Test Laboratuvarları

LVT Test Laboratuvarları Ltd. Şti.

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TÜRKAK Test TS EN ISO/IEC 17025 AB-0341-T

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

DENEY RAPORU

Test Report

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 tanınma antlaşmasını imzalamıştır.
The Turkish Accreditation Agency (TURKAK) 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 tamamlayıcı 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*
	Ata Gürül ARSLANLI	Cahit GÖKSEL

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

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LVT Test Laboratuvarları Ltd. Şti.

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

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 606011:2009+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)* : -

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6. **Dağıtım Bilgileri** *Distrubition 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 oranında 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 %.*

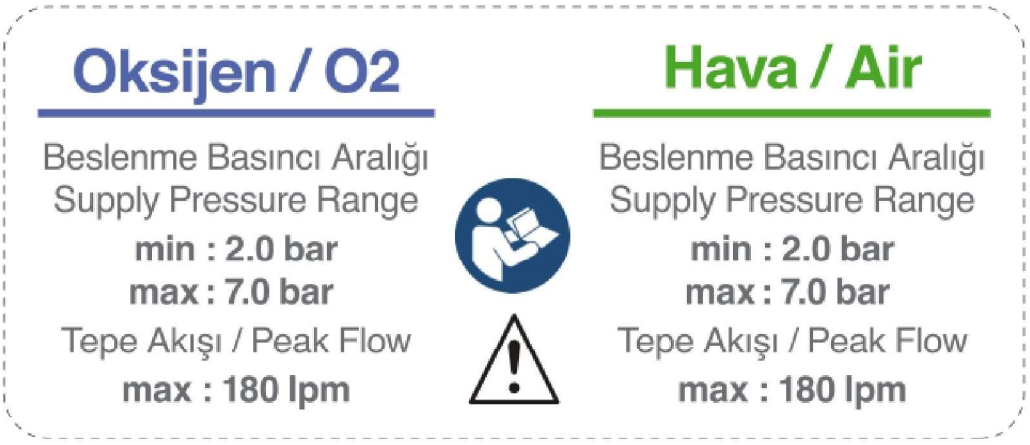
Deney bilgisi *Test details*	**Cihaz kodu** *Device code*	**Ölçülen değer** *Measured value*	**Ölçüm belirsizliği** *Measurement uncertainty*
Ambient Temperature	LC349	Cl. 3.1	%1,6
Ambient Moisture	LC349	Cl. 3.2	±2,98
Creepage dıstances and aır clearances	LC365	Ins. Diagram	±0,0758
Creepage dıstances and aır 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
Accessıble parts and applıed parts	LC30	See Table 8.4.2	%1,34
ME equıpment 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 patıent auxılıary 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

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.



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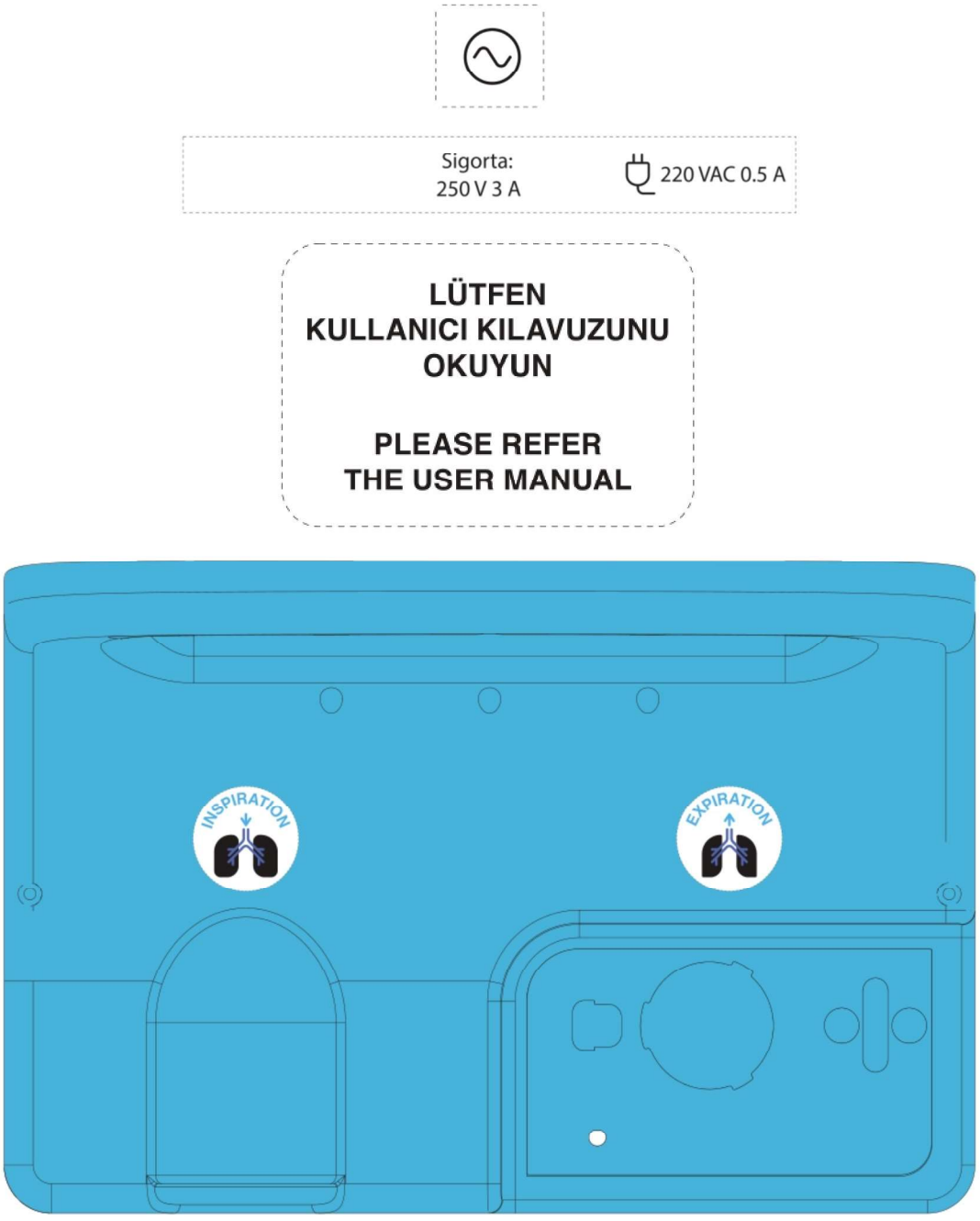

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Mobile
Device type (component/sub-assembly/ equipment/ system) :	Equipment
Intended use (Including type of patient, application location) :	Intensive care unit
Mode of operation ..... :	Continuous
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.

INSULATION DIAGRAM