

# **HELiOS™ Series**



# **User Controls & System Status Indicators**

ISO 7000: Graphical symbols for use on equipment—Index and synopsis



Read user's manual before operation. Reg. # 1641



Storage or operating temperature range. Reg. # 0632



Storage humidity range Reg. # 2620



Atmospheric pressure limitation. Reg. # 2621



Keep away from rain, keep dry. Reg. # 0626



Name and address of manufacturer. Reg. # 3082



Caution, consult accompanying documents. Reg. # 0434A



Catalog Number. Reg. # 2493



Serial Number. Reg. # 2498



This way up. Reg. # 0623



Fragile, handle with care. Reg. # 0621

#### ISO 7010: Graphical symbols—Safety colors and safety signs—Registered safety signs



Frostbite may occur on contact with cold liquid or gaseous oxygen, or frosted parts. Warning low temperature. To warn of low temperature or freezing conditions. Reg. # W010



Keep away from open flame, fire, sparks. Open ignition source and smoking prohibited. Reg. # P003



Do not smoke near unit or while operating unit. Reg. # P002



Type BF applied part (degree of protection against electric shock). Reg. # 5333



Warning, Reg. # W001

#### Council Directive 93/42/EEC; concerning medical devices

EC REP Authorized representative in the European Community



If the product unique device identifier (UDI) label has the CE#### symbol on it, the device complies with the requirements of Directive 93/42/ EEC concerning medical devices. The CE#### symbol indicates notified body number.



This device complies with the reguirements of Directive 2010/35/EU concerning medical devices. It bears the pi marking as shown.

#### ADR: European Agreement concerning the International Carriage of Dangerous Goods bv Road



Non-toxic gas.



Hazard Oxidizing substances: fire intensifying risk. Oxidizing agents cause fires to burn more vigorously.

Refrigerated Liquid, USP; Produced by Air Liquefaction

#### Internal Symbols



Keep unit well ventilated at all times



Keep away from flammable materials, oil and grease.



Portable Empty



Portable Full



Always keep Portable in one of the following positions: upright, flat on its back, or any position in between.



Wipe connector with clean dry cloth before filling.

# IEC 60417: Graphical Symbols for use on equipment



Do not cover unit or carry portable unit under your clothing. These units normally vent oxygen. No. 5641

#### 21 CFR 801.15: Code of Federal Regulations Title 21

RX ONLY

Federal law restricts this device to sale by or on the order of a physician.

Council Directive 2012/19/EU: waste electrical and electronic equipment (WEEE)



WEEE

IEC 60601-1: Medical electrical equipment Part 1 General requirements for basic safety and essential performance



Drip Proof

This product may be covered by one or more patents, US and international. Please visit our website below for the listing of applicable patents. Pat.: www.caireinc.com/corporate/patents/

#### **Warning Information**

**Important:** Read this manual thoroughly before operating the H300/H850.



WARNING: A WARNING IDENTIFIES A SITUATION WHICH, IF NOT AVOIDED, COULD RESULT IN DEATH OR SERIOUS INJURY. A WARNING MAY ALSO DESCRIBE POTENTIAL SERIOUS ADVERSE REACTIONS AND SAFETY HAZARDS.

WARNING: THIS DEVICE IS NOT INTENDED FOR LIFE SUSTAINING USE. IF CONTINUITY OF OXYGEN SUPPLY IS REQUIRED, ENSURE THAT AN ADEQUATE SUPPLY OF OXYGEN AND/OR A SECONDARY OXYGEN SUPPLY IS AVAILABLE AT ALL TIMES DURING THERAPY.

WARNING: IF YOU FEEL THE EQUIPMENT IS NOT OPERATING PROPERLY, CALL YOUR HEALTH CARE PROVIDER. DO NOT ATTEMPT TO REPAIR OR ADJUST THE UNIT YOURSELF.

WARNING: DO NOT MODIFY THIS EQUIPMENT WITHOUT AUTHORIZATION FROM THE MANUFACTURER.

WARNING: THE POSSIBILITY OF FIRE EXISTS WHEN THE COMBINATION OF A FUEL, SOURCE OF IGNITION, AND OXYGEN IS PRESENT. HIGH CONCENTRATIONS OF OXYGEN (AIR IS APPROXIMATELY 21% OXYGEN) GREATLY ENHANCE THE POSSIBILITY OF COMBUSTION.

