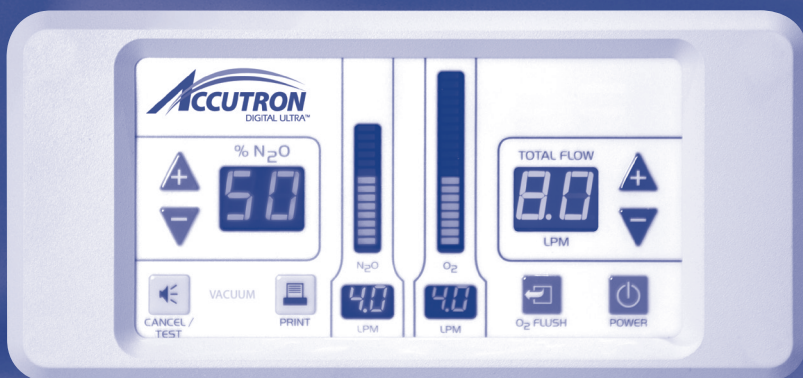


Digital Ultra™ Flowmeter User Manual



- **Flushmount**
- **Flexmount**
- **Digital Newport™ Flowmeter System**

INDICATIONS FOR USE

To be used in nitrous oxide-oxygen sedation systems for delivering to a patient a mixture of nitrous oxide and oxygen gases with a maximum nitrous oxide concentration of 70%.

CONTRAINDICATIONS

Contraindications for use of nitrous oxide/oxygen inhalation may include:

1. some chronic obstructive pulmonary diseases;
2. severe emotional disturbances or drug-related dependencies;
3. first trimester of pregnancy;
4. treatment with bleomycin sulfate;
5. methylenetetrahydrofolate reductase deficiency.
6. severe asthma

Whenever possible, appropriate medical specialists should be consulted before administering analgesic/anxiolytic agents to patients with significant underlying medical conditions (e.g., severe obstructive pulmonary disease, congestive heart failure, sickle cell disease, acute otitis media, recent tympanic membrane graft, acute severe head injury.¹ Operator must review patient history with regard to these health issues.

¹ American Academy of Pediatric Dentistry. Clinical Guidelines: Guidelines on Use of Nitrous Oxide for Pediatric Dental Patients. *Pediatr Dent* 2009;31(6):148-151. Available at: "<http://www.aapd.org/media/policies.asp>". Accessed February 23, 2010.

WARNINGS

To be used only by a professional trained in the use of nitrous oxide, using titration method.

Patient should always be closely monitored during nitrous oxide use. If patient has an adverse reaction, reduce or stop the flow of nitrous oxide as needed. The O₂ flush button can be used to rapidly purge the lines of N₂O. If patient does not show signs of quick recovery, remove nasal hood and treat with pure oxygen from either the O₂ resuscitator fitting or an auxiliary oxygen tank using a demand valve, oxygen assisted manual resuscitator, or equivalent. Call for emergency assistance if rapid response is not achieved.

Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.

For use with 100-240 V AC, 50/60 Hz only.

Use only hospital grade power cord connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade." For emergency power shut-off and isolation, unplug power cord from wall outlet.

Unit is calibrated at the factory to $\pm 5\%$ per industry recommendations.

Verify that the correct gases are being delivered to the correct flowmeter inlets by performing the oxygen failsafe test in section VII.

NIOSH recommends N₂O levels in operator area be kept below 25 PPM.

Administer pure oxygen to patient for at least 5 minutes after nitrous oxide procedure.

Contaminants, especially greases and oils can catch fire in the presence of oxygen. Do not allow hand lotions or unapproved lubricants to touch seals, gaskets, or gas contact surfaces. Take care to keep oxygen ports/lines clean and covered unless changing cylinders or moving portables within a facility. Movement between facilities requires repackaging in original protective packaging. Failure to do so may cause fire and may void warranty.

CAUTIONS

Federal (U.S.) law restricts this device to sale by or on order of a dentist or physician.

Do not attempt to repair, alter, or calibrate this device. Unauthorized repair, alteration or misuse of this device is likely to adversely affect the performance and will void the warranty.

Safety features contained in this notice should be routinely checked to assure proper function. If any of these safety features are not functioning properly, contact your dealer or Crosstex and arrange for the necessary repairs before reusing the machine.

Always use clean, dry medical gases. Introduction of moisture or other contaminants into analgesia gas machines may result in defective operation.

Users of electronic flowmeters that control % oxygen should be aware that Accutron Flowmeters control % nitrous oxide.

ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment passes radiated emissions requirements for CISPR 11 Class B devices and EM field immunity requirements of IEC6100-4-3. Operating other radio frequency devices in the vicinity of this equipment should be evaluated accordingly. The minimum distance between this equipment and other RF devices is given by the formula below and the table. The minimum distance is determined by the power of the RF device operating in the vicinity of the digital flow meter.

$$\text{minimum distance: } d = \frac{\sqrt{(\text{Power})}}{0.388} \text{ meters}$$

Power	Distance (meters)	Distance (feet or inches)
0.01 Watts	0.258	10 inches
0.1 Watts	0.816	2 feet and 8 inches
1 Watts	2.58	8 feet and 6 inches
10 Watts	8.16	26 feet and 9 inches
over 10 Watts	Operating the digital flow meter within close proximity of such a transmitter is not recommended.	

Warning: Changes or modifications to the equipment may result in unsafe operation.



Recycling

Old electrical and electronic equipment must be disposed separately and may not be included in the regular domestic waste. Dispose in accordance with prevailing ordinances. Alternatively, the unit can be handed over to Crosstex for correct recycling.

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I. TECHNICAL SPECIFICATIONS

Physical

Flushmount Main Unit	8x4x7.5" (20,3x10,2x19 cm)	Weight: 5.2 lbs (2,4 kg)
Flushmount Controller	9x4x1.5" (22,9x10,2x3,8 cm)	Weight: 1.0 lbs (0,8 kg)
Flexmount	8x4x7.5" (20,3x10,2x19 cm)	Weight: 8.2 lbs (3,7 kg)
Digital Newport™ Flowmeter	19x32x22" (48x80x56 cm)	Weight: 75 lbs (34 kg)

Electrical

100-240 V AC 50/60 Hz. 24 W
Socket is IEC/EN 60320-1 C14 and accepts an IEC/EN 60320-1 C13 connector
Power cords available for most countries

Internal Battery

Lithium coin battery, 3v CR2032

Fuses

T500mA, 250v (quantity 2) part number 26456-FRU

Gas Supply

Oxygen: 100 LPM at 50-66 psi (3.5-4.5 bar)
Nitrous Oxide: 10 LPM at 50-66 PSI (3.5-4.5 bar)

Gas Fittings

Oxygen Inlet: Male DISS CGA 1240
Nitrous Oxide Inlet: Male DISS CGA 1040
Mixed Gas Outlet: Male DISS CGA 1160 or 1/4" Hose Barb
Oxygen Resuscitator Connection: 1/4" I.D. Quick Disconnect

