

# Incubator-Based Active Noise Control



Improving the lives of newborns



# Executive Summary

**Neonatal intensive care unit noise is a well-recognized, serious problem with adverse effects on vulnerable infants**

- Poorer sleep hygiene
- Slower growth
- Increased stress
- More susceptibility to pain
- Longer lengths of stay

**Invictus' Neoasis® is an FDA-cleared novel non-contact method for attenuating noise inside an incubator**

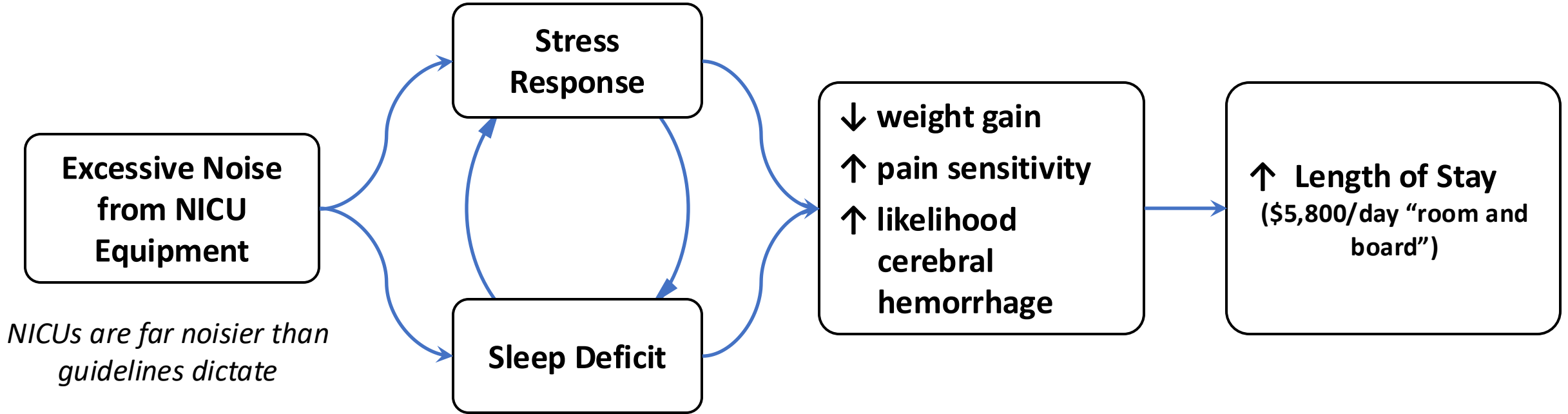
**Cost to care for preterm infants is disproportionally high compared to full term infants due to long lengths of stay**

**Medicaid reimbursements fall below hospital costs, especially for neonatal patients**

**Invictus' Neoasis® protected by 12 issued US patents**



# Cascade of Effects of NICU Noise



*Hospitalized infants should sleep >18 hours but are awakened frequently by alarms*

***Neonatal thought leaders support cause-effect relationship between noise and clinical deficits***

“By **lowering the sound levels** that reach the neonate, the resulting stress ... can be diminished, thereby **promoting growth and reducing adverse neonatal outcomes.**”

- Almadhoob A, Ohlsson A. Sound reduction management in the neonatal intensive care unit for preterm or very low birth weight infants. Cochrane database Syst Rev. 2015

“If **noise abatement** and sound control are achieved within the recommended levels, benefits include **increased physiologic stability ... , better growth rates for infants...**”

- Graven SN. Sound and the developing infant in the NICU: conclusions and recommendations for care. J Perinatol. 2000.

“Although **recommendations for safe exposure** to sound have existed for more than three decades, reports indicate that **these recommendations are not being followed.**”

- Krueger C, Horesh E, Crossland BA. Safe Sound Exposure in the Fetus and Preterm Infant. JOGNN - J Obstet Gynecol Neonatal Nurs. 2012.

“**Sound levels** recorded in all the NICUs were **considerably higher** than those recommended by the [American Academy of Pediatrics], placing vulnerable neonates at risk for developmental disorders. Mental **abilities to distinguish useful sounds are not developed.**”

- Neille J, George K, Khoza-Shangase K. A study investigating sound sources and noise levels in neonatal intensive care units. SAJCH South African J Child Heal. 2014

***The problem of NICU noise is well established and broadly understood***

# Existing Approaches Are Ineffective

## NICU Reconstruction

- Minimal changes (4dB) to average sound levels and no change to sound levels exceeded 10% of the time, levels remained in excess of AAP guidelines (Krueger, 2012)

## Single Family Rooms

- Single rooms not quieter than double rooms (Parra, 2017)
- Open ward and single rooms differ by between +0.7 and -4.3dB (Pineda, 2017)

## Staff Education

- No decrease in noise levels after implementing noise awareness program (Milette, 2010)

## Light Warnings

- After implementing, no significant difference in noise levels (Chang, 2006)

## Ear Coverings or Ear Plugs

- Concerns about adhesive's effect on delicate skin (Duran, 2012)
- Nursing concerns over aspiration, frequent repositioning (Lasky, 2009)

