# DIAMOND SUCTION

SUCTION EQUIPMENT; INSTRUCTIONS FOR USE

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|---|---|---|
|  |  |  |
| DIAMOND HIGH SUCTION (RED BACK) | DIAMOND LOW SUCTION (ORANGE BACK) | DIAMOND THORACIC SUCTION (GREEN BACK) |

THERAPY EQUIPMENT
BY ECE MEDICAL

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# 1. FOREWORD

Vacuum regulators are medical devices classified as class IIa according to the Medical Device Directive 93/42/EEC. Their Compliance with essential requirements of 93/42/EEC Medical Device Directive is based upon EN ISO 10079-3 standard.

# 2. INTENDED USE

The Suction Equipment is intended to remove liquids, mucus, secretions, solids, or gases during a range of clinical applications ( e.g. surgical operations, resuscitation, thoracic and gastric drainage). It is intended for use with any pipeline vacuum source. The level of vacuum is adjustable via a control and monitored with a gauge. It may be used on all patients where suction is indicated.

The function of the Diamond Range Suction is to provide a controllable Suction level from a Piped Vacuum supply.

The medical device is not intended to be powered from:

- a pressure gas source

# 3. OPERATIONAL, TRANSPORT AND STORAGE SAFETY REQUIREMENTS

⚠ **Keep the medical device and its associated equipment away from:**

- oil or grease (take care in the use of hand creams),
- water,
- dust.

⚠ **The medical device and its associated equipment must be prevented from falling over.**

Before initial use the medical device should be kept in its original packaging. Manufacturer recommends use of the original packaging (including internal sealing bag and caps) if the medical device is withdrawn from operation (for transport, storage). Statutory laws, rules and regulations for medical gases, accident prevention and environmental protection must be observed.

| OPERATING CONDITIONS | | STORAGE AND TRANSPORT CONDITIONS | |
|---|---|---|---|
|  | -10/+40 °C |  | -20/+60 °C |
|  | 10/70 % |  | 10/100 % |
|  | 950/1100 mbar |  | 600/1200 mbar |

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## 4. PERSONNEL INSTRUCTIONS

The medical device provider must ensure that all personnel handling the medical device are provided with the operating instructions & performance data.

### 4.1. INTENDED USER

The intended user is any Healthcare professional who has read and understood the instructions for use and is able to operate the device correctly.

⚠ **Do not use the medical device without proper familiarization of the medical device and its safe operation as defined in this Instructions for use.**

⚠ **The Diamond Suction should only be used by Hospital personnel authorised and trained in its use.**

⚠ **Read all instructions before using – DO NOT USE the Suction device if you do not understand the instructions given in this document.**

*Note: In case of doubt regarding the use of the device as described by this Instructions for use, contact the medical device provider or manufacturer.*

## 5. MEDICAL DEVICE DESCRIPTION

The suction unit is a mechanical device, which attaches to a piped vacuum supply, such as a hospital vacuum system and is used to control vacuum level.

Diamond Suction range includes 3 models:

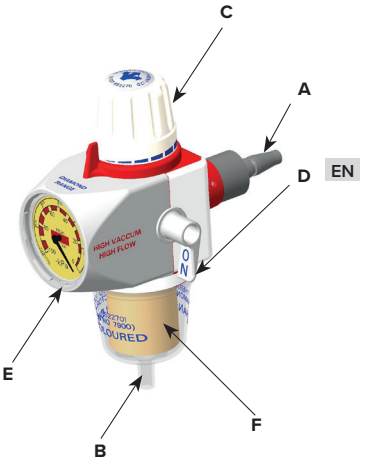
- Diamond High Suction (red back): for a vacuum level from 0 to > -500mm Hg (-67kPa) / flowrate >55 l/min
- Diamond Low Suction (orange back): for a vacuum level from 0 to -150 mmHg (-20 kPa) / flowrate > 20 l/min

  Model is equipped with relief valve (full relief) set at 180 mmHg (-24 kPa)
- Diamond Thoracic Suction (green back): for a vacuum level from 0 to -60 cmH2O (-6 kPa) / flow rate > 20l/min

  Model is equipped with relief valve (full relief) set at -75 cmH2O (-7,4 kPa)

**⚠ If the medical pipeline vacuum level is lower than the maximum vacuum level attainable of vacuum regulator, the medical pipeline vacuum level is the maximum level attainable.**

**⚠ The achievable vacuum depends on atmospheric pressure. Every 100 meters increase in altitude causes a decrease in the achievable vacuum about 1.4 kPa.**




**A. VACUUM SIDE CONNECTION**

Vacuum regulator is connected to the medical gas pipeline vacuum source
(terminal unit) by a vacuum specific probe. This is the device inlet.