Gas Delivery

Total Flow: Legacy 1.0-9.9 LPM, Hi-flo 1.0-18.0 LPM O2 % 30-100 N2O %: 0-70
Oxygen Flow: Legacy 1.0-9.9 LPM Hi-flo 1-18 lpm
(accuracy per ISO 15002, greater of ± 0.5 lpm or ±10% Flow)
Nitrous Oxide Flow: Legacy 0-6.9 lpm Hi-flo 0-12.6 LPM
(accuracy per ISO 15002, greater of ± 0.5 lpm or ±10% Flow)
Oxygen Flush: Minimum 20 LPM
Oxygen Resuscitator Flow: Minimum 100 LPM, 100% O2

Environmental

Transportation/Storage: Temperature: -40°C to +70°C (-40°F to 158°F)
Humidity: 10-100%

Operating Conditions: Temperature: 15°C to 32°C (68°F to 90°F)
Humidity: 30-75%
Atmospheric Pressure: 72-101 kPa (543-760 mmHg)

Accessories

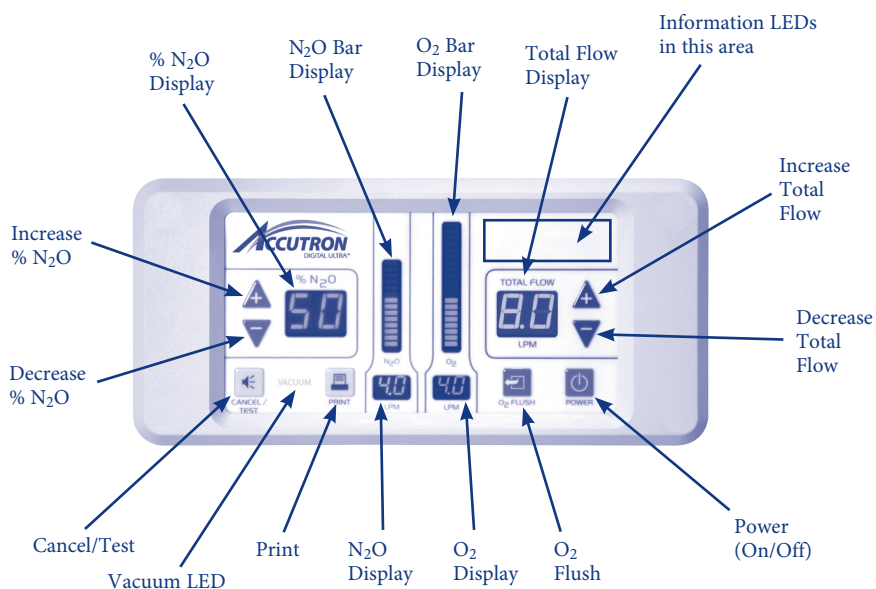
Printer
Remote Control

Applied Part (rated BF)

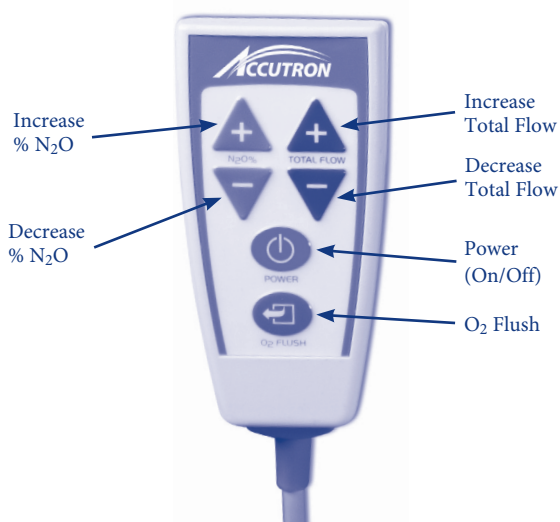
PIP+™ Scavenging Circuit II	PN 32007
PIP+™ Remote Flow System Scavenging Circuit II	PN 32009
ClearView™ Scavenging Circuit II	PN 43004
ClearView™ Remote Flow System Scavenging Circuit II	PN 43005
Axess™ Scavenging Circuit	PN 53005
Axess™ Remote Flow System Scavenging Circuit	PN 53006

II. CONTROL/DISPLAY FEATURES

Front Control/Display Panel



Remote Control



Front Control/Display Panel & Remote Control

Control/Display Panel – Easy-to-use control panel allows setting Total Flow and N₂O concentration with the touch of a finger. Bright, color-coded displays make it simple to monitor status, even from a distance. Optional hand-held Remote allows functional control at patient chairside.

Total Flow Control – Allows setting of Total Flow in either (.1) LPM or (.5) LPM increments. Once set, the Total Flow will remain constant even if % N₂O is changed.

Total Flow Display – Shows Total Flow in numeric LPM format with yellow LEDs.

% N₂O Control – Allows setting of N₂O concentration in either 1% or 5% increments up to a maximum of 70%. Once set, % N₂O will remain constant even if Total Flow is adjusted.

% N₂O Display – Shows % N₂O in numeric format with blue LEDs.

Power – Turns unit on and off with the push of a button.

Flush Control – Ceases N₂O Flow and provides a minimum of 20 LPM of pure O₂ as long as button is pressed.

O₂ Flow – Two green LED displays show O₂ Flow in both LPM numbers and graphic bars simulating standard flow tube.

N₂O Flow – Two blue LED displays show N₂O Flow in both LPM numbers and graphic bars simulating standard flow tube.

Print – When optional printer is installed, provides printout of current conditions.

Cancel/Test – During an alarm mode, turns off audio alarm for one minute. During normal mode, performs self-check of all displays.

Information LEDs – Informs administrator of failures with O₂ supply, N₂O supply, O₂ flush, or mixed gas line to patient. Also indicates if remote vacuum is connected.

Model Numbers and Configurations

Model numbers have a 5 digits base number that indicates a basic configuration such as 56100. Some models may have additional differences and will have an additional -XX or -XXX on the end of the base number such as 56100-UK or 56100-AUS. Unless otherwise noted, all -XX or -XXX models are essentially the same as the base models and will not be listed separately in each section. For Example, if it references 56100 it applies to 56100-UK, 56100-SS, 56100-BWR etc. unless stated otherwise.

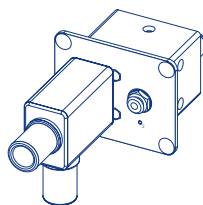
III. FLOWMETER MODELS

FLUSHMOUNT MODEL



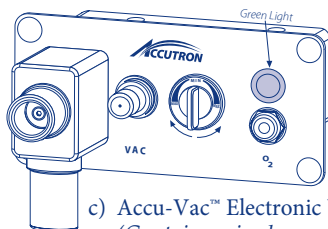
Two piece design for easy installation into a cabinet or a wall. Thin control module located away from main module, power, and gas lines, requires remote outlet.

