

## MAINTENANCE AND USAGE MANUAL

### HYDROGEN-OXYGEN BREATHING DEVICE



Model Nefess20

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# 1. FOREWORD

## 1.1 1.1 Intended Use of the Manual:

This guide is provided by BBDS Enerji San. Tic Ltd. The Hydrogen-Oxygen Breathing Machine produced by Şti is designed to serve the operators. All operating instructions, product images, screen graphics, troubleshooting / error messages, warnings, precautions and other relevant information are included in this manual. It is the user's responsibility to ensure that all safety instructions specified in this manual are followed..

## 1.2 1.2 Intended Use / Indications for Use; / Usage Methods

The Hydrogen-Oxygen Respirator is normally used in the clinical environment or home environment for the treatment of respiratory failure, for support purposes and typically, it is mixed with oxygen and hydrogen in certain proportions by electrolysis method and delivered to the patient.

The best way to use hydrogen is to breathe it in. For this, you can breathe hydrogen with a nasal cannula. Another method is to put the gas in nylon by wrapping the area with wound, eczema etc. Make sure that no gas escapes. 3. One way is to drink hydrogen rich water. When the machine is running, the water in the humidifier bowl is enriched in hydrogen after 10 minutes. You can also drink this water.

### In which ailments is hydrogen effective?

Corona virus provides very fast recovery in Covid-19 disease

Provides 2 times faster recovery in flu and cold ailments

It reduces the shortness of breath caused by smoking and allows you to breathe more comfortably.

Provides a decrease in the desire to smoke

With its anti-inflammatory effect, it reduces and prevents all pain in the body.

Provides rapid recovery in the treatment of COPD, Asthma and lung conditions

Hepatype B disease treatment

It renews the skin, gives a tighter and brighter skin.

It reduces cough, itching, etc. allergic reactions caused by dust and similar allergens.

It relieves rheumatism.

Stimulates energy metabolism to help prevent weight gain

Increases stamina and general physical condition

It regulates your antioxidant system (glutathione, catalase, SOD etc.)

Reduces hydroxyl free radicals (the main cause of aging)

Provides a reduction in blood pressure

Provides detoxification

Increases mental clarity, strengthens memory

Neurotherapeutic - supports post-injury neurogeneration (promotes rapid healing of wounds)

Protects against allergies and asthma

Removes systemic oxidative stress better than any other nutrient (smallest, most obtainable antioxidant molecule, scavenges ONLY the most destructive radicals, turns them into water - no toxic byproducts)

Improves cellular hydration

Alkalizes and neutralizes acidic land

Stimulates ATP production outside the mitochondrial electron transport chain

Neuroprotective - effect can reduce sports risks  
Low saturated fat levels  
It reduces cellulite and wrinkles  
Stronger and thicker hair. Hydrogenated water opens the pores and provides 2 times faster blood flow. It reduces hair loss.  
Like other gaseous signaling molecules (eg, NO, CO, H<sub>2</sub>S), H<sub>2</sub> has cell signal modulating activity that provides this with anti-inflammatory, anti-obesity and anti-allergy benefits.  
Protects against radiation damage  
Supports glucose homeostasis  
Ulcers and wounds healing  
Faster recovery from illnesses  
Much more effective than other antioxidants (vitamin C, vitamin E, glutathione)  
Decreases exercise-related lactic acid  
Prevents age-related decline in cognitive capacity Prevents allergy  
It lowers cholesterol levels  
Eliminates warts and lightens scars  
Provides improvement in various types of cancer.

### 1.3 Contraindications of the Device;

1.4 The device works with normal drinking water and distilled water. It should be added when there is less water.

### 1.5 Design Change Disclaimer

1.5 Due to design changes and product improvements, the information in this guide is subject to change without notice. BBDS Enerji San. Tic Ltd. Şti reserves the right to change the product design without prior notice, which may affect the content of this manual later. BBDS Enerji San. Tic Ltd. Şti assumes no responsibility for any errors that may appear in this manual. BBDS Energy will make every reasonable effort to ensure that this manual is up to date and will be compatible with the Hydrogen-Oxygen Respirator shipped. The screens shown in this instruction manual are for illustration only. Depending on the software version of the system, there may be slight differences between actual usage screens and those shown in this manual.