WARNING: THE UNIT CONTAINS LIQUID OXYGEN WHICH IS EXTREMELY COLD, ALMOST -300°F (-184 C°). EXPOSURE TO SUCH A LOW TEMPERATURE CAN CAUSE SEVERE FROSTBITE.

WARNING: LIQUID AND GASEOUS OXYGEN, THOUGH NONFLAMMABLE, CAUSE OTHER MATERIALS TO BURN FASTER THAN NORMAL. THIS HAZARD, ALONG WITH THE LOW TEMPERATURE OF LIQUID OXYGEN, WARRANTS CERTAIN SAFETY PRECAUTIONS.

WARNING: KEEP FLAMMABLE MATERIALS AWAY FROM THIS EQUIPMENT. AEROSOL SPRAYS, OILS AND GREASE, INCLUDING FACIAL CREAMS AND PETROLEUM JELLY, IGNITE EASILY AND MAY BURN RAPIDLY IN THE PRESENCE OF OXYGEN

WARNING: DO NOT USE OR STORE YOUR UNIT WITHIN FIVE FEET OF ELECTRICAL APPLIANCES, ESPECIALLY STOVES, HEATERS, TOASTERS, AND HAIR DRYFRS



WARNING: DO NOT SMOKE WHILE OPERATING THE UNIT.

WARNING: DO NOT ALLOW SMOK-ING, CANDLES, OR OPEN FLAMES IN THE SAME ROOM WITH THE DEVICE.

WARNING: SMOKING WHILE WEARING AN OXYGEN CANNULA CAN CAUSE FACIAL BURNS AND POSSIBLY RESULT IN DEATH.

WARNING: REMOVING THE CANNULA AND PLACING IT ON CLOTHING, BEDDING, SOFAS, OR OTHER CUSHION MATERIAL WILL CAUSE A FLASH FIRE WHEN EXPOSED TO A CIGARETTE, HEAT SOURCE, SPARK OR FLAME.

WARNING: IF YOU SMOKE PLEASE: (1) TURN OFF THE HELIOS PORTABLE, (2) TAKE OFF THE CANNULA, AND (3) LEAVE THE ROOM WHERE THE DEVICE IS LOCATED. WARNING: KEEP YOUR UNIT IN A WELL-VENTILATED AREA. DO NOT STORE LIQUID OXYGEN EQUIPMENT IN A CLOSET, CAR TRUNK, OR OTHER CONFINED AREA. DO NOT PLACE BLANKETS, DRAPERIES, OR OTHER FABRICS OVER EQUIPMENT. THIS WILL CAUSE AN OXYGEN ENRICHED ATMOSPHERE WHICH IS A FIRE HAZARD.

WARNING: DO NOT CARRY THE PORTABLE UNIT UNDER YOUR CLOTHING. DO NOT STORE LIQUID OXYGEN EQUIPMENT IN A CLOSET, CAR TRUNK, OR OTHER CONFINED AREA. DO NOT PLACE BLANKETS, DRAPERIES, OR OTHER FABRICS OVER EQUIPMENT. THIS WILL CAUSE AN OXYGEN ENRICHED ATMOSPHERE WHICH IS A FIRE HAZARD.

WARNING: IN THE EVENT OF AN ACCIDENTAL TIP-OVER, IMMEDIATELY BUT CAUTIOUSLY RETURN THE UNIT INTO AN UPRIGHT POSITION IF POSSIBLE. IF ANY LIQUID OXYGEN IS ESCAPING, LEAVE THE AREA IMMEDIATELY AND CALL YOUR HEALTHCARE PROVIDER. DO NOT ATTEMPT TO MOVE THE UNIT OR STOP THE LIQUID OXYGEN FROM ESCAPING.

WARNING: DO NOT TOUCH FROSTED PARTS OF ANY UNIT.

WARNING: DO NOT STORE OR OPERATE THE HELIOS PORTABLE COUPLED TO YOUR RESERVOIR.

WARNING: THIS PRODUCT CAN EXPOSE YOU TO CHEMICALS INCLUDING NICKEL, WHICH IS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER. FOR MORE INFORMATION, GO TO WWW.P65WARNINGS.CA.GOV.