Flushmount Remote Outlets Options



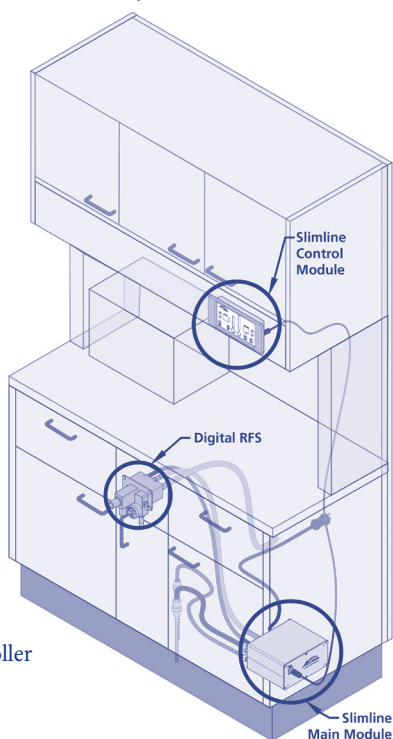
- a) Standard
(Contains mixed gas outlet and O₂ resuscitator connection)

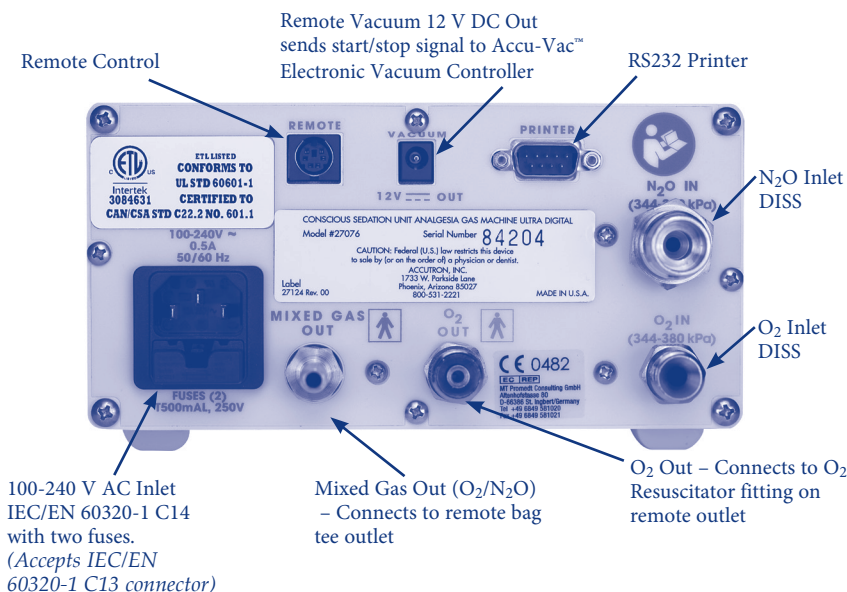
- b) RFS™ Remote Flow System
(Contains mixed gas outlet, O₂ resuscitator, and vacuum controller with gauge display)



- c) Accu-Vac™ Electronic Vacuum Controller
(Contains mixed gas outlet, O₂ resuscitator, and vacuum controller with LED display)

Sample Installation





Flushmount Main Module Utility Connections

O₂ Inlet – Labeled O₂ IN – Equipped with male CGA 1240 DISS fitting to prevent gas mix-up.

N₂O Inlet – Labeled N₂O IN – Equipped with male CGA 1040 DISS fitting to prevent gas mix-up.

O₂ Out – Labeled O₂ OUT – Equipped with male CGA 1240 DISS fitting, provides oxygen for resuscitator.

Mixed Gas Port – Equipped with male CGA 1160 DISS fitting (Medical Air)

Power Cord Inlet – Clearly labeled 100-240 V AC, 50/60 Hz and protected by two fuses for added safety. Fuses are 240 V, 0.5A, slow-blow. To disconnect power, unplug cord. Do not position where this disconnection would be difficult.

RS232 Printer Connector – Clearly labeled and designed for use with optional Crosstex-approved printer.

Remote Control Connector – Remote Control connection. Using the Remote Control, general adjustments can be made from a distance of up to 10 feet away from device.

Remote Vacuum Valve Connector – Clearly labeled and designed to actuate a vacuum valve in the Accu-Vac™ Automatic Vacuum Scavenging Port (PN 56955).

O₂ Out Connector – Direct connection to oxygen for use with resuscitator. Provides minimum of 100 LPM of oxygen.

FLEXMOUNT MODEL

51000 series, 56100 series, 56200 series, 56300 series, 56400 series, 56500 series



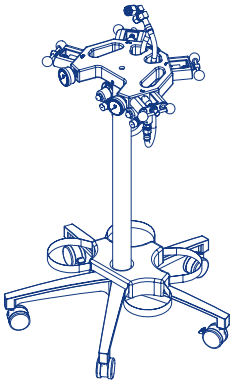
Can be mounted on a number of different devices.

O₂ Resuscitator Fitting

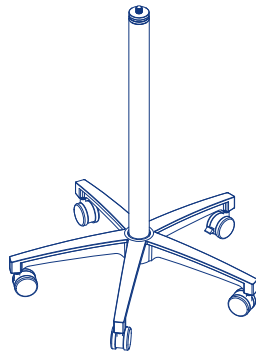
Mixed Gas Port for Bag Tee

Flexmount Mounting Options

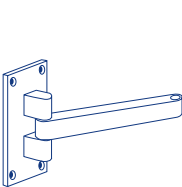
Warning! Portable systems are designed for movement within a facility. Care must be taken that contaminants do not enter gas ports/lines. Keep hoses/cylinders attached unless changing. See Warning on page 2.



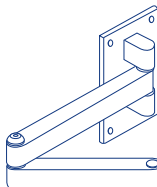
4-Cylinder Portable System
Setup per instruction 28372