### 1.6 Usage Permissions

User manual or any part of it, BBDS Enerji San. Tic Ltd. Şti without the written consent of it, it cannot be reproduced, photocopied or transmitted electronically.

## 1.6 User Operations Assistance Statement

If you have any difficulty in operating a Hydrogen-Oxygen Respirator, please contact BBDS Enerji San. Tic Ltd. Şti. Please contact the distributor company.

## 2.1 1. INTRODUCTION

### 2.2 Device Description

**BBDS Enerji San. Tic Ltd. The Hydrogen-Oxygen Breathing Machine designed and produced by Şti provides separation of water into its components with the help of ELECTROLY.**

### 2.3 Usage recommendations

Continuous cycle in the form of the set working time and waiting time of the device

If it is required to operate, the "Standby Active / Passive" box is checked. If it is not checked, the machine will work and stop for the set time. It remains on hold until you press start again. Start gas production by pressing the Start / Stop button. A second beep will sound when gas production starts and the light will illuminate on the on / off switch

## Technical Specifications and Usage Options of the Device

Gas production volume Hydrogen + oxygen	Pure oxygen maximum amount	Pure hydrogen maximum amount	Operating pressure	Working Timer duration	Standby timer time	Working modes are time adjusted
20-800 ml/ minute	267ml/ minute	533ml/ minute	-8 / +8kpa	1dk-256min	1dk-256min	timed loop mode

## 2.4 Components and structure of the device

The device consists of the parts described below.



2.5 The device consists of the parts described below.

#### a) Movement Mechanism

The device has a base and flat floors in order to ensure easy transportation and installation.

#### Application Panel

Cihaz hastaya uygulanacak süre ve güç değerlerinin ayarlandığı LCD kontrol paneline sahiptir. LCD ekran aşağıda belirtilen güç değerlerini ekrandan ayarlamaya ve sistemi kontrol etmeye yardım eder.

Screen Parameters			
Display Indicator	min	maks	Fonksiyon
Current	20ma	17amper	Shows the working current of the electrolysis cell
Basınç	-8kpa	+8kpa	The system shows the working pressure. When + 7kpa pressure is reached, gas production is stopped, alarm sounds for 10 seconds and on-off The green light on the switch goes off. When the pressure drops to 6kpa and below, the device restarts gas production and the green light on the on-off switch turns on.
Maintenance	0	999 clock	It shows how many hours the device has produced gas.
Gas amount	0 ml	772ml	It shows the average gas production per minute of the device.
Timer Set	1min	999min	Indicates the working time that the device is set
Timer remaining			Shows the remaining operating time of the device from the set time
Timer standby	1min	999min	How long the device will wait without working at the end of its working period has been.
Main tank level	Null	Full	If the main tank water level is sufficient, it is full, if it is insufficient, it is empty.
Filter tank level	Null	Full	If the water level of the filter tank is sufficient, it will be full, if insufficient, it will be empty.
Standby Active / Passive box			If it is checked, it produces gas during the set time. It waits without producing gas during the set waiting period, and continues to ring again in a loop at the end of the time.
Start / Stop	Active	Passive	Start red when the device is not working, green during operation stop text appears. When the start is pressed, the alarm sounds for 1 second and the green light lights on the on / off switch. When the early stop is pressed, the alarm sounds for 2 seconds and the green light on the power switch goes off.
Settings			Opens the settings page to set the time
Settings page			
Operation time	1min	999min	The desired working time is set.
Standby time	1min	999min	While the cycle mode is active, the waiting time of the device without producing gas is set.
save			The adjustments made are saved.



#### a) Power cable

It has a power cable that will provide the operating voltage of the device. It is provided by a power cord with 220-230V AC power values, which is the operating voltage required for the device.

