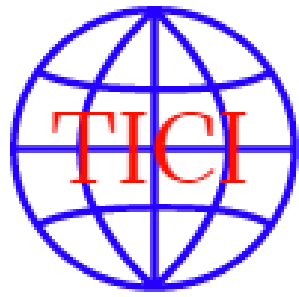


# TRAFALGAR HOLDINGS GROUP U.S.A. & LATIN AMERICA

AUTHORIZED DISTRIBUTOR IN U.S.A & LATIN AMERICA

Email. [Info@consultrafalgar.com](mailto:Info@consultrafalgar.com)

Phone.+1-314-499-3717



## BIYOVENT

Intensive Care Type  
Mechanical Ventilator Device



# BREATHE THE FUTURE

Intensive Care Type  
Mechanical Ventilator Device





# OUR BUSINESS: SOURCE OF THE LIFE

We produce technology for breathing, and breathing for health.

As Biosys, we offer solutions for the deficiencies in the medical sector with competent engineers and specialist doctors having many years of R&D experience since 2012. In our working process, we are progressing with the awareness that benefiting from health services is the most fundamental social right and that this right must be provided to every individual and we develop our technologies with this awareness.

We make our ideas a reality in our R&D center in order to meet both national and global needs in the field of health by developing new generation medical technologies. We know that even the smallest work and business we carry out can affect the health of an individual on earth, and for this, we carry out meticulous and deep studies to design every detail in our products perfectly. Thanks to our effective and safe production approach, we produce new generation medical technologies at high quality and reliability, and we hope for a healthy life.

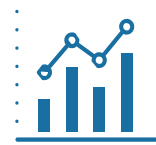
In the technologies we have developed for the needs and demands of the health sector, we do not only advance and improve by relying on our engineering expertise, but also we carry out a multidisciplinary study shaped by the opinions of doctors in every step we take. Thus, we make a difference in the health sector with medical devices that have high technological threshold values and fully meet the needs, and have the best design, software and technology. With this difference, we continue to progress confidently to affect the health of every individual and to be the gateway to a healthy life in the world.

# DETAILED RESEARCH, EXCELLENT RESULT

## We make a Difference in Intensive Care Systems with New Generation Technology.

As Biosys, as a result of the researches we conducted to meet the needs of the health sector, we realized that there are deficits especially in intensive care systems and that these deficits directly affect both healthcare professionals and patients. In line with this awareness, as a result of 5 years of R & D activity that we have carried out with the opinions of specialist doctors, we have developed the Biyovent Intensive Care Type Mechanical Ventilator Device.

In the production of intensive care type mechanical ventilator device with Biyovent which we have developed with the supports of Republic of Turkey Science, Industry and Technology Ministry, Scientific and Technological Research Council of Turkey (TUBITAK) and Bilkent University Cyberpark, we make a difference in the world health sector. In addition to achieving great success in a short time with this new generation technology, we contribute to the health of many individuals in the world.



**5000+**  
Devices

With our thousands of devices that are actively used all over the world, we affect the lives of many people and become hope for your loved ones.