Mobile Stand
Setup per instruction 27420

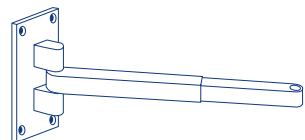


9" Wall Arm



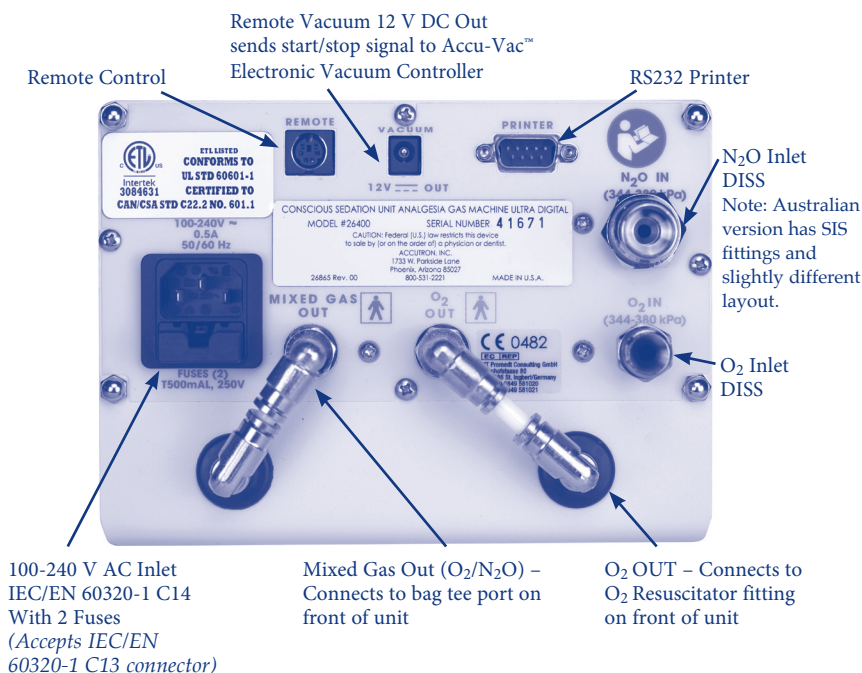
16" Bi-fold Wall Arm

All wall arms use instruction 28931

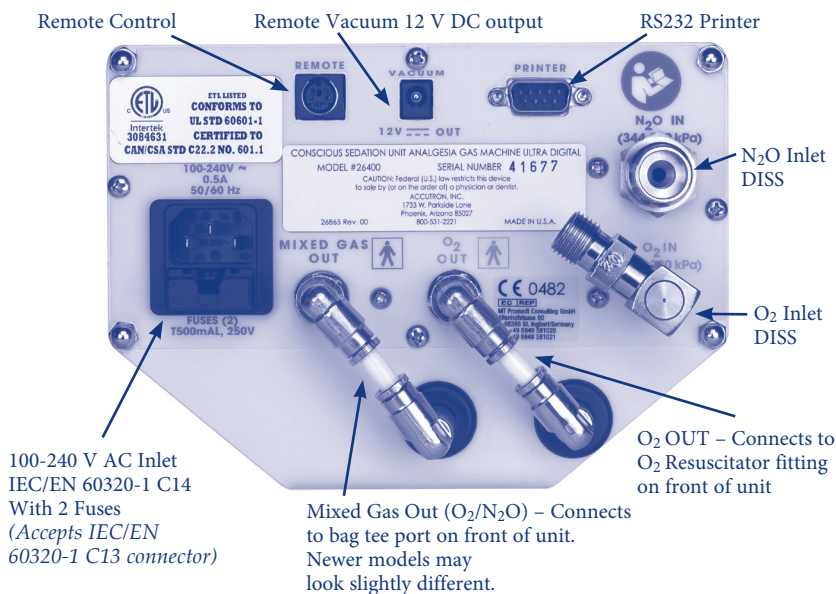


Telescoping Wall Arm
(Extends 12"-17")

Wall Arm and Mobile Stand version



4 Cylinder version



Flexmount Utility Connections

O₂ Inlet – Labeled O₂ IN – Equipped with male CGA 1240 DISS fitting to prevent gas mix-up.

N₂O Inlet – Labeled N₂O IN – Equipped with male CGA 1040 DISS fitting to prevent gas mix-up.

O₂ Out – Labeled O₂ OUT – Connects to oxygen resuscitator fitting on front.

Mixed Gas Out – Connects to bag tee port on front.

Power Cord Inlet – Clearly labeled 100-240 V AC, 50/60 Hz and protected by two fuses for added safety. Fuse ratings are 240 V, 0.5 A, slow-blow. To disconnect power, unplug cord. Do not position meter where this disconnection would be difficult.

RS232 Printer Connector – Clearly labeled and designed for use with optional Accutron-approved printer.

Remote Control Connector – Remote Control connection. Using the Remote Control, general adjustments can be made from a distance of up to 10 feet away from device.

O₂ Out Connector – Direct connection to oxygen resuscitator fitting on front. Provides minimum of 100 LPM of oxygen.

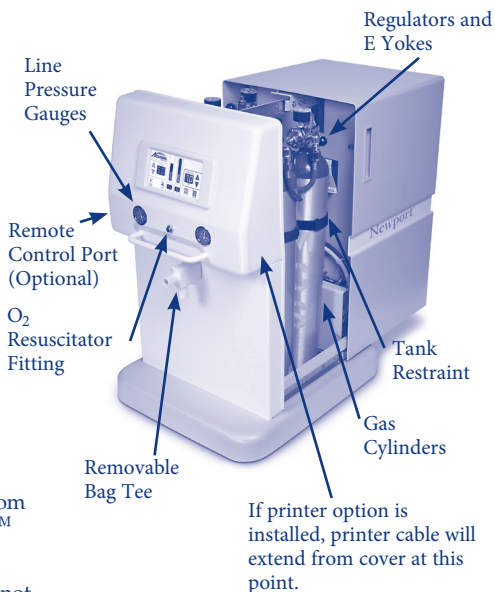
DIGITAL NEWPORT™ FLOWMETER SYSTEM

Handle
Warning: Do not
hold handle
when
opening
cabinet.

10'
Hospital
Grade
Power
Cord

Power Socket
Note: Power Cord must be either
unplugged from socket or unwound from
storage cleats when opening Newport™
Flowmeter System.

To disconnect power, unplug cord. Do not
position where this would be difficult.



Digital Newport™ Flowmeter System Setup and Connections

View – When looking at the front of the Newport™ Flowmeter System cabinet, Nitrous Oxide is on the left as shown by the blue Nitrous Oxide gauge. Oxygen is on the right as shown by the oxygen gauge.

Opening Newport™ Flowmeter System Cabinet – Open the Newport™ Flowmeter System by placing one hand on the front cover and the other in the handle on the side. Pull handle back all the way. Make sure the power cord is unplugged from the socket in the skirt first. Do not hold push handle when opening as it may pinch fingers.

Install Gas Cylinders –

1. Undo Velcro straps
2. Angle tank into position
3. Strap tanks loosely
4. Remove regulators from accessories box
5. Attach regulators to tanks by loosening yoke handle, verifying seal is in place, aligning seal with gas opening, aligning pins with holes in yoke, tightening yoke onto cylinder

NOTE: Regulators are pinned to match gas cylinders. Connect gas hoses to regulator outputs.

NOTE: Hoses and regulators use DISS fittings to prevent mix up. Rotate cylinders so that regulators fit inside.

Open Gas Cylinders – Pick one tank of each gas to be “in use” tank and attach “in use” label to cylinder. Open these cylinders using the cylinder wrench provided in accessory box. Close Newport™ Flowmeter System cabinet.

Connect Power –

1. Plug cord back into skirt outlet
2. Plug other end of cord into receptacle

NOTE: System will operate from 100-240 V, 50-60 Hz. Internal power supply will switch automatically.

Scavenging Circuit –

- Install bag tee from accessories box into front of Newport™ Flowmeter System.
- Attach scavenging circuit to bag tee.
- Connect vacuum hose to system vacuum.
- Install nasal hood into scavenging circuit and start vacuum flow per scavenging instructions.

Start up – See Section VII , Directions For Use

Digital Newport™ Flowmeter System: Managing Gas Supply

Note: Power Cord must be either unplugged from socket or unwound from storage cleats when opening Newport™ Flowmeter.

