

Positive Airway Pressure Device ST730 ST730W



Mode: CPAP | BPAP-S | AUTO BPAP-S | BPAP-T | BPAP-ST Pressure: 4-30cmH₂O

BPAP-ST

The device augments any breath initiated by the patient, but will also supply additional breaths should the patient breath rate fall below the clinician's set "Backup" breath rate.

Delivering 2 levels of pressure (IPAP / EPAP) and Spontaneous / Timed mode meets different needs of patients . Reserve the breathing frequency to ensure the auxiliary ventilation maintained during apnea , improve blood oxygen and easily discharge carbon dioxide.

Quiet as Spring Drizzle

• Patented multi-mean noise control and pressure regulating technologies promise high-performance ultra-quiet operation (≤ 29dB at 10cmH₂O), creating a quiet sleep and treatment environment for the user with affirmatory efficacy.

More Comfortable Treatment

• Independently developed high-performance blower, combined with unique respiration-synchronized airflow delivery algorithm provides a more comfortable treatment experience while preventing the user from strong impact of airflow.

Much Warmer Humidification

• High-efficiency humidification system with preheating ensures continuous warmed and moisturized air throughout the treatment.

More Sensitive Response

• Real-time high-precision sensors working with the i-Sense algorithms can capture every subtle respiration airflow change accurately and delivery the optimal treatment pressure dynamically.

Intelligent Healthcare Cloud



· System Structure Diagram



Care

Based on the Internet of Things and cloud computing technology, the iHypnusCare[™] creates a bridge between the users and the service teams, providing considerate and constant service to the users and making treatment without worries.

Bluetooth

The pulse oximeter can be connected to device wirelessly to show real-time oxyhemoglobin saturation (SpO₂) on ventilator screen.

Device Specifications

Model	ST730	ST730W
Mode	CPAP , BPAP-S , Auto BPAP-S , BPAP-T , BPAP-ST	
Pressure	4-30cmH ₂ O	
Voltage regulation technology	SAP	
Respiratory frequency	5-40bpm	
Delayed boost	5-45min	
Noise level	$\leq 29 dB$ (Measured reachable)	
Humidifier	Five gear regulation	
Heating pipe temperature	Temperature setting (16°c - 30°c)	
Data management	SD card can store data for about two years, which can be accessed and saved permanently with Pule intelligent health cloud	
Recognition of respiratory events	AH, FL, SNORE, LEAK, CSA, CSR, BIOT	
Leakage compensation	Adaptive leak baseline adjustment technology can ensure synchronization and accuracy of event identification in case of leak	
Breathing lamp	Breathing follow lamp	
Bluetooth & Wifi	_	Support







EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III) **No. G1 004385 0003 Rev. 01**

Manufacturer:

Facility(ies):

Product Category(ies): Positive Airway Pressure Devices, Continuous Positive Airway Pressure (CPAP) Masks

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

GZ1834503

Valid from: Valid until: 2019-06-19 2023-11-28

Date, 2019-06-19

1. Pumil

Stefan Preiß Head of Certification/Notified Body

Page 1 of 1 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TUV®

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中华人民共和国医疗器械注册证

注册证编号: 粤械注准 20182540586

注册人名称	
注册人住所	
生产地址	
产品名称	正压通气治疗机
型号、规格	CP720、 CA720W、 CA720M、 CA720W-B、 CA720、 CA720W-HB、 CA720-HB、 CB725W、 CB725M、 BA720W、 BA720M、 BA720W- B、 BA725W、 BA725M、 BA725W-B、 ST720W、 ST720M、 ST720W-B、 ST725W、 ST725M、 ST725W-B、 ST730W、 ST730M、 ST730W-B、 AU725W、 AU725M、 AU730W、 AU730M
结构及组成	由主机、湿化器、加温呼吸管路(选配)和电源适配器组成。工作模式: CPAP、 APAP、 BPAP-S、 Auto BPAP-S、 BPAP-ST、 BPAP-T
适用范围	提供气道正压,用于治疗体重在 30 公斤以上患有阻塞性睡眠呼吸暂停的患者,可在家庭和医院环境使用。不可用于生命支持。 不能用于治疗中枢性睡眠呼吸暂停。
附件	产品技术要求。
其他内容	无
备注	THE REAL PROPERTY OF
审批部门: 广	上 「东省食品药品监督管理局 批准日期: 2023 第0器用 日 有效期至: 2023 第5日章29 E

注册证号: 粤械注准20182540586

中华人民共和国

医疗器械注册变更文件

注册证编号: 粤械注准20182540586

产品名称	正压通气治疗机
变更内容	适用范围由"提供气道正压,用于治疗体重在30公斤以上患有 阻塞性睡眠呼吸暂停的患者,可在家庭和医院环境使用。不可用 于生命支持。不能用于治疗中枢性睡眠呼吸暂停。"变更为"提 供气道正压,用于治疗体重在30公斤以上患有阻塞性睡眠呼吸 暂停的患者。BPAP-ST和BPAP-T模式还可用于呼吸功能不全患者 的治疗。可在家庭和医院环境使用。不可用于生命支持。"。
备注	本文件与"粤椷注准20182540586"注册证共同使用。 新《医疗器械分类目录》管理类别: II类,分类编码: 08-01 呼吸设备。
审批部门:	广东省食品药品监督管理局 批准日期: 2世8年14月09日 注册专用章

中华人民共和国

医疗器械注册变更文件

注册证编号: 粤械注准20182540586

产品名称	正压通气治疗机
变更内容	 一、型号、规格由"CP720、CA720W、CA720M、CA720W-B、CA720、CA720W-HB、CA720-HB、CB725W、CB725M、BA720W、BA720M、BA720W-B、BA725W、BA725W、BA725W-B、ST720W、ST720M、ST720W-B、ST720W-B、ST725W、ST725W、ST725W-B、ST730W、ST730W-B、AU725W、AU725M、AU730W、AU730M"变更为"CP720、CA720W、CA720M、CA720W-B、CA720W-B、CA720W-HB、CA720-HB、CB725W、CB725M、BA720W、BA720W、BA720M、BA720W-B、BA725W、BA725M、BA725W-B、ST725W-B、ST725W、ST725M、ST725W-B、ST730W、ST730M、ST730W-B、AU725W、AU725M、AU730W、AU730M、BA725、ST730"。 二、注册证附件"产品技术要求"变更内容见附页(共25页)。
备注 审批部门:	本文件与"粤械注准20182540586"注册证共同使用。 新《医疗器械分类目录》管理类别:II类,分类编码:08呼吸、 麻醉和急救器械-01呼吸设备。 广东省药品监督管理局 批准日期:2020年01月30年
审批部[]:) 乐省约而监督管理同 批准日期: 2020年01月30日 医疗器械注册专用章