

INSTRUCTIONS FOR USE

ABOUT THE INSTRUCTIONS FOR USE

This Instructions For Use (IFU) provides general instructions for the Dechoker operations. It is important to read the IFU and familiarise yourself with the device and procedures on how to use the Dechoker. Observing the warnings and cautions listed within this manual will provide effective use of the device.

REQUIREMENTS

The Dechoker is used within the home healthcare environment, restaurants, hospitals, and within commercial facilities.

Operators of the Dechoker shall be familiar with this manual.

INDICATIONS FOR USE

The Dechoker is a device that creates suction to clear a complete obstruction of the upper airway in choking victims 12 months of age and older. It is used by appropriately trained individuals aged 18 years of age and older. Dechoker should only be used after a first aid treatment has been administered for choking victims have failed to clear the obstruction and should be used in conjunction with CPR.

RECOMMENDED SIZES

- 01DCH01 Toddler (1 yr to 3 yrs)
- 01DCH03 Child (3 yrs to 12 yrs)
- 01DCH02 Adult (12 yrs and up)

RECOMMENDATIONS FOR SPECIAL CIRCUMSTANCES

- Dentures: Dechoker recommends removing dentures before use.
- Wheelchairs: Dechoker can be administered in sitting postion.

CONTRAINDICATIONS

The Dechoker is contraindicated for use by patients/users with the following:

- The Dechoker should not be used without contacting 000
 (Australia) / 111 (New Zealand) or emergency services.
- The Dechoker should not be used on infants (less than 1-year-old)
- Dechoker is not recommended for <u>incomplete airway</u> <u>obstruction</u>: The victim can vocalise, cough, or move air.
- Not for use in persons having an allergic reaction, such as anaphylaxis.
- Not for use in persons with Eosinophilic Esophangitis.

AIRWAY OBSTRUCTION

Dechoker recommends use on a complete airway obstruction only. The use of this device for incomplete airway obstruction could worsen the severity of the choking victim.

WHAT KINDS OF AIRWAY OBSTRUCTIONS ARE THERE?

- Incomplete airway obstruction: The victim can vocalise, cough, or move air.
- <u>Complete airway obstruction:</u> The victim cannot breathe, speak, or cough.

TECHNICAL SUPPORT

For questions regarding the Dechoker, please contact Aero Healthcare Customer Service at 1800 628 881 or via email at customerservice@aerohealthcare.com. If a serious incident occurs involving this device, please report it to Aero Healthcare immediately. When contacting Dechoker, have the Lot number (found on the Dechoker package label) ready for reference.

SINGLE USE & DISPOSAL REQUIREMENTS

The Dechoker is a patient individual single use device. Once used on the individual to remove the acute obstruction, do not clean the device. Dispose of the device with the regulations of the country in which it was sold.

WHOM TO CALL FOR HELP

Always **call 000 (Australia) or 111(New Zealand)** prior to using the device on a person with an obstructed airway during emergency. In the event that the Dechoker is inoperable revert to other acute airway obstruction method of relief.

Caution: Do not attempt to disassemble the device.

The manufacturer or an authorised representative must perform device failure evaluation.

DECHOKER WARRANTY/RETURNS

For questions regarding the Dechoker warranty and returns, please contact Aero Healthcare Customer Service at 1800 628 881 or via email at customerservice@aerohealthcare.com.

IMPORTANT SYMBOLS

The table below shows all symbols and the corresponding meaning of the symbols used within this manual and on the Dechoker labeling. Operators must pay careful attention to these symbols as they provide important safety precautions and warnings.

Label Symbol	Meaning
\triangle	Attention, Caution, Warning, Danger, Important, Note, or Refer to Accompanying Documentation
③	Refer to Instruction Manual / Booklet
(2)	Do not reuse
LOT	Batch code
	Use by date
	Date of manufacture
-30°C 140°F -32°C -22°E	Keep between temperatures of -30 and 60 celsius degrees
LATEX PREE	Does not contain latex
	Recyclable box

Table 1: Important Symbols and Descriptions

GENERAL WARNINGS

It is important to read all warnings before using the Dechoker. Reference the next table below for specific warnings.

Warning	Statement
\triangle	All users must read and understand the Dechoker IFU, including indications, contraindications, operating instructions, warnings and precautions before using the device. Failure to do so may result in injury.
<u> </u>	Equipment is not suitable or use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide.
\triangle	The Dechoker plastics are latex free. Skin irritation may result with the constant handling of the device for individuals who have sensitivity or allergic reaction to ABS materials.
\triangle	Safety and effectiveness of the Dechoker has not been established for uses outside of those specified.