1. Identify the two in-use tanks (N_2O and O_2) by attaching “in-use” identification tags to them.
2. When one of the in-use tanks is empty, close the tank by turning the valve clockwise. Leave the empty tank in place.
3. Move the “in-use” tag to the appropriate reserve tank, which now becomes the in-use tank. Replace the empty tank with a new tank, which then becomes the reserve tank.
4. Open the valve of the new in-use tank by turning counterclockwise.
Note: Do not open the reserve tank until the in-use tank is empty. When changing gas tanks, make certain both same gas cylinders that are involved in the exchange are closed. Always remember to switch the “in-use” tags over to the new tanks.
5. Contact gas supplier to request new gas cylinders as needed.

Digital Newport™ Flowmeter System: Changing Gas Cylinders

Always use clean, dry medical grade gases. Introduction of moisture or other contaminants into Accutron Analgesia gas machines may result in defective operation.

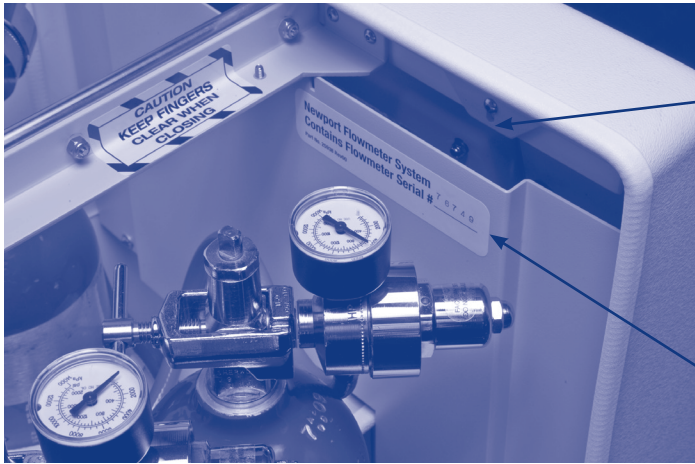
The Digital Newport™ Flowmeter System is designed to operate with a 50-55 psi line pressure on each gas (O_2 and N_2O). The line pressure can be determined by reading the O_2 and the N_2O line pressure gauges that are located on the front panel of the Newport™ Flowmeter.

The Digital Newport™ Flowmeter System has features incorporated to make cylinder change-out easy. To assure proper operation of the system, 4 cylinders must be properly installed at all times. Please review the following cylinder replacement procedures before attempting to change cylinders.

Note: Power Cord must be either unplugged from socket or unwound from storage cleats when opening Newport™ Flowmeter.

1. Open the tank enclosure by sliding the cover to the rear.
2. Close the valve on the empty tank (clockwise).
3. Release the restraint on the empty tank.
4. Tilt the empty tank out slightly.
5. Loosen the round handle on the regulator yoke.
6. Remove the regulator from the empty tank (make certain that the regulator is not dropped or damaged while it is off the tank).
7. Lay the empty cylinder down on the floor (cylinders should only stand upright when properly restrained as they can easily fall over).
8. Pick up the full replacement tank and place the bottom of the tank onto the floor of the Newport™ Flowmeter, leaving it slightly tilted outward for easy replacement of the regulator.
9. Check to assure that the sealing gasket has remained on the regulator's E yoke.
10. Reattach the regulator to the new full tank by sliding the yoke (attached to the regulator) over the top of the tank post aligning the index pins with the corresponding holes in the tank post.
11. Tighten the round handle on the regulator yoke.
12. Push the tank into an upright position. Attach and tighten the tank restraint.

Digital Newport™ Flowmeter System: Control Module and Main Module Locations



Control Module is behind shield at front of unit.

Serial # Label



Main flowmeter module is behind shield at rear of unit. Fuses are located in fuse tray at power cord socket on back of flowmeter.

IV. SAFETY FEATURES

O₂ Fail Safe System – Offers assurance that N₂O ceases if the O₂ supply is interrupted or reduced. Alarm will sound, FAILURE OXYGEN LEDs will light, and N₂O flow will cease.

N₂O Supply Warning – Triggers an alarm if the N₂O supply cannot keep up with user's needs. Alarm will sound and FAILURE NITROUS LEDS will light. Flow switches to 100% oxygen.

Mixed Gas Flow to Patient – Monitors pressure in mixed gas line and triggers an alarm if flow to patient is obstructed. Alarm will sound and FAILURE NITROUS OXYGEN LEDS will light.

Emergency Air Valve – Automatically provides patient with ambient air if gas flow is interrupted. Located on remote bag tee.

Directional Check Valve – Prevents re-breathing of exhaled gases and protects against CO₂ buildup. Located on remote bag tee.

O₂ Resuscitator Connection – Direct connection to O₂ for use with resuscitator. Port is always open and provides 100 LPM minimum of pure oxygen.

Gas Specific Connections - DISS or SIS fittings allow only correct connections to gas hoses. and regulators. Pin Index Safety system only allow correct connections to gas cylinders.

V. GENERAL INSTRUCTIONS

1. Warranty

Unpack Digital Ultra™ Flowmeter and inspect to make certain that the unit has not been damaged during shipment.

The unit's serial number is located on the back of Digital Ultra Flowmeter (see page 17 for Digital Newport™ serial number location). Record the serial number in the area provided at the back of this booklet. Once Digital Ultra™ Flushmount Flowmeter is mounted into a cabinet, the serial number will no longer be visible. Always reference the serial number when corresponding with Crosstex.

Complete the warranty card supplied with Digital Ultra Flowmeter System and mail to Crosstex. Completion of this step ensures proper device warranty coverage. Accutron Digital Ultra™ Analgesia Machines carry a two-year limited warranty (see Warranty on page 26 for details).

2. Gas Supply Connection

Always use clean, dry medical gases. Introduction of moisture or other contaminants into Accutron analgesia gas machines may result in defective operation.

After device installation, connect the oxygen and nitrous oxide supply lines to the Diameter Specific Instant fittings or DISS fittings located on the back of the device. See pages 14-16 for information specific to the Digital Newport™ Flowmeter System. It is important that the regulators for both gases be set to give pressures in the range of 50-60 PSI.

Verify that the correct gases are being delivered to the correct ports on device before initial use. This can be done by performing the oxygen failsafe test in section VII. Correct before using.

3. Power Connection

Device is designed to run on 100-240 V AC and 50/60 Hz. There is no need to flip an external switch as the unit automatically adjusts for any power. A medical-grade power cord is required and supplied with US units and must be used per regulations. It is important that in the US, this US power cord be plugged into an outlet marked "Hospital Only" or "Hospital Grade." International units do not have this requirement. The power cord is plugged into the AC entry, which contains two fuses and is located on the back of the device. International power cords are offered for some countries while others are given Schuko cords along with adapters to fit their country. Use only 240 V, 0.5A, slow-blow fuses. Fuses can be ordered from Crosstex as part number 26456-FRU.

4. Auxiliary Connections

Plug remote control into remote port on back of Digital Ultra™ Flowmeter or on front cover of Digital Newport™ Flowmeter System if ordered as option.

Plug Accu-Vac™ Electronic Vacuum Controller signal line into vacuum connector on back of Digital Ultra Flowmeter (Flushmount only). Vacuum LED should light when Digital Ultra Flowmeter is powered indicating vacuum is flowing.

