



CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-481

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

**KARE MEDİKAL ve ANALİTİK CİHAZLAR
SANAYİ ve TİCARET LİMİTED ŞİRKETİ
(KARE MEDICAL AND ANALYTICAL DEVICES
LIMITED COMPANY)**

Head Office: Ziya Gökalp Cad. 36/23 Yenişehir Çankaya, Ankara, Turkey
Factory: Ankara II. Organize Sanayi Bölgesi Alcı OSB Mahallesi 2017.Cadde
No:24 Sincan, Ankara, Turkey

Products: PAP Therapy Systems, Portable Suction Units, Compressor Nebulizers, Nebulizer Sets, Oxygen Concentrators, Oxygen Humidifiers, Ventilators, Ultrasonic Nebulizers

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.4611.06
Date of first issue: 12 January 2018
Date of last issue: 14 December 2020
Revision Number: 02
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

14 December 2020, Istanbul, Turkey

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-18-481, Revision Number: 02

Concerned medical devices;

Product: PAP Therapy Systems

Model: Sleepone Cpap, Sleepone Auto Cpap, Sleepone Pediatric Cpap, Sleepone Bilevel S, Sleepone Bilevel ST, Sleepone Bilevel Auto, Sleepone Bilevel ST Auto, Sleepone Pro SV, Sleepone Pro VT, Sleepone Pro PSV, Sleepone Heated Humidifier, Sleepone Pro PSV Heated Humidifier

Product: Portable Suction Units

Model: Ecoaspir, Ecoaspir Plus

Product: Compressor Nebulizers

Model: Hikoneb Aerocare II, Hikoneb A103

Product: Nebulizer Sets

Model: Purebreath Nebulizer Set

Product: Oxygen Concentrators

Model: Hikoneb Oxybreath 10L, Hikoneb Oxybreath Mini 5, Hikoneb Oxybreath Mini 3

Product: Oxygen Humidifiers

Model: Purebreath Nemlendirici 6-3

Product: Ventilators

Model: KMV5010, Sleepone Pro PSV plus

Product: Ultrasonic Nebulizers

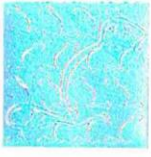
Model: Hikoneb 906 S/Lcd, Hikoneb 908 DC

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

A handwritten signature in black ink, appearing to read "Muhteşem Gökhan Yücel".

Muhteşem Gökhan Yücel
Head of Notified Body

14 December 2020, Istanbul, Turkey



CERTIFICATE

KARE MEDİKAL VE ANALİTİK CİHAZLAR SAN. VE TİC. LTD. ŞTİ.

HEAD OFFICE: ZİYA GÖKALP CADDESİ 36/23 YENİŞEHİR
ÇANKAYA - ANKARA - TÜRKİYE
FACTORY: ANKARA II. ORGANİZE SANAYİ BÖLGESİ ALICI OSB MAHALLESİ
2017. CADDE NO: 24 SİNCAN - ANKARA - TÜRKİYE

with a scope of

DESIGN, MANUFACTURING AND DISTRIBUTION OF AEROTHERAPY DEVICES

Medical devices - Quality management systems - Requirements for
regulatory purposes

"Following elements of the standard are excluded"

"7.5.3" "7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016

Certificate No : M 10303
Initial Certification Date : 04 January 2016
Certification Date : 14 September 2018
Expiration Date : 13 September 2021



Medical Device Q.M.S.
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO
YS-7267-741E

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Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.



KARE MEDICAL

www.karemedical.eu

2018





KMV 5010 delivers both pressure and volume ventilation, either invasively or non-invasively, to adult and pediatric patients weighing 5 kg or more (tidal volume >50 ml).

Extreme portability and freedom of operation brought by a weight of 3.5 kg, 7-hour internal battery and 15-hour hotswap battery.

Wide selection of both pressure and volume ventilation modes; including pressure modes CPAP ASB, PSV, aPCV, PCV and SIMVp, volume modes VCV and SIMVv.

The KMV 5010 delivers complex and versatile ventilation therapy together with a user-friendly interface. It is easy to use with simple menus, easy to enter and lock clinical menu and a secure patient menu.

Patient follow-up is also so easy with essential alarms, on-screen real time graphics and patient trends data.

“Volume Targeting” feature available in PSV, aPCV and PCV modes increases pressure automatically if the patient’s tidal volume cannot reach the target volume that is set. Maximum pressure increase of this function can be adjusted from 3 to 20 cmH₂O.



Volumetric Ventilation



Key Features:

- Low source Oxygen inlet
- Both pressure and volume ventilation, including SIMVv/SIMVp modes
- Modes: CPAP ASB, PSV, aPCV, PCV, VCV, SIMVv, SIMVp
- Portable: only 3.5 kg
- 7-hour internal battery & 15-hour external hotswap battery
- Easy to enter and lock clinical menu, a secure patient menu
- "Volume Targeting" available on PCV and PSV modes.
- On-screen real time graphics of pressure, flow and volume
- Up to 1 week of patient Trends could be examined from the device screen
- On-screen patient trends data of pressure, frequency and volume
- Alarms: High Volume, Low Volume, High Frequency, Low Frequency, High Leakage, High Ti Max, Low Ti Max, High Pressure Difference, Low Battery.



Technical Specifications :

	CPAP ASB	PSV	aPCV	PCV	VCV	SIMVv	SIMVp
PEEP	0 – 20 cmH ₂ O	0 – 20 cmH ₂ O	0 – 20 cmH ₂ O	0 – 20 cmH ₂ O	0 – 20 cmH ₂ O	0 – 20 cmH ₂ O	0 – 20 cmH ₂ O
Pressure Support	0 – 50 cmH ₂ O	0 – 50 cmH ₂ O				0 – 50 cmH ₂ O	0 – 50 cmH ₂ O
IPAP			3 – 50 cmH ₂ O	3 – 50 cmH ₂ O			3 – 50 cmH ₂ O
Frequency		4 – 40 bpm	4 – 40 bpm	4 – 40 bpm	4 – 40 bpm	4 – 40 bpm	4 – 40 bpm
Ins Trigger	1 – 10 l/min, Auto	1 – 10 l/min, Auto	1 – 10 l/min, Auto		1 – 10 l/min, Auto	1 – 10 l/min, Auto	1 – 10 l/min, Auto
Exp Trigger	10% - 90%, Auto	10% - 90%, Auto				10% - 90%, Auto	10% - 90%, Auto
Tidal Volume					50 – 2000 ml	50 – 2000 ml	
I:E Ratio			1:0.3 - 1:4.0	1:0.3 - 1:4.0	1:0.3 - 1:4.0	1:0.3 - 1:4.0	1:0.3 - 1:4.0

SLEEPONE PROPSV

Versatile with pressure controlled and support modes, together with volume targeting.