WARNING: IN THE EVENT THERE IS A SERIOUS INCIDENT OCCURRING WITH THIS DEVICE, THE USER SHOULD IMMEDIATELY REPORT THE INCIDENT TO THE PROVIDER AND/OR THE MANUFACTURER. A SERIOUS INCIDENT IS DEFINED AS AN INJURY, DEATH, OR POTENTIAL TO CAUSE INJURY/DEATH SHOULD THERE BE A REOCCURRENCE OF THE INCIDENT. THE USER CAN ALSO REPORT THE INCIDENT TO THE COMPETENT AUTHORITY IN THE COUNTRY WHERE THE INCIDENT OCCURRED.



Caution: RX Only. Federal law restricts this device to sale by or on the order of a physician.

Caution: Use the H300/H850 Portable only as directed by your doctor.

Caution: If the unit has been dropped, please contact your health care provider to ensure the unit is still in working condition.

**Caution:** Do not allow untrained personnel to handle or operate this device.



Caution: A caution identifies a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment or other property.

Caution: RX Only. Federal law restricts this device to sale by or on the order of a physician.

Caution: Use the H300/H850 Portable only as directed by your doctor.

Caution: If the unit has been dropped, please contact your health care provider to ensure the unit is still in working condition.

**Caution:** Do not allow untrained personnel to handle or operate this device.

Note: Notes provide important information about using the equipment properly.

Note: Use of this device is prohibited on commercial passenger and cargo air flights by the Federal Aviation Administration.

Note: Applicable EMC information can be found in the HELiOS Portable Technical Service Manual at www.caireinc.com.

## **Specifications**

- · Mode of Operation: Demand and Continuous Flow
- Type of Protection Against Electrical Shock: Internally Powered Equipment
- · Degree of Protection Against Electrical Shock: Type BF Applied Part
- · IPX1 Classification According to the Degree of Protection Against Ingress of Water: Drip
- · Equipment not suitable for use in the presence of flammable mixtures

	HELiOS Plus	HELIOS
	(H300)	Marathon
		(H850)
LOX capacity	0.9 lb (0,41 kg)	2.0 lb (0,91 kg)
Gaseous equivalent capacity	308 L	685 L
Weight, filled	3.6 lb (1,63 kg)	5.6 lb (2,54 kg)
Weight, empty	2.7 lb (1,22 kg)	3.6 lb (1,63 kg)
Height includ- ing handle	10.5" (267 mm)	15.0" (381 mm)
Typical use time at 2 LPM demand mode	9 hours	22 hours
Typical use time at 2 LPM continuous mode	N/A	6.1 hours
Operating pressure	22 psi (152 kPa)	22 psi (152 kPa)
Normal evapo- ration rate	1.0 lb/day (0,45 kg/day)	0.85 lb/day (0,39 kg/day)
Standard flow control range	Continuous: off, .12, .25, .5, .75 Demand: off, 1, 1.5, 2, 2.5, 3, 3.5, 4	Continuous: off, 1,2,3,4,5,6 Demand: off, 1.5, 2, 2.5, 3, 4

#### Introduction

A liquid oxygen system is designed to provide supplementary oxygen as prescribed by a physician. Your liquid oxygen system includes a HELiOS portable unit and a stationary reservoir. The reservoir is the larger container that is used to fill your HELiOS portable. This user manual contains only the instructions for using the HELiOS portable. Refer to the user manual supplied with your reservoir unit for information on its operation.

HELiOS portable liquid oxygen units are designed to be an ambulatory source of oxygen for an extended period of time. They are filled with liquid oxygen from a reservoir unit with a compatible fill connector. HELiOS portables are available in two different sizes.

The H300 Plus is primarily a conserving device and holds 0.38 Liters of liquid oxygen. It provides demand (pulse) flow settings 1-4, and limited low dose continuous flow settings at 0.75 LPM and below only.

The H850 Marathon can be used as a conserving or continuous flow device and holds 0.84 liters of liquid oxygen. It provides continuous flow from 1-6 LPM and demand flow on settings of 1-4.



H300 and H850 portable units shown.