Plug printer cable from Able printer, if used, into RS232 printer port. Do not use this port for any other devices. If printer is ordered on Digital Newport™ Flowmeter System as option, printer cable will extend from front cover. Note: Use only Able printer supplied by Crosstex.

VI. Directions For Use

Read instructions completely before operating Digital Ultra® Flowmeter device.

Note: The steps listed below provide a basic functional description of the Digital Ultra™ Flowmeter usage. A training course that emphasizes a practical, hands-on approach combined with instructions on safe techniques for administration of nitrous oxide-oxygen (sedation) is recommended before use of this flowmeter. Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system. Unit must be connected to O₂ and N₂O gases at 50-55 PSI. Unit must be plugged into 100-240 V AC, 50/60 Hz power outlet. Use titration method for administering nitrous oxide.

Power button will shut off Digital Ultra™ Flowmeter normal functions (reference diagram on page 8). For Emergency shutoff, unplug power cord.

NOTE: Detailed information on users, patients, and conditions can be found at the end of section VI.

General Operating Instructions

Setup:

Verify the presence of separate means of oxygen resuscitation and that appropriate staff are trained in its operation.

WARNING: In cases of adverse reactions, discontinue nitrous oxide procedure, remove scavenging circuit, utilize auxiliary resuscitation measures and equipment, and contact Emergency Responders (911).

Verify that oxygen and nitrous gases have not been mixed up by performing the Oxygen Failsafe Test on page 23. Note: the only significant source of injury from nitrous oxide procedures is gas mix-up.

Open inlet gas supplies for oxygen and nitrous oxide by:

- Turning on manifolds in central systems or
- Opening gas cylinders in Newports and 4 cylinder mobile stands

Verify scavenging vacuum is turned on and properly set per scavenging circuit Instruction for Use Verify power to flowmeter

Operation:

- 1) Push POWER button on front membrane or on Remote Controller.
(Initial flow is set to 5.0 lpm at factory but can be adjusted per instructions on page 21)
- 2) Install scavenging circuit per scavenging circuit Instructions for Use.
- 3) Adjust proper breathing flow by using the TOTAL FLOW and TOTAL FLOW buttons. Reservoir bag should inflate and deflate in response to patient breathing but never go completely full or completely empty. (Increments are set at factory to 0.5 lpm but can be reset to 0.1 lpm increments per instructions on page 20).
- 4) Gradually add nitrous oxide by using the % N₂O. It is recommended that % start at 10% and be increased by 10% intervals until desired reaction is achieved. Allow time between each change for patient to adjust since rapid increasing of N₂O % can cause nausea. (Increments are set at factory to 5% but can be adjusted to 1% per instructions below)

Note: Total flow does not change if % N₂O changes and % N₂O does not change if Total Flow changes.

Caution! Accutron controls % N₂O. Refer to page 22 for possible Use Error for those who are used to meters that control % O₂ such as Matrx® Flowmeter.

- 5) Max % N₂O is set at the factory to 70%. This limit can be changed to 50% by following instructions on page 21.
- 6) Adjust Total Flow and % N₂O as needed to maintain proper anxiety relief and proper flow levels.
- 7) Turn % N₂O to 0 at the end of the procedure by using the % N₂O. Continue with pure oxygen for 5 minutes.
- 8) Stop gas flow by pushing POWER at the end of the procedure. Remove scavenging circuit and close vacuum.

Additional Functions:

Print - If a Printer is installed, a snap shot of current O₂ flow, N₂O flow, Total Flow, % N₂O, Time and Date can be printed by pushing PRINT.

Mute - During an alarm condition, sound is muted by pushing CANCEL/TEST

Led Test - During normal operation, CANCEL/TEST will cycle though all Leds to verify all are operational

Flush - A minimum 20 lpm of pure oxygen will flow when FLUSH is pushed

Setting Step Size of Total Flow and % N₂O

1. To set the % N₂O step size to 5%: Plug in Digital Ultra™ Flowmeter and leave off. Press and hold % N₂O Up (+) button until beeps (approx. 5 seconds).
2. To set the % N₂O step size to 1%: Plug in Digital Ultra Flowmeter and leave off. Press and hold % N₂O Down (-) button until beeps (approx. 5 seconds).
3. To set Total Flow step size to 0.5 LPM increments: Plug in and turn off Digital Ultra Flowmeter. Press and hold Total Flow Up (+) button until beeps (approx. 5 seconds).
4. To set Total Flow step size to 0.1 LPM increments: Plug in and turn off Digital Ultra Flowmeter. Press and hold Total Flow Down (-) button until beeps (approx. 5 seconds).

Setting Date and Time

1. Plug in Digital Ultra™ Flowmeter and leave off.
2. Press and hold Print button down until beeps (approx. 5 seconds). This will start year setting.
3. Display will show 20 in % N₂O box and flashing display in Total Flow box.
4. Adjust to current year using Total Flow Up/Down buttons. Push % N₂O Up (+) button to store value and proceed to next step.
5. % N₂O box now displays months. Set the month with Total Flow Up/Down buttons.

- Push % N₂O Up (+) button to store value and proceed to next step.
6. Total Flow box now displays days. Set the day with Total Flow Up/Down buttons. Push % N₂O Up (+) button to store value and proceed to next step.
 7. N₂O box now displays the hours. Set the hour with Total Flow Up/Down buttons. Push % N₂O Up (+) button to store value and proceed to next step.
 8. N₂O box now displays minutes. Set the minute with Total Flow Up/Down buttons. Push the cancel button to save value and exit program.

Changing Starting Total Flow Rate

With power connected and flowmeter off, press and hold CANCEL/TEST and Total Flow + (up) Arrow together until beep (5-7 seconds). Current Total Flow will be shown. Adjust to desired flow rate using Total Flow + Up and Total Flow - Down buttons. Acceptable values are 1.0 to 9.9 LPM. Press Flush button to accept new value. Starting Total Flow will now start at the new value.

Changing Max N₂O Percentage (50% 70%)

With power connected and flowmeter off, press and hold CANCEL/TEST and N₂O % Up + buttons together until beep (5-7 seconds). This will toggle between 50% and 70%.

Changing Operating Mode (Normal/Demo)

With power connected and flowmeter off, press and hold CANCEL/TEST and O₂ FLUSH buttons together until beep (5-7 seconds). This toggles between Normal (gas flow) mode and DEMO (no gas flow). When in Demo mode, unit will start up flashing SALES for 5 seconds. In this mode, controls and displays will act normal but no gas will be needed or allowed to flow.

Set to Constant 50/50 Mode

This is done at the factory via an internal switch. In 50/50 mode, unit will supply a constant 50% Nitrous Oxide/50% Oxygen mix. Total Flow can be adjusted but will remain 50/50. As a safety feature, the unit can be toggled back and forth between 50/50 and 100% oxygen by using the Nitrous % Up and Down Arrows. 50/50 mode is often used in ERs to minimize shock and in Obstetrics for labor pains.

Application Specifications

Intended Use

The Accutron Digital Flowmeter is used to reduce anxiety in dental patients so that traditional treatments can be performed more efficiently and with less stress on the patient.

