses of the relevant standards.*

5. Şartnamelere Uygunluk (Gerekli Hallerde) / *Conformity to Specifications (If Necessary)* : -

6. Dağıtım Bilgileri / *Distribution Information* : BİOSYS BİYOMEDİKAL MÜH. SAN. ve TİC. LTD. ŞTİ.

7. Açıklama / *Explanation* : -

8. Ölçüm Belirsizliği / *Uncertainty of Measurement* : Detaylar aşağıdaki tabloda verilmiştir. / *The details are mentioned table below.*

Beyan edilen genişletilmiş ölçüm belirsizliği, standart belirsizliğin k=2 olarak alınan genişletme katsayısı ile çarpımı sonucunda bulunan değerdir ve %95 olasılıkla güvenilirlik sağlamaktadır.
The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k=2 which for a normal distribution corresponds to a coverage probability of approximately 95 %.

Deney bilgisi / *Test details*	Cihaz kodu / *Device code*	Ölçülen değer / *Measured value*	Ölçüm belirsizliği / *Measurement uncertainty*
Ambient Temperature	LC349	Cl. 3.1	%1,6
Ambient Moisture	LC349	Cl. 3.2	±2,98
Creepage distances and air clearances	LC365	Ins. Diagram	±0,0758
Creepage distances and air clearances	LC443	Ins. Diagram	%0,06
Power input	LC96	See Table 4.11	%1,31
Humidity preconditioning treatment (Temperature)	LC215	See Clause 5.7	±1,26
Humidity preconditioning treatment (Humidity)	LC215	See Clause 5.7	±3,91
Accessible parts and applied parts	LC30	See Table 8.4.2	%1,34
ME equipment intended to be connected to a power source by a plug	LC30	See Table 8.4.3	%1,34
Impedance and current-carrying capability	LC85	See Table 8.6.4	%3,96
Leakage currents and patient auxiliary currents	LC91	See Table 8.7	%3,6
Dielectric strength	LC85	See Table 8.8.3	%1,91
Mechanical strength and resistance to heat	LC100	See Table 8.8.4.1	%2,67
Gaps Measurement	LC365	See Table 9.2.2.2	±0,0539
Gaps Measurement	LC443	See Table 9.2.2.2	%0,06
Instability in transport position	LC284	See Table 9.4.2.1	%1,33
Instability excluding transport position	LC284	See Table 9.4.2.2	%0,66
Audible acoustic energy	LC44	See Clause 9.6.2.1	%0,31
ME equipment not intended to produce diagnostic or therapeutic x-radiation	LC320	See Table 10.1.1	±0,0612
Maximum temperature during normal use	LC74	See Table 11.1.1	±1,39
Push test	LC204	See Table 15.3	%0,59
Mould stress relief test	LC100	See Table 15.3	%2,67

9. Deney Uygulamaları:
Test Applications

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Test specification:	
Standard ..... :	IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
Test procedure ..... :	Type Test
Non-standard test method ..... :	
Test Report Form No ..... :	IEC60601_1P
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	2019-10-11

Lvt Test Laboratuvarları
Elektrikli Tıbbi Donanım Deneyleri
Medical Electrical Equipment Tests

copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Biosys Biyomedikal Mühendislik San. Tic. Ltd. Şti.
ATG Bölgesi, Cyberpark, Cyberplaza A Blok, 303C
Çankaya/Ankara/TÜRKİYE, 06800
www.biosys.com.tr
REF Biyovent
Türk Malı /Made in Turkey

IP20 CLASS I CE 2292
220V AC, 0.5A, 50Hz, 110VA
Dok.No:TD.01/2.0 Yayın Tarihi:01.11.2016
Rev.No:03 Rev. Tarihi:01.04.2020

biosys
TÜSEB tarafından lisanslanmıştır.
arçelik tesislerinde üretilmiştir.

Oksijen / O2	Hava / Air
Beslenme Basıncı Aralığı Supply Pressure Range min : 2.0 bar max : 7.0 bar Tepe Akışı / Peak Flow max : 180 lpm	Beslenme Basıncı Aralığı Supply Pressure Range min : 2.0 bar max : 7.0 bar Tepe Akışı / Peak Flow max : 180 lpm

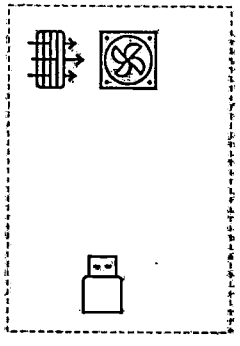
FRT.01/Rev06/0220 6/103 AB-0341-T-20-1129-R0-N1-(04-20
Evrakın elektronik imzalı suretine http://e-belge.saglik.gov.tr adresinden 8695fe10-a133-4757-818d-428165d2c2ec kodu ile erişebilirsiniz.
Bu belge 5070 sayılı elektronik imza kanuna göre güvenli elektronik imza ile imzalanmıştır.

