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Contents Enclosed in Package

Listed below are the contents of the shipping package for the PNT 1000 Unit:

- (1) PNT 1000 Suction Unit
- (1) CUI Inc. Model HK-B524-A12 Power Supply

  Input 100 - 240 VAC/0.6A : Output 12 VDC/2A.
- (1) 6 ft. piece of Silicon Medical tubing
- (1) Acrylic 4 -way tubing connector
- (3) 1 ½ inch Silicon Medical tubing pieces
- (1) Instructional video demonstrating the PNT procedure
- (1) Information For Use (IFU) booklet

Introduction

Pneumatic trabeculoplasty (PNT) is a non-invasive method of safely lowering IOP in glaucomatous eyes. PNT utilizes a specially designed fixation ring made of disposable plastic and has three equally spaced vacuum tubulatures.

The PNT Suction Ring comes prepackaged and sterile – ready for use. It is attached to the vacuum pump by means of three pieces of silicon tubing leading to a four-port adaptor which is attached to tubing attached to the pump inlet. The pump is preset at the factory to deliver an optimum level of vacuum. The pump is controlled through a digital timer. Entering any number (corresponding to seconds of time) and pressing [ENTER] starts the pump which turns off when the entered number counts down to zero. The pump may be stopped and vacuum relieved by pressing the [CANCEL] key on the console at any time.

The mechanism of action of PNT is unclear, but there is supporting evidence to show that it acts on the trabecular meshwork. This evidence comes in the form of measured increases in accommodative amplitude in early presbyopes undergoing PNT, albeit of a temporary nature. There is corroborating evidence from the studies of Schacher and Thornton in which expansion of the sclera over the ciliary body either by means of implanted plastic ring segments (Schacher) or radial incisions (Thornton) was accompanied by a measured decrease in post-surgical IOP. The mechanism may well involve stretching of the zonule which stretching produces some form of change in the trabecular meshwork either physiologically, through chemical mediators, or through a mechanical opening of the trabecular

pores. Additional evidence that the mechanism of action involves improvement in outflow is that patients who respond well to latanoprost (Xalatan) also seem to do well with PNT. There is no evidence that PNT causes any form of cyclodialysis and no cases of PNT have shown either flare or cells post-treatment.

The Model 1000 unit is intended for use under the supervision of a qualified ophthalmologist. It is not intended for home use or self-administration.

Indications

1. Patients 18 years of age or older
2. Patients with:
    a. Primary open angle glaucoma (POAG)
    b. Pigmentary glaucoma (PG)
    c. Glaucoma secondary to pseudoexfoliation of the lens capsule (PXG)
    d. Eyes with moderate ocular hypertension (OHT), defined as any non-glaucomatous eye with an IOP in the range of 22-25 mm Hg
    e. With or without concomitant medication

Note The application of PNT to patients with diabetic retinopathy, significant retinal disease or significant optic nerve disease has not been investigated to date. Care and appropriate patient monitoring should be employed with these patients