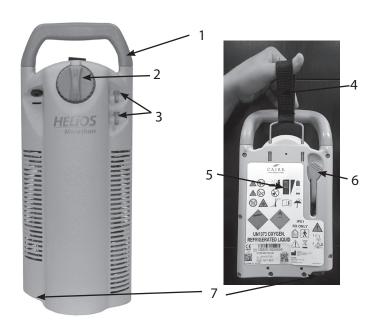
#### Intended Use

The CAIRE HELiOS Liquid Oxygen unit is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

#### **Controls**

- 1. Carrying Handle
- 2. Flow Control Knob
- 3. Dual Lumen Cannula Barbs
- 4. Contents Indicator Strap

- 5. Contents Indicator Window
- 6. Vent Valve Lever
- 7. Fill Connector (QDV)



## **Fill Connector Compatibility**

The H300 and H850 can be filled from any CAIRE top-fill (TF) reservoir that has a CAIRE-style male fill connector. The compatible male and female connections for the HELiOS portable units are shown here.



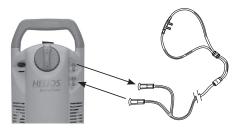
CAIRE male (reservoir) and female (H300/H850) fill connectors

#### **Dual Lumen Cannula**

In order to breathe from your H300 or H850, you must do so through a dual lumen nasal cannula. This type of cannula has two connections to the portable unit. One connection is used to detect when you inhale, and the other connection is used to deliver oxygen to your nose.

A single lumen cannula cannot be used on the H300/H850. Your breath through the cannula provides the force necessary to open the flow control valve and deliver oxygen. You must use a dual lumen cannula and inhale through your nose on ALL flow settings to ensure that oxygen is properly delivered.

Note: Oxygen will only be delivered through the top cannula barb.



Dual lumen nasal cannula operation: Oxygen is delivered through top port. Breath is detected through bottom port.

Note: To Equipment Provider: The following oxygen administration accessories are recommended for use with the HELIOS:

- Nasal Cannula: CAIRF Part Number 6-778057-00.
- Firebreak: CAIRE Part Number 21126636 A firebreak is recommended for use with any cannula.
- CAIRE offers a firebreak intended to be used in conjunction with the oxygen portable. The firebreak is a thermal fuse to stop the flow of gas in the event that the downstream cannula or oxygen tubing is ignited and burns to the firebreak. It is placed in-line with the nasal cannula or oxygen tubing between the patient and the oxygen outlet of the HELiOS. For proper use of the firebreak, always refer to the manufacturer's instructions (included with each firebreak kit).
- For any additional recommended accessories, please see the Accessories Catalog (PN ML-LOX0010) available on www.caireinc.com.

# Operating Instructions – Filling

1. Clean the fill connectors on the H300/H850 and the reservoir with a clean, dry, lint-free cloth.



WARNING: THE FILL CONNECTORS MUST BE CLEAN AND DRY WITH A LINT-FREE CLOTH ON BOTH THE STATIONARY AND PORTABLE UNITS TO PREVENT FREEZING AND POSSIBLE EQUIPMENT FAILURE.

WARNING: DO NOT DEPRESS OR DISTURB THE POPPET ON THE FILL CONNECTOR WHEN DRYING IT. THIS CAN CAUSE LEAKAGE OF LIQUID OXYGEN.

- 2. Turn the flow control knob on the H300/H850 to the off ("0") position.
- Hold the H300/H850 with both hands and position its fill connector over the reservoir fill connector.
- 4. Lower the portable onto the reservoir until you feel the connectors engage.



- 5. Place one hand on top of the H300/H850 and apply a constant downward force.
- Open the vent valve by pulling downward on the vent valve lever to begin the filling process. You will hear a hissing sound that is perfectly normal.



- 7. You may see vapor around the fill connection. This is normal due to the great difference in temperature between the liquid oxygen and the warm surrounding air.
- Maintain a downward force on the H300/H850 with one hand during the entire filling process and keep the vent valve lever open with the other hand.
- Approximately 20-30 seconds into the fill, close and re-open the vent valve one or more times.
   This will prevent the valve from freezing open.
- 10. The unit is full when the hissing sound changes in tone and a dense white vapor is seen coming from under the shroud of the reservoir. When this is observed, close the vent valve by raising the vent valve lever. This will terminate the fill.
- Hold the handle on the H300/H850 and push the release button on the reservoir until the portable separates (release button varies by model of reservoir)



12. Check the contents indicator to verify that the unit is full.



WARNING: DO NOT LEAVE UNIT UNATTENDED WHILE FILLING.