## Moderating Alarms

- Concerns about lowering alarm volumes resulting in missed alarms (Disher, 2017)

***Existing means of noise attenuation are either contraindicated or are ineffective***

# Product: Neoasis<sup>®</sup> Solution



Disposable elements inside incubator; single patient use



Reusable hardware affixed to existing incubator

- **Non-contact active noise control system**
- **Attenuates noise with cancelling sound waves**
- **Adds parents' voice to permit directed communication to infant**
- **Automatically adapts to changing environment**

*Safe to use, no behavior changes needed, works with existing equipment*

## CLINICAL RESEARCH ARTICLE

### Incubator-based active noise control device: comparison to ear covers and noise reduction zone quantification

George M. Hutchinson<sup>1</sup>✉, Preston S. Wilson<sup>2</sup>, Scott Sommerfeldt<sup>3</sup> and Kaashif Ahmad<sup>4</sup>

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<sup>1</sup>Invictus Medical

<sup>2</sup>Mechanical Engineering, University of Texas at Austin

<sup>3</sup>Department of Physics and Astronomy, Brigham Young University

<sup>4</sup>Pediatric Neonatology, National Director Clinical Research

## Study Methodology

1. Neoasis<sup>®</sup> compare to passive ear covers
2. Quantification of noise reduction zone

## Study Implications

Quiet environment provided by ear covers has clear health benefits

Ear covers are contraindicated and unreliable

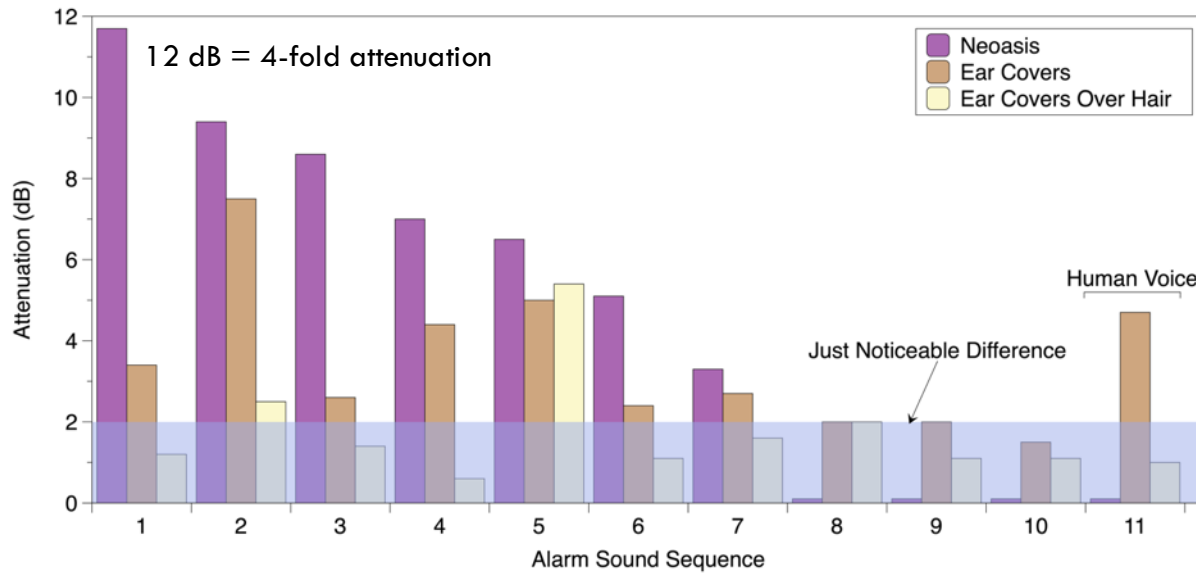
Neoasis<sup>®</sup> provides better noise attenuation than ear covers

Neoasis<sup>®</sup> should at least match health benefits of quiet environment found with ear covers

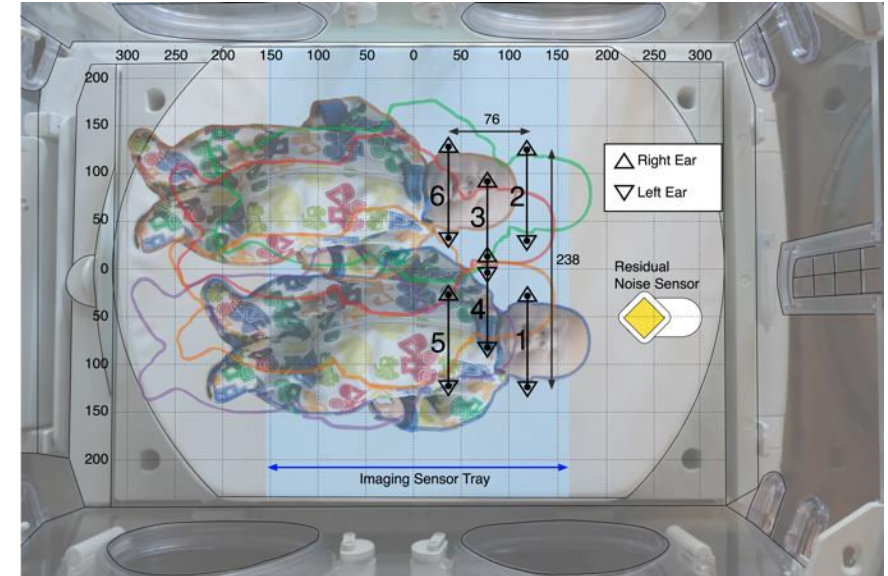


# Neoasis Effectiveness Demonstrated

Attenuation Achieved By Neoasis And Ear Covers In Response To 10 Sound Sequences And Voice