**B. PATIENT SIDE CONNECTION**

Patient side connection for connection of associated equipment tube 8.5mm conical connection (ISO-5356). This is the outlet of the device.

**C. VACUUM LEVEL CONTROL KNOB**

Vacuum level control knob controls and adjust level of vacuum at patient side from 0 to maximum regulator vacuum level.
Vacum level at patient side increases by turning the knob anti-clockwise and clockwise to decrease.

**D. ON/OFF TAP**

On/Off Tap is used to open or shut off the vacuum source. Source is shut off when sign “OFF” is facing towards
vacuum level indicator. Source is open when sign “ON” is facing towards vacuum level indicator.
On/Off tap also prevent units from being left on and draining the vacuum source.

**E. VACUUM LEVEL INDICATOR**

Vacuum regulator is equipped with vacuum level indicator showing vacuum level at patient side set by control knob.

**F. DIAMOND PIPELINE PROTECTORS**

The Pipeline Protector is a complete plastic bowl fitted to the bottom of the Diamond Range Suction Controller. The unit is supplied complete with a Hydrophobic Filter that automatically shuts down the Suction Controller when the filter comes into contact with fluid, thereby giving protection against possible contamination of the Vacuum Pipeline. To assist end users in identifying Pipeline Protectors that have activated, the filter will turn pink.

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The Pipeline Protector should be changed immediately if the filter turns pink or discoloured (the original colour is white). It is also recommended that the Pipeline Protector be changed routinely as follows:
High Usage Area i.e. Theatres, HDU etc. - Every 3 months
Low Usage Area i.e. Wards etc. - Annually
The Pipeline Protector is changed by turning the plastic bowl in an anti-clockwise direction until the bayonet mechanism releases. The entire plastic bowl complete with filter should be disposed of and replaced with new. The new Pipeline Protector should be fitted by lining up the 'lugs' on the Bowl with the mating sections of the underneath of the Suction Unit, and turning in a clockwise direction until the bowl is locked into place.
The function checks detailed under Preventative Maintenance should be carried out after any dismantling and reassembly of the unit, including Pipeline Protector changes.

**RECEIVER JARS**
A Suction Receiver Jar Assembly should always be used in conjunction with Suction Controllers.
Whilst Therapy Equipment supplies its own Receiver Jar system, the Suction Controllers can be used with any manufacturer's Jar System, including Disposable Liner Systems. Standard Receiver Jars can be used with High and Low Suction Controllers, however more specialist Drainage systems are required for use with Thoracic Suction Controllers to maintain the very low levels of Suction being applied.

***Detailed information about the performance and technical data related to your device can be found in Appendix Nr. 1. Appendix Nr. 1 is in form of symbols. Explanations for the symbols are available in Chapter 12 - Glossary.***

## 6. INSTALLATION

Not applicable for this medical device.

## 7. OPERATION

**VISUAL INSPECTION BEFORE FITTING**
Remove the vacuum regulator from the packaging and inspect for damage. If there is any damage, DO NOT USE, and contact manufacturer.

**SOURCE OF SUPPLY: REGULATOR**

1. Unpack the Controller from the packaging:
   - Check if there is visible external damage on the vacuum regulator and its associated equipment (including medical device labels and marking). If it shows sign of external damage, remove the medical devices from service and identify its status.
   - Visually check if the regulator and its associated equipment are contaminated; if needed, refer to and apply the cleaning procedure.

2. Push the Controller Probe into the Yellow Vacuum Wall Outlet.
   - Refer to appendix Nr 1 to get information about quick coupler type on your medical device.
   - Refer to appendix Nr 2 to get information about connecting / disconnecting procedure.
   - For regulators fitted with a rail clip and a flexible hose, clip the vacuum regulator on the rail prior to connect the quick coupler.
3. Push the ¼" Bore Plastic Suction Tubing over the coned end of Pipeline Protector Bowl at the bottom of the unit, ensuring that a good fit is achieved, and that the tubing cannot come loose. The Suction Tubing should be a maximum of 2 Metres between the Suction Controller and Receiver Jar.
4. Turn the unit on using by moving the On/Off Tap on the side of the unit 180° so that the ON is showing.
5. The level of vacuum required can then be adjusted by turning the Control Knob on the top of the unit. (Increase – clockwise; Decrease – anti-clockwise).
6. Conduct a functional test and leakage test before use
   - Set the vacuum regulator to on by moving the On/Off tap.
   - Increase the vacuum level by adjusting the control knob
   - Check that there is significant vacuum level at the patient side by locking the patient side with your finger or by occluding the tube connected to the patient side and observing the gauge.
   - Set the vacuum regulator off by turning the On/Off tap and check the vacuum level drops
7. To pre-set the vacuum level before use, occlude the Suction Tubing between the Controller and the Receiver Jar. Turn the Control Knob until the required level of suction reads on the gauge at the front of the unit. The Suction Unit can now be switched off, and will apply the set vacuum level, the next time the unit is switched on.
8. The unit should be switched off by moving the On/Off Tap on the side of the unit back to the fully OFF position whenever not in use.
9. Before disconnecting the vacuum regulator from the medical pipeline system
   - Turn it off by moving the On/Off tap
   - Remove suction tubing connected at the patient side
   - Visually check if the safety container and filter are not contaminated. If contaminated then mark accordingly and following cleaning and replacement instructions.