With its internal lithium-ion battery, ProPSV can provide approximately three hours of portable operation. This makes it suitable for more serious patients. Wide and colorful LCD screen provides real time pressure and flow graphics. Optional integrated heated humidifier helps for preventing the symptoms of upper airway dryness. Ventilation therapy data saved in the SD Card can be downloaded easily for viewing and creating reports. Remote control and monitoring via realtime graphics (Patient Flow/Leak with event notifiers, Pressure and Tidal Volume) is also possible with SleepOne Desktop Software.

“Volume targeting” feature, when enabled, will increase pressure automatically if the patient’s tidal volume cannot reach the set target volume. Pressure increase range of this function can be adjusted from 3 to 10 cmH₂O.

Alarms, both audio and visual, including high/low pressure, high/low volume, high frequency, high leak and low battery.

Technical Specifications

Ventilation modes	CPAP, PSV, Assisted PCV, PCV, ProSV, ProVT
Pressure Range	3 - 35 cm H ₂ O
Target tidal volume	50 - 2000 ml
Breath rate	4 - 50 bpm
I:E Ratio	1:0.3 - 1:4.0
Ins. Trigger	1 - 5, Auto
Exp. Trigger	10% - 90%
Size	18.1 x 15.5 x 11.7 cm
Weight	1.260 kg
Noise level	< 30 dBA
Humidification	Optional SleepOne Heated Humidifier
Alarms	High pressure, Low pressure, High volume, Low volume, High frequency, High leak, Low battery, SD card out
Monitoring	Pressure, Flow, Tidal Volume, Frequency
DC power source	12 V, 8 A
Data management	SD Card stores up to 365 nights of detailed therapy data.
Software	Data stored in the SD card can be processed via SleepOne TrackPro software Remote control and monitoring via realtime graphics is also possible with SleepOne Desktop software.

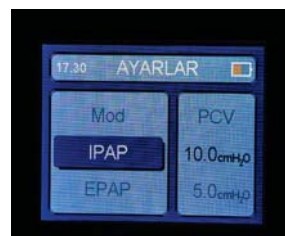
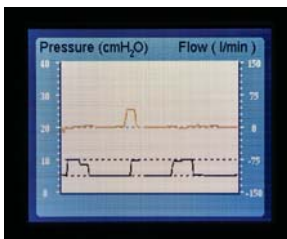


Invasive & Non Invasive pressure support ventilator



Suitable for the following diseases:

- Obstructive respiratory disorders such as COPD
- Restrictive respiratory disorders such as scoliosis, deformities of the thorax
- Neurological, muscular and neuromuscular disorders that affect respiratory
- Central respiratory regulation disorders
- Obstructive sleep apnea syndrome (OSAS)



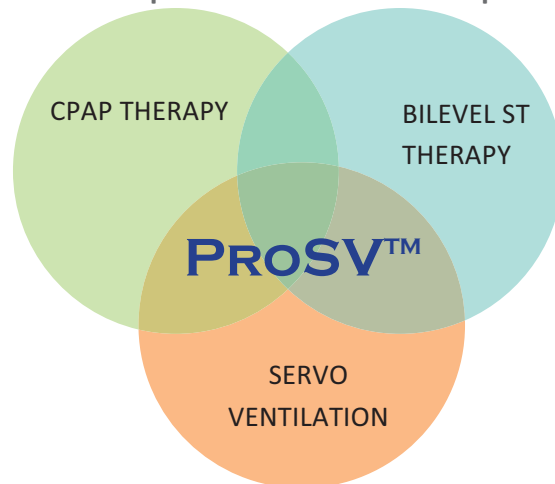
SLEEPONE PROSV

Cheyne-Stokes Respiration, Central Apnea, Obstructive Apnea
All-in-One Solution

Servo Ventilation + Auto Cpap + Respiratory Backup = SleepOne ProSV™

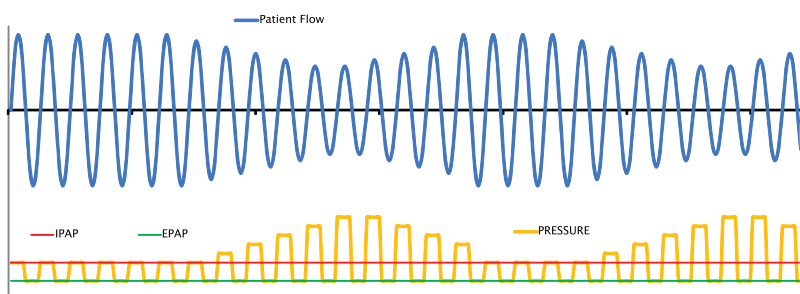
- Auto Pressure Support
- Auto EPAP
- Auto Backup Rate
- Can also work as CPAP Mode Servo Ventilation (Min Pressure Support = 0)

Obstructive Apnea Central Apnea



Cheyne-Stokes Respiration

A Complex Device for increased Patient Complexity !



ProSV gives instant reaction to changes in patient effort.

Technical Specifications

Pressure Range	4-35 CmH ₂ O
Working Mode	ProSV Active Servo Ventilation, CPAP
Ventilation Type	Leakage Ventilation
Voltage	100 - 240 V AC
Humidifier	SleepOne Heated Humidifier
Data management	SD Card stores up to 365 nights of detailed therapy data.



Event

- Obstructive Apnea
- Hypopnea
- Vibratory Snore
- Patient Flow Decrease
- Complex Apnea
- RERA
- High Leak
- Periodic Breathing
- Low Respiratory Rate

Action

- EPAP Change
- EPAP Change
- EPAP Change
- Pressure Support Change
- Airway blockage test
- EPAP Change
- Marked for Reporting
- Marked for Reporting
- Backup Breath



Active Servo Ventilation Device



Active Patient Control on Breath-by-breath basis

SleepOne ProSV™ is an active and also proactive device which responds to patients breath by breath changes. Patient who suffers from Cheyne-Stokes Ventilation, Central Apnea, Obstructive Apnea or Complex Apneas can benefit from the active/proactive algorithm of ProSV™. Device monitors several parameters from the patients and adjust pressure and breath rate according to the change. Patients who don't get enough from standard Bilevel therapy, or Auto-Bilevel algorithms can find the ProSV™ is a problem solver for complex patients.

Patient Focused Flexible Algorithm

ProSV™ targets to keep the patient flow to the %90 of the 3 minute moving average. During a normal breathing cycle, in which patient's respiratory effort is minimum, device keeps the pressure level to a minimum also. If there is no respiratory effort, patient is forced with the backup rate. According to the measured patient flow, ProSV™ categorizes the events. During complex apneas, device does not respond. Obstructive apneas are responded with a pressure increase after multiple events. Hypopneas are also responder events with pressure increase after multiple events. Snores are also responder events. Pressure increase is monitored and the amount is interactively chosen by the algorithm. ProSV™ decreases the pressures during no-event times. Patient is always treated with necessary pressure. High Leak Flows, Periodic breathing (Cheyne-Stokes Ventilation) and all other events are recorded for reporting.

Tidal Volume monitoring and targeting with ease



SleepOne ProVT™ Pressure Support Ventilation Device

Stabilizing Tidal Volume with ease

SleepOne ProVT™ constantly monitors changes in the Tidal Volume of the patients. With Tidal Volume Targeting, It changes patient's Pressure Support according to the Volume Target set. Pressure support ventilation for moving patient needs, easy as Bilevel therapy.

