

***Negative Pressure Instrument
Operating and Maintenance Information
For Models NP-2, NP-4 and NP-V***

Rev 11/04

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INTRODUCTION

The Negative Pressure Cutaneous Suction System was developed by Electronic Diversities as an experimental device to meet specific dermatological research needs.

Over the years, suction blisters have been recognized as an important research tool for various dermatological and allergy studies. Researchers have resorted to various schemes to create suction blisters but our instrument provides a complete portable system that has successfully been used within the United States, as well as abroad, and found to be a simple, yet effective, method with high repeatability and reliability.

Since the inception of the Negative Pressure Instrument System, there have been constant improvements and its use has expanded to accommodate the needs of researchers in several medical disciplines. This instrument represents one of the latest versions of the system, incorporating all changes and improvements to date. Currently, there are 3 models. The NP-2, a two heated chamber unit, the NP-4, a four chamber heated unit and the NP-V. The NP-2 and

GENERAL DESCRIPTION

The Negative Pressure Cutaneous Suction System is a self-contained instrument package that combines all the necessary elements to successfully create suction blisters on a patient's skin. The blisters are created through the use of suction chambers that are attached to the patient's skin. The instrument console contains the power source, vacuum pump, temperature controls and all related controls to operate multiple suction chambers. The suction chambers are connected to the console by a flexible connection. Each of the chambers is controlled by a preset temperature control to provide an optimal skin warming temperature. Both chambers share an adjustable common vacuum source that affects all chambers equally.

STARTUP

Because each chamber is calibrated separately, it is important that the numbered chambers be connected to the proper chamber control channel. Failure to connect the chambers properly may result in chamber temperature calibration errors.

Connect the blister chambers to the instrument observing the chamber numbering. Any number of chambers, up to the capacity of the instrument (2 or 4) can be used. The vacuum and electrical connections are simply plugged into the control console connections.

Do not connect the vacuum connections of chambers that you do not intend to use. This will cause a large vacuum leak and adequate vacuum to the operating chambers will be impossible.

PREHEATING

Preheating can be accomplished with the chambers either on or off the patient. It is a decision that can be made based on research criteria, patient comfort and researcher's desire. To start pre-heating, turn the **POWER** switch on. The power lamp should glow and the chamber lamps should come on. At this time the chambers are heating. The temperature of the chamber is preset typically to 40 degrees centigrade unless specified otherwise. As each chamber reaches it's preset temperature, the chamber lamps will cycle on and off. Typically, it takes 5 to 10 minutes for the chamber temperature to stabilize.

Do not allow vacuum to be connected to a chamber that is preheating and not connected to a patient. The volume of airflow through the open chamber will cool the chamber faster than it can preheat!

If you connect the vacuum line to an unused chamber while other chambers are in use, a sudden drop of vacuum will be experienced as chamber is evacuated by the system. This may damage any blisters already being formed.

CHAMBER APPLICATION

The chamber must be secured to the patient's skin by use of the hook and loop straps supplied. A leak proof fitting must be made between the skin and orifice plate or the vacuum will not form blisters. Once the process is started, the fit is usually not as critical as the vacuum tends to self-seal as the blisters are formed through the orifice openings. The chamber heating system, which provides a slight warming of the orifice plate and the patient's skin surface, enhances blister formation

VACUUM CONTROL

Open the VACUUM control valve fully (CCW rotation) and turn on the VACUUM power switch. The VACUUM lamp should glow and the vacuum pump will run. At this time the vacuum gauge should read zero. Slowly close the vacuum control valve (CW rotation). The vacuum should start to increase as the connected chambers are evacuated. Adjust the vacuum bleeder valve for the vacuum desired. The gauge shows the vacuum for all chambers. The blister chambers cannot be adjusted individually.

If the gauge does not show adequate vacuum there is a leak in either a chamber itself or the chamber/patient fit. Go to the vacuum troubleshooting chart for more information.