Technical specifications	
Operating voltage	220-230 V Ac
Insurance value	3 A
Weight	5 kg
Device Dimensions	20,2x27,2x32 cm
LCD Monitor motion capability	constant

## 2.6 Software Features of the Device

a) The device is designed in accordance with the EN 62304-2006 + A1-2015 Medical device software standard.

#### - functional and ability requirements;

- The device is designed to be applied according to 20 mA - 17 A Adjustable power value.
- - performance (eg software purpose, timing requirements),
- - According to the adjustable power value, the application of electrolysis in the system for the given time and completion at the end of this period shows that it meets the software requirements.
  - - The device uses c ++ language
- Using arm gcc and standard st lib as compiler
- • Uart serial communication protocol is used on the nextion screen to access the processor memory.
- • Stm32f407vgt6 arm cortex m4 is used as processor
  - the computing environment where the software will be implemented (e.g., Hardware, memory size, processing unit, time zone, network infrastructure)
    - Flash: 512 kb
    - SRAM: 192 kb
    - EEPROM: 512 Byte

Requirement for compatibility with upgrades or other device versions has been identified

#### SOFTWARE SYSTEM inputs and outputs;

In numerical format

#### b) Interfaces between the SOFTWARE SYSTEM and other SYSTEMS;

The software connection works in harmony with the DWIN LCD screen.

**c) Software driven alarms, alerts and operator messages;**

- h)** In case the device starts the application, it emits a double beep and reports that the system is turned on. It also warns with a single beep when the process is completed.

**the installation and acceptance conditions of the delivered MEDICAL DEVICE SOFTWARE, operation and maintenance place or sites;**

Software maintenance can only be done by the device manufacturer. The necessary information is specified in the user manual and Risk analysis.

**i) requirements for operation and maintenance methods;**

- j)** Software operation and maintenance methods are made by the manufacturer.

**user documentation to be developed;**

**It is specified in the user manual.**

**user maintenance requirements**

**There is no need for user maintenance regarding the software.**

**regulatory requirements.**

**Product and accessories to be used with**

- Based on Article 1, Definitions, section 2 (b) of MDD 93/42 / EEC, accessories; without a device, it is an object specifically designed by the manufacturer of the device for use with a device, to allow the use of a device and to be used for compatibility with that device.

A pack of potassium hydroxide

## **1. Installation and Operation of the Device**

After removing the device from the box, open the protective cover of the adhesive behind the plastic holder that holds the humidifier container and stick it to the screw hole on the right side. Then fix the screw well. Place the humidifier cup in the stabilizer and attach the hose to the gas outlet on the right side of the machine. If you want to remove the hose again, pull the hose while pressing the blue plastic against the machine.

Add a pack of potassium hydroxide to the main tank of the device and add pure water or reserve osmosis filter water up to the black level sensor in the tank. Do not use tap water.

Impurities in tap water can cause harmful gas production. Do not add more water than the level of the tank level sensor. The main tank water level will appear FULL on the screen.

Put a pack of lemon salt into the filter tank and put pure water or reserve osmosis water on it up to the level sensor. . Do not add more water than the level of the tank level sensor. The filter tank water level will be FULL on the screen.

Put 3/4 drinkable water into the humidifier bowl. You can consume the water here as hydrogenated water after use. Replace the water in the humidifier with a new one each time you use it.

Connect the power plug of the device to the 220 volt grounded mains and turn on the on / off switch.



## 1.1 1. Control Panel Description and Device Usage

### 1.2 Preparing the System

Prepare the system Place the Hydrogen-Oxygen Respirator on a flat surface.

Start the system by pressing the power switch.

- Click the settings icon to enter the setting page.
- In the operating time section, click the number section and enter the time you want from the keypad that opens.
- Press the arrow button.
- Click on the waiting time section, enter the waiting time you want and press the ok button.
- Click the Save button.
- Return to the main screen by pressing the main menu button.

### 1.3 Important Steps Before Opening the System

It is the user's responsibility to make sure that it is working properly before starting treatment with the Hydrogen-Oxygen Breathing Machine. Please consider the following mandatory points to make sure the system works properly. Aygıtı, aksesuarları ve bağlantı kablolarını görünür hasar açısından inceleyiniz. Elektrik sistemini kontrol ediniz.