Intended Medical Indication

Nitrous oxide in Accutron Flowmeter approved applications is used for anxiety relief and is not a treatment for any particular medical indication per se. It is used to calm patients so that other treatments may be performed. It is proscribed for nitrous oxide-oxygen (sedation) only and not for use with other anesthesia agents.

Intended patient population

Nitrous oxide is routinely given to healthy individuals over 2 years of age without distinction of age, sex, or weight. See pages 2 and 3 for contra-indications.

NOTE: Patient reaction to nitrous oxide can vary widely between individuals and even in same individuals over time. Some individuals can not tolerate any N₂O.

Intended part of the body

Nitrous oxide is a gas and is delivered to the nose via a mask connected to gas supply tubing. The patient inhales the gas which is then absorbed in the lungs.

Intended user profile

Medical professionals such as doctors, dentists, dental assistants, dental hygienists, and nurses who have been formally trained in the use of nitrous oxide and who have studied the operating instructions in the User Manual.

Intended conditions of use

The Accutron Digital Flowmeter is intended to be used in medical facilities such as dental offices and hospitals with standard controlled room environments. See section I for further environmental specifications. Units may be mounted in cabinets, on extension arms, on sliding brackets, or on mobile carts. Units are not meant to be hand mobile by personnel and are not meant to be used in emergency vehicles. Frequency of use can vary from rare (once a month) to (frequent) 10-15 times per day. The user interface is designed for asepsis cleaning.

Description and operating principle

The Accutron Digital PC Flowmeter is a microprocessor-controlled device that precisely meters Oxygen and Nitrous Oxide gases for analgesic purposes in Dental Offices and Hospitals. The flowmeter is powered by 100-240 VAC, 50/60Hz via a power cord that is plugged into a filtered inlet. This voltage is then automatically converted to 12 VDC by a switching medical grade power supply. All components within the flowmeter as well as the user interface are operated on 12 VDC or less.

Precise flow of both oxygen and nitrous oxide are achieved through a feedback circuit containing a proportioning solenoid, a medical grade mass flow sensor, and the main microprocessor. The mass flow sensors measure flow electronically giving real time updates to the circuit board which directs the solenoids to maintain desired flow rates. The processor monitors these flows and gives alarms as needed if the flow of either gas can not match the desired rates. The software also prevents nitrous oxide from flowing without oxygen and maintains oxygen levels at 30% or more at all times.

Clinical operation is very simple as there are only two items to control, TOTAL FLOW and %N₂O. Press POWER to start flow which comes on at 5.0 LPM Total Flow and 0 %N₂O. Adjust Total Flow with the + and – keys until it matches the patients breathing rate. Increase % N₂O by using the + and – keys until proper relaxation is achieved. Decrease % N₂O to 0 at end of procedure and continue with pure oxygen for 5 minutes. Turn Power off. Total Flow and %N₂O can be adjusted during procedure as needed. Pure oxygen flush is available at any time. Print option is also available.

Possible Use Errors

- Administering too much N₂O or increasing the %N₂O too quickly.
- Mistaking the %N₂O with %O₂ used by other electronic flowmeters.
- Not taking sufficient patient history before starting procedure.
- Not reading the instructions for use or undergoing nitrous oxide training prior to starting procedure.

Abnormal Use

Disregarding the instructions and warnings is considered abnormal use.

Training

The intended use is the basis for training which is considered mandatory for all operators prior to use. Requirements may be different between countries so check local regulations prior to performing Nitrous Oxide procedures. General Theory on nitrous oxide use and procedures are described in such books as *Nitrous Oxide and Oxygen Sedation* by Clark and Brunick, and *Lachgas* by Dr Mathers. US training can be found in numerous ADA sponsored continuing education courses.

German training can be obtained through the Institute for Dental Sedation, Cologne, Germany (<http://www.sedierung.com>) or through BIEWER medical (<http://www.biewer-medical.com/en/sedation-training>), Koblenz, Germany.

UK training requirements are listed in the IACSD Standards for Conscious Sedation in the provision for Dental Care Section 5 and Appendices 1 and 2. Contact RA Medical for further information at Tel: 01535 652444 or email info@ramedical.com.

VII. PERIODIC EQUIPMENT CHECKS

CAUTIONS

Do not attempt to repair, alter, or calibrate this device. Unauthorized repair, alteration or misuse of this device may adversely affect the performance and will void the warranty.

IMPORTANT

Safety features contained in this notice should be routinely checked to assure proper function. If any of these safety features are not functioning properly, contact your dealer or Crosstex and arrange for the necessary repairs before reusing the machine.

Display Test

Check Before Each Use

Turn Digital Ultra® Flowmeter on and press CANCEL/TEST button. All displays should light sequentially with an audio beep, including alarms.

Cleaning

Perform After Each Use

Wipe with damp cloth. Do not allow liquids to touch rear auxiliary connections or enter case. Do not spray directly onto unit.

Oxygen Flush Valve Test

Check Monthly

- Turn Digital Ultra™ Flowmeter on at 5.0 LPM and leave nitrous oxide at 0%.
- Disconnect the corrugated tube from the bag tee outspout. Reservoir bag should remain connected to the bag tee downspout.
- Push the Flush button on Front Panel or Remote Control while blocking the flow from the outspout.

Reservoir bag should fill within 5-10 seconds. Remove any blockage when test is complete.

Outspout Check Valve Test

Check Monthly

- Digital Ultra™ Flowmeter should be off.
 - Reservoir bag should be connected to the bag tee downspout.
 - Mixed Gas tube should be connected to the outspout but not connected to the white patient delivery tubing.
 - Force air into the open end of the corrugated tube.
- The reservoir bag should not fill.

Override Air Valve Test

Check Monthly

- Digital Ultra™ Flowmeter should be off.
- Reservoir bag should be connected to the bag tee downspout.
- Mixed gas tube should be connected to the outspout but not connected to the white patient delivery tubing. Reservoir bag should be deflated.
- Draw air through the open end of the corrugated tube.

The Override Valve should open and allow air to enter the corrugated tube. Place your finger over the Override Valve and remove it to verify that air is entering the bag tee through the Override Valve. If the Override is not functioning, do not use Digital Ultra™ Flowmeter until it is repaired or replaced.

Oxygen Failsafe / Crossed line test

Check prior to first use, when meter is

moved, or monthly

- Set flow to 8 lpm TOTAL FLOW AND 50% N₂O and then shut off all oxygen cylinders.
- Unit should go into OXYGEN FAILURE alarm and N₂O flow should stop.

Note: This may take a few minutes for large central systems to use up gas in O₂ passages.

- If gas continues to flow, N₂O gas may be coming in on oxygen lines or circuit board could be damaged.
- Discontinue use immediately and contact Crosstex as patients could suffer severe injury.

Factory Check

Recommended every 2 years or more frequently as required by prevailing local and national codes.

Send equipment to authorized Service Center for operational check, battery replacement, and recalibration. Note: battery used for time and date info only, loss of battery does not affect safety or operation.