The application of a moderate negative pressure from the instrument console, to the chamber interior, causes the patient's skin to be gently drawn through the opening(s) in the orifice plate. The results are typical suction blisters, approximately the size of the opening(s) in the orifice plate. The skin and blister area is generally not damaged and patient discomfort is minimal.

Time and vacuum values are strictly experimental and can best be achieved through trial and error. Excessive vacuum will cause rupture of the blister roof while inadequate vacuum will cause improperly formed blisters.

MAINTENANCE

NEGATIVE PRESSURE CHAMBER

The negative pressure chamber is fabricated of mostly plastic components, with two removable threaded caps. The upper cap is fitted with a clear viewing lens so that the actual blister formation can be observed. The opposite end of the chamber is fitted with a removable orifice plate that is placed on the patient's skin. Since this plate is simply threaded onto the chamber end, multiple plates with different opening patterns can be interchanged as desired.

CHAMBER CLEANING

*Do not use water or a steam autoclave to clean the chambers or connecting tubing.
Damage to the electrical components will result.*

The plastic chambers should be cleaned only with alcohol swabs or wipes. The blister orifice plates, once removed from the chambers, can be cleaned in a like manner, washed, or steam autoclaved. After many autoclave cycles it is possible that the metal to plastic bond on the orifice plate will loosen. If this happens, the plates can be easily repaired by you (see orifice plate repair) or returned for service.

If the chamber is disassembled for any reason pay particular attention to the positioning of the vacuum seals beneath the caps. Lubricate these seals with a small amount of lubricant such as K-Y jelly to assure a leak free seal.

ORIFICE PLATE REPAIR

If the metal orifice plate becomes loose in the orifice plate housing, the silicon seal has failed. The temperatures encountered in autoclaving and the dissimilar expansion and contraction of the metal plate and the surrounding plastic cap usually cause this. If you desire to repair the orifice plate, simply clean all traces of old silicon adhesive from the plate and collar. Thoroughly clean all parts with alcohol and allow to dry. Spread a small bead of silicon adhesive (General Electric-RTV or equal) around the groove of the orifice collar, Insert the orifice plate and allow the silicon to exude from the joint. Wipe excesses with a cotton ball dampened with alcohol and allow to cure at least 12 hours. Optionally, The orifice plate and collar can be returned for factory service.

VACUUM LEAKS

The vacuum system is a common manifold system, which means that all the chambers will se the same vacuum. The vacuum in the manifold is equalized to the atmospheric pressure by the vacuum adjustment Valve. With this design, a leak in any component will be reflected throughout the system.

Vacuum leaks can be easily isolated since the vacuum gauge can be used to provide critical system information. Follow the vacuum troubleshooting chart for quick vacuum problem diagnosis.

TEMPERATURE CONTROL

The blister chambers are controlled individually by a solid state control system. Since each chamber is separate, the chambers are calibrated at the time of production for each channel and are marked. If the chambers are improperly connected, a calibration error will result in the temperature of the chamber. When this unit was produced, the chambers were calibrated for an orifice plate temperature of _____degrees centigrade. Should another temperature be required the chambers can be adjusted by the user or returned for factory

Temperature Calibration

Note: Generally, temperature calibration is unnecessary and it is not considered to be a user adjustment. By the nature of the instrument design, chamber and plate temperature fluctuations are normal and generally do not affect the success of the blister formation.

CAUTION!

HIGH VOLTAGE AND MOVING PARTS WILL BE PRESENT WHEN THE INSTRUMENT IS OPERATED WITHOUT THE OUTER CASE. ONLY PERSONS FAMILIAR WITH THE OPERATION OF ENERGIZED EQUIPMENT SHOULD PERFORM THIS PROCEDURE. TESTING SHOULD BE PERFORMED TO INSURE THE ELECTRICAL SAFETY OF THE UNIT AFTER REASSEMBLY

MATERIALS REQUIRED

- Small common blade screwdriver
- Accurate digital thermometer with a remote sensing element
- cotton balls
- Rubber bands