- **Performance testing with NICU alarms**
- **Comparison to adhesive ear covers**
  - Affixed directly to manikin over hair on manikin
  - These ear covers are NOT widely adopted due to complications with the adhesive on infant skin
- **Neoasis had superior performance for all alarm sounds**
  - Attenuations below the JND are considered equivalent
- **NOT attenuating voice is beneficial to language development**



- **Zone of attenuation covers essentially all positions infant would be placed in incubator**



“Sure noise is a problem **but what can I do?** Turn off the ventilators? Do without the alarms?”

- Dr Inder, Chief of Pediatric Medicine, Brigham and Women’s Hospital

“This product will be a **significant advance**...and will **improve outcomes** for this vulnerable population”

- Dr Wearden, NICU Medical Director, Baptist Health System

“It’s going to reduce the noise but at the same time **the parent’s voice can reach the baby which is a great thing.**”

- Dr Maliha Shareef, Medical Director, Loyola University Medical Center

“The research is there to show that **noise impacts neurodevelopment** in these kids, and the **neonatologists and developmental pediatricians believe this** too.”

- Jenny Brandenburg, NICU Nursing Director, Carle Foundation Hospital

“Since **we are looking at reducing noise levels** in our NICU ... please keep us updated.”

- Carol Bennett, Pediatric Clinical Nurse, Cleveland Clinic

“That’s **nothing compared to the rest of the expenses** in the NICU.” [referring to the price]

- Sheila Guinn, Value Analysis Nurse Manager, Cook Children’s Hospital

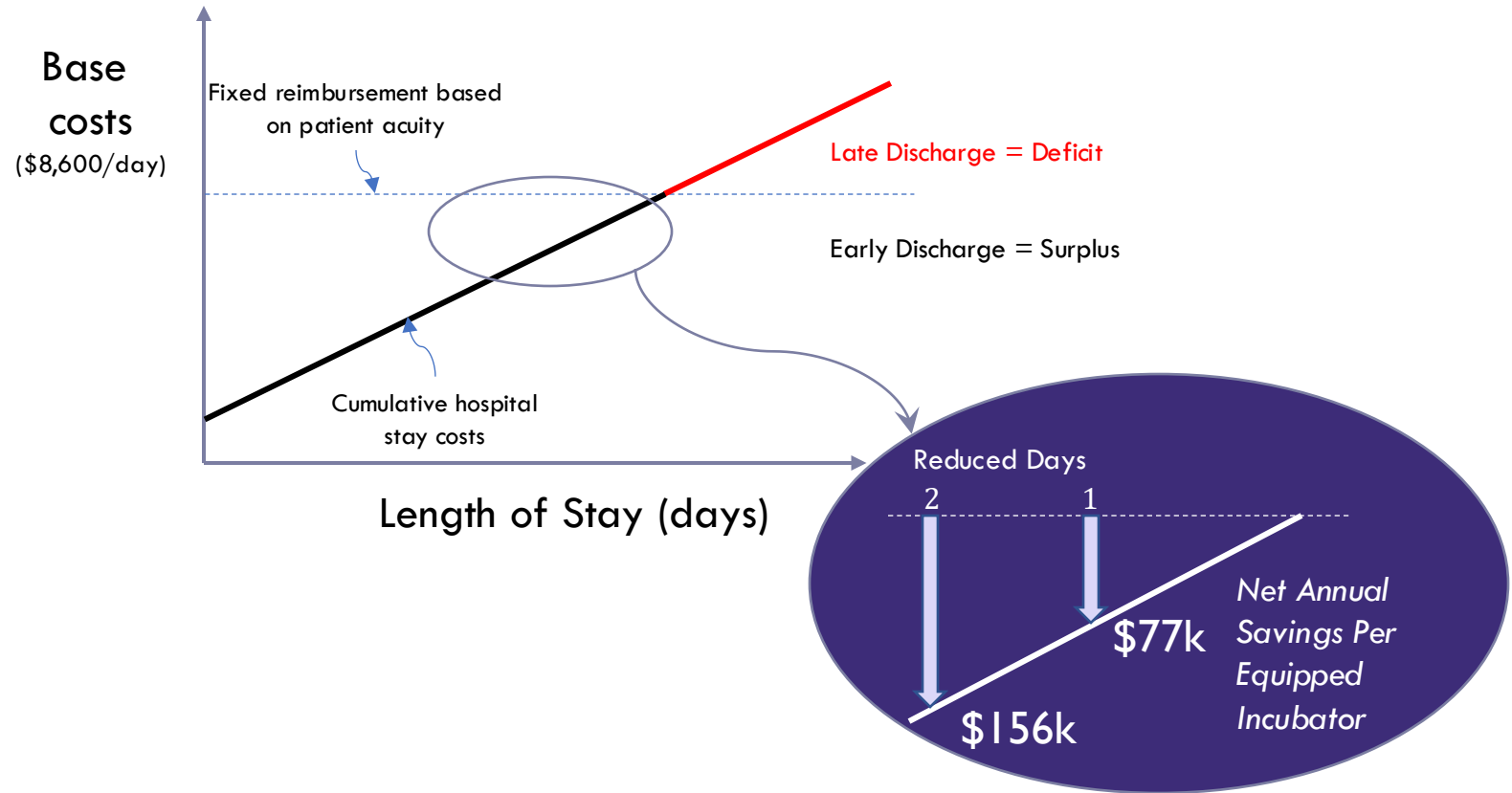
*Invictus’ interactions on NICU noise problem confirm the literature*