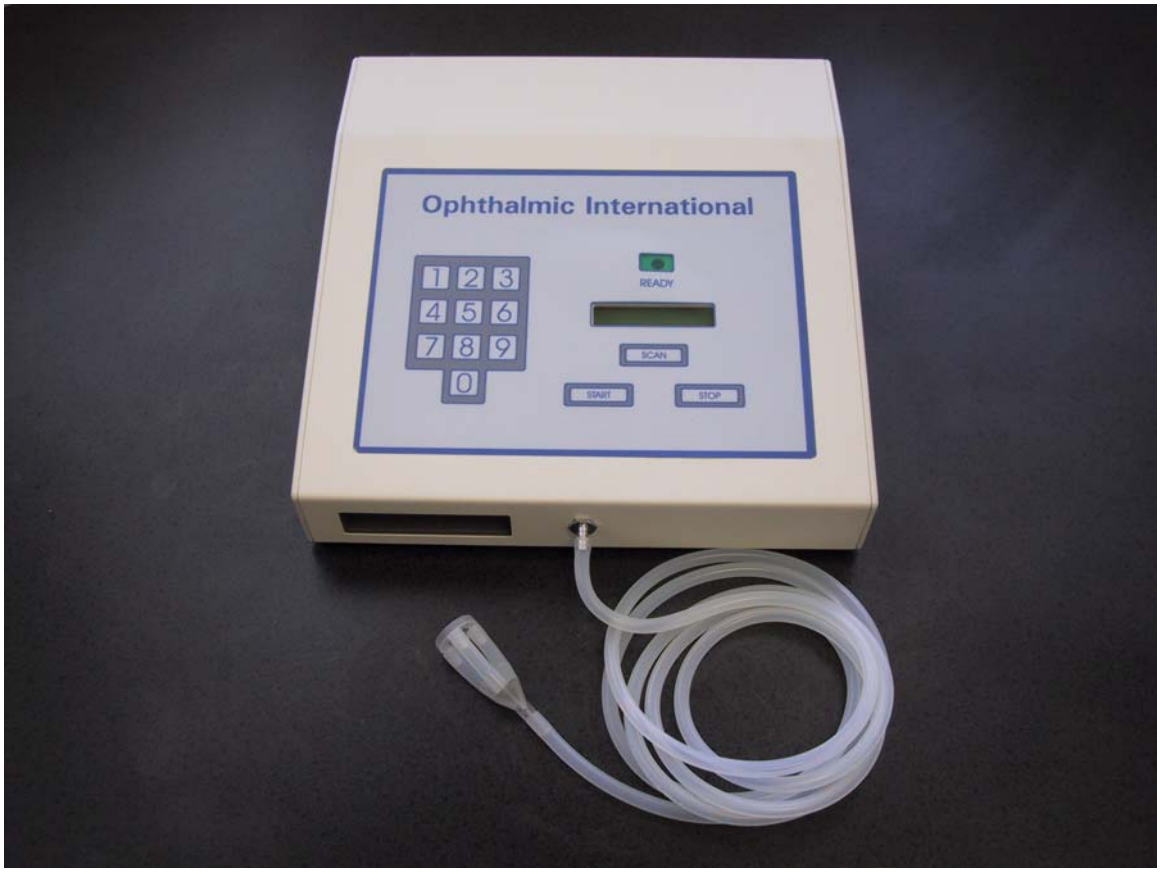
Contraindications

1. Chronic iritis/uveitis in either or both eyes
2. History of glaucoma secondary to uveitis/iritis, hemorrhagic glaucoma, glaucoma associated with trauma, phakolytic glaucoma, acute glaucomatocyclitis crisis, or angle closure glaucoma in either or both eyes
3. History of penetrating keratoplasty (corneal transplants), diabetes with rubeosis iridis, severe cupping (90% to complete; excavation), narrow angles and/or moderate to extensive visual field changes (*i.e.*, only a central island of vision (advanced visual field loss within 10 degrees of central fixation as determined by automated perimetry) in either or both eyes.

   Moderate visual field defect is defined as:

   a. MD loss greater than or equal to -12 dB
   b. PDP: <50% (37) points are depressed below 5% and <20 points are depressed below 1%
   c. No point in central 5° has sensitivity of 0 dB
   d. Only one hemifield may have a point with sensitivity of <15 dB within 5° of fixation
4. Patients with macular degeneration (wet or dry) in either or both eyes
5. Patients who have undergone a surgical trabeculectomy. Prior ATL and SLT procedures are not considered to be contraindications
6. Patients with keratitis
7. Patients whose angles are not fully open (i.e. narrow angle, atypical angle, closed angle).
8. Patients with severe dry eye syndrome associated with Fuch's Corneal Dystrophy
9. Patients with corneal abnormalities or corneal disorders
10. High Myopia defined as myopsis in excess of 6 diopters[1]

[1] PNT has not been specifically investigated in high myopes but as a precaution is contraindicated given the increased risk of retinal detachment reported in this patient group following general ophthalmic procedures



Model 1000 Vacuum Unit: Directions for Installation and Assembly

1. Place the PNT 1000 Suction Unit on a level, sturdy surface close to the patient.[2]
2. Connect the power cord to the AC power supply provided (Note: Only use the power supply enclosed with the unit. Contact your distributor representative for a replacement power supply, if needed).
3. Plug in the power cord to a suitable power outlet (100- 240V; 50-60Hz)
4. Connect open end of single line tubing to vacuum inlet.

[2] To find an appropriate spot for placement, treat the PNT 1000 Unit with the same consideration as any other precision medical device. Use of cellular phones near the PNT 1000 unit should be avoided. Use the equipment in a static free environment.

5. Connect the three short pieces of tubing to the triple prong end of the 4 -way acrylic connector. Connect the single prong end of the 4 –way acrylic connector to one end of the single piece of tubing . Care should be used to avoid twisting or knotting of the silicon tubing.

6. Connect the open end of short pieces of tubing to the stems on the pre-packaged, single use disposable pre-sterilized PNT Suction Ring.