Routine Maintenance

There is no required routine maintenance as long as recommended factory check is at least in the recommended period or more frequently as required by prevailing local and national codes. Unit should only be repaired by trained individuals with specialized equipment. Unauthorized opening of equipment will put individual at risk of electrical shock and will void Warranty.

Disinfecting

Disinfect the front touch pad area after use, or remove barrier. Do not allow liquid to enter any connectors on back of unit. Do not spray directly onto unit. Do not allow liquid to enter any connectors on back of unit. Do not spray directly onto unit. Recommended products for disinfection include AdvantaClear™ Surface Disinfectant

NOTE: DO NOT USE BLEACH

VIII. TROUBLESHOOTING GUIDE

Only authorized factory trained technicians may open Accutron flowmeters. Unauthorized Repairs by others may put users and patients at risk and void warranty

PROBLEM	POSSIBLE CAUSE	REMEDY
Display off	<ol style="list-style-type: none"> 1. Power cord loose 2. No power to wall outlet 3. Fuse blown 	<ol style="list-style-type: none"> 1. Connect cord firmly 2. Check circuit breaker and/or call electrician 3. Replace fuse in holder under AC socket.
Oxygen Failure alarm	Low O ₂ pressure	<ol style="list-style-type: none"> 1. Verify O₂ input to flowmeter 2. Verify valves are open
Nitrous Failure alarm	Low N ₂ O pressure	<ol style="list-style-type: none"> 1. Verify pressure in N₂O cylinder 2. Verify valves are open
Nitrous & Oxygen Failure alarm	Obstructed flow to patient	Remove kinks or obstructions from mixed gas line to patient
Front panel buttons are not operating	<ol style="list-style-type: none"> 1. Defective panel 2. Internal problem 	Contact Crosstex Customer Service
Remote Control is not operating	<ol style="list-style-type: none"> 1. Loose connection to unit 2. Defective Remote 3. Internal problem 	<ol style="list-style-type: none"> 1. Check remote plug connection on back 2. If problem persists contact Crosstex Customer Service
Displays don't work	Broken display / circuit board	Contact Crosstex Customer Service
Automatic Vacuum port (Accu-Vac™ Electronic Vacuum Controller) doesn't work	<ol style="list-style-type: none"> 1. Loose connection in back 2. Defective valve 3. Internal problem 4. Insufficient vacuum 	<ol style="list-style-type: none"> 1. Check plug connection 2. Verify output of vacuum outlet is 12 +/- 3 V DC 3. Verify system vacuum is > 8 in Hg 4. If not solved, contact Crosstex Customer Service
Flush does not have enough oxygen flow	Filter clogged O ₂ solenoid damaged	Contact Crosstex Customer Service
Flush does not work at all	1. Internal Problem	Contact Crosstex Customer Service
Flow doesn't appear to be accurate	<ol style="list-style-type: none"> 1. Calibration error 2. Internal problem 	Check output with Oxygen Analyzer if available Contact Crosstex Customer Service
Unit freezes, doesn't respond, gas won't shut-off	1. Processor problem	Unplug power cord Plug back in (Reboot)

IX. WARRANTY

CROSSTEX 2-YEAR FLOWMETER LIMITED WARRANTY

IF AN CROSSTEX FLOWMETER NEEDS TO HAVE REPAIR WORK OR REPLACEMENT PARTS DURING THE 2-YEAR WARRANTY PERIOD DUE TO MANUFACTURING DEFECTS, CROSSTEX WILL PROVIDE THE PARTS AND LABOR AT NO CHARGE. THE FLOWMETER OWNER IS RESPONSIBLE ONLY FOR A \$35.00 SHIPPING AND HANDLING FEE, WHICH WILL BE ASSESSED EACH TIME A FLOWMETER IS RETURNED TO CROSSTEX FOR WARRANTY WORK.

WARRANTY TERMS

Limited Warranty and Disclaimer: Crosstex (“Seller”) warrants that its product will be free from manufacturing defects subject to the terms, conditions, and limitation set forth hereinafter, for a period of 2 years for flowmeters and 1 year for other equipment products. Seller’s obligations under this limited warranty are contingent on Buyer’s full payment of the product purchase price. Except as specifically set forth above, Seller and its affiliates make no warranties, expressed or implied, and specifically disclaim any warranties of merchantability or fitness for a particular purpose.

The liability of Seller and its affiliates for any claims, losses, damages, or expenses from any cause whatsoever (including acts or omissions of third parties) regardless of the form of the action, whether in tort, contract, or otherwise, shall not exceed the repair cost, replacement cost, or purchase price of the product that directly gives rise to the claim. Seller and its affiliates shall not be liable for any incidental, special, reliance, consequential, or indirect loss or damage rising out of this agreement or the products. As used in this paragraph, consequential damages include, but are not limited to, lost profits, lost revenues, property damage, personal injury damage to the Purchaser or third parties, loss of business or profits, and/or loss of business reputation. It is the sole responsibility of Purchaser to determine the suitability of the products for the Purchaser’s intended use. Seller’s obligation to repair, replace or refund, as set forth above shall be Buyer’s exclusive remedy.

This warranty constitutes the entire warranty. This warranty and Seller’s liability hereunder shall be construed according to the laws of the State of Arizona without regard to conflict of law principles.

To activate the Flowmeter Warranty, complete and mail the warranty registration card that accompanies Flowmeter.

Crosstex warranties are subject to the following conditions: Crosstex products and equipment are warranted to be free from defects in material and workmanship under normal use and service, including all component parts. This warranty shall not apply to defects resulting from accidents, alterations, or misuse. If modifications have affected the operation of the product to render it faulty, this warranty shall be void. This warranty shall be void if any part not of Crosstex manufacture or supply has been incorporated into the product.

THIS WARRANTY IS GIVEN IN PLACE OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE.

No statement or claim about the product by any employee, agent, representative or dealer of Crosstex shall constitute a warranty by Crosstex or give rise to any liability or obligation of Crosstex.

X. WARRANTY AND RETURNED GOODS POLICY

All warranty resolution issues and merchandise returns will be handled through the local authorized Crosstex distributor. Contact distributor where unit was purchased. See VIII for warning about unauthorized repairs.

XI. REPAIR SERVICE POLICY

All service issues will be handled through the local authorized Crosstex distributor. Contact distributor where unit was purchased. Check Troubleshooting Guide on page 25 prior to contacting distributor.

XII. ASSISTANCE

For Assistance, contact your local dental distributor or call Crosstex Customer Service at:

Toll-free: (800) 531-2221

Local: (623) 780-2020

Fax: (623) 780-0444

Hours of operation: 7:00 AM – 4:30 PM MST

Service ship-to address:

Crosstex International Inc., a Cantel Medical Company

1733 W. Parkside Lane

Phoenix, AZ

USA 85027

Visit our website: www.accutron-inc.com

XIII. OWNERSHIP INFORMATION

Dr. Name: _____

Street Address: _____

City/State/Zip: _____

Digital Ultra™ Flowmeter

Device Serial Number: _____

 Accutron, Inc.
1733 W Parkside Lane, Phoenix, AZ 85027 USA

EC	REP
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Made in USA

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