CNEP DEVICE
(CONTINUOUS NEGATIVE EXTERNAL PRESSURE)
SOCIETY OF ANESTHESIA AND SLEEP MEDICINE
6TH ANNUAL MEETING
CHICAGO, IL

Nicholas S Hill MD
Tufts Medical Center
Boston, MA

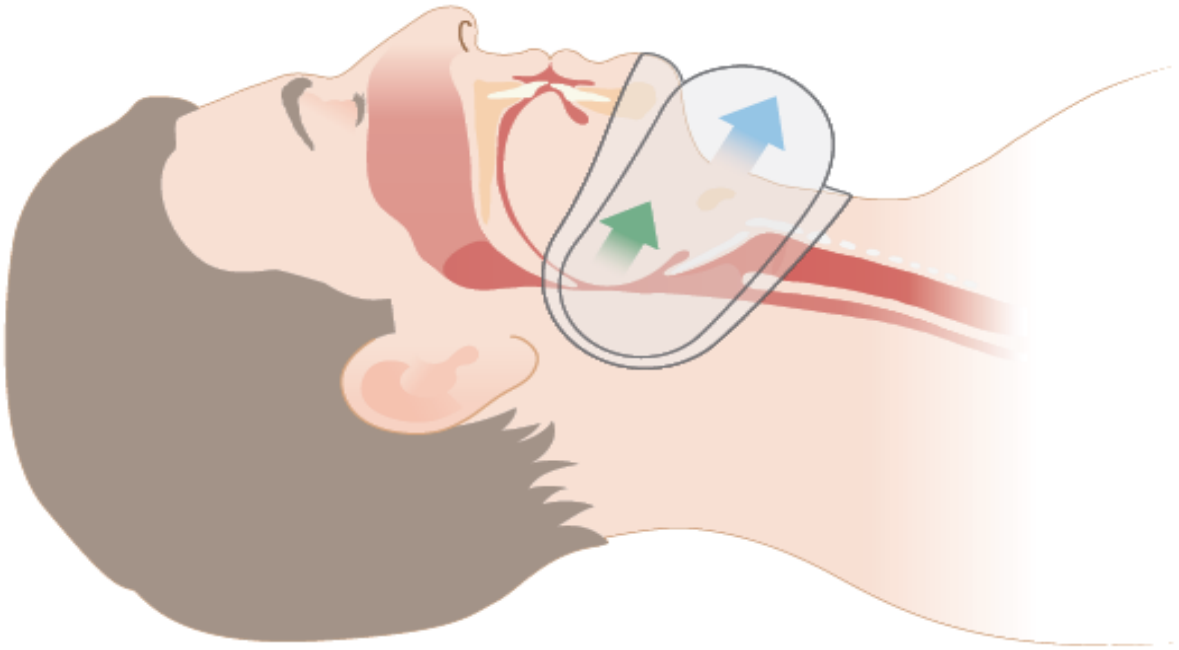
Disclosures

- Consultant Sommetrics
- San Diego, CA

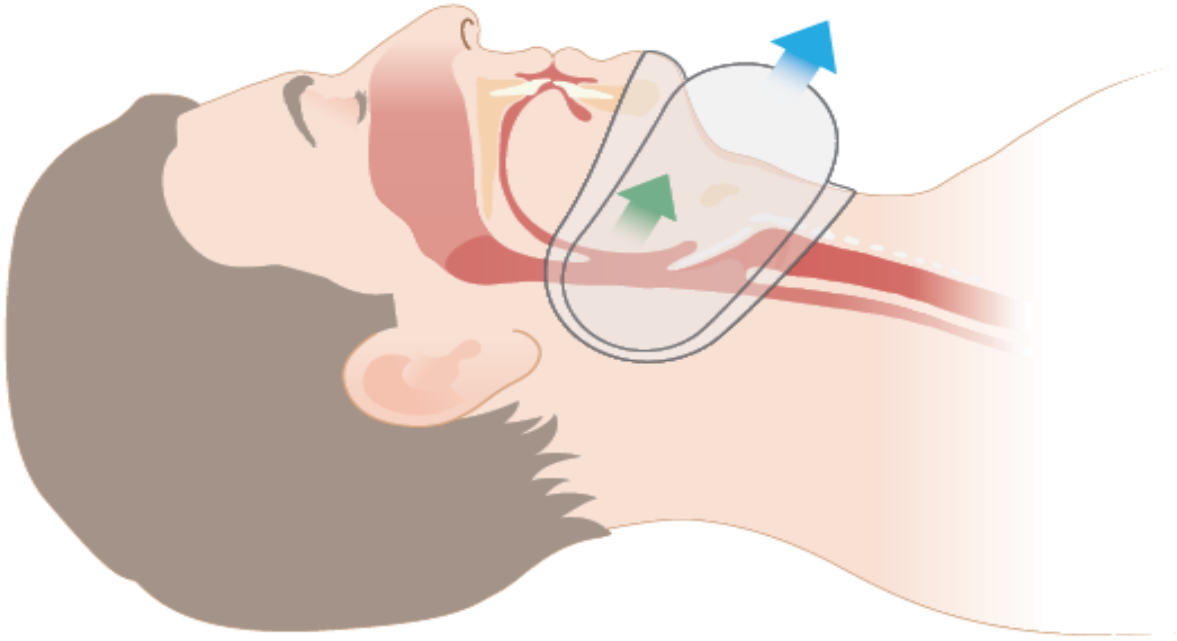
The Concept

- If positive airway pressure prevents upper airway closure in sleep apnea and other conditions
- Then negative pressure applied to the upper airway in the right location should do the same
- Both increase intramural v extramural pressure gradient, but one pushes and the other pulls

cNEP Concept



cNEP Concept