Warning

The sterilized PNT Suction Ring is a disposable, single use product and cannot be autoclaved. Solution sterilization methods are inadequate and therefore not recommended since material from prior procedures and/or the sterilization media can become trapped in the tubulatures and be transferred to the patient. The Model 1000 Vacuum Unit is designed to work specifically with the sterilized pre-packaged PNT Suction Ring. The PNT Suction Ring should only be used with the Model 1000 Vacuum Unit

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Note: A transient increase in IOP, which is believed to be associated with some transient inflammation, was seen in some patients during the earlier clinical trials. Several investigators have found that diclofenac eyedrops (x3) starting the day before and then for 1 week after the PNT is sufficient to minimize/eliminate this transient.

Model 1000 Vacuum Unit: Directions for Use

The Model 1000 Vacuum Unit should only be used under the supervision of a qualified ophthalmologist

1. Place the ON/OFF switch on the back of the unit to the ON position
2. Instill topical anesthesia ophthalmic solution (not supplied) 1 gtt to selected eye 1 Q5 min X 3 doses [3]
3. Place patient in supine position
4. A Chan wrist-rest or similar device may be useful for the medical professional
5. To prepare the unit for the procedure first press the "SCAN" button on the face of the controller. The prompt "Scan Ring" will now be visible within the

[3] The procedure is performed under topical anesthesia. It has never been found necessary to employ peri- or retro-bulbar anesthetics nor pre-treatment sedation. A 1-2% topical application of a suitable anesthestic has been found to increase patient comfort during the procedure

window of the LCD display. The unit is now ready to scan the bar code on the package containing a fresh PNT Suction Ring.

6. With the barcode located on the back of a fresh PNT Ring pouch facing the unit, pass the barcode in front of the barcode reader window which is located on the front-left side of the PNT Model 1000. The LCD window will now display "Ring Accepted". If a barcode has been previously scanned, indicating that the ring has already been used, "Ring Rejected" will be displayed in the LCD window. To use the unit a new ring will need to be scanned.

   If the unit is turned off after a ring has been scanned, a new bar code will need to be scanned in order to operate the PNT Unit 1000.

7. Following the successful scanning of a new ring, the LCD will display "enter time". The unit has been designed to allow for multiple vacuum cycles over a 15-minute period, so as to allow a complete PNT treatment to be performed. The 15-minute window starts at the beginning of the first vacuum, cycle.

8. Using the numeric keypad on the face of the unit the operator should program one minute into the controller. (One minute is entered by pressing the 6 key, then the 0 key. The LCD timer displays 60.[4]

9. After the anesthetic drops have been administered, the lids are gently spread with the corresponding fingers of the surgeons hand or with a Barraquer wire lid speculum.

[4] Application times in excess of one minute (60 seconds) have not been investigated and should be avoided.

10. The sterilized PNT Suction Ring must be centered on the selected eye, around the clear cornea.

11. Press the “ENTER” key to start suction. The pump will run for one minute and then stop automatically. As noted above the unit will now be operable for 15 minutes once the first cycle with a new PNT Suction Ring has been initiated. **During the last two (2) minutes, the green pump light will flash indicating the 15 - minute window will soon expire.**

12. Following the initiation of the 1 minute vacuum cycle the LCD will display a countdown of the time remaining for the vacuum cycle as well as the vacuum being applied (measured in Hg). (**Please note that once the “ENTER” key has been pressed, if the PNT Unit 1000 machine loses power (for example by way of the on/off switch on the back of the unit), the 15 - minute window will automatically expire and a new barcode will be needed to scan in order to continue).** If the operator notices that the display does not appear to be counting down properly the operator should turn off the unit and arrange for servicing.

13. Care should be exercised to avoid excessive downward pressure on the ring during the procedure. Good suction is also aided by insuring that the eye is wet when the ring is applied.

14. In the cases of narrowed palpebral fissures, it is helpful for the patient to look up whereupon the ring is slid down into the inferior cul-de-sac until the upper lid is cleared.

15. After the first 60 seconds of application, wait 5 minutes then repeat one minute vacuum application.

16. A slight downward pressure on the PNT Suction Ring just prior to the end of the vacuum cycle will prevent it from suddenly popping off the eye as the suction is released. This prevents startling of the patient and possible discomfort due to a sudden release of vacuum.

17. Following completion of the PNT procedure, instill one drop of tobramycin (not supplied) or similar (Drops containing corticoids should be avoided to prevent any possibility of secondary glaucoma occurring in steroid-sensitive patients.).