### 1.4 Opening the System

Plug the power cord plug into an earthed socket. After plugging in, turn the main power switch on the front of the Hydrogen-Oxygen Breathing Machine to the ON position. This switch provides AC mains power to the system, thus displaying the main menu on the LCD screen.

#### Using the LCD Screen

When the LCD screen starts to work, the following opening screen will appear.



5-If the device is required to operate continuously in the form of the adjusted working time and waiting time, the "Standby Active / Passive" box is checked. If it is not checked, the machine will work and stop for the set time. It stays on hold until you press start again.

Start gas production by pressing the Start / Stop button. When gas generation starts, a beep will sound for a second and the green light will light on the on / off switch.

6- Set the power setting to 12 amps with the lower right button on the front panel. Do not exceed 15 amps during operation. Using more than 15 amps may damage the device. You can see the amount of gas production on the screen.

The amperage may also increase as the machine heats up during operation. Check the ampere from time to time and adjust it to 12 amps. When the time expires, a two-second beep will sound and the light on the switch will turn off.

7- Attach the cannula to the humidifier. Place the other breathing end in your nose. You can use it as a cure for 30-60 minutes 3 times a day. It can be used more frequently if you wish. There is no harm in over use. Do not use for more than 60 minutes in a single use.

#### [Instrument Troubleshooting Table](#)

<b>ERROR / PROBLEM</b>	<b>POSSIBLE CAUSE</b>	<b>SOLUTION</b>
10 seconds long beep machine gas production stopped	Gas outlet hose is obstructing the crushed gas outlet	Humidifier bowl air stone may be clogged. Check the nasal cannula tubing if gas outlet is seen in the humidifier container.
Touchscreen does not respond to touch	Display socket connections may be disconnected.	Check the plug connections of the display.
The device is working, but the display does not appear on the touchscreen. does not come.	Display socket connections may be disconnected. Graphics card connections and sockets it may be displaced.	Check the card connections and socket connections.
Error Please contact technical service contact)	Device calibration It may have deviated +/- 20% from its values.	Calibration of the device by contacting the technical service must be done.
The device does not work at all	Power cord may not be connected or fuse may have blown.	Check the power cable and input fuse.
The LED in the power button does not light at all	Power cord may not be connected or fuse may have blown.	Check the power cable and input fuse.



**Device Power Button**

The power button is only used for turning the device on and off.

## 5- Tag Information

the device must be operated under the label conditions stated below. It should be operated considering the input power and current values.

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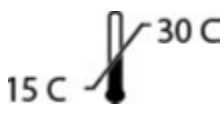





Ürün Adı	Hidrojen-Oksijen Solunum Makinası		
Markası	Nefess20	Beyan Akımı	0,92 A
Modeli	S1D	Maksimum Akım	2,27 A
Seri Numarası	A0001	IP Kodu	IP20
Beyan Gücü	500 W	Ağırlık (kg)	5kg
Çalışma Gerilimi	220 V, 50 Hz	Üretim Tarihi	06-2020









CLASS II	NO DRINKING WATER	KURU TUTUN	WEEE	0 ° ~ +40 °

## 6.Label Warning Signs

Warning and symbol signs are short symbols containing information about the device and preventing dangerous situations by warning the operator during operation and when the device is operated. The device should be operated by considering the warnings and signs stated below. Please pay attention to the warnings and signs.

### SYMBOLS AND WARNINGS

Symbol Image	Definition
	Please refer to the user manual before starting the device.
	CE Conformity mark.
	Operate the device in suitable environmental conditions. Working temperature limits
	Device serial number
	Warning sign. Please observe the warnings on the label and in the user manual.
	Device Production Place Date of Manufacture
	Keep away from moisture and water ** Max. moisture level is stated on the label
	Protect the device from direct sunlight. * * Max. the temperature level is indicated on the label.