CALIBRATION PROCEDURE

1. Remove the four screws in the corners of the front panel and the two screws on the bottom of the instrument
2. Gently slide the instrument from its housing. Take caution that the wire for the rear fan does not become damaged or detached
3. Locate the chamber calibration controls on the bottom of the chassis. If the instrument is an NP-2 there is one circuit board. If the instrument is an NP-4 there are two circuit boards. Each circuit board is divided into two sections. Each section controls one chamber. The boards control the chambers nearest to them.
4. Each section contains two controls. The control pointing outward is a multi-turn control, and is the fine temperature adjustment. The control on the board, facing upward is the coarse temperature adjustment. These may be covered with a tape dot or other sealer. In any either the tape can be removed and the control turned.
5. Attach the sensor of the digital thermometer to the orifice plate with a rubber band. Make sure it is in contact with the plate. This is critical!
6. Completely cover the orifice plate with a 1/2-inch minimum layer of cotton balls and secure with additional rubber bands.
7. Locate the chamber away from any abnormal airflow that could affect the heating of the chamber.
8. Turn on the control console power. Do not operate the vacuum pump or air will be pulled through the chamber and calibration will be impossible.

9. *The reading displayed on the thermometer will be the orifice plate temperature. The actual internal chamber temperature will be somewhat higher. Wait until the reading becomes stable. This typically takes 5-10 minutes. The chamber is heating when the lamps are on. When the chamber has become stable, the lamps operate briefly, making only small corrections to the chamber temperature.*
10. Slowly adjust the fine, multi-turn control for the associated chamber to increase or decrease the chamber temperature. Allow time for the chamber to stabilize before making additional adjustments. The coarse adjustment may be used if the desired setting can not be achieved with the fine adjustment.
11. Repeat as required for each chamber until a satisfactory temperature is achieved.
12. Reassemble the instrument into the housing. Make sure that the rear fan cable did not disconnect or become pinched and that it is free of moving parts.
13. Install all removed screws

ELECTRICAL TESTING

Note:

If care is taken during the calibration procedure, it is not expected that the safety aspects of the instrument will be compromised. It is still recommended that the electrical tests be performed to assure safe operation since we have no control over repairs or other activities after the instrument leaves our facility.

Electrically test the instrument to verify that the instrument grounding and leakage values are within acceptable limits.

The ground resistance should be less than .5 ohm and the chassis leakage should be less than 300ua (NFPA-99/7)

WARRANTY AND SERVICE POLICY

The Negative Pressure System is considered to be a research instrument, therefore no guarantees regarding its fitness for any intended use or purpose is offered or implied.

Electronic Diversities is not in a position of medical advisement, therefore, the customer and user(s), by purchasing and use of this instrument, agree to take full responsibility and liability for the determination of suitability and use of this system.

No other warranty is either expressed or implied. Electronic Diversities shall not be held responsible for any consequences, harm or loss resulting from the use of this Negative Pressure Instrument System, the procedures involved or medical, mechanical or technical failures of any sort.

The Negative Pressure Cutaneous Suction System is guaranteed to be free of defects in material and workmanship for a period of one year from the date of delivery. All repairs must be performed at our facility.

Systems requiring service must be shipped prepaid, with all chambers, to Electronic Diversities. The system will be promptly serviced and returned via ground shipping, at no charge, within the continental U.S. Shipping charges will apply for return shipping to locations outside of the continental U.S. or for air shipping service if requested.

Charges will apply for any non-warranty service, at our prevailing rate, plus shipping costs.

ORDERING PROCEDURE

Consult our web site www.electdiv.com for current pricing and updated information, information, or contact us directly to request a quotation.

All orders must be placed via purchase order, and may be placed placed via e-mail. Facsimile or standard mail.

Since these units are custom fabricated, we cannot accept verbal orders. Terms are Net 30 days, payable in U.S. Funds, to rated US corporations and institutions for U.S. delivery. Unless other arrangements have been made, prepaid orders are required for foreign or non-rated corporation orders. VAT or other duties, that may be applied to foreign orders, are the responsibility of the purchaser.