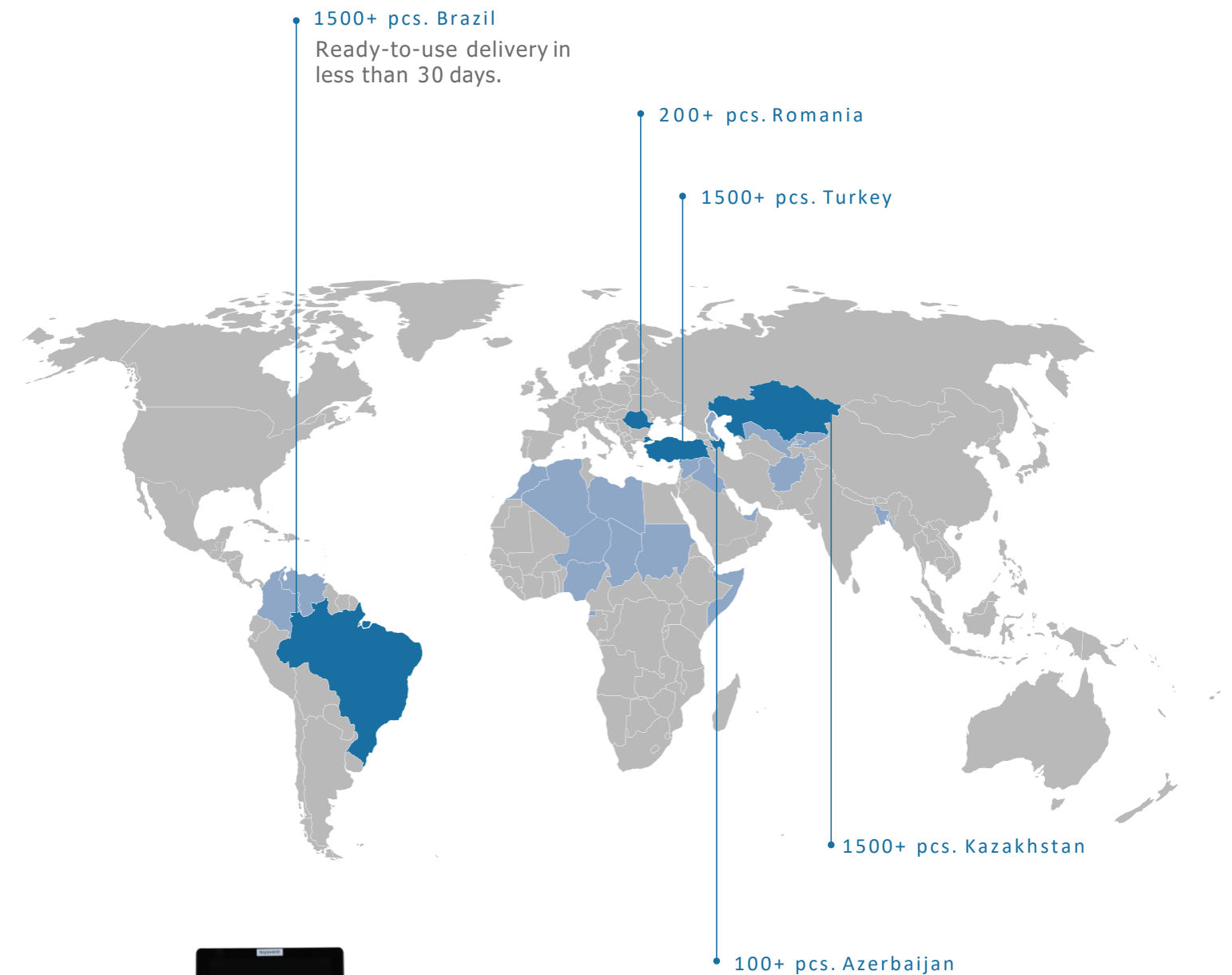
**25+**  
Countries

We continue to help all healthcare professionals and patients in difficult times of the world, such as the Covid 19 process.



**20**  
Delivery in less  
than 20 Days

We know that time is valuable for health, when dispatching/sending devices abroad, we deliver them ready to use in less than 20 days.



We take firm steps forward in our goal of  
**being the gateway to health.**

**BIYOVENT**

Intensive Care Type  
Medical Ventilator Device



# THE NEXT STEP IN VENTILATOR TECHNOLOGY



Biyuvent, which was developed with the aim of offering products with high technological threshold value, fully meets the needs with its new generation technology. It offers high quality in terms of both technology and health, thanks to its features that cover all the deficits that the ventilator devices used up to this time cannot offer and the doctors cannot meet the demands.

With every detail designated from design to hardware, from software to technology and developed with a holistic approach, Biyuvent adds value to health with its modern and ergonomic design, user-friendly interface, traditional and innovative operating modes, and adaptable structure to different patient groups. In

the ventilators used until this time, the fact that there are more parts that change according to the needs of the patient and these parts are very expensive in terms of cost are minimized with Biyuvent.

This situation, which causes economic and technical disadvantages in ventilator devices, is no longer a disadvantage with the new generation ventilator technology developed for the need. With its ability to meet the needs of many patients by itself and the need for minimum extra parts, Biyuvent adds an innovative understanding to ventilator device technology and provides an advantage with its economic structure.

# DESCRIPTION OF PERSONALIZED TREATMENT

## Effective Treatment For the Needs of Every Patient

The medical state and needs of every patient are different. Biyvent which is developed with this awareness, offers a customizable structure based on patient needs. Thus, it provides advantages to both the patient and the doctor for the most effective treatment.

With Biyvent, in which every detail is considered for health, characteristics such as height and weight of the patients are entered during use in pediatric and adult patients, and the most appropriate treatment method is provided to the patient.

In addition, the changing clinical needs can be followed up by recording the values related to the patient's condition besides

physical characteristics. Thus, it is ensured that the most appropriate and correct treatment can be performed to each patient.