WARNING: DO NOT OPERATE THE H300/H850 WHILE ATTACHED TO THE RESERVOIR UNIT.

WARNING: SHOULD LEAKAGE BE EXCESSIVE TO THE POINT THAT A STREAM OF LIQUID IS PRESENT, LEAVE THE AREA AND CALL YOUR HEALTH CARE PROVIDER IMMEDIATELY.

WARNING: IF LARGE AMOUNTS OF VAPOR ARE ISSUING FROM THE UNITS DURING FILLING, STOP FILLING, LEAVE THE ROOM AND CALL YOUR HEALTH CARE PROVIDER.

WARNING: IF PROLONGED HISSING IS HEARD, STOP USE AND CONTACT YOUR HEALTH CARE PROVIDER IMMEDIATELY

WARNING: IF THE H300/H850 DOES NOT SEPARATE EASILY, DO NOT USE FORCE. THE UNITS MAY BE FROZEN TOGETHER. LEAVE THE UNITS CONNECTED AND WAIT UNTIL THEY WARM UP – THEN THEY WILL SEPARATE EASILY. DO NOT TOUCH ANY FROSTED PARTS.



Caution: Should there be any liquid leakage from the portable after separating the units, , set the H300/H850 aside, ensuring it remains vertical, leave the room, and call your health care provider immediately.

Caution: Should there be any liquid leakage from the reservoir after separating the units, open windows in the room, leave the room immediately, and call your health care provider.

**Caution:** Check the liquid level only after the vent valve is closed.

Caution: If the H300/H850 is being refilled immediately after a period of use, fill it, and then wait approximately one (1) hour after filling with the flow control knob set to off ("0") for the pressure to stabilize. Then operate as normal.

NOTE: If the HELiOS portable is warm or has not been filled recently, it may take approximately 90 seconds to fill an H300 or approximately four (4) minutes to fill an H850.

## Operating Instructions -**Breathing From the Portable**

1. Attach both ends of a dual-lumen cannula to the connection ports on the H300/H850. Either end of the cannula may be attached to either connection port on the portable.



- 2. Position the nasal cannula properly on your face so that you will be able to breathe comfortably.
- 3. Turn the flow control knob until the setting prescribed by your physician is fully visible in the window on top of the H300/H850.



4. Breathe normally, inhaling through your nose. Oxygen delivery will not begin until you inhale through the nasal cannula.

NOTE: If the unit is on a demand (pulse) setting, you will notice a small pulse at the beginning of each inhalation. Oxygen is delivered during this pulse, and continues as long as you inhale. Oxygen flow stops when you stop inhaling.

NOTE: If the unit is in continuous flow, the H300/ H850 will deliver a steady stream of oxygen. You must continue to breathe through the nasal cannula normally to continue receiving continuous flow.

Note: Due to the possibility of excessive moisture/ ice build up it is recommended that the H300/ H850 remain idle for 1 hour after use to decrease moisture buildup.

- 5. You should be receiving oxygen flow now. Verify that you feel oxygen delivery.
- 6. Use the duration charts available at www. CAIREmedical.com as a guideline to determine the length of time the H300/H850 will operate.
- 7. Under certain conditions (especially continuous use when the portable is not moved) the H300/ H850 may develop frost on the case. You may reduce this frost by wiping any accumulated frost off the case
- 8. To stop the flow of oxygen, turn the flow control knob to the off (0) position.



Caution: Always turn the flow control knob off (0) when not in use.

NOTE: Do not open the vent valve during normal operation.

NOTE: The H300/H850 may be operated in an upright position, flat on its back, or any position in between these two locations.

#### Operating Instructions – Level Verification

- Lift the H300/H850 by the contents indicator strap.
- 2. Push the bottom backside of the unit forward until it is straight up and down.
- Observe the green bar in the contents indicator window. The window is completely filled with the green bar when the unit is full of liquid oxygen.

Portable Full









Checking the H300/H850 contents indicator

#### **User Troubleshooting**

The following information is intended to help you troubleshoot and solve simple operational problems that you may experience when using your HELiOS Portable.