Design Evolution - Collar

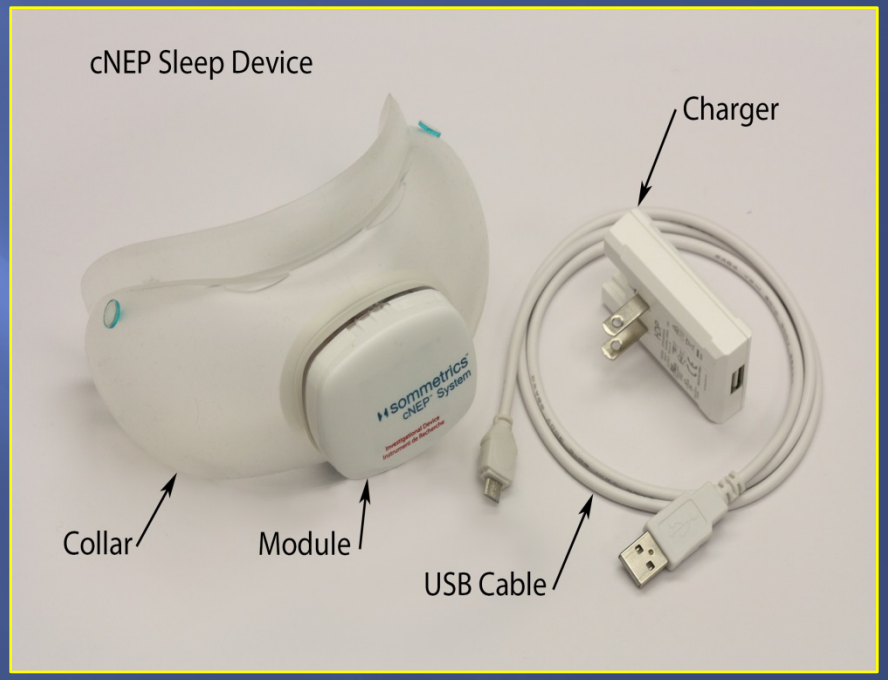
- First collar

- Need flexibility, load distribution

- Need more volume, Avoid skin reactions

cNEP® Sleep System

- **Soft Silicone Rubber Collar**
  - Different sizes to accommodate size and craniofacial features such as retrognathia
- **Vacuum Pump Module**
  - Contains micropump and sensors controlled by a circuit board
  - Charged daily; 10-12 hrs of battery life
- **System Features**
  - Micropump provides vacuum range of 20-40 cmw; very quiet operation
  - Sensor data reported from Sleep System to Cloud-based server via Sommetrics -provided portal unit