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⚠ **The unit should never be left or operated in any other position other than fully OFF or fully ON.**

⚠ **High/Low Suction controllers should not be used for continuous drainage.**

⚠ **It is the responsibility of the end user to ensure that the correct unit and vacuum level is selected. The manufacturer accepts no responsibility for the selection of an incorrect unit or vacuum setting.**

⚠ **ENSURE all connections are tight and leak free.**

## 8. ASSOCIATED EQUIPMENT

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**To be connected to the Patient side connection (Device outlet)**

- Suction hose: Use suction hoses with an inner diameter of 6mm.
- Collection container: Use the collection container with the required connection.
- Safety container: Use safety containers with the required connection.

## 9. CLEANING

Wipe over the outside of the unit and the gas supply hose with an alcohol or disinfecting wipe. If you suspect that the unit is contaminated, remove it from use and refer the device to the appropriate department. We do not recommend the use of Detergent Based Hard Surface Wipes. Used cleaning solution shall comply with Oxygen cleanliness standards for Oxygen devices.

⚠ **Ensure that no Cleaning Solutions or fluids enter the Safety Relief Valve on the side of the Low and Thoracic Suction units, during the cleaning procedure. Excessive fluid can cause the Valve to malfunction/stick.**

⚠ **DO NOT immerse in liquid, or use if the Suction Controller becomes internally contaminated.**

⚠ **Do not expose to high temperatures (such as autoclave).**

⚠ **Do not use cleaning products containing ammonia.**

## 10. MAINTENANCE

### 10.1. ROUTINE INSPECTION

Whilst the Suction Controllers are supplied with a Lifetime Function Warranty (7 years), the unit should be included in an annual service inspection.

- The unit should be wiped with an Alcohol or Disinfecting Wipe to clean

**For Diamond High Suction Units:**

*Leakage Check:*

1. Turn Suction Controller on and adjust Control Knob to maximum
2. Occlude Pipeline Protector/Filter Jar and wait for full vacuum (in excess of –500mmHG) to register on gauge.
3. Adjust Control Knob to minimum.
4. The gauge should not drop showing the unit is leak tight

*Function/Flowrate Check:*

1. Turn Suction Controller on and adjust vacuum to maximum

2. Occlude Patient side on Receiver Jar and ensure that a vacuum of –400mmHG (High Suction) is registered within 4 seconds.

**For Diamond Low and Thoracic Suction Units only:**

1. Turn the Low or Thoracic Diamond Range Suction On/Off tap downwards so the ON is showing
2. Occlude the Pipeline Protector and turn the Control Knob clockwise to MAXIMUM and make sure the Vacuum level reaches -150mmHG (Low) or in excess of -50cmH2O (Thoracic)
3. While still occluded, turn the Control Knob to MINIMUM and make sure the Vacuum Gauge registers zero.
4. A leak test is not possible, due to the operation of the Safety Valve.



Regular strip down maintenance on the Suction Controller is not required.

## 10.2. SERVICE

Not applicable for this medical device.

## 10.3.TROUBLESHOOTING

| PROBLEM | ANALYSIS | ACTION |
|---|---|---|
| Faulty Gauge | Suction Controller indicating wrong vacuum | • Return to the Hospital Department responsible for maintenance or Manufacturer |
| Relief Valve on Thoracic or Low Suction Malfunctions | Too high vacuum maybe applied to the patient | • Return to the Hospital Department responsible for maintenance or Manufacturer |
| Pipeline Protector malfunction or has been contaminated | Suction Controller will not function or if Pipeline Protector becomes contaminated it will cease to function | • Exchange adequate safeguard against contamination of Controller<br>• Ensure that the new Pipeline Protector is functional if contamination has occurred. |

| | | |
|---|---|---|
| Breakage of On/Off Tap | If Tap is in Off Position the Controller will not function | • If Tap is in On Position the Controller can be turned off by means of the Control Knob<br>• Visual Inspection to ensure that the Suction Controller is not damaged<br>• If damaged return the unit to the Hospital Department responsible for maintenance or Manufacturer |
| Leaking On/ Off Tap | When the unit is turned to ON the Suction will creep up to maximum when occluded | • Preset the unit to -100mmHg, occlude the Pipeline Protector and ensure the suction maintains the correct level<br>• If creeping return the unit to the Hospital Department responsible for maintenance or Manufacturer |