# Positive Financial Impact For Hospital

## Timely Patient Discharge Essential For NICU Financial Solvency

- Infants exposed to quieter environments grow faster
  - ~230g more growth over avg length of stay<sup>1-3</sup> (about 10% of total weight)
- Evidence of growth is necessary for discharge

**Base costs accumulate each day, eventually exceeding fixed reimbursement**



1. Abou Turk C, et al. A randomized clinical trial evaluating silicone earplugs for very low birth weight newborns in intensive care. J Perinatol. 2009 May;29(5):358–63.
2. Abdeyazdan Z, et al. Motor responses and weight gaining in neonates through use of two methods of earmuff and receiving silence in NICU. ScientificWorldJournal. 2014;2014:864780. PMID: 25614898
3. March of Dimes. Special Care Nursery Admissions. March Dimes Perinat Data Cent. 2011;1–3.

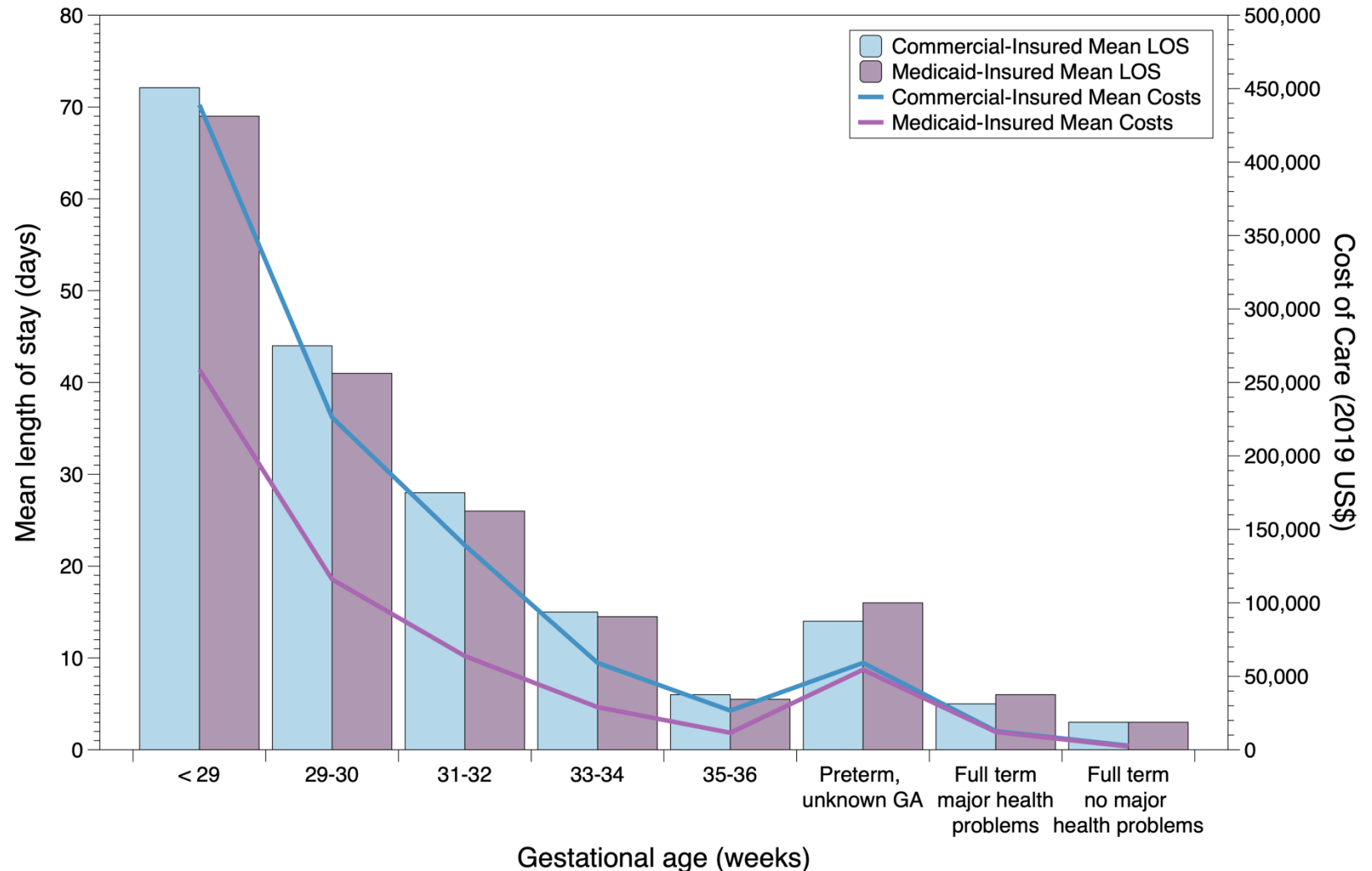
***Early Safe Discharge Keeps Hospitals Under Budget***