Design Evolution – Vacuum Unit

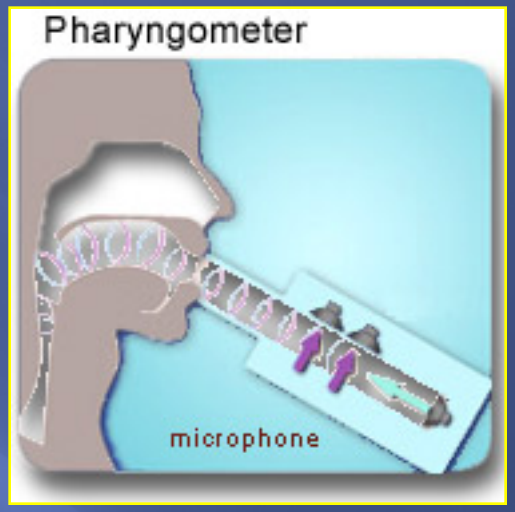
- Initial vacuum source

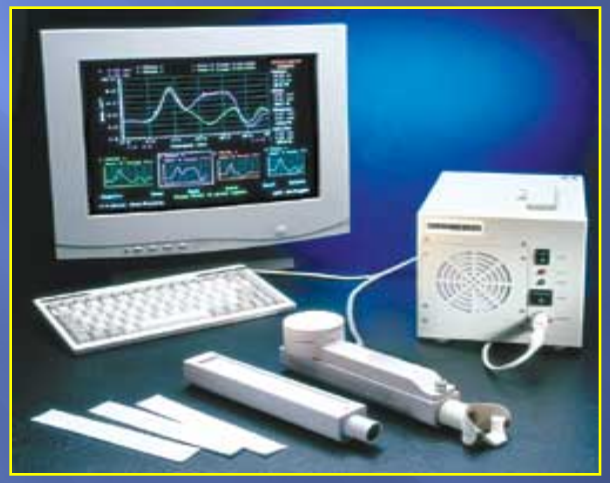
- Pocket unit used to prove concept portability

- MiniVac unit for clinical trials

Acoustic Reflection Technology

Acoustic reflection to assess changes in upper airway dimensions to determine ideal collar size