In terms of usage, Biyvent helps healthcare professionals to reach information they need and provides the opportunity to choose Non-Invasive, Invasive Ventilation and N-CPap, HFO therapy methods in performing the treatment method that the patient needs. With its advanced software features, Biyvent, which establishes a safe infrastructure for treatment, maximizes safety with the ability to select the length and thickness of the air canal circuit to be used for the patient from the air canal settings and adjustable alarm limits.



Invasive and Non-Invasive Ventilation



Integrated Nebulizer



High Flow Oxygen Therapy and N-CPAP (nasal C-PAP)



Suitable for Neonatal (Optional)  
Pediatric and Adult Patients



Smart Ventilation Modes

# INNOVATIVE DESIGN, COMPREHENSIVE SOLUTIONS

## Design Suitable for Quick and Easy Installation

Biyuvent is installed quickly and easily with its triple structure. Thanks to its ergonomic design consisting of foot, support and main body parts connected to the screen, it provides ease of installation. Biyovent, which allows parts to be

connected with each other with eight screws, helps to operate quickly in a solution-oriented manner thanks to its simplified installation system rather than a complex configuration during device installation.



- 15inch high definition color screen
- Sensitive touch
- Easy to switch between modes
- Easily adjustable mode parameters
- Simultaneous monitoring of more than 30 parameters.

- Power supply for humidifier
- External Nebulizer Input (USB)
- Emergency valve



- Multiple-use autoclavable Expiratory block
- Nebulizer outflow



- Wheels with increased shock absorption
- Lock mechanism
- Safe design
- Easy to use



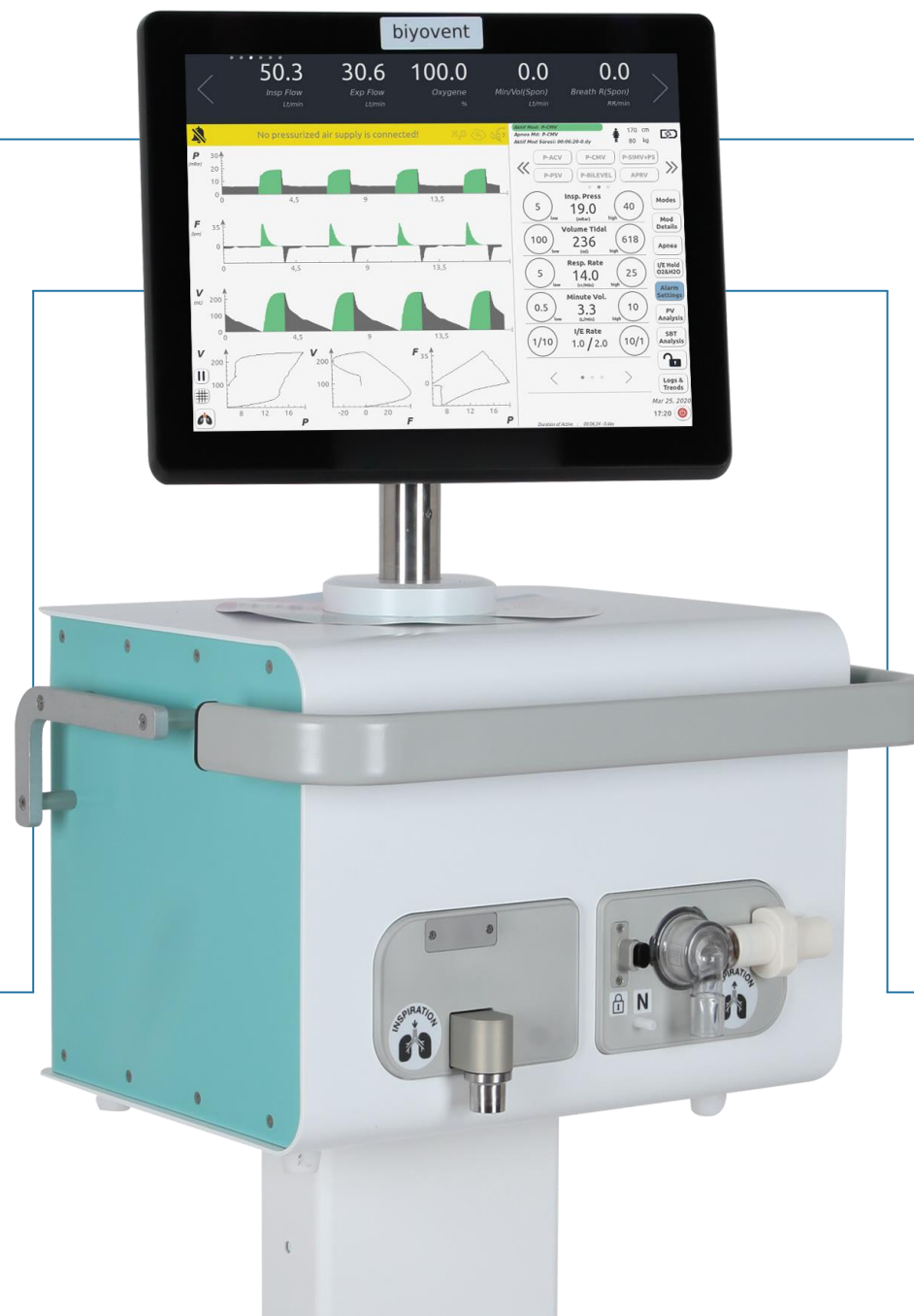
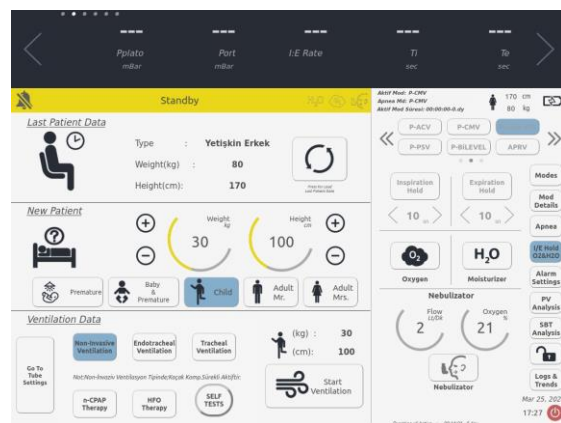
# ADVANCED SOFTWARE, EASY TO USE