# Preterm Infants' High Cost To Treat

Premature infants consume disproportionate resources

- Greater length of stay
- Higher cost of care

Youngest premature infants most likely to require incubators

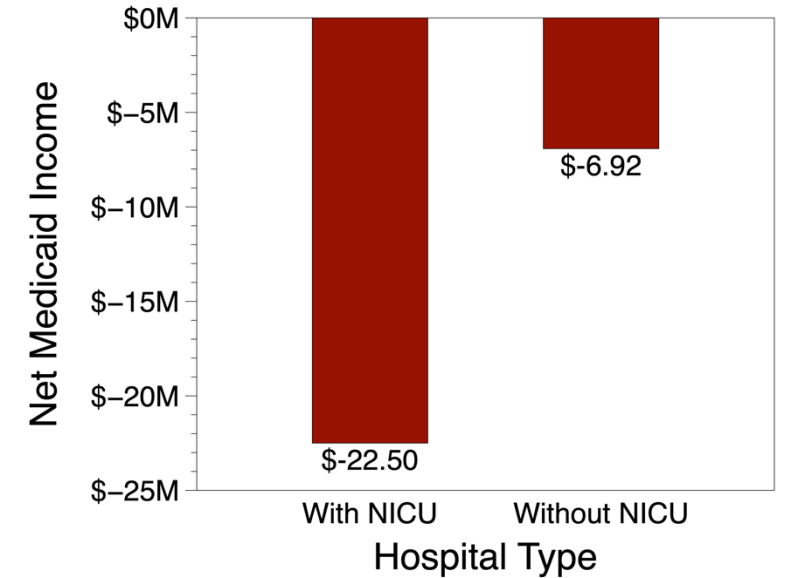
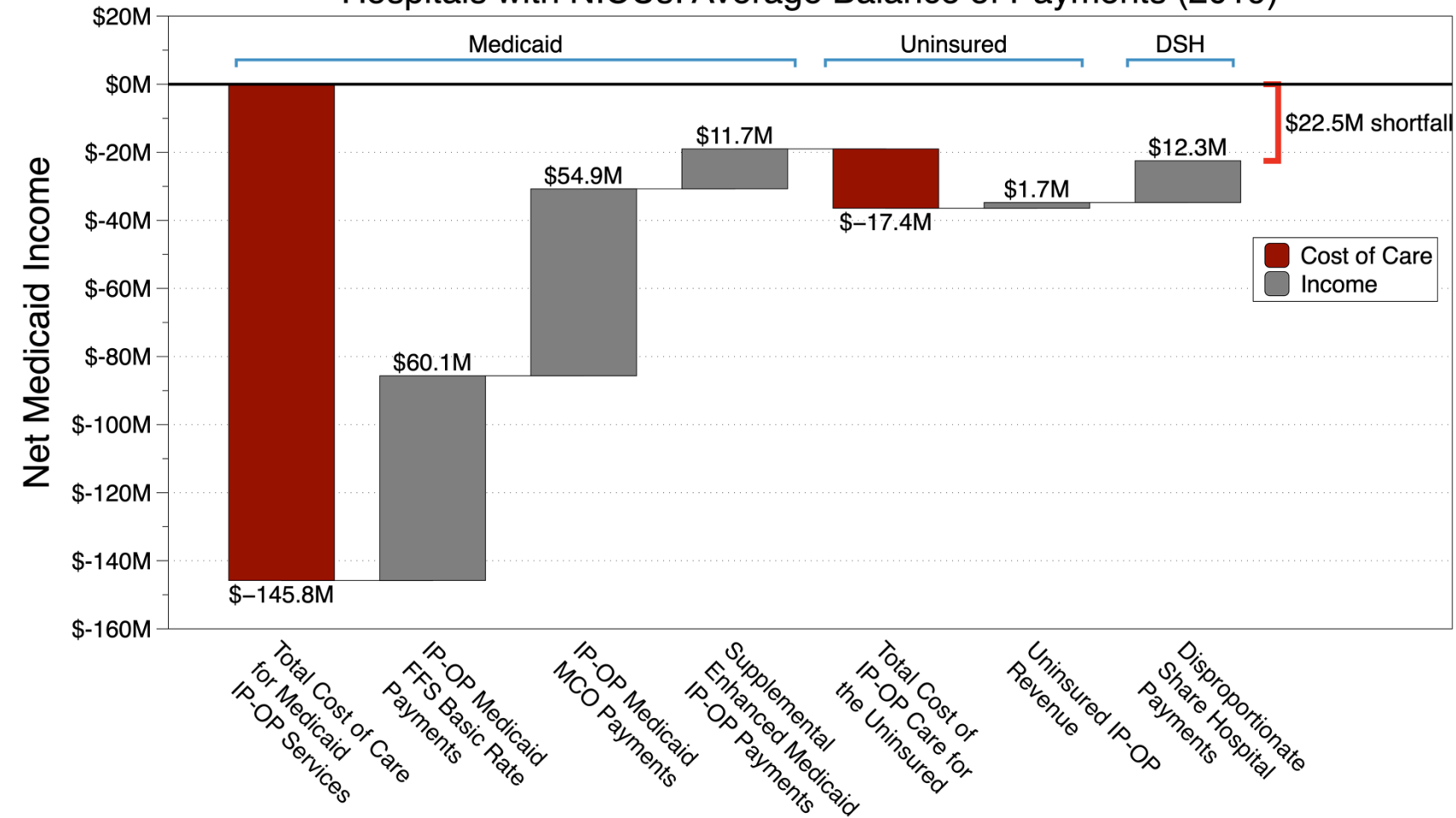