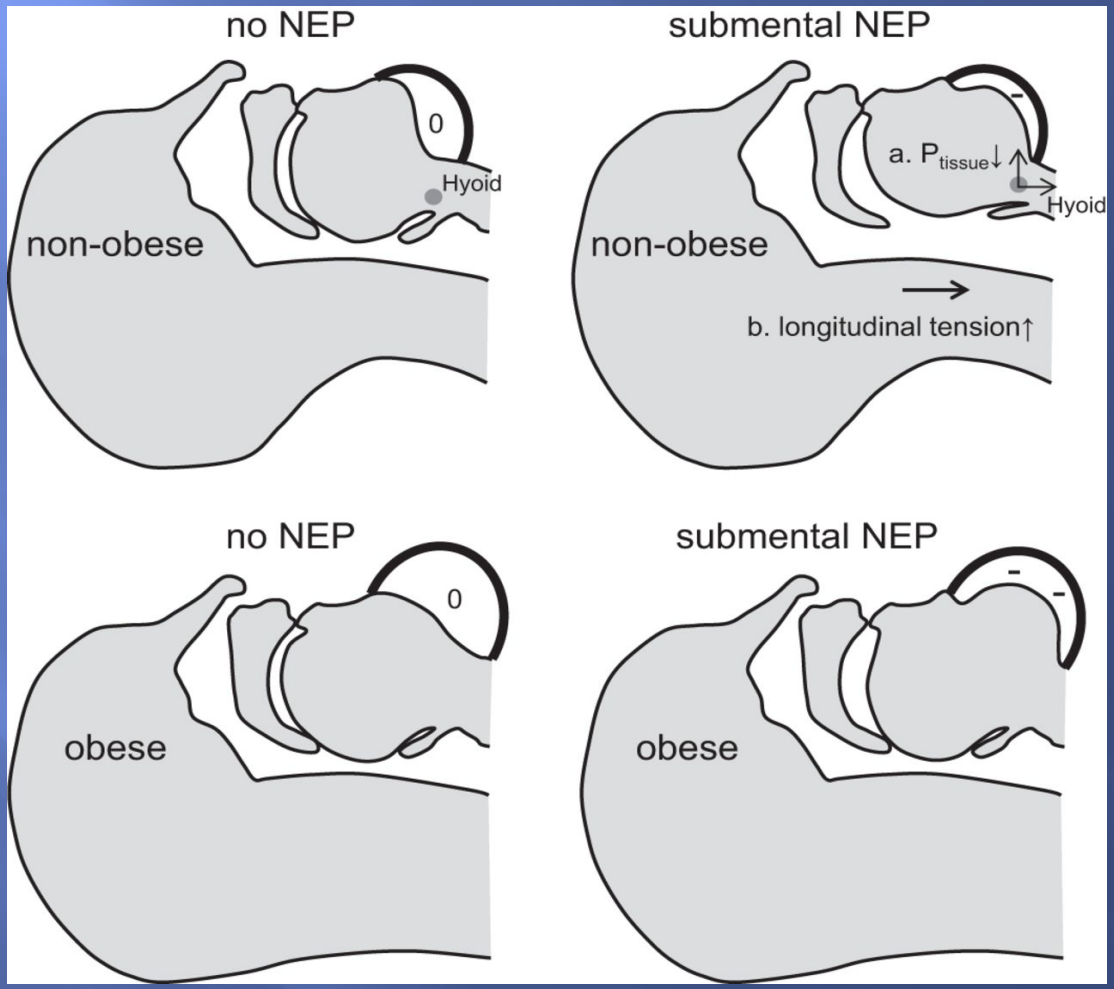


Acoustic Reflection Detects Upper Airway Responses to cNEP

- cNEP expands mean cross sectional area of the upper airway in "dose-response" fashion:

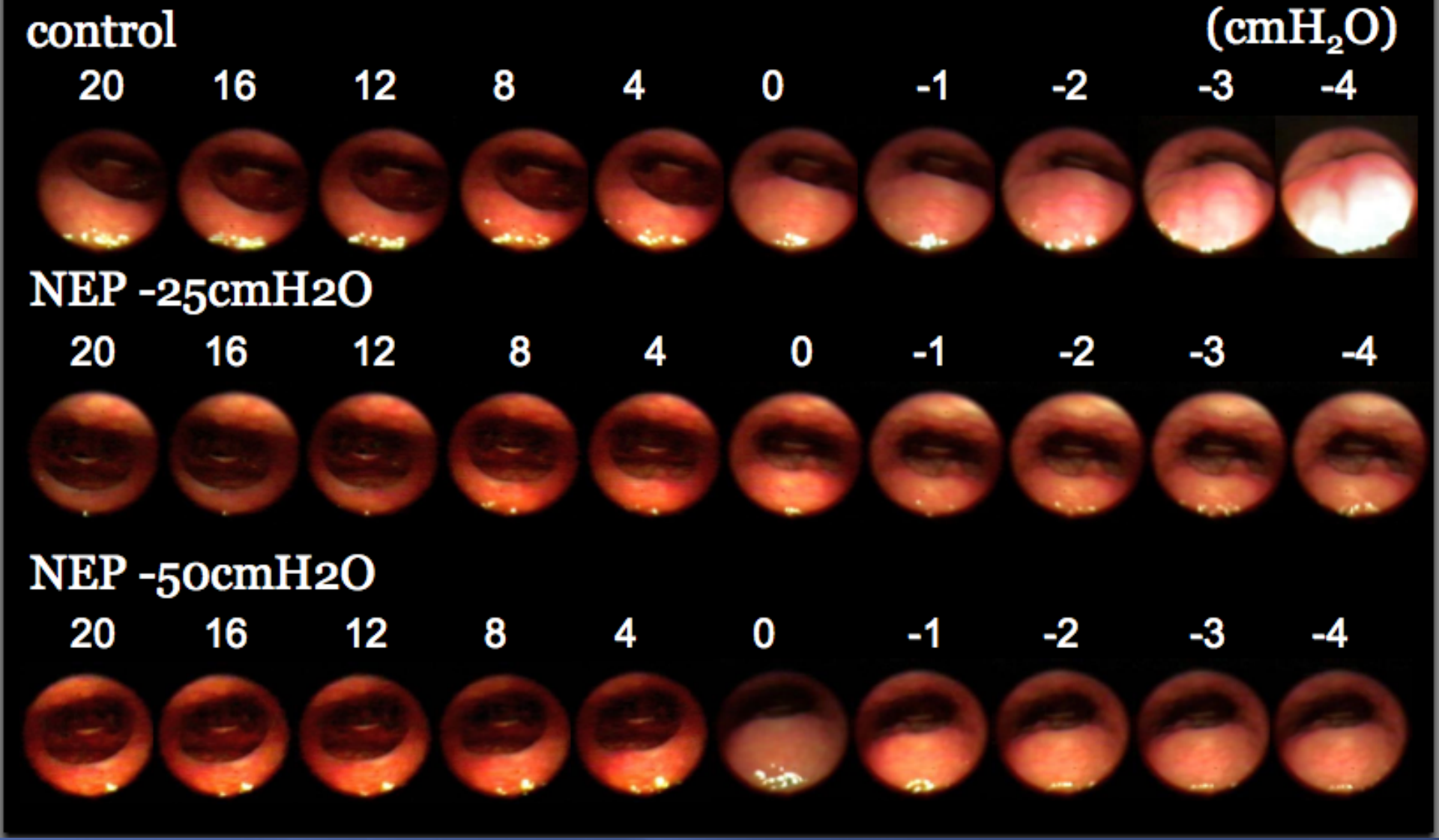
Vacuum (neg inches Hg)	Cross Sectional Area (cm^2)
0	3.32
8	4.60
10	4.40
12	4.70
14	4.90
16	5.20
18	4.90
20	4.60