- 1. The Portable makes a hissing sound.
  - Hissing can occur to maintain the correct operating pressure within the Portable. It is most likely to hiss after filling or when the position of the Portable is changed. Hissing can last for approximately 10 minutes after filling. Additionally, it can occur when the flow control valve is at a low setting.
- 2. The Portable does not pulse after filling.
  - If during the filling process, the Portable is disengaged with the vent valve lever down, pressure may be reduced within the Portable causing a delay in the conserving device function. It may require as much as 60 minutes to restore adequate pressure for accurate oxygen flow. Additionally, improper filling or lower than normal operating pressure in the Reservoir will contribute to the unit not pulsing.
- 3. The Portable stops pulsing during use.
  - Ensure that both connections of the dual lumen cannula are firmly attached to the Oxygen Outlet and Sensor connectors.
  - Change the cannula if water droplets are present from humidified exhaled gas. Replacing
    the cannula with a dry one enhances the
    ability of the Portable to pulse.
  - Ensure that the cannula is not kinked.
  - Ensure that the cannula tips remain in your nostrils and do not slide to one side.
  - Ensure that there is oxygen in the Portable.
  - With the cannula on, close your mouth and breathe only through your nose to verify that the Portable has stopped pulsing.
- 4. The Portable does not fill.
  - Verify that there is oxygen in the Reservoir.
  - Ensure that the Portable and Reservoir fill connectors are fully engaged throughout the filling process.
- 5. The Portable vent valve does not close properly at the end of the filling process.
  - If the vent valve fails to close and the hissing sound and oxygen vapor cloud continue, carefully remove the Portable by depressing the release button on the Reservoir. Venting from the bottom of the Portable will stop in a few minutes. Allow the unit to warm until you can close the vent valve. The Portable may require as much as 60 minutes to restore

adequate pressure for accurate oxygen flow. If needed, use an alternate source of oxygen such as a flow control valve attached to the Reservoir

- 6. The Portable does not disengage easily from the Reservoir after filling.
  - The Portable and Reservoir fill connectors may have become frozen DO NOT USE. FORCE. Allow a few minutes for the frozen parts to warm, then disengage the Portable when the ice has melted. To prevent the units from freezing together, always wipe the male fill connector on the Reservoir and the female fill connector on the Portable with a clean. dry cloth before filling.

NOTE: It is recommended that routine maintenance be performed annually on this equipment. Please contact your Health Care Provider to ensure this routine maintenance is being completed.

#### **Cleaning Standard**



WARNING: DO NOT ALLOW WA-TER INTO ANY OF THE CONTROLS. THE FILL CONNECTOR, OR THE OXYGEN SUPPLY CONNECTOR.



Caution: Clean only after the unit is empty and vented.

- Clean using a solution of mild dish washing detergent and water.
- · Apply cleaning solution directly to a lint-free cloth. Do not spray cleaners directly on the H300/H850.
- Wipe the outside surface with the lint-free cloth until the outside surface is clean.



Caution: Do not use high temperature and high pressure washing equipment to clean these units.

- Do not get cleaner on any internal components or valves.
- · Allow the unit to dry thoroughly before us-

#### **WEEE and RoHS**



This symbol is to remind the equipment owners to return it to a recycling facility at the end of its life, per Waste Electrical and Electronic Equipment (WEEE) Directive.

Our products will comply with the restriction of Hazardous Substances (RoHS) directive. They will not contain more than trace amounts of lead or other hazardous material content.

#### **Transport and Storage**

The device should be stored in the upright position well ventilated. Do not allow the device to be tilted forward or laying on its front. Operating temperature range of 14°F to 104°F (-10°C to 40°C). Storage temperature ranges from -40°F to 158°F (-40°C to 70°C).

#### Maintenance

Clean the fill connectors on both the stationary and portable units with a clean, dry, lint-free cloth between each fill to prevent freezing and possible equipment failure.

NOTE: Any additional maintenance needed must be done by a qualified service technician or service provider.

#### Accessories







Hip pack—HELiOS H300



H850 Cart



www.caireinc.com





CAIRE Inc. 2200 Airport Industrial Dr., Ste. 500 Ball Ground, GA 30107 U.S.A.

EC REP

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