## 11. MEDICAL DEVICE LIFE TIME

### 11.1. LIFE TIME

Maximum life time of the medical device is 7 years.
At the end of the medical device's life time, the medical device must be withdrawn from service (max. 7 years).

### 11.2. SERIAL NUMBER AND DATE OF MEDICAL DEVICE

Format: - XYYDDDXXXX
X - Product Family
YY - year of production
DDD - Day of year
XXXX...14 - Sequence Number
Example - V240600001
Suction, 2024, Feb, 29, Sequence 0001

## 11.3. MARKING UDI CODING IMPLEMENTATION

**Device UDI**

(01)12345678901234 Fourteen numbers with (01) prefix GTIN Global Trade Number

(240)1234567890123 Thirteen alphaneumeric digits with (240) prefix - Additional ID

(21)Vyydddnnnn Thirty alphanumeric digits with (21) prefix - Serial Number

(17)yymmdd Six numbers with (17) prefix - Expiry Date

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**Packaging UDI**

(01)12345678901234 Fourteen numbers with (01) prefix - GTIN Global Trade Number

(10)A2C4E6G89J Twenty alphanumeric digits with (10) prefix - Batch / LOT Number

(21)Vyydddnnnn Thirty alphanumeric digits with (21) prefix Serial Number

(17)yymmdd Six numbers with (17) prefix - Expiry Date

## 11.4. DISPOSAL OF WASTE MANAGEMENT

The owner of the medical device shall prevent the reuse of the medical device and handle the medical device in compliance with “Directive of European Parliament and Council 2008/98/EC on waste“.

Contact your local representative for further details, before returning or removing the medical device. All components should be disposed of according to local environmental laws applicable in the country of disposal. If required, a list of component materials is available from the manufacturer.

## 11.5. REACH AND RoHS

In accordance to Article 33 of REACH responsible manufacturer shall inform all customers if materials containing 0.1% or more of substances included in the list of Substance of Very High Concern (SVHC).

The most commonly used brass alloys used for bodies and other brass components contain 2-3% of lead (Pb), EC no. 231-100-4, CAS no. 7439-92-1. The lead will not be released to the gas or surrounding environment during normal use. After end of life the medical device shall be scrapped by an authorized metal recycler to ensure efficient material handling with minimal impact to environment and health.

To date we have no information that indicates that other materials containing SVHC of concentrations exceeding 0.1% are included in any medical device.

## 11.6. REPORTING OF A SERIOUS INCIDENT

If any suspected serious incident has occurred in relation to this medical device, notify the manufacturer, e-mail: adverse_events@gcegroup.com and the competent authority of the State in which the user and/or patient is established.

By reporting a suspected serious incident, you can help obtain more information about the safety of this medical device.

## 12. GLOSSARY

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| | | | |
|---|---|---|---|
|  | Consult Instructions for use |  | Suitable for Hospital care use |
|  | Caution | REF | Catalogue number |
|  | Keep away from heat and flammable materials | UDI | UDI Symbol |
|  | Keep away from oil and grease | LOT | Batch code |
|  | Keep dry! | SN | Serial number |
|  | Fragile, handle with care |  | Date of manufacture |
|  | Temperature limit |  | Manufacturer |
|  | Inlet parameter | MD | Medical Device |
|  | Outlet parameter | HIGH VACUUM HIGH FLOW | High Vacuum/ High flow |
|  | Humidity limit | LOW VACUUM HIGH FLOW | Low Vacuum/ High flow |
|  | Ambient pressure limit | THORACIC DRAINAGE | Thoracic drainage |
| UK REP | UK Responsible Person | CHANGE IF PINK OR DISCOLOURED | Change if pink or discoloured |

## 13. WARRANTY

The Standard Warranty period is 7 years from date of receipt (or if this is not known, 7 years from time of the medical device manufacture shown on the medical device).
The standard warranty is only valid for medical devices handled according to the Instructions for use (IFU) and general industry good practice and standards.

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# THERAPY EQUIPMENT

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