SleepOne ProVT™ monitors the patients Tidal Volume changes, and reacts according to the set Tidal Volume. Result is a much more stable Tidal Volume for patient. Auto Backup Rate is also calculated according to patient averages. Backup rate could also be set manually. Device slowly adjusts pressure, without disturbing the patients breathing.

Another feature in ProVT™ algorithm enables the healthcare professionals to adjust the speed of Pressure Support increase. This is adjustable between 1 cmH₂O/min - 4 cmH₂O/min. Also tolerance for Tidal Volume Target is adjustable from %10 to %60. These settings enable the healthcare professionals to adjust the ProVT™ in accordance with patient's needs.

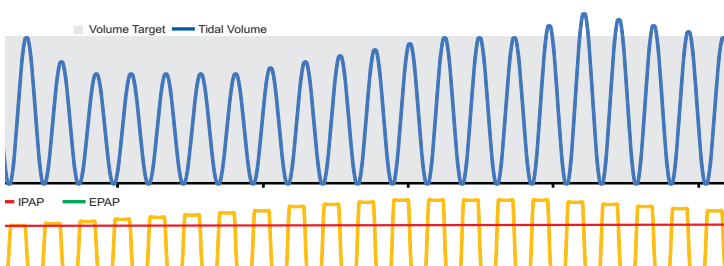
ProVT™ ensures that the patient is treated with minimum pressure needed to properly ventilate the patient. By tracking tidal volume, it provides easy operation and traceable compliance for the healthcare professionals.

Pressure Support with Volume Target



Changing Pressure Support for changing needs

Tidal Volume changes, sometimes according to sleep stages or body position or else. Whatever the reason for changing Tidal Volume, ProVT™ can cope with the situation and give the patient needed pressure to fulfill Target Volume at the right time.



ProVT changes pressure support in order to stabilize tidal volume.

Technical Specifications

Pressure Range	4-35 CmH ₂ O
Working Mode	ProVT, CPAP
Ventilation Type	Leakage Ventilation
Voltage	100 - 240 V AC
Humidifier	SleepOne Heated Humidifier
Data management	SD Card stores up to 365 nights of detailed therapy data.



SLEEPONE CPAP

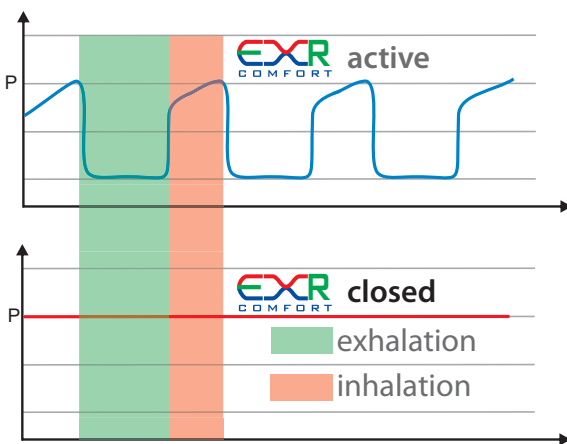
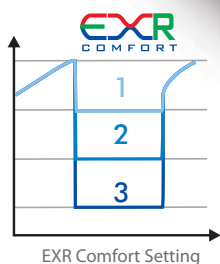


SleepOne CPAP creates a high comfort therapy for fixed pressure OSA patients. Small, lightweight and robust design makes it very portable together with universal power supply. Easy to adjust integrated heated humidifier, wide pressure range operation, Auto on and off functions fulfill all the needs for a successful therapy.

Forget about costly accessories, you do not need to pay much for a decent therapy. No need to pay for getting your sleep data. Everything is included in this small, durable machine for a comfortable night sleep. A data logging function ensures you get the right therapy all the time. Bundled with the SleepOne Software package, you can get your reports with just connecting the device with a USB cable. Whether you use an AutoCPAP or a standard one; nightly reports could be fetched from the device with the aid of the SleepOne Software.

Internal power supply, ensures easy handling during travel and prevents the bulky mess in your bedroom. Only a thin power cable is enough to run the device. Optional accessories are available on demand. An oxygen enrichment adapter; a converter for use with 12V jack in the cars, trucks and boats;

SleepOne Platform gives the patient comfort, reliability and cost effectiveness.



Key Features



- Built in memory allows detailed sleep reports, no need to pay extra for data logging modules
- Auto Leak Compensation
- Auto Altitude Compensation
- Low Noise Operation
- Compact carry bag stores everything (mask, heated humidifier, tubing, power cord)

Technical Specifications

Pressure Range (cmH ₂ O)	3 - 20 cm H ₂ O (0.5 increments)
Flow	0 cm H ₂ O 180 L/Min 20 cm H ₂ O >50 L/Min
Altitude Adjustment	Automatic
Dimensions (WxDxH)	18.1 x 15.5 x 11.7 cm
Weight	1.27 Kg.
Power Consumption	65 Watt
Voltage	100-230 V AC
Warranty	2 Years
Noise Level	<29 dB
Report Software	SleepOne Software
Auto-On/Auto Off	Yes
Mask Off	Yes
Adjustable Parameters	Ramp time, Ramp Starting Pressure, Auto-on, Auto-Off, CPAP Pressure mask alert



SLEEPONE AUTO



SleepOne AutoCPAP device provides a comfortable therapy with the lowest possible therapy pressure. This is done by the internal algorithm. Reaction to Snoring is adjustable by the "Snore Sensitivity" Parameter. Small, lightweight and robust design makes it very portable together with universal power supply. Easy to adjust integrated heated humidifier, wide pressure range operation, auto on and off functions fulfill all the needs for a successful therapy.

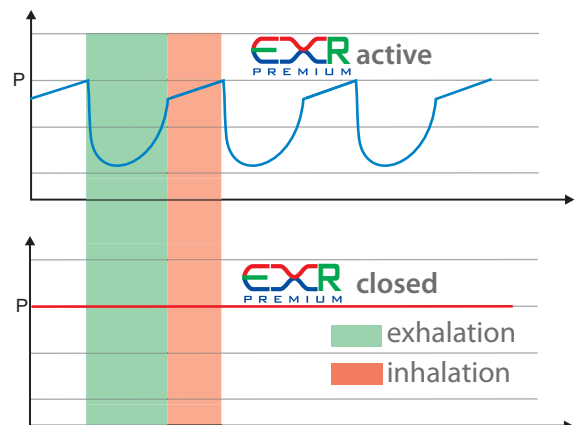
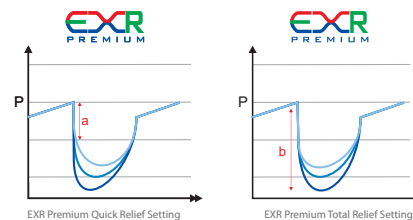
Forget about costly accessories, you do not need to pay much for a decent therapy. No need to pay for getting your sleep data. Everything is included in this small, durable machine for a comfortable night sleep. A data logging function ensures you get the right therapy all the time. Bundled with the SleepOne Software package, you can get your reports with just connecting the device with a USB cable. Whether you use an AutoCPAP or a standard one; nightly reports could be fetched from the device with the aid of the SleepOne Software.