Possible mechanical actions of submental NEP

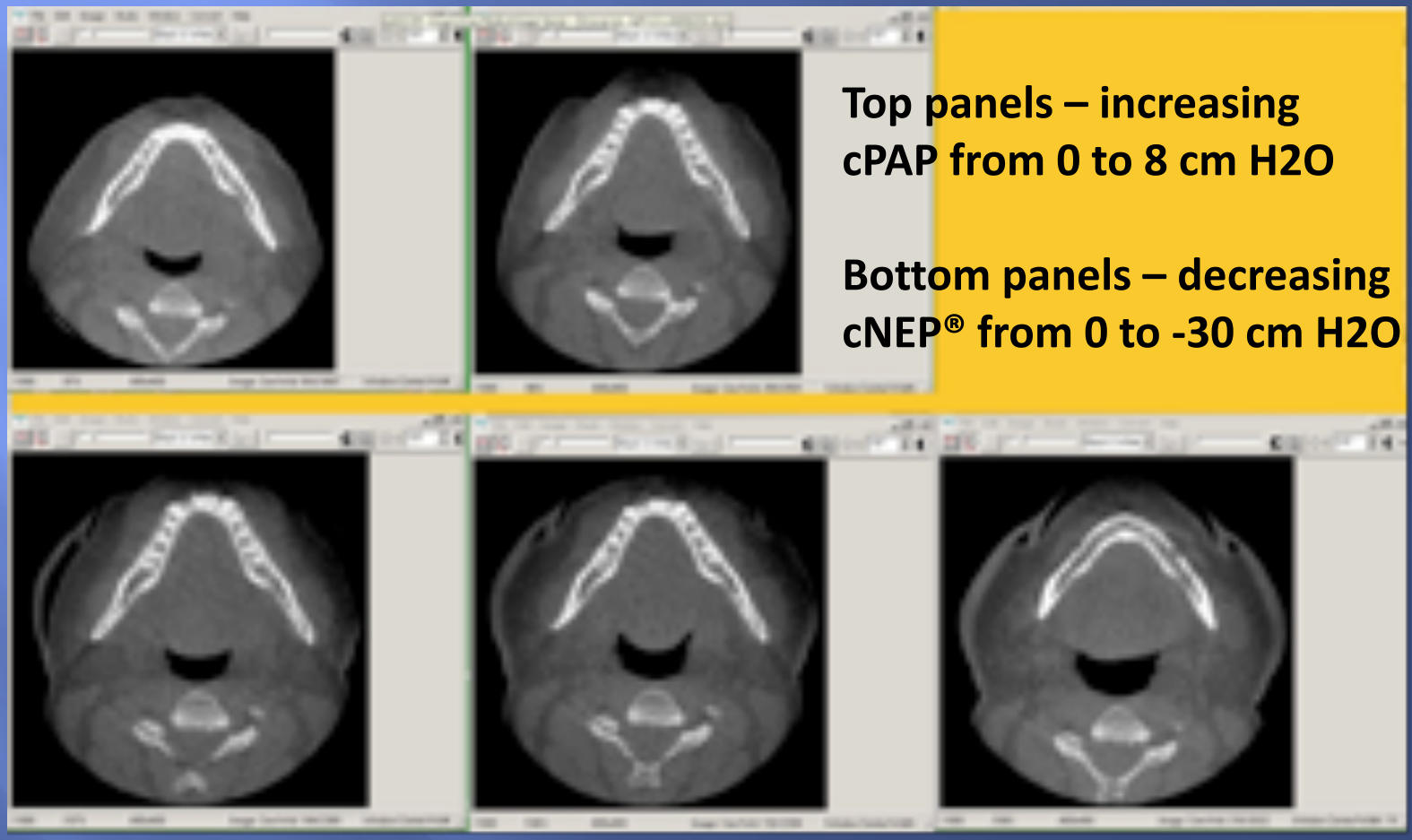


S Kato et al. J Appl Physiol 2015;118:912-920

Effect of cNEP on Critical Closing Pressure (pCrit) in Non-obese Japanese Women



cNEP® Alters Upper Airway Structure and Function



Top panels – increasing cPAP from 0 to 8 cm H2O

Bottom panels – decreasing cNEP® from 0 to -30 cm H2O

Clinical Experience – Sleep Apnea

Results of full night cNEP titration studies

Disease severity at baseline	Subjects exhibiting a therapeutic response*
Mild (AHI 10-15)	10 of 12
Moderate (AHI 15-30)	16 of 22
Severe (AHI >30)	14 of 22

- Most subjects improve at ≤ 30 cmw

**Assessed by accepted criteria for CPAP*

- Average AHI reduced from 25.3 to 2.14 in responders
- Non-responders tended to have larger neck circumference and BMI
- Mild, self-limited local irritation seen in minority of subjects

cNEP Reduces Resp Impairment During Endoscopy

Design

cNEP (-45 cm H2O) applied to 30 consec pt undergoing Screening colonoscopy (18f, Age 60, BMI 26, STOP BANG 2.6. Compared to 25 earlier colonoscopies in matched non cNEP pts

Kais SS et al, Endoscopy 2016

cNEP Reduces Resp Impairment During Endoscopy

	No cNEP	cNEP
All apneas	1.78	0.38
Obstructive	0.91	0.07
Central	0.74	0.31
Mixed	0.13	0
O2 > 2l/min	42%	10%

12 with mild erythema of neck

Kais SS et al, Endoscopy 2016

FDA Approval Aug 2014

INDICATION FOR USE

The cNEP Airway Management System is to be used as an aid for maintaining the patency of the upper airway in spontaneously breathing adults undergoing medical procedures less than 2 hours in duration, where the patient is intended to have mild to moderate sedation with non-propofol containing medications.