	Emergency stop
	IEC60601-1 TYPE B Applied Sections
	Power ON / OFF switch
	Warning sign.
	Protected ground mark
	Hold with the arrows pointing up
	WEEE
	Do Not Use Drinking Water

## 6. Environmental Requirements

The operating temperature and humidity values of the device are indicated on the label.



Operating outside the specified environments carries serious risks as it will affect the calibration values..

## 6. Installation



Installation of the device does not require any special measures..

## 6. Periodic maintenance, calibration and cleaning / disinfection requirements

Preventive maintenance is required for the use of the device. It should be kept away from clean and dusty environments or environments with extreme heat and humidity. A soft, slightly damp cloth can be used to clean the system. Regularly clean the control panel dirt and dust with a dry, soft brush. The exterior of the system can be cleaned using a lint-free cloth moistened with soapy water or isopropyl alcohol. Do not immerse the system in liquid or pour liquid into the system.

The calibration period of the device is one year. Calibration can only be done by the authorized company.



Before cleaning, turn off the system and unplug the power supply cord from the mains.

Drain the water in the main tank and the filter tank by turning the machine upside down every 150 hours. Put new potassium hydroxide and water in the main tank instead. Put clean water and lemon salt in the filter tank.

Have an authorized service maintenance at the end of every 450 hours of operation.

## 6. Storage and Transport

The product storage humidity should not be lower or higher than  $38 \pm 2\%$ , the product storage temperature ratio should be  $20 \pm 2$ . Do not put other parcels on it and handle it carefully. Radioactive materials and

/ or do not store or store near flammable materials.



## 6. Guidelines and Statement of Electromagnetic Compatibility

The device complies with the general requirements for safety of medical electrical devices and IEC 60601-1-2 with the electromagnetic safety requirements of electrical medical devices, when used as specified in the manufacturer's instructions and the manual.

This device has been tested and performed in accordance with the medical device standard in accordance with IEC 60601-1 LVD and IEC 60601-1-2 EMC tests.

The Hydrogen-Oxygen Respirator is intended for use in the electromagnetic environment specified below. The customer or user of the device must ensure that the device is used in such an environment.

### ELECTROMAGNETIC EMISSIONS

<b>Emission test</b>	<b>Compatibil ity</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Grup 1	The device is not used for RF energy function. Cause interference it is less likely to happen.
RF emissions CISPR 11	Class B	The device is suitable for use in all types of systems, including domestic systems and systems directly connected to a low-voltage network that powers buildings used for residential purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000- 3-3	Easy going	

<b>Electromagnetic interference resistance</b>		
<b>Prevention test</b>	<b>Compatibility degree</b>	<b>Electromagnetic environment - guide</b>
Electrostatic discharge (ESD) IEC 61000-4-2	2, 4,6,8 kV contact ± 15 kV air	The floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be less than 30%.
Electrical fast transient / burst IEC 61000-4-4	± 0.5 kV for input / output lines ± 1 kV, 2kV and 4 Kv 100 kHz	Mains power quality, for typical commercial or hospital environment must be of the quality used
Current IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Mains power quality, for typical commercial or hospital environment must be of the quality used.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	220-230V	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device needs continuous operation during mains power cuts, the device is powered from an uninterruptible power supply. is recommended.
MAINS FREQUENCY MAGNETIC FIELD (50 / 60Hz) magnetic field IEC 61000-4-11	30 A/m	Power frequency magnetic fields, typical commercial environment or hospital at levels applicable to a typical location in its environment
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz ila 30 MHz	Portable and mobile RF communications equipment, including cables, should be located closer to the device than the recommended separation distance obtained from the equation applicable to the frequency of the transmitter. should not be used.

## 6. Important Notices

The device should be used in accordance with the warnings and signs specified in the user manual. Otherwise, it may cause serious injury.



To avoid electrical shocks, this equipment should only be connected to a mains protective earth. The system is designed for continuous operation using an external connector..



Work should not be started before reading the device user manual. Failure to do so may result in serious injury or death..



The device should only be operated at the power values specified on the label. Failure to do so may result in serious injury or death..