# Medicaid Shortfall Affects NICUs

Disproportional Share Hospitals with NICUs have large annual shortfalls

Hospitals with NICUs suffer greater impact

Hospitals with NICUs: Average Balance of Payments (2019)



Medicaid Disproportionate Share Hospital payments.  
<https://www.medicaid.gov/medicaid/financial-management/medicaid-disproportionate-share-hospital-dsh-payments/index.html>

# Regulatory Clearance Received

- Neoasis<sup>®</sup> is cleared by the FDA
- De Novo pathway defines this as a new device
  - “Active noise attenuation system for infant incubators”
- Indications for use
  - “Intended to reduce noise levels inside an infant incubator in NICU”
- Any new indications for use require only a 510(k) submission

*Neoasis<sup>®</sup> is an entirely new class of device*

## IP Highlights

- Current product embodiment
- Growth features
- Alternate embodiments for wider moat
- No royalty stack on any licensed patents

### 12 Issued US patents

***11 of 12 expiration dates from 2030 to 2040***

Claims generally directed towards:

- Safeguard techniques
- Mechanical design of ANC system
- Aesthetic design of mechanical system
- Automatic adapting to different environments
- Eliminating calibration
- Hardware for improved attenuation performance
- Voice pass-through with ANC system
- Cry analysis

### 1 Pending Application Family

***Earliest utility patent expiration date is 2041***

Claims generally directed towards:

- Alternate mechanical embodiments
- Mechanical design for passive noise control in incubators

**Neoasis® Registered Trademark**



## Key Operational Team

### **George Hutchinson PhD, CEO**

- 35+ years of innovation experience in medical devices
- PhD Engineering Marquette University, Alumni Harvard Business School
- Admitted to practice before US Patent & TM Office

### **Eric Eisbrenner, CFO**

- 35+ years of financial mgmt and ops experience
- Co-founder Vidacare Corp (\$300 million exit)

### **Paul Voith, Engineering**

- 30+ years of DSP, real-time algorithm development
- Extensive experience in medical device design

### **Kaashif Ahmad MD, MSc**

- Research Director of Neonatal Clinical Trials, MEDNAX National Medical Group
- Neonatologist, The Women's Hospital of Texas

### **Preston Wilson, PhD, Acoustics**

- Expert in acoustic transducers
- Mech Eng Professor, Univ of Texas at Austin
- Co-chief scientist for Office of Naval Research acoustics

### **Scott Sommerfeldt PhD, ANC**

- Expert in Active Noise Control
- Former Dean, Dept of Physics and Astronomy, BYU
- Authored >100 papers on ANC and acoustics

## Board of Directors

### **Steve Dufilho, Chairman of the Board**

- Former Chairman of the Board and current board member of Ascension Health, largest US nonprofit health system
- Former CEO Compass Bank & The Trust Company
- Former Chairman of CHRISTUS Santa Rosa Health Care

### **Lynne Nauss, Board Member**

- 30+ years executive leadership in medical devices
- Former EVP KCI, CEO KCI, Japan
- Former Global President, Therapeutic System, KCI

### **Dennis Kane, Board Member**

- Over 40 years of R&D, sales, and marketing in pharma, diagnostics and devices
- Served on private & public healthcare company boards