Internal power supply, ensures easy handling during travel and prevents the bulky mess in your bedroom. Only a thin power cable is enough to run the device. Optional accessories are available on demand. An oxygen enrichment adapter; a converter for use with 12V jack in the cars, trucks and boats;

SleepOne Platform gives the patient comfort, reliability and cost effectiveness.

Technical Specifications

Pressure Range (cmH ₂ O)	3 - 20 cm H ₂ O (0.5 increments)
Flow	0 cm H ₂ O 180 L/Min 20 cm H ₂ O >50 L/Min
Altitude Adjustment	Automatic
Dimensions (WxDxH)	18.1 x 15.5 x 11.7 cm
Weight	1.28 Kg.
Power Consumption	65 Watt
Voltage	100-230 V AC
Warranty	2 Years
Noise Level	<29 dB
Report Software	SleepOne Software
Auto-On/Auto Off	Yes
Mask Off	Yes
Data management	SD Card stores up to 365 nights of detailed therapy data.
Adjustable Parameters	Ramp time, Ramp Starting Pressure, Auto-on, Auto-Off, CPAP Pressure low limit, CPAP Pressure high limit, Apnea parameter, Mask alert



Key Features

- Optimized algorithm enables high breathing comfort, allows ultimate patient compliance and increases the chance of therapy success
- Auto Leak Compensation
- Auto Altitude Compensation
- Low Noise Operation



SLEEPONE BILEVEL S

Affordable Spontaneous Bilevel Therapy, up to 25 cm H₂O IPAP...




Kare Medical is proud to present the Bilevel devices from the SleepOne product line. SleepOne Bilevel devices are designed to provide accurate spontaneous bilevel breathing support. With the enhanced algorithm, they are quite accurate to identify the patients breathing attempts.

Adjustable triggering sensitivity increases patient compliance, and makes the device useful for different patient groups. Inspiration Trigger is adjustable from 2 l/min to 20 l/min flow. To increase the device-patient synchronization, both IPAP-EPAP and EPAP-IPAP pressure change curves could be rounded in 5 steps. This setting improves the patient comfort thus it increases the synchronization.

Internal power supply, ensures easy handling during travel, and prevents the bulky mess in your bedroom. Only a thin power cable is enough to run the device. Optional accessories are available on demand. An oxygen enrichment adapter; a converter for use with 12V jack in the cars, trucks and boats;

Technical Specifications

Pressure Range (cm H ₂ O)	<ul style="list-style-type: none"> • CPAP MODE 3 - 20 cm H₂O (0.5 increments) • IPAP Range Bilevel Mode 6 - 25 cm H₂O (0.5 increments) • EPAP Range Bilevel Mode 3 - 22 cm H₂O (0.5 increments)
Inspiration Trigger	2 l/min - 20 l/min adjustable
Expiration Trigger	%10 - %90 of inspired flow
I:E Ratio	1:0.5 to 1:4.0
IPAP Rounding	0 - 5
EPAP Rounding	0 - 5
Altitude Adjustment	Automatic
Dimensions (WxDxH)	18.1 x 15.5 x 11.7 cm
Weight	1.20 Kg.
Power Consumption	65 Watt
Voltage	100-230 V AC
Warranty	2 Years
Noise Level	<29 dB
Report Software	SleepOne Software
Auto-On/Auto Off	Yes
Mask Off	Yes
Data management	 SD Card stores up to 365 nights of detailed therapy data.

SLEEPONE BILEVEL AUTO



Intelligent Auto Bilevel Therapy...

Kare Medical is proud to present the Bilevel devices from the SleepOne product line. SleepOne Bilevel devices are designed to provide accurate spontaneous Bilevel breathing support. With the SleepOne Bilevel Auto, patients could also be treated with auto adjusting bilevel modes. Adjustable triggering sensitivity increases patient compliance, and makes the device useful for different patient groups. Inspiration Trigger is adjustable from 2 l/min to 20 l/min flow. To increase the device-patient synchronization, both IPAP-EPAP and EPAP-IPAP pressure change curves could be rounded in 5 steps. This setting improves the patient comfort thus it increases the synchronization.

Mode 1 - Auto Bilevel Constant Delta P

This mode starts with the minimum EPAP, Maximum IPAP, Pressure Support, Ti Min and Ti Max set by the physician. Device auto titrates the IPAP pressure and defines the EPAP according to fixed parameter Pressure Support(IPAP-EPAP). So there is always a constant pressure difference between IPAP and EPAP. Device responds to Apnea, Snore, Hypopnea, RERA(Respiratory Effort Related Arousal)

Mode 2 - Auto Bilevel Variable Delta P

This mode starts with the minimum EPAP, Maximum IPAP, Pressure Support, Min Pressure Support, Max Pressure Support, Ti Min and Ti Max set by the physician. Device auto titrates both IPAP and EPAP pressures. So there is a changing Pressure Support. Device responds to Apnea, Snore, Hypopnea, Flow Limitation(RERA).



Technical Specifications

Available Modes	CPAP, Auto Bilevel Constant, Auto Bilevel Variable
Inspiration Trigger	2 l/min - 20 l/min adjustable
Expiration Trigger	%10 - %60 of inspired flow
I:E Ratio	1:0.5 to 1:4.0
IPAP Rounding	0 - 5
EPAP Rounding	0 - 5
Altitude Adjustment	Automatic
Dimensions (WxDxH)	18.1 x 15.5 x 11.7 cm
Weight	1.29 Kg.
Power Consumption	65 Watt
Voltage	100-230 V AC
Warranty	2 Years
Noise Level	<29 dB
Report Software	SleepOne Software
Auto-On/Auto Off	Yes
Data management	SD Card stores up to 365 nights of detailed therapy data.



SLEEPONE BILEVEL ST

Kare Medical is proud to present the Bilevel devices from the SleepOne product line. SleepOne Bilevel devices are designed to provide accurate spontaneous Bilevel breathing support. With the SleepOne Bilevel ST, patients could also be treated with spontaneous timed and timed ventilation. Either patient triggers the device or device is triggered by the backup rate, SleepOne Bilevel ST is a reliable therapy device. With the enhanced algorithm, they are quite accurate to identify the patients breathing attempts.

Adjustable triggering sensitivity increases patient compliance, and makes the device useful for different patient groups. Inspiration Trigger is adjustable from 2 l/min to 20 l/min flow. To increase the device-patient synchronization, both IPAP-EPAP and EPAP-IPAP pressure change curves could be rounded in 5 steps. This setting improves the patient comfort thus it increases the synchronization.