The device should be kept away from dusty and humid environment for stable operation. Keeping the application head away from dust should be cleaned with a clean and soft cloth..



The position of the patient and the device should be fixed during the application. The distance between the device and the patient must be precisely adjusted and the power values must be checked. Other applications may cause serious injuries as they may change the power values..



The cable of the product should be kept away from hot surfaces. Otherwise, it may cause electric shock and fire. Do not operate with damaged power cord..



Turn off the system and unplug the wall plug before maintaining or cleaning (disinfecting) equipment. Never pull the wires to unplug the power cord. Hold the power cord plug and pull it out to disconnect. Equipment, power cord  
Place it so that it is not difficult to unplug..



Position the power cord so that it cannot be stepped on, tip over, bent, bent, pinched, or accidentally pulled from the wall socket.



If the cable of the device is damaged, if you notice that it is not working properly, if you drop it and your product is damaged, it should not be used and the technical service should be informed..



The device should not be used while drowsy or under the influence of alcohol..



. Beyond what is described in this manual, all services made to the system are only authorized by the authorized BBDS Enerji San. Tic Ltd. Make sure it is carried out by the staff of the facility..



Do not use the equipment near water and be careful not to spill liquid on any part..



Using accessories that are not supplied with the product may cause incompatibility of the device..



Maintenance or repair of the system should never be done during the application to the patient.



MRI and Unsafe - Keep away from magnetic resonance imaging equipment.



Do not use a damaged or defective device. The use of such devices / or may harm the patient



Keep the device away from flames and sparks. As hydrogen is a flammable gas, it can cause fire and damage the device..

## 13- DOCUMENTS

### CE DOCUMENT



## UYGUNLUK SERTİFİKASI SERTİFİKA

### BBDS ENERJİ SANAYİ TİCARET LİMİTED ŞİRKETİ

BOĞAZ KÖYÜ OSB 3 SK. 1 APT No:11 MERKEZ / NEVŞEHİR / TÜRKİYE

Ürün: HİDROJEN -OKSİJEN ÜRETEK SOLUNUM CİHAZI

Marka / Model : NEFESS20

#### *İlgili Standartlar / Direktifler / Yönetmelikler*

EN ISO 14971 Tıbbi cihazlar-Tıbbi cihazlara risk yönetiminin uygulanması

EN 1041+A1 Tıbbi cihaz imalatçıları tarafından sağlanan bilgi

EN ISO 15223-1 Tıbbi cihazlar - Tıbbi cihaz etiketlerinde, etiketlemede ve sunulacak bilgide kullanılacak semboller - Bölüm 1: Genel gereklilikler

#### *Sertifikasyon Zemini*

Teknik Dosya No: BBDS-CE-001

Üretici tarafından sunulan ve yukarıda belirtilen teknik dosya

"Avrupa Topluluğu 93/42/EEC direktifi EK VII Sınıf IIa" gerekliliklerine uygundur.

İlgili ürünle ilgili olarak sertifika çalışması:

-AT Uygunluk Beyanı Hazırlanması

-CE İşaretinin Ürüne Yapıştırılması

Sertifika No: AQN-TR-2058

Sertifika İlk Düzenleme Tarihi: 26 Haziran 2020

Sertifika Düzenleme Tarihi: 26 Haziran 2020

Sertifika Geçerlilik Tarihi: 25 Haziran 2021

Belgelendirme Süresi: 3 Yıl

Bu sertifika, AQNCERT Certification | Inspection | Supervision | Training of Private Company'nin malidir ve tatmin edici gözetim denetimlerine bağlı olarak geçerliliğini sürdürür.

AQNCERT Certification | Inspection | Supervision | Training of Private Company

Address: 1, Anand Dhaan, Opp Kukrail Tower Gate, Lucknow - 224715, India Phone: +91-9554643880 E-Mail: info@aqncert.com To check this certification validity please visit www.aqncert.com



## İSO 13485 CERTIFICATE



## İSO 9001 CERTIFICATE



## 14- Customer Support

For any support and technical problems regarding the operation of the device, please contact the company below..