18. Wait 15 – 20 minutes, then check patient's vision; wait 60 minutes, then check patient's IOP

19. Transient hyperemia is sometimes seen following PNT. Treatment methodologies normally use to manage associated symptoms may be utilized.

20. Recheck patient's IOP within 24 to 48 hrs.

21. Repeat procedure within 7- 10 days of the initial treatment.

22. A reduction of anti-glaucoma medication can be considered 3 weeks following the repeat procedure. Refer to the section "Considerations for Reduction in Medication" for further information.

Potential Adverse Events

Adverse events reported following PNT are generally mild in nature and resolve within a few days. The patient should be instructed to report any unusual symptoms or symptoms which do not resolve in a few days to their physician

Patients receiving PNT typically experience transient 'gray-out' of vision sometimes associated with multicolored light patterns during the application of the vacuum ring. These phenomena typically vanish with 30-40 seconds upon release of the vacuum. Patients BCVA is to be assessed within 15-20 minutes of receiving the PNT treatment. There should be no visual depression beyond 1 line at that time. Patients should be instructed to immediately report persistent blurring of vision in excess of 2 hours following the PNT treatment

Patients may experience some mild ocular discomfort following the PNT procedure. This discomfort will typically resolve, without treatment, within a few hours but may last as long as a day or two. Patients should be counseled that if the discomfort becomes prolonged or increases in intensity they should notify their physician immediately

Adverse events which may be associated with PNT

Venous/arterial occlusion [1]	Acceleration of visual field lost [1]
Intravitreal hemorrhage [1]	Pulse/blood pressure changes [1,4]
Retinal detachment [1]	Inflammation[1]
Significant IOP elevation post-treatment[2]	Corneal Abrasion [1,5]
Loss of BCVA [1]	Subconjunctival edema[6]
Subconjunctival hemorrhage [1]	Endothelial cell loss[1]
Lid edema [3]	Blindness / loss of eye[1]
Ocular infection [1]	
Hyphema [1]	

[1] not reported or experienced to date

[2] maximum immediate post-PNT IOP rise reported is 5 mmHg. No significant (<2 mmHg) increase in IOP has been reported 1-day post-PNT in cases in which anti-glaucoma medication was continued during the initial treatment period. However in one study where in which patients were 'washed out' and off all anti-glaucoma medications – short-term IOP increases in excess of 8 mmHg were reported. No such elevations were seen in patients with ocular hypertension. Hence, it is recommended that patients be retained on their anti-glaucoma medications during the initial PNT treatment phase.

[3] typically the upper lid

[4] No changes in blood pressure have been observed to date. One report of a patient exhibiting a transient decrease in pulse, which quickly resolved following cessation of PNT, has been noted. Blood pressure and pulse should be monitored in patients with significant cardiovascular history.

[5] No corneal abrasions noted to date. Mild superficial punctuate, believed to be associated with topical anesthesia has been observed in some patients

[6]Mild conjunctival edema has been observed in patients following PNT and usually resolves within a few hours without medical treatment

Other Potential Health Risks

Oculocardiac reflex (Vaso-vagal response)

It is a known phenomenon that pressing upon the eyes can produce a slowing of the heart rate and is employed as an emergency measure in cases of premature auricular tachycardia [1]. Pulling on the extraocular musculature has been shown to produce premature ventricular contraction (PVC's) [2]. These cardiac changes have been reported in cases of artificially elevated IOP [3]. It is probably direct pressure on the extraocular muscles and not the elevated IOP which is causative in these cardiac changes [4-6]. The electrocardiogram (ECG) remains the best standard of measuring cardiac changes due to vagus nerve stimulation via the trigeminal plexus.

Considerations for Reduction in Anti-Glaucoma Medication

Generally speaking, reduction of anti-glaucoma medications can begin three weeks following the PNT repeat application. Given the numerous variations in anti-glaucoma medication regimes, it is not possible to recommend a single specific medication reduction strategy.

In general, the reduction should be done in a step-wise fashion, waiting at least a week between adjustments. For example, twice-a-day medication dropping to once daily, etc. A reduction in medications can be attempted even if the patient's IOP has not changed significantly from the pre-treatment levels. The patient's whose IOP may have been controlled on one or more medications prior to the addition of PNT, can achieve a benefit following PNT by having their medication requirements significantly reduced or eliminated while maintaining IOP control.