Internal power supply, ensures easy handling during travel, and prevents the bulky mess in your bedroom. Only a thin power cable is enough to run the device. Optional accessories are available on demand. An oxygen enrichment adapter; a converter for use with 12V jack in the cars, trucks and boats;



- **Spontaneous**
- **Spontaneous Timed**
- **Timed Bilevel Therapy, up to 35 cm H₂O IPAP...**



Technical Specifications

Available Modes	CPAP, Bilevel S, Bilevel ST, Bilevel T
Pressure Range (cm H ₂ O)	<ul style="list-style-type: none"> • CPAP MODE 3 - 20 cm H₂O (0.5 increments) • IPAP Range Bilevel Mode 6 - 35 cm H₂O (0.5 increments) • EPAP Range Bilevel Mode 3 - 32 cm H₂O (0.5 increments)
Backup Rate	4 - 40 BPM
Inspiration Trigger	2 l/min - 20 l/min adjustable
Expiration Trigger	%10 - %90 of inspired flow
I:E Ratio	1:0.5 to 1:4.0
IPAP Rounding	0 - 5
EPAP Rounding	0 - 5
Altitude Adjustment	Automatic
Dimensions (WxDxH)	18.1 x 15.5 x 11.7 cm
Weight	1.20 Kg.
Power Consumption	65 Watt
Voltage	100-230 V AC
Warranty	2 Years
Noise Level	<29 dB
Report Software	SleepOne Software
Auto-On/Auto Off	Yes
Data management	SD Card stores up to 365 nights of detailed therapy data.



SLEEPONE BILEVEL ST AUTO



All in One Solution for Developing Markets...



Modes Included

- 1- Cpap
- 2- AutoCpap
- 3- Bilevel S
- 4- Bilevel T
- 5- Bilevel ST
- 6- Bilevel Auto Fixed PS
- 7- Bilevel Auto Variable PS
- 8- Bilevel Auto ST Fixed PS
- 9- Bilevel Auto ST Variable PS

SleepOne Bilevel ST Auto is the newcomer from the SleepOne Product Line. With its powerful blower device can go up to 35 cmH₂O in allowed modes.

It is a solution developed for developing countries. Single product fits wide range of patients. This aspect makes the product charming to the professional users. When the patient is ready to go home, or a less complicated solution is needed after the intensive care, SleepOne Bilevel ST Auto provides the freedom to try different modes on the patient to choose which one is the best.



*Together with the SleepOne Desktop software, all the settings can be changed, modes can be changed or the patient can be monitored realtime with several graphics**

Graph 1 : Pressure

Graph 2 : Flow Graph including Patient Flow Curve, Leak Flow Curve, Event Notifiers (Apnea, Hypopnea, etc.)

Graph 3: Lung Fill Curve

All the curves give you realtime data at your fingertips. No additional hardware needed, other than a USB port and a Windows PC.

Data management : SD Card stores up to 365 nights of detailed therapy data.



• Realtime monitoring and Graphics are done via SleepOne Desktop Software



SLEEPONE HEATED HUMIDIFIER



SleepOne Humidifier helps for preventing the symptoms of dryness that most Cpap users experience. User friendly designed truly integrated unit allows ultimate patient compliance and increases the chance of therapy success.



Key Features

- Easy to clean
- Easy to adjust via Cpap Menu, even in the dark
- Compact design, easily fits to SleepOne Cpap bag
- High volume chamber

Technical Specifications

Dimensions	262x159x130 mm (LXWXH)
Weight	51 gr
Chamber Volume	600 ml
Chamber	ABS Lid, Polycarbonate Body, Stainless Steel Plate (SS 316)
Docking Station	Thermoplastic
Heater Plate	Stainless Steel(SS 316)
Voltage	100-230V AC,50/60Hz
Power	85W
Heater Plate Temperature Range	30-65° C
Heater Plate Safety Cutout	105° C

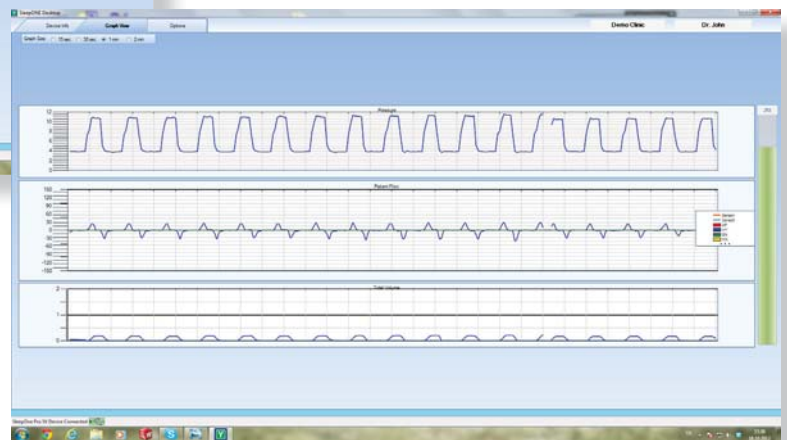
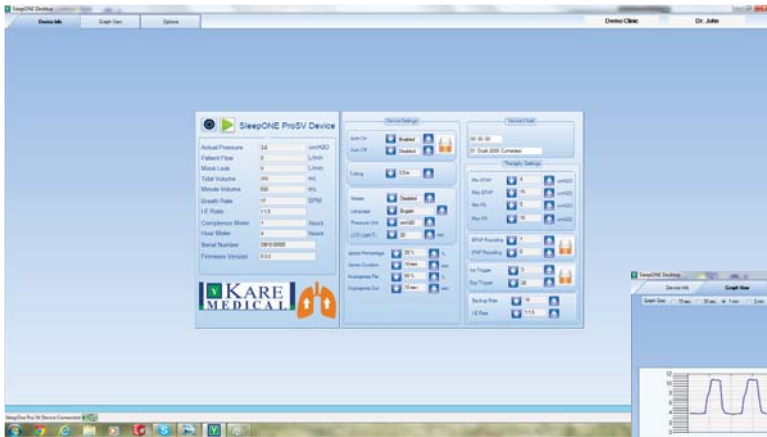


SLEEPONE DESKTOP



SleepOne Desktop for Online Control and Monitoring of SleepOne Devices

SleepOne Desktop enables the SleepOne Devices to be controlled for Windows PC. All the settings could be adjusted on the fly. Realtime Graphics help the healthcare professionals to monitor the patient and the compliance. 3 Graphs could be seen in Realtime. Patient Flow/Leak, Pressure, Tidal Volume.