## User-Driven Display System

With its advanced software features and user-driven interface design, Biyovent simultaneously displays 3 graphics, 3 cycles and lung dynamic status. Thanks to the visual aided interface design used in accessing information, it provides convenience in learning and practice, allowing access to more than 30 parameters on the same screen. With its high definition of 15inches, it shows the information on the system clearly and in detail. Adjustments are made easily on the screen,

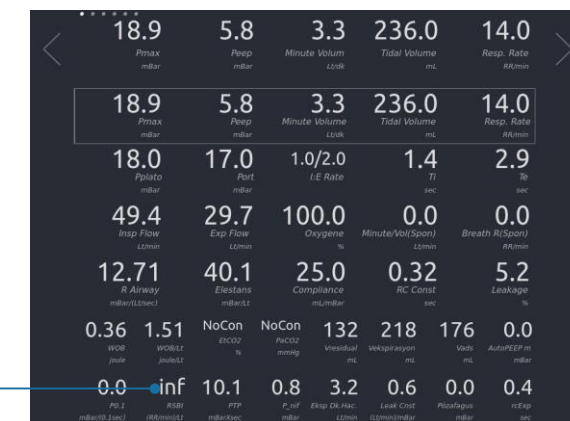
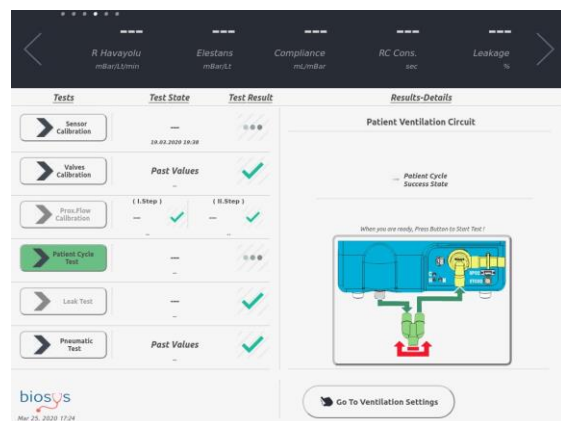
which has sensitive touch feature, and quick steps are taken for the necessary adjustments in the appropriate treatment for the patient. In addition to being able to monitor the instantaneous measurement values by displaying graphically for sudden situations related to the patient, it also helps to get quick intervention by giving warnings in case of alarm. In addition, it allows to see the dynamic state of the lung with the lung diagram, which offers intelligent ventilation monitoring.

With its easy-to-use interface design, patient details can be entered easily and the device provides the opportunity to customize parameters according to the patient.