Copy of marking plate

Periyodik bakımların
yapıldığından emin olun!

ENGELLEME!
DO NOT OBSTRUCT!

Hava Acil Giriş Portu
Emergency Air Port



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Elektrikli Tıbbi Donanım Deneyleri
Medical Electrical Equipment Tests

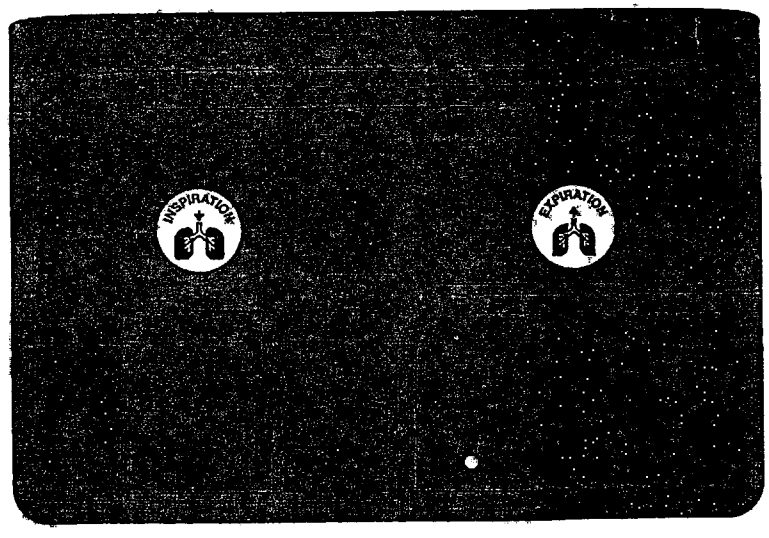
Copy of marking plate

Sigorta:
250 V 3 A

220 VAC 0.5 A

LÜTFEN
KULLANICI KILAVUZUNU
OKUYUN

PLEASE REFER
THE USER MANUAL



GENERAL INFORMATION

Test item particulars (see also Clause 6):

Classification of installation and use	Mobile
Device type (component/sub-assembly/ equipment/ system)	Equipment
Intended use (including type of patient, application location)	Intensive care unit
Mode of operation	Continuous
Supply connection	Internally powered / appliance coupler
Accessories and detachable parts included	Control screen declarated.
Other options include	None
Name and Address of factory(ies)	ARÇELİK A.Ş. Elektronik İşletmesi Çerkezköy Organize Sanayi Bölgesi Karaağaç Mah. 8.Sokak No:1A 59510 Kapaklı/Tekirdağ

Testing

Date of receipt of test item(s)	16.04.2020
Dates tests performed	16.04.2020 – 28.04.2020

Possible test case verdicts:

- test case does not apply to the test object	N/A
- test object does meet the requirement	Pass (P)
- test object was not evaluated for the requirement	N/E (collateral standards only)
- test object does not meet the requirement	Fail (F)

Abbreviations used in the report:

- normal condition: N.C.	- single fault condition: S.F.C.
- means of Operator protection: MOOP	- means of Patient protection: MOPP

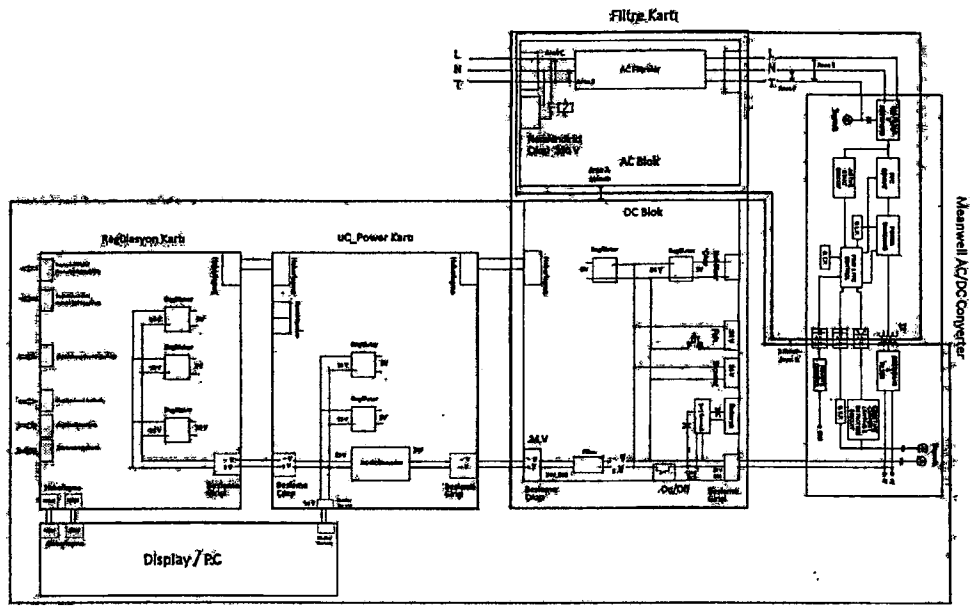
General remarks:

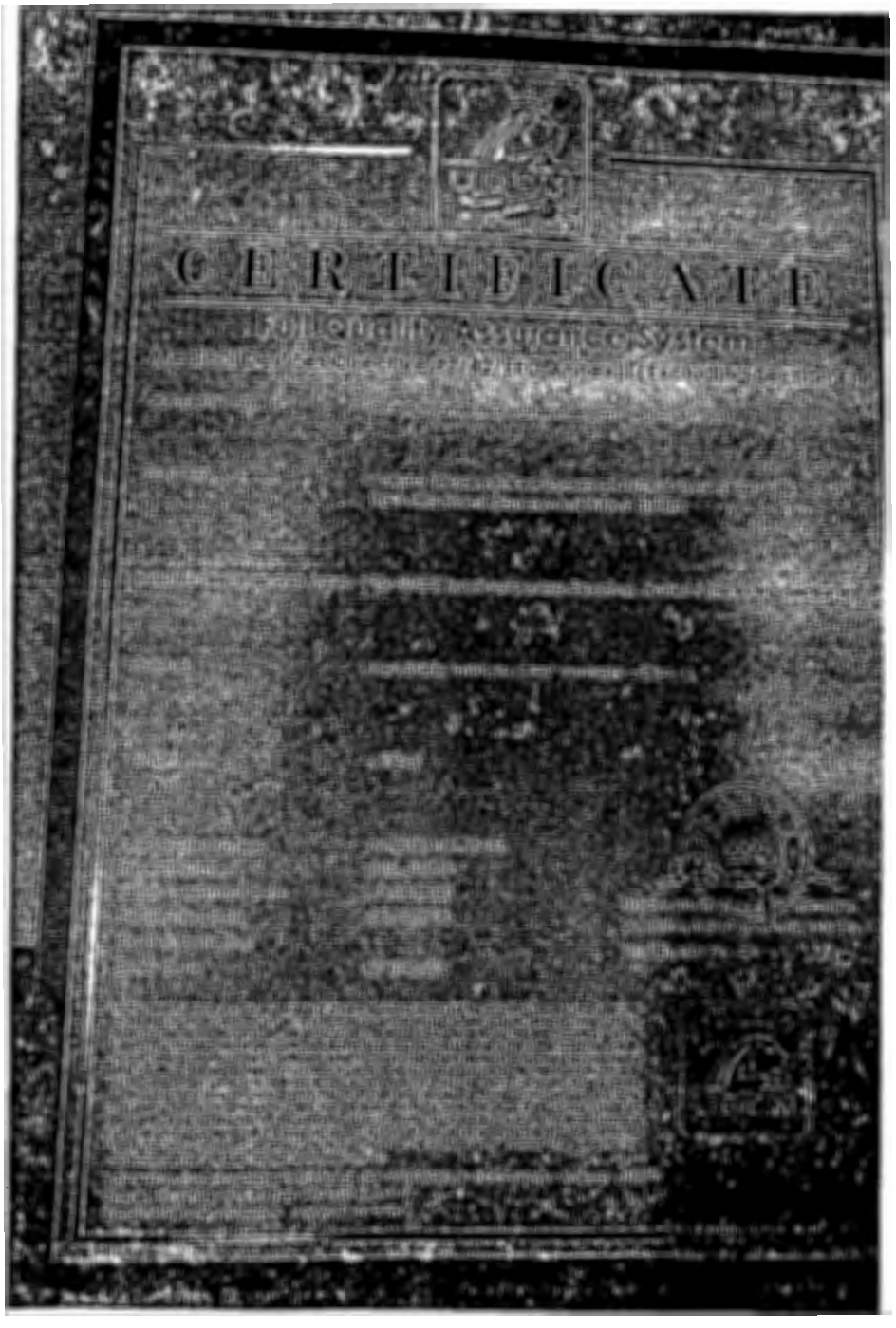
Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "K" of TRF for IEC for 60601-1 3rd edition with Amendment 1.
"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

Lvt Test Laboratuvarları
Elektrikli Tıbbi Donanım Deneyleri
Medical Electrical Equipment Tests

INSULATION DIAGRAM




CERTIFICATE


TCS
Sertifika
ISO 13485:2016