When a patient is on multiple medications the ophthalmologist may consider reducing/eliminating medications in the following order: Diamox. Pilocarpine and similar medications such as carbachol, followed by beta-blockers and prostoglandins. Given the prolong latency period of beta-blockers, particularly Timolol, the treating physician should allow at least 14 days to elapse before reducing or removing any other anti-glaucoma medication(s) from the patient's regimen.

Cleaning, Maintenance and Disposal

PNT Model 1000 Controller

The PNT Model 1000 controller contains no field serviceable parts nor is any field calibration needed. If the equipment or any of its accompanied parts is in need of service, repair or exhibiting excessive wear, please contact your distributor representative for assistance.

Care should be taken when using and storing the PNT Model 1000 controller. As with all electrical equipment direct contact with liquids should be avoided. Do not use or store the equipment in damp or elevated temperature environments. The surfaces of the controller case and keypad should be cleaned by wiping with a clean, anti-static cloth.

The control unit can be disposed of as any other piece of electronic equipment in compliance with local regulations at the end of its operating life

Connector Tubing and 4-port Acrylic Adapter

The 4-port adaptor and short silicon tubes, which connect the ring to the 4-port adaptor should be rinsed and autoclaved prior to use. As a reminder, the PNT Suction Ring cannot be re-sterilized (see below). The 6-ft section of silicon tubing can be cleaned by rinsing and air drying. The 6-ft section of silicon tubing can also be autoclaved if desired.

The tubing and 4-port adaptor can be disposed of as normal medical waste in compliance with local regulations

PNT Rings

The PNT rings are supplied as single use, individually packaged, disposable sterilized units. Each ring pouch is supplied with a unique bar code label. This barcode needs to be scanned prior to the use of the PNT 1000 Unit. Any attempt to re-sterilize the rings may impact their structural integrity and negatively effect how they will perform during the PNT procedure. The pouch should be inspected prior to opening. The ring should not be used if there is any reason to suspect a sterility failure of the primary packaging. The ring can be disposed of as normal medical waste in compliance with local regulations.

Explanation of Labeling

Suction Ring-

REF

20-100-00

Read Instructions

Sterile, Ethylene Oxide

xxxxx

Manufacturing Date

Single Use Only – Do Not Reuse

PNT Unit 1000

REF

Read Instructions

SN xxxxxxxx

CE

0476

Class II Isolation

as per EN 60601-1

IEC 60601-1 Type CF

XXXXXX
Lot Number


YYYY-MM
Expiration Date


0476

[ENTER]
START

[CANCEL]
STOP

[VACUUM]
The unit is running
and generating vacuum

Technical Information

The PNT 1000 Unit is in compliance with the EN 60601-1-2 requirements. This standard encompasses all of the technical aspects of the PNT 1000 unit including all critical components as well as emissions and immunity tests.

To ensure proper storage, store the PNT 1000 Unit in a cool, dry area. (Note: the temperature where the unit is stored should not be below -10^{o}C or above 70^{o}C.). The normal operating temperature range for the equipment is between 10^{o}C and 40^{o}C.

AC Power Adapter:

- CUI Inc. Model HK-B524-A12 Power Supply

  Input 100 - 240 VAC/0.6A, 50/60 Hz : Output 12 VDC/2A.

Trouble Shooting

1. Has the PNT Unit 1000 been plugged in to a 110-220 Volt power outlet?
2. Has the on/off rocker switch been turned to the ON position? (When in the ON position, the LCD will illuminate).
3. Verify that the barcode on the ring pouch has not previously been scanned. (Note: a previously scanned barcode will not allow the PNT Unit 1000 to operate).
4. After scanning a barcode, a new barcode can only be scanned when the 15-minute time frame has elapsed OR if the PNT Unit 1000 is turned off then turned back on. (Note: if the physician scans a barcode, treats a patient then wishes to treat a second patient, the 15-minute time frame should expire OR the physician should turn off the PNT Unit 1000, turn it back on, then scan a new barcode for the new patient).
5. If the characters on the LCD do not display properly, prior to scanning a barcode, turn the PNT Unit 1000 off, wait five seconds, then turn it back on.

If a problem occurs and troubleshooting does not help, please contact your local representative.

Sample Bar Codes

Below are sample bar codes, similar to what is affixed to the ring pouch. These samples can be used for training purposes or for emergency use. The bar codes are one-time use only and when used should be marked as such in order to avoid mistakenly being used again in the future.

Contacts

In case an incident or accident occurs, contact the authorized representative in the EU:

- Donowa Consulting Srl
  Piazza Albania 10
  00153 Rome, Italy

For any additional questions or comments contact:

- Ophthalmic International

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  Fax: 480-837-6870