SLEEPONE TRACK PRO

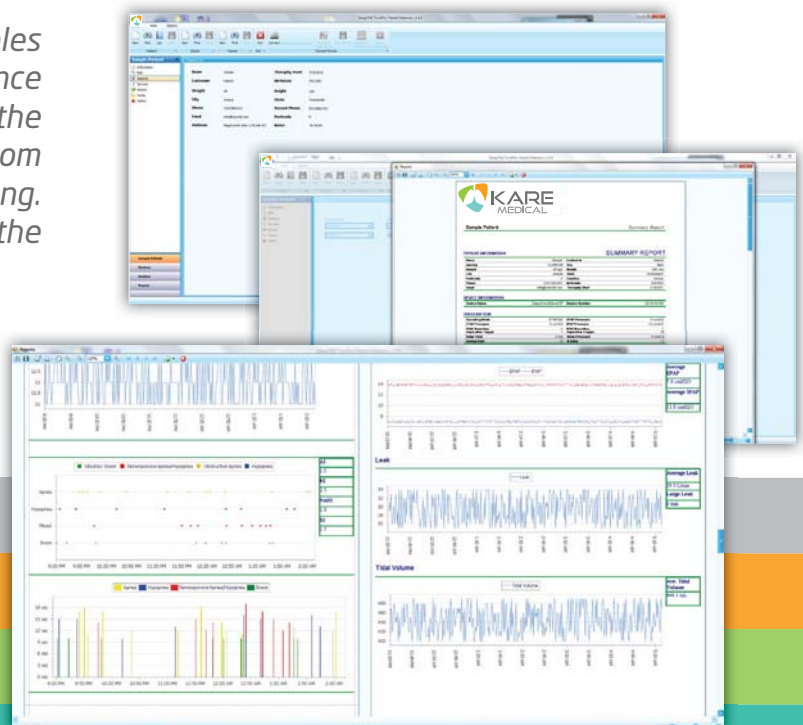
SleepOne TrackPro Patient Database for Compliance Monitoring and Reporting.



SleepOne TrackPro Patient Database enables healthcare professionals, providers, insurance institutions to monitor the compliance of the patients. Therapy data could be fetched from device to the database for storing or reporting. Easy to use, user friendly interface makes the software very easy to learn.

SleepOne TrackPro Patient Database

- Patient Tracking
- Device Tracking
- Payer Tracking
- Doctor Tracking
- Reporting
 - o Short Summary Report
 - o Daily Trends Report
 - o Full Detailed Report



AEROCARE II

PISTON TYPE COMPRESSOR NEBULIZER

Hikoneb® AeroCare II Piston Type Nebulizer is designed to be used on living environment of the patient. AeroCare II unit is perfect for daily usage of a single patient.

Nebulizer is a device used to administer medication to people in forms of a liquid mist to the airways. It is thus used in treating respiratory diseases. Piston type nebulizers pump air through a liquid medicine to turn into a vapor, which is then inhaled by the patient.

These medicines are frequently steroids and the reason they are inhaled instead of digested is to limit their effect to the lungs / respiratory system only. Otherwise, that amount of steroid saturated throughout the body would be toxic.

Technical Specifications

Operating Voltage	230V / AC
Mains Frequency	50 Hz.
Power	70 W
Maximum Pressure	3 bar
Nebulization Rate	0-5 ml/min
Weight	1.75 Kg
Type	B
Class	II



Main Areas of Usage

- Drug Nebulization
- Specific - Non specific lung diseases
- Bronchial Asthma
- Pneumonias
- Acute and Non-acute bronchial





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HOME-TYPE

ULTRASONIC NEBULIZER

Hikoneb® Home-Type ultrasonic nebulizer is designed to be used on living environment of the patient. Home-Type unit is perfect for daily usage of a single patient. Included accessories; adult mask, children mask, mouthpiece and disposable tubing is perfect for single patient use. Supplied medicine cups allow patient to take the medicine easily. 400 ml water tank makes it unrivalled. Adjustable nebulization is another positive specialty, which makes the unit last more than 2 hours with the full tank.

Main Areas of Usage

- Room Humidification
- Drug Nebulization
- Specific and non-specific lung diseases
- Bronchial Asthma
- Pneumonias
- Acute and non-acute bronchial

Main Features

- Constant vapour output
- Multifunction On/Off/Adjust switch
- Light alarm for malfunction and low water level
- Oscillator heating protection
- Small amount of drugs can be applied(5-7ml)
- High nebulizing performance, low energy consumption.

Technical Specifications

Operating Voltage	230V / AC
Mains Frequency	50-60 Hz.
Oscillator Frequency	1.7 Mhz
Power	25 W
Particle Size	0.5a - 6 micron
Nebulization Capacity	0-5 ml/min
Polycarbonate	
Nebulization Vessel	400 ml
Weight	1.7 Kg
Type	B
Class	II



908 DC

ULTRASONIC NEBULIZER

Hikoneb® 908 DC Ultrasonic Nebulizer is designed to be used on hospital environment. Fully digital control panel, and utilized microcontroller technology allows unit to be precisely controlled. Built in timer function helps hospital staff and unit works for the needed period only. 908 DC unit is perfect for intensive use on clinical environments. Included accessories, hytel tubing, water bottle, bacterial filter, air filter and mobile stand is perfect for hospital use. All the parts other than filters, are autoclavable up to 132° Celcius. Supplied medicine caps allow the hospital staff to provide medicine to the patient efficiently. 650 ml water tank and 1000 ml additional tank guarantees long operation. Adjustable nebulization is another positive speciality, which enables the adjustment of the given medicine amount in time. By the help of automatic heating mechanism, unit can supply warm vapour up to 38° C.

Hikoneb® Ultrasonic Hospital nebulizers are sold with complete accessories. You do not spend extra charges for the trolley, hoses, filters, etc. Spare parts are available at reasonable costs, unlike other products in the market. All the parts in contact with the patient are autoclavable.

Main Features

- Specially designed for continuous use.
- Digital control panel, allows precise and easy operation.
- Built in timer, adjustable up to 90 minutes.
- Automatic heating mechanism, heats vapour up to 38° C.
- Constant vapour output
- On/Off Switch, select, increase, decrease buttons.
- Light alarm for malfunction and low water level
- Oscillator heating protection
- Small amount of drugs can be applied (5-7ml)
- High nebulizing performance, low energy consumption.
- High Performance plug module system for easy serviceability.
- Oxygen adapter for supplying respiratory gases with the vapour.
- Double filtering mechanism for reducing risk of contamination.
- Aluminium panel, Aluminum case and flexible arm supporting system.
- Special design eases the change of the oscillator.

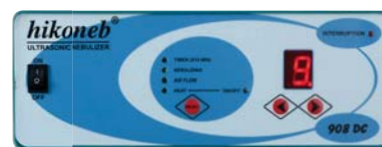
Main Areas of Usage

- Anesthesia, Surgery, Pediatrics
- Intensive Care
- Internal medicine applications
- Specific and non-specific lung diseases
- Bronchial Asthma
- Pneumonias
- Acute and non-acute bronchial
- Ear, nose and throat
- Plastic surgery model
- Humidification of respiratory gases
- Drug Nebulization

Technical Specifications

Operating Voltage	230V / AC
Mains Frequency	50-60 Hz.
Oscillator Frequency	1.7 Mhz*
Power	70 W
Particle Size	0.5 - 6 micron
Nebulization Capacity	0-5 ml/min
Polycarbonate	
Nebulization Vessel	650 ml
Heating	3
Weight	4 Kg
Type	BF
Class	I

*Optional 110V is available
**Optional 2.4 Mhz is available





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906 S/LCD

ULTRASONIC NEBULIZER

Hikoneb® 906 S/LCD Ultrasonic Nebulizer is designed to be used on continuously hospital environment. Liquid Crystal Display, 3 button control panel and utilized microcontroller technology allows unit to be precisely controlled. Built in timer function helps hospital staff and unit works for the needed period only. 906 S/LCD unit is perfect for intensive use on clinical environments. Included accessories, hytel tubing, water bottle, bacterial filter, air filter and mobile stand is perfect for hospital use. All the parts other than filters, are autoclavable up to 132° Celcius. Supplied medicine caps allow the hospital staff to provide medicine to the patient efficiently. 650 ml water tank and 1000 ml additional tank guarantees long operation. Adjustable nebulization is another positive speciality, which enables the adjustment of the given medicine amount in time. By the help of automatic heating mechanism, unit can supply warm vapour up to 38° C.