Table 2: Warning Descriptions

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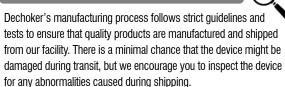




- Remove the Dechoker package from the box
- Open the Dechoker bag and remove the Dechoker device
- 3 Inspect device for defects
- Read IFU and familiarise yourself with the Dechoker
- Store the Dechoker in a safe and accessible location

Q Cross Slit **1** Device Quick 7 Pull Valve Reference Guide Handle **1** Tonque **Depressor** Device **6** Enclosure Labeling (Outer Cylinder) **Respirator Exhaust** A Suction Mask Valve **Barrel**

INSPECTION GUIDE



- 1. Visually inspect the device for any cracks in the body or facemask.
- 2. Visually inspect that the exhaust valve and cross slit valve are not separating from the body of the unit.
- 3. Visually inspect that the rim on the mask contains air and is not deflated.
- 4. Pull on the handle to test that the cylinder slides back and forth smoothly.

DECHOKER COMPONENTS

- **Tongue Depressor -** Prevents mouth cavity from collapse
- **Respiratory Mask** The respiratory mask covers the mouth and nose of the individual the device is being used on.
- **3** Exhaust Valve The exhaust valve permits the pull handle to move the piston back to its original position to allow another suction attempt in removing the acute obstruction.
- **4** Suction Barrel The sealed suction barrel encapsulates the piston to create the appropriate set suction level to remove the acute obstruction.
- **Device Labeling** The device has a label on the package identifying the device manufacturer and sponsor, and reference the device lot number when making any inquiries.

- **6** Enclosure (Outer Cylinder) The enclosure is used as a protective housing separating the user from the internal suction components of the Dechoker. Do not attempt to disassemble the device.
- **Pull Handle** The pull handle provides a simple grip to drawing back the piston.
- **8 Device Quick Reference Guide** The Dechoker has an operator's quick reference device instructions wrapped around the barrel of the device. These instructions are also printed on the last page of this document.
- **9 Cross Slit Valve** Prevents air or obstructions from going back into the patient.

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- 1. Select the new mask to be installed. See **Recommended Sizes** on Page 1.
- 2. Remove the mask from its packaging.
- 3. Inspect all parts of the new mask: Check for any visible damage, cracks, or defects in the **Mask Body**, **Nozzle**, **Face Cushion**, and **Tongue Depressor**.
- 4. Remove the old mask by rotating the **Nozzle** counterclockwise, until the mask detaches from the main device body.
- 5. Inspect the now-exposed threaded connector on the main device body for any visible damage or defect.
- 6. Attach the new mask onto the main device body by affixing the threaded end of the **Nozzle** to the threaded connector of the main device body and rotating the mask clockwise until hand-tight. **DO NOT OVERTIGHTEN, AS THIS CAN RESULT IN DAMAGE TO THE DEVICE.**
- 7. Confirm that the mask profile is symmetrical to the cylinder on the main device body (Figure 1).

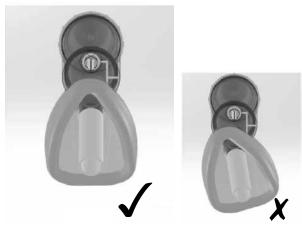
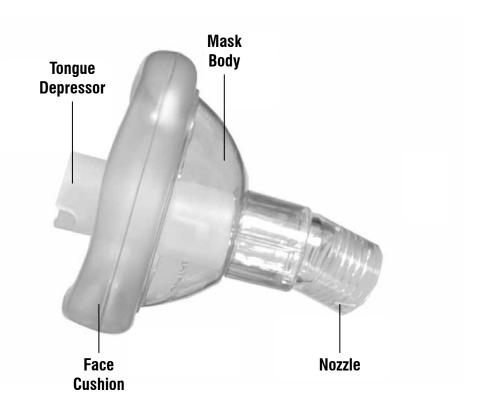


Figure 1: Mask symetrical to the cylinder

8. Store the Dechoker in a safe and accessible location. Store additional masks in original packaging for future use.



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HOW TO USE



① Dechoker recommends first action to dial your local emergency number, 000 (Australia) / 111 (New Zealand), and perform Basic Life Support for Airway Management. If first aid treatment for management of choking or foreign body airway obstruction is not effective or feasible, continue treatment with the Dechoker. Remove Dechoker from the package and assure choking victim that help is on the way.



• Continue to apply firm pressure on the mask while forcefully pulling the handle.



2 Tilt head back and lift chin for optimal access to airway.



6 If victim is still choking, repeat steps 4, 5 and 6. Multiple attempts can be performed to create additional suction if necessary.



(3) Insert tongue depressor into mouth with respirator mask covering mouth and nose.



Once debris has been dislodged, roll individual over on their side to allow additional debris and/or fluid out of the mouth.



A Hold respirator mask between your thumb and fingers and apply firm pressure to form a seal between the face and mask.



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CHOKING EMERGENCY ASSISTANCE