It allows to monitor/ see the dynamic state of lung with lung diagram, which provides intelligent ventilation monitoring.

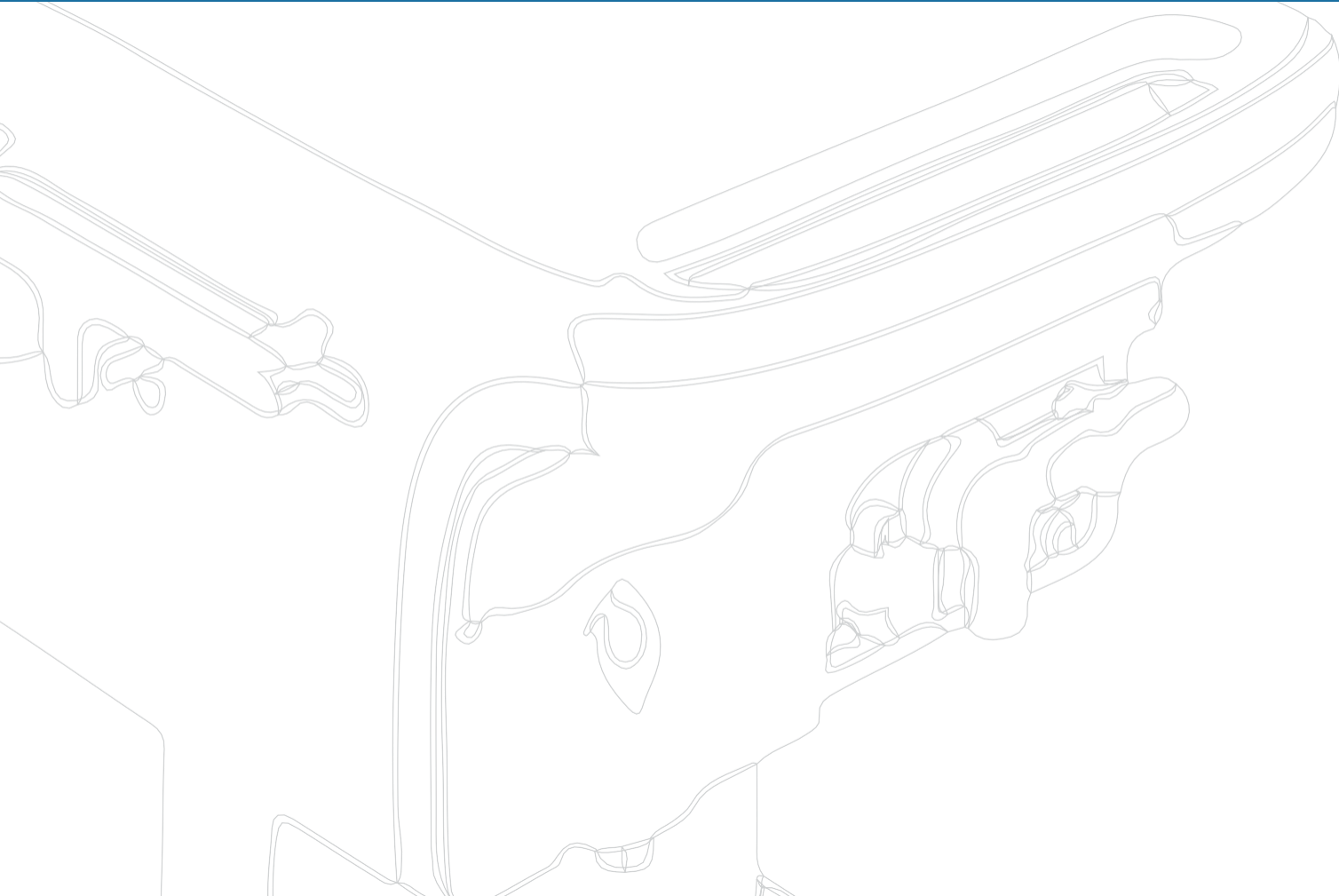
Allows easy calibration in 3 steps with directions on the screen.



Monitoring parameters can be accessed on a single screen, allowing more than 30 parameters to be monitored simultaneously.