Delivery can be anticipated, in most cases, within 6 to 8 weeks from receipt of your order. We attempt to expedite fabrication whenever possible. An order confirmation, including total costs, terms, scheduled shipping date and estimated delivery date will be provided shortly after acceptance of your order.

PLEASE PROVIDE THE FOLLOWING INFORMATION:

1. Instrument model (NP-2, NP-4 or NP-V) and any options or accessories.
2. Desired temperature set point calibration, if other than 40°C.
3. If ordering special orifice plates specify hole pattern and hole size or use a copy of the Orifice Plate drawing to illustrate the desired configuration. A company purchase order showing the complete delivery address or special delivery instructions with the name of a contact person telephone and fax numbers,
4. Prices posted do not include shipping charges.
5. Unless otherwise requested, shipping is via UPS Ground Service

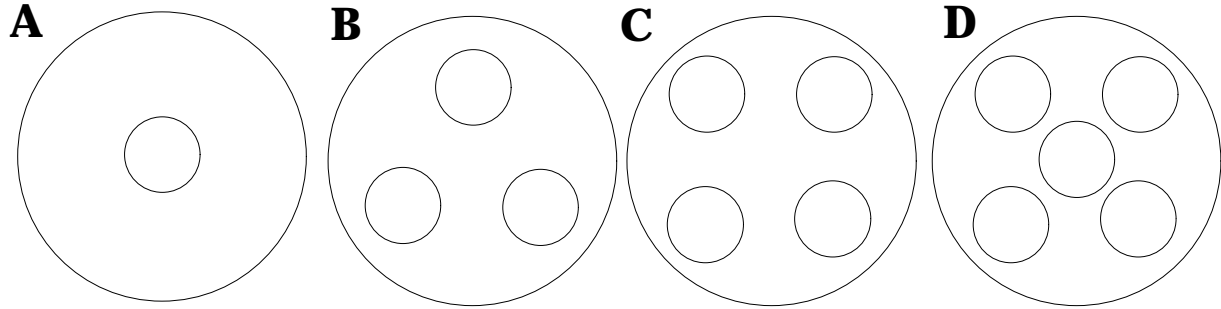
Foreign Orders.

- 1. You must specify the proper operating voltage and frequency for your location.**
All units are fabricated as 120 VAC/60 HZ units. Transformers can be supplied for other voltages or can be locally obtained if desired.
2. Please advise us of any specific customs or import limitations on foreign orders.
3. Payment of VAT and other duties is the responsibility of the purchaser.
4. Unless otherwise requested, all shipments are made via UPS International service.

Direct all orders and inquiries to...

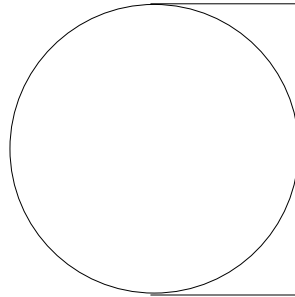
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ALL ARE 38mm DIAMETER WITH 10mm ORIFICES**