Hikoneb® Ultrasonic Hospital nebulizers are sold with complete accessories. You do not spend extra charges for the trolley, hoses, filters, etc. Spare parts are available at reasonable costs, unlike other products in the market. All the parts in contact with the patient are autoclavable.

Main Features

- Specially designed for continuous use.
- Liquid Crystal Display.
- Built in timer, adjustable up to 120 minutes.
- Automatic heating mechanism, heats vapour up to 38° C.
- Constant vapour output
- On/Off Switch, 3 operation buttons on the front panel
- Light and sound alarm for malfunction and low water level
- Oscillator heating protection
- Small amount of drugs can be applied(5-7ml)
- High nebulizing performance, low energy consumption.
- High Performance plug module system for easy serviceability.
- Oxygen adapter for supplying respiratory gases with the vapour.
- Double filtering mechanism for reducing risk of contamination.
- ABS plastic case and flexible arm supporting system.
- Special design eases the change of the oscillator.
- Multilanguage menu display (English, French, German, Turkish)

Main Areas of Usage

- Anesthesia, Surgery, Pediatrics
- Intensive Care
- Internal medicine applications
- Specific and non-specific lung diseases
- Bronchial Asthma
- Pneumonias
- Acute and non-acute bronchial
- Ear, nose and throat
- Plastic surgery model
- Humidification of respiratory gases
- Drug Nebulization

Technical Specifications

Operating Voltage	230V / AC*
Mains Frequency	50-60 Hz.
Oscillator Frequency	1.7 Mhz**
Power	70 W
Particle Size	0.5 - 6 micron
Nebulization Capacity	0-5 ml/min
Polycarbonate	
Nebulization Vessel	650 ml
Heating	3
Weight	4 Kg
Type	BF
Class	I

*Optional 110V is available

**Optional 2.4 Mhz is available



Aerocare Pediatric

A101- A102 PISTON TYPE NEBULIZER

Hikoneb® AeroCare 101 and 102 Piston Type Nebulizer is designed to be used for pediatric patients. Both of the units have attractive design that makes the therapy more enjoyable for kids.



A101



A102

Main Areas of Usage

- Drug Nebulization
- Specific - Non specific lung diseases
- Bronchial Asthma
- Pneumonias
- Acute and Non-acute bronchial

Technical Specifications

Operating Voltage	230V / AC
Mains Frequency	50Hz
Power	70 W
Maximum Pressure	3 bar
Nebulization Rate	0-5 ml/min
Weight	(101) 1.42 KG (102) 1.4 KG
Type	B
Class	II



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OXYBREATH 10L



OXYGEN CONCENTRATORS

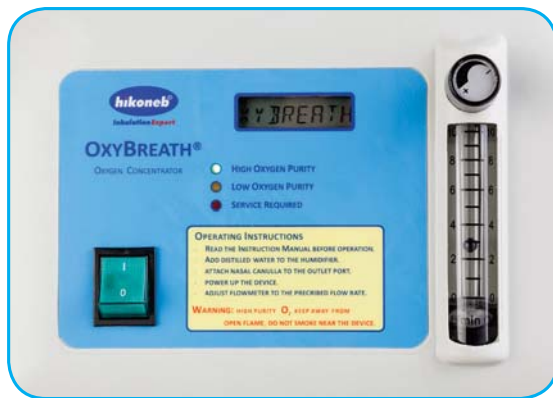
Hikoneb® OxyBreath 10L Oxygen Concentrator can work on high temperature countries because it utilizes powerful fan compressor cooling mechanism. Fan is located under the machine so even patients use the device near to the walls, airflow is not disturbed. Two filters in the device are very easy to change and the dust filter has very easy access in order to provide easy maintenance. Device could be used in dusty environments if the regular dust filter maintenance is supplied.

Oxygen concentrators are stationary, electrical units that take in nitrogen from the air around you and provide a streaming flow of oxygen. Oxygen concentrators are less expensive than liquid oxygen and are the most cost-effective source of oxygen therapy. Almost 80% of home oxygen patients use oxygen concentrators in their daily lives.

Before oxygen concentrators were around, it was necessary to use heavy steel aluminium cylinders which served as a supply of pure oxygen. Things changed after the oxygen concentrator was invented. A concentrator does not store oxygen like the aluminium cylinders of the past. It produces and distributes oxygen on a continuous basis. It takes the regular air, which normally contains 21% oxygen, and removes the nitrogen. The resulting air is 95 % percent pure oxygen...

Technical Specifications

Part Number	OXY5100
Operating Voltage	220-240V / AC
Mains Frequency	50-60 Hz.
Power	550 W
Oxygen Flow	1-10 LPM
Oxygen Saturation	1-9 LPM 92% ±3%; 10LPM 90%
Oxygen Outlet Pressure	±3%
Operating Temp.	0,09-0,13Mpa
Gross Weight	5-40° C
Net Weight	28 Kgs.
Type	24 Kgs.
Class	B
	II



Key Points

- For patients with high flow oxygen needs
- Easy to operate
- Reliable, long operating life
- Does not need any refills, just plug and play
- High quality molecular sieve



Kare Medical proudly presents the new Oxybreath Mini series, Mini 3 and Mini 5.

Both with the non medical look, low volume design that saves transportation costs of providers and makes the therapy easier for patients. Mini 3 is specially designed for low flow patients in order to save them from the cost of 5 liter machines. Mini 5 is for patients that require regular therapy in a smaller and power efficient platform.