# APPROPRIATE TREATMENT FOR EVERY PATIENT



## Ventilation Modes for All Ages and Conditions

- ▶ Pressure Controlled Modes (P-ACV P-SIMV+PS P-CMV P-PSV P-Bi-level APRV)
- ▶ Volume Controlled Modes (V-ACV V-ACV(PRVC) V-CMV V-SIMV+PS, V-SIMV(PRVC)+PS)
- ▶ Spontaneous Modes (SPN-PS SPN-VS)
- ▶ Smart Modes [SAV(WOB Optimisation)]

**BIYOVENT**

Intensive Care Type Mechanical Ventilator Device

# TECHNICAL SPECIFICATIONS

Pressure-Targeted Modes
P-ACV
P-SIMV+PS
P-CMV
P-PSV
P-Bilevel
APRV
Volume-Targeted Modes
V-ACV
V-ACV(PRVC)
V-CMV
V-SIMV+PS
V-SIMV(PRVC)+P
Spontaneous Modes
SPN-PS
SPN-VS
Optional Features
Use in neonatal patients
SAV (WOB Optimisation)

Monitoring Parameters	
Ppeak (cmH2O)	Compliance (mL/cmH2O)
Peep (cmH2O)	RC Constant (sec.)
Minute Volume (Lt/mins.)	Leakage (%)
Tidal Volume (ml)	WOB (joule)
Breath Number (Number/mins.)	WOB/Lt (joule/Lt)
Pplato (cmH2O)	Vresidual (mL)
Port (cmH2O)	Vexpiratory (mL)
I:E Rate	Vinspiration (mL)
Ti (sec.)	AutoPEEP (cmH2O)
Te (sec.)	P0.1 (cmH2O/ 0.1s)
Inspiration Peak Flow (Lt/mins.)	RSBI (ss/min)Lt
Expiratory Peak Flow (Lt/mins.)	PTP (cmH2OXsec)
Oxygen (%)	P_nif (cmH2O)
Minute Volume (Spn) (Lt/mins.)	Expiratory Volume/mins. (Lt/mins.)
Breath Number (Spon) (Number/min.)	Leakage Constant (Ltr/m)/cmH2O
R Airway (cmH2O/ Ltr/sec)	Instant Tidal Volume (mL)
Elstance (cmH2O/Ltr) Elestance (cmH2O/Ltr)	rcExp (sec.)

Patient Suitability and Performance Suitability Child, Paediatric
Breath Number: 1-150/mins.
T inspiration: 0.1-10sec.
Tidal Volume: 0.02-0.3 Litre
Flow: 1-60 Litre/Mins.
Adult
Breath Number: 1-100/mins.
T inspiration: 0.1-10sec.
Tidal Volume: 0.1-3 Litre
Flow: 2-120 Litre/Mins.

Operation Features
Inspiration Pressure: 2-100 mBar
Inspiration Duration: 0.1-10 Sec.
Peep Pressure: 0-50 mBar
Breathe Speed: (ç) 1-150/mins. (y) 1-100/mins.
Flow: (ç) 1-60 lt/mins. (y) 2-120 lt/mins.
O2 Mixture: 21-100%
Spontaneous Pressure Support: 0-100 mBar
I/E Rate: 1:10 (x60*)-10:1 (ç): Child, (y): Adult

Pressure Welding Features
O2 Pressure: 2.5 - 7 Bar CentralSystem/Tube
Air Pressure: 2.5 - 7 Bar CentralSystem/Tube
Automatic change and alarm display at the end of welding
Operating with Medical compressor / Regulator
Electrical Features
Battery Duration: 2 hours + 8 hours (Optional)
Mains Voltage: 180 - 264 VAC
Power Consumption: 47 - 63 Hz 100W
Size and Weight
H: 150 cm / D: 58 cm / W: 58 cm
Weight: 55 Kg
Display movement: To the right or left 150° to up and down 15°
Display: Full touch screen

Digital Interfaces
USB: 4 pcs. / COM: 2 pcs.
HDMI: 1pcs. / LAN: 2 pcs.
Display Port: 1pc.
Mic. In: 1pc.



INTERNATIONAL CERTIFICATION

# Sertifika

**BIOSYS BİYOMEDİKAL MÜHENDİSLİK  
SAN. VE TİC. LTD. ŞTİ.**

kuruluşunun,

MERKEZ: ANKARA TEKNOLOJİ GELİŞTİRME BÖLGESİ CYBERPARK NO:4/A CYBERPLAZA A BLOK 3. KAT NO:A303C  
BİLKENT-ÇANKAYA/ANKARA  
ARÇELİK ÜRETİM TESİSİ: ATATÜRK CAD. KARAĞAÇ MAH. 59510, KAPAKLI/TEKİRDAĞ

adresinde,

**YOĞUN BAKIM VENTİLATÖRÜ TASARIMI, ÜRETİMİ, DAĞITIMI VE TEKNİK SERVİS HİZMETLERİ**

kapsamında,

## ISO 13485:2016

**Medikal Cihazlar-Kalite Yönetim Sistemi**

Uygulanmayan Maddeler, 7.5.5,7.5.7,7.5.9.2  
şartlarını sağladığı kanıtlanmıştır.