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NO SCALE

NEGATIVE PRESSURE NP-2 / NP-4

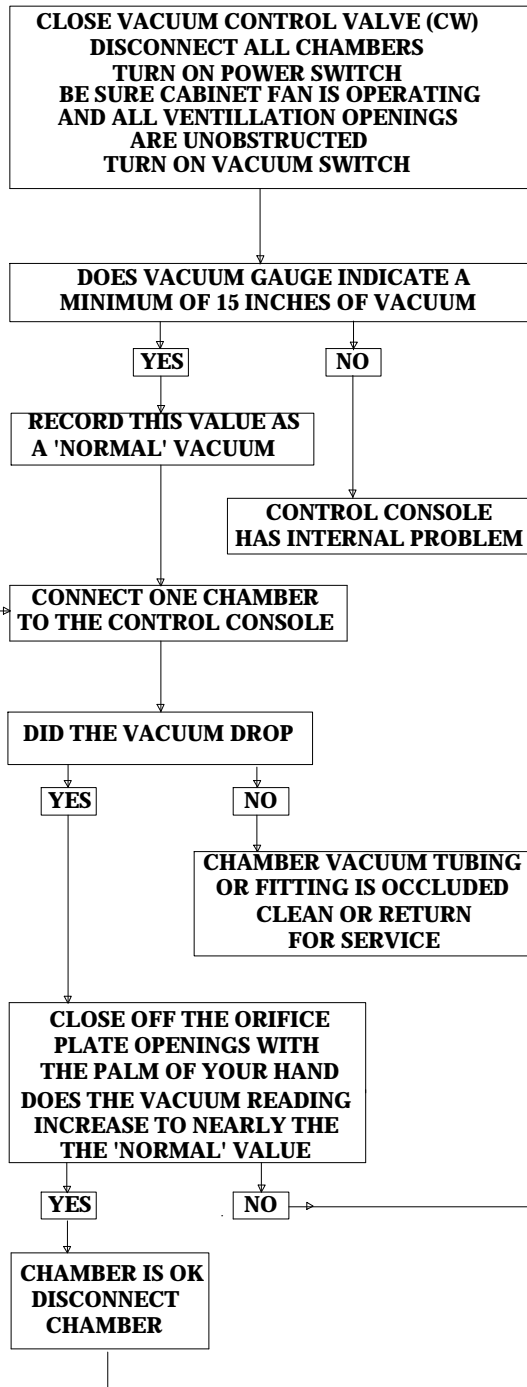
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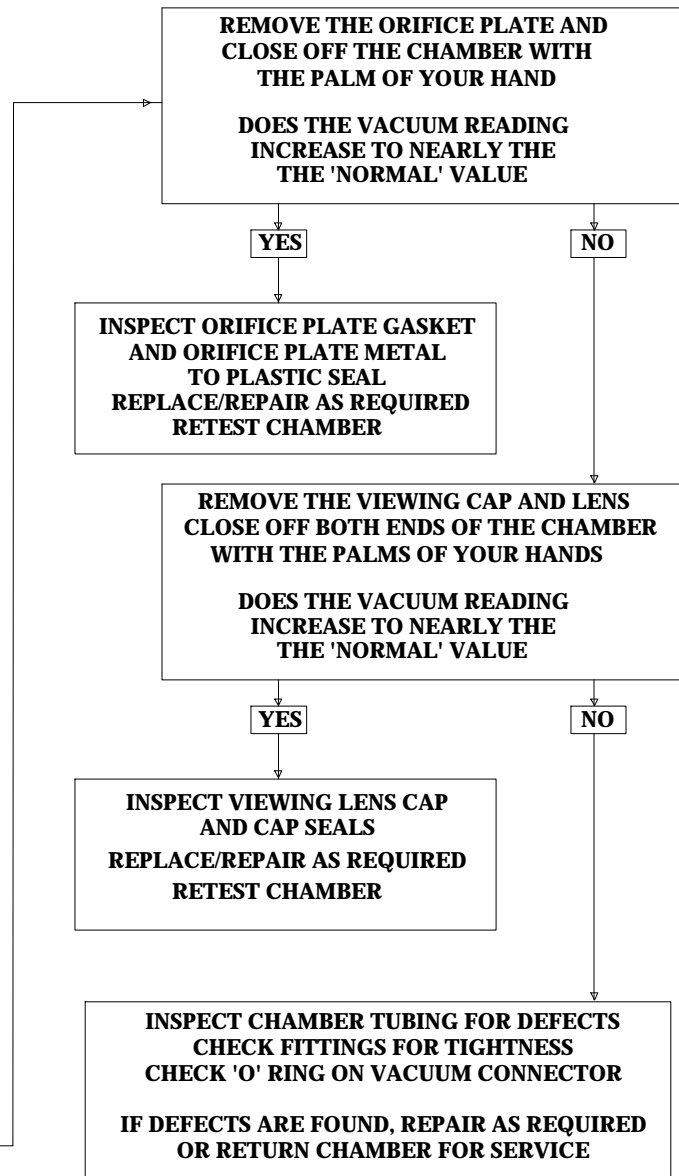
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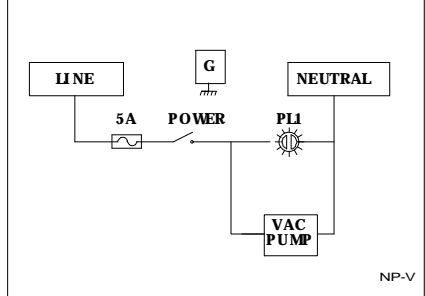
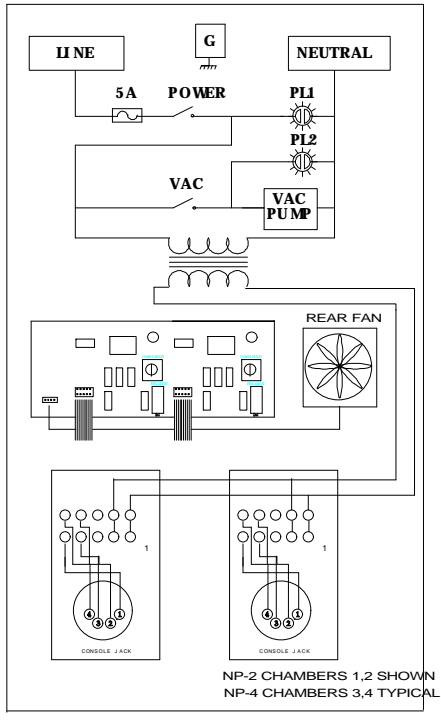
VACUUM PROBLEM TROUBLESHOOTING