Mini 3 Technical Specifications

Part Number	OXY6300
Operating Voltage	220-240V / AC
Mains Frequency	50-60 Hz.
Power	165 W
Oxygen Flow	0,5-3 LPM
Oxygen Saturation	1-3 L 93 ± 3%
O ₂ Monitor	- High Oxygen %O ₂ > 82% - Low Oxygen %O ₂ < 82% - Technical Service Required < 70%
Operating Pressure	0,07-0,09 Mpa
Operating Temp.	5-40° C
Gross Weight	14,4 Kgs
Net Weight	12 Kgs.
Type	B
Class	II

3 - 5



Key Points

- Ultra low volume decreases shipping costs (288 pcs in a 20' container)
- Very small visual appearance and non medical look
- Low power consumption & less heat production
- 3 liter version is available for low flow patients, saves from unnecessary power cost and extra weight of 5 liter machines
- No maintenance required for 2 years
- Silent operation

Mini 5 Technical Specifications

Part Number	OXY6500
Operating Voltage	220-240V / AC
Mains Frequency	50-60 Hz.
Power	330 W
Oxygen Flow	0,5-5 LPM
Oxygen Saturation	1-5 L 93 ± 3%
O ₂ Monitor	- High Oxygen %O ₂ > 82% - Low Oxygen %O ₂ < 82% - Technical Service Required < 70%
Operating Pressure	0,07-0,09 Mpa
Operating Temp.	5-40° C
Gross Weight	17,5 Kgs
Net Weight	15,1 Kgs.
Type	B
Class	II

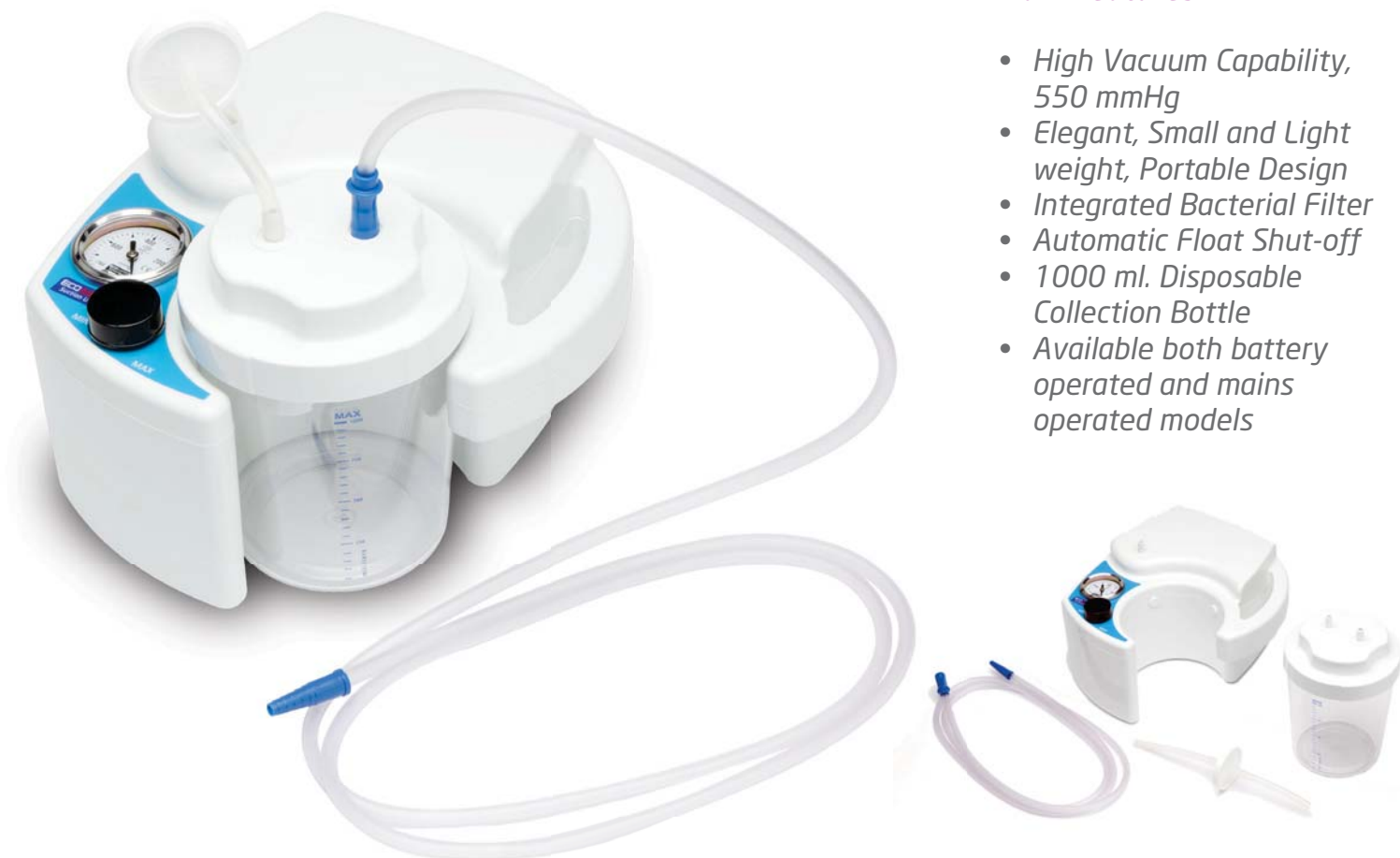
ECOASPIR

PORTABLE SUCTION UNITS

ECOASPIR series compact suction units specially designed to be lightweight and comfortable for home use. ECOASPIR has 1000 ml. disposable collection bottle with automatic float shut-off. It meets the ISO 10079 standards.

Main Features

- High Vacuum Capability, 550 mmHg
- Elegant, Small and Light weight, Portable Design
- Integrated Bacterial Filter
- Automatic Float Shut-off
- 1000 ml. Disposable Collection Bottle
- Available both battery operated and mains operated models



Mains Operated Model Technical Specifications

Weight	2,200 gr. *
Dimensions	240 x 270 x 145 mm (W x D x H)
Collection Bottle	Volume
	1000 ml.
Float Safety	Integrated Float Valve
Max. Vacuum	550 mmHg **
Min. Vacuum	100 mmHg **
Max. Flow	18 Liter/min **
Voltage	220 V/AC 50Hz
Power	80 Watt

Battery Operated Model Technical Specifications

Weight	3000 gr. *
Dimensions	240 x 270 x 145 mm (W x D x H)
Collection Bottle	Volume
	1000 ml.
Float Safety	Integrated Float Valve
Max. Vacuum	590 mmHg **
Min. Vacuum	100 mmHg **
Max. Flow	18 Liter/min **
Voltage	230 V/AC 50-60 Hz
Power	45 Watt

SLEEP MASKS

SLP-9100



SLP-9150



SLP-9160



SLP-9250



Full Face Masks

- SLP9100-A BASIC FULLFACE MASK SMALL
- SLP9100-B BASIC FULLFACE MASK MEDIUM
- SLP9100-C BASIC FULLFACE MASK LARGE
- SLP9150-A FULLFACE MASK SMALL WITH ADJ HEADGEAR
- SLP9150-B FULLFACE MASK MEDIUM WITH ADJ HEADGEAR
- SLP9150-C FULLFACE MASK LARGE WITH ADJ HEADGEAR
- SLP9160-A DOUBLE BELLOW FULLFACE MASK SMALL
- SLP9160-B DOUBLE BELLOW FULLFACE MASK MEDIUM
- SLP9160-C DOUBLE BELLOW FULLFACE MASK LARGE

Nasal Face Masks

- SLP9250-A DOUBLE CUSHION NASAL MASK SMALL
- SLP9250-B DOUBLE CUSHION NASAL MASK MEDIUM
- SLP9250-C DOUBLE CUSHION NASAL MASK LARGE



KARE
MEDICAL



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