Sertifika No : C-US-20314871  
Belgelendirme Tarihi : 15.05.2020  
Düzenleme Tarihi : 15.05.2020  
Geçerlilik Tarihi : 14.05.2021  
Belge Periyodu : 3 Yıl

TGS  
International Certification



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Tel : +90 216 327 09 77(Pbx) Fax : +90 216 546 05 70

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# S E R T İ F İ K A

**Tam Kalite Güvence Sistemi  
93/42/AT Tıbbi Cihazlar Direktifi Ek II (Madde 4 Hariç)**

Firma Adı : Biosys Biyomedikal Mühendislik San. ve Tic. Ltd. Şti.

Firma Adresi : Ankara Teknoloji Bölgesi Cyberpark No:4/A Cyberplaza A Blok 3.Kat  
No:A 303 Bilkent Çankaya ANKARA / TÜRKİYE

İlgili Yönetmelikler ve Ekler : 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek II (Madde 4 Hariç)

Ürünler : Non-Steril Yoğun Bakım Ventilatorü - Sınıf IIB

GMDN : 47244

Sertifika Numarası : M.2020.106.13453

Rapor Numarası : MD.4068.IB

İlk Belgelendirme Denetimi : 14.02.2020

Tescil Tarihi : 30.03.2020

Revizyon Tarihi/No : -

Geçerlilik Tarihi : 27.05.2024



UDEM Uluslararası Belgelendirme  
Denetim Eğitim Merkezi  
San. ve Tic. A.Ş.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek II, madde 4 hariç gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen Üretici Kalite Güvence Sistemi uyguladığını ve Ek II madde 5'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder. Sınıf III olarak piyasaya arz edilecek ürünler için Ek II madde 4'e göre AT Tasarım inceleme sertifikası gereklidir. Belge kapsamında yer alan sınıf I ürünler ile ilgili UDEM'in sorumluluğu ürün steril ise, steril şartların güvence altına alınması ve sürdürülmesi ile ilgili imalat konuları; ölçüm fonksiyonlu ise, ürünlerin metrolojik gereklere uygunluğuyla ilgili imalat konuları ile sınırlıdır. Bu belgenin mülkiyeti hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. ve Tic. A.Ş. 'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir. CE Markalamasının kullanımı Üretici beyarı ile firma sorumluluğundadır. Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini [www.udem.com.tr](http://www.udem.com.tr) internet sayfasından kontrol edebilirsiniz.

Adres: Muflukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya - Ankara - TÜRKİYE  
Tel: +90 312 443 03 90 Faks: +90 312 443 03 76  
E-posta: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)





## 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



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

### DENEY RAPORU

Test Report

1/193

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.
Deneysel Numunesi / Test Sample	: BİYOVENT
Marka / Trade Mark	: BİOSYS
Deneysel 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)
Deneysel 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

Deneysel 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.  
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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

Deneysel Sorumlusu  
Person in Charge of Test

Laboratuvar Müdürü  
Head of Testing Laboratory



Rapor detaylarını karekod ile kontrol edebilirsiniz.  
You can check the report details via QR code.

Ata Gürül ARSLANLI

Cahit GÖKSEL



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FRT.61/Rev06/0220

ARÇELİK A.Ş. Ürün Güvenliği ve EMC Laboratuvarı  
Kapaklı TEKİRDAĞ / TÜRKİYE  
Arçelik A.Ş. Product Safety and EMC Laboratory  
Kapaklı TEKİRDAĞ / TURKEY

ELEKTROMANYETİK UYUMLULUK DENEY RAPORU  
ELECTROMAGNETIC COMPATIBILITY TEST REPORT



AB-1178-T
AB-1178-T
2010029
04-2020

Rapor Numarası / Report Number	: AR-2010029-00
Talep Numarası / Request Number	: 6280_20_M4 EMC 6292_20_DT EMC
Başvuran / Applicant	: Biosys Biyomedikal Mühendislik San. ve Tic. Ltd. Şti.
Adres / Address	: Üniversiteler Mahallesi, 1606 Caddesi, Cyber Plaza, A303 06800 Bilkent / Çankaya / Ankara / TR
Telefon / Telephone	: +90 532 698 32 48
Model Adı / Model Name	: Biyovent Solunum Cihazı
Ürün Tipi / Product Type	: Solunum Cihazı / Mechanical Ventilation Equipment
Marka / Brand	: Biosys
Seri No / Serial Number	: 00400051
Üretici / Manufacturer	: Arçelik A.Ş. Elektronik İşletmesi
Test Sonucu / Test Result	: Olumlu / Pass
Sayfa Sayısı / Page Number	: 62