### **George Hutchinson, Board Member**

### **Eric Eisbrenner, Board Member**

## Consultants

### **Merge, Marketing Communications**

### **ProximaCRO, Regulatory Affairs**

### **Rosenthal, Pauerstein, Sandoloski, Agather LLP Corporate Legal Affairs**

### **Lawler IP, Intellectual Property**

### **i3 Product Development, Mechanical Design**

### **TUV Rheinland, Testing and Certification**

### **Steris, Disinfection Testing and Consulting**

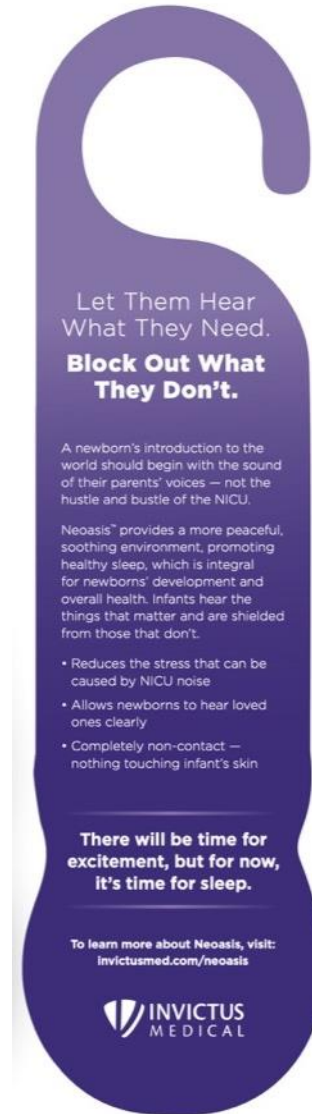
### **Virtex Assembly, High Level Assembly**

# Babies need their sleep



It simply makes sense!

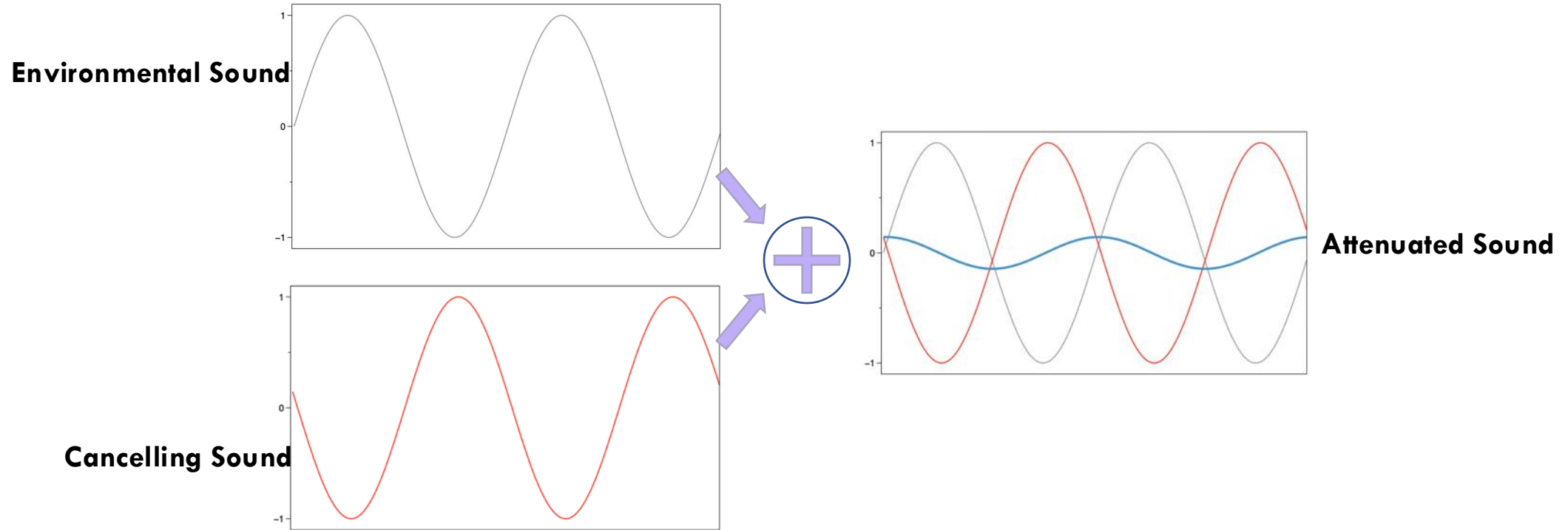
George Hutchinson  
[ghutchinson@invictusmed.com](mailto:ghutchinson@invictusmed.com)