VACUUM SYSTEM TROUBLESHOOTING



BLISTER CHAMBER TROUBLESHOOTING





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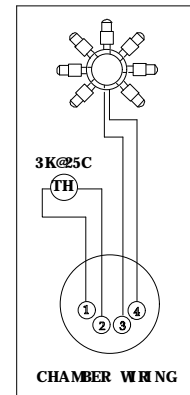
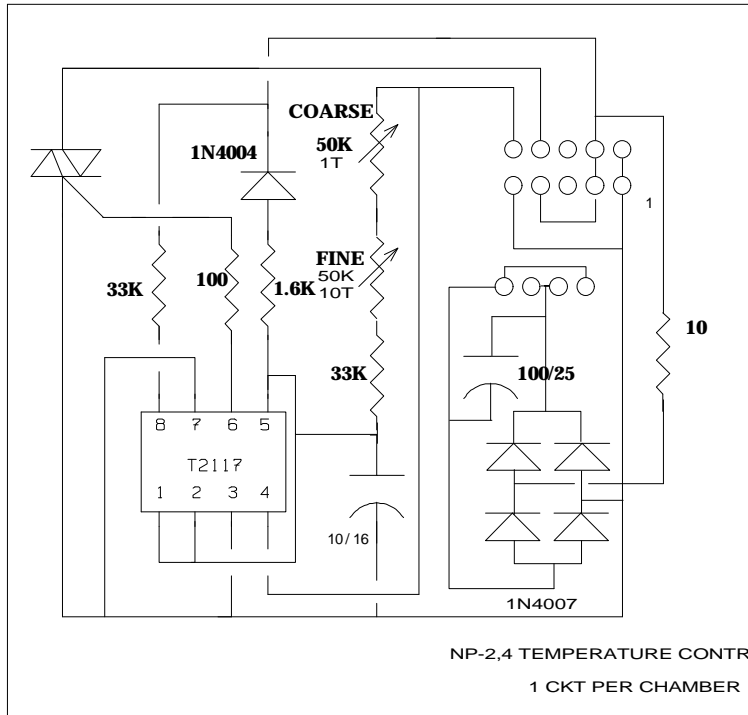
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NEGATIVE PRESSURE INSTRUMENT NP- X

VACUUM / ELECTRICAL DATA



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NEGATIVE PRESSURE INSTRUMENT NP- X

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