Deneysel laboratuvarı olarak faaliyet gösteren Arçelik A.Ş. Ürün Güvenliği ve EMC Laboratuvarı, TÜRKAK'tan AB-1178-T ile TS EN ISO/IEC 17025 standardına göre akredite edilmiştir. Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınırlığı konusunda Avrupa Akreditasyon Birliği (EA) ile Çok Taraflı Anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanıma anlaşmasını imzalamıştır. Deneysel ve / veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri ( olması halinde ) ve deneysel metodları bu sertifikanın tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir. "\*" işaretli sonuçlar akreditasyon kapsamı dışındadır. Arçelik A.Ş. Product Safety and EMC Lab accredited by TÜRKAK under registration number AB-1178-T for TS EN ISO/IEC 17025 as test laboratory. Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the recognition of test reports. The test and/or measurement results, the uncertainties ( if applicable ) with confidence probability and test methods are given on the following pages which are part of this report. Results marked "\*" are excluded from the scope of accreditation.

ONAY VERİLİŞ TARİHİ :28.04.2020  
DATE OF ISSUE

	Digitally signed by BEKİR YALIN DN: c=TR, serialNumber=52606304174, cn=BEKİR YALIN Date: 2020.04.28 15:42:26 +03'00'		Digitally signed by SERKAN GÜLER DN: c=TR, serialNumber=40279259570, cn=SERKAN GÜLER Date: 2020.04.28 14:59:00 +03'00'
Onaylayan / Approved by: Approvals Test Lab Manager Onaylar Test Lab Müdürü		Düzenleyen / Compiled by: EMC Test Engineer EMC Test Mühendisi	

Test sonucu bu raporda belirtilen deneylere göre değerlendirilmiştir. Numuneler müşteri tarafından sağlanmıştır dolayısıyla bu rapor sadece test edilen örnek için geçerlidir. Test sonucu sadece bu rapor içerisinde gerçekleştirilen testlere göre verilmiştir. Test laboratuvarının izni olmadan raporun kısmen kopyalanması yasaktır. Sonuçlar bu raporda sunulmuştur. İmzasız raporlar geçersizdir.

The result has commented stated tests at this report. The test result only responds to the tested sample. Please pay attention that the final judgement is only valid for the actually performed tests documented in this test report. It is not allowed to copy a part of this report partly without the allowance of the test laboratory. The result has commented stated tests at this report. Test reports without signature and seal are not valid

Testreport No.: AR-2010029-00  
Test Date: 28.04.2020

Page 1 of 62  
FRM-17865-4



# TRAFALGAR HOLDING GROUP U.S.A. & LATIN AMERICA

## Authorized Distributor for USA & Latin America

### BIYOVENT

Intensive Care Type  
Mechanical Ventilator Device

TD.15-AC/1020/Rev01





**No:** 2020/482

**Subject:** Biosis/Biyovent Invasive ICU Ventilator

**TO WHOM IT MAY CONCERN**

To the governmental departments, registration and certification institutions, health authorities and/or import offices in USA, Chile, Peru and Bolivia.

**Authorization Letter**

This letter confirms that TRAFALGAR HOLDINGS GROUP U.S.A. & LATIN AMERICA, 16607 Benton Taylor Drive Saint Louis Missouri 63005, USA is authorized by:

USHAŞ ULUSLARARASI SAĞLIK HİZMETLERİ A.Ş  
Sağlık Bakanlığı Bilkent Yerleşkesi Üniversiteler Mah. Dumlupınar Bulvarı 6001. Cadde No:  
9 Kat: 8 ÇANKAYA 06800 ANKARA - TÜRKİYE

to sell our Biosis/Biyovent Invasive ICU ventilator for the USA, Chile, Peru and Bolivia.

Validity: 12 months from the date of this letter.

Termination: Confirmation ends automatically on 10<sup>th</sup> of November, 2021 and can be renewed or canceled by 30 days notice in advance.

  
**Mehmet Ali KILIÇKAYA**  
Director General  
10th of November 2020