# Backup Information

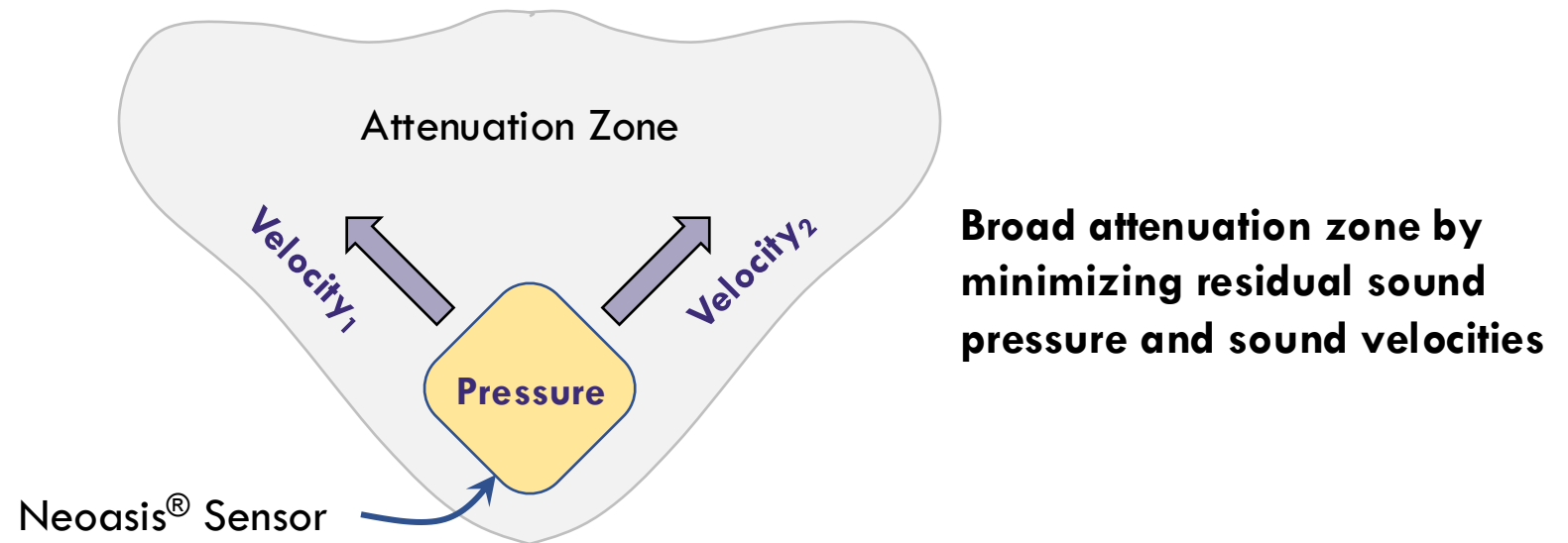
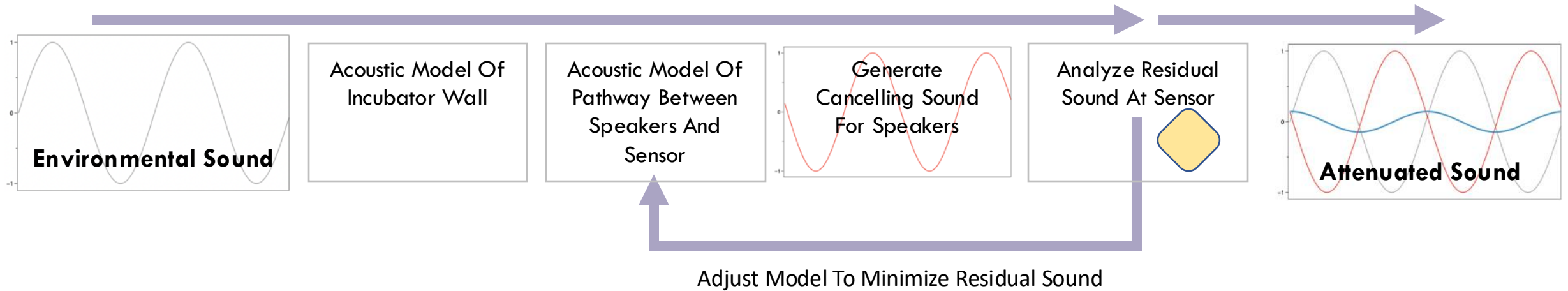
Technical Details of Active Noise Control

# Active Noise Control Theory



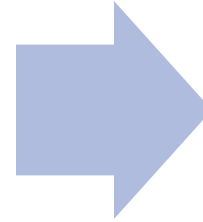
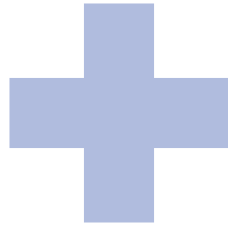
***Incident Waves Sum: Out Of Phase Waves Cancel***

# Neoasis<sup>®</sup> Proprietary System



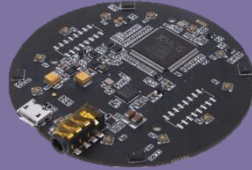
# ANC Leveraged To Other Applications

## Invictus Algorithms



## Enabling Technologies

- Inexpensive microphone arrays
  - Sound localization
- Remote Virtual microphones
  - ANC residual “sensor” in subject’s ears
- Tensor processing units
  - Machine learning coprocessor
- Small/thin speakers + Vision-based subject tracking
  - Beam forming cancelling sound waves



## Expansion Markets

### Healthcare

- All intensive care beds (100k\*)
- Nursing homes beds (1.7m\*)

\* USA only

### Residential/Hospitality

- Retirement communities
- Hotel rooms
- Residential bedrooms

### Commercial

- Cubicle office environments

### Heavy equipment

- Earth moving
- Farming
- Industrial