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An InnerSpace, Inc. White Paper

AirPulse ICP Bench Top Comparison

AIRPULSE ICP

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November 8, 11

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AirPulse AMS Patient Cable

Introduction

There have been many milestones in ICP monitoring ranging from directly monitoring the fluid pressure in the ventricle to the introduction of a fiber-optic and transducer tipped catheters placed intra-parenchymally.

The Hummingbird AirPulse™ ICP is the next leap forward in ICP monitoring technology offering a complete ICP system with:

- No capital hardware
- Recalibrate In Situ
- No leveling required
- Parenchymal ICP Sensor

The Hummingbird AirPulse ICP addresses all concerns documented over the stability of ICP measurement using current generation parenchymal sensors.(Piper IR 1999)

Problem Statement

Further improvement in ICP monitoring technology should focus on developing ICP devices that can provide simultaneous ventricular CSF drainage and parenchymal ICP measurement. This would allow in situ recalibration and give accurate ICP measurements in case of transient fluid obstruction.(Brain Trauma Foundation 2007)

Previous Options

Current generation ICP monitors measure pressure through an external transducer (strain gauge), transducer tipped catheter (strain gauge) or fiber-optic tipped catheter technology.

The ventricular catheter connected to an external transducer is considered to be an accurate and reliable method of monitoring ICP. It provides the ability to be recalibrated in situ, but is susceptible to

ventricular catheter occlusions, which can cause inaccuracy of the ICP measurement. Furthermore, the external transducer needs to be leveled (positioned at the same height) to a fixed point of reference relative to the patient's cranial anatomy to avoid measurement offset. Maintaining the transducer's position relative to the patient's anatomy may be challenging as patients are moved, their heads settle into the pillow, and their beds are adjusted.

Parenchymal sensing, utilizing a strain gauge or fiber-optic technology, is designed to be calibrated prior to placement and cannot be recalibrated in vivo. If the device drifts, malfunctions, or breaks after placement, it cannot be recalibrated and the potential exists for an incorrect reading. Additionally, these (traditional) parenchymal sensing technologies can be cost-prohibitive with hardware costs ranging from $10k - $15k per bed.

InnerSpace Solution

The Hummingbird AirPulse ICP addresses the challenges of current generation technology:

- No capital hardware
- Recalibrate In Situ
- No leveling required
- Parenchymal ICP sensor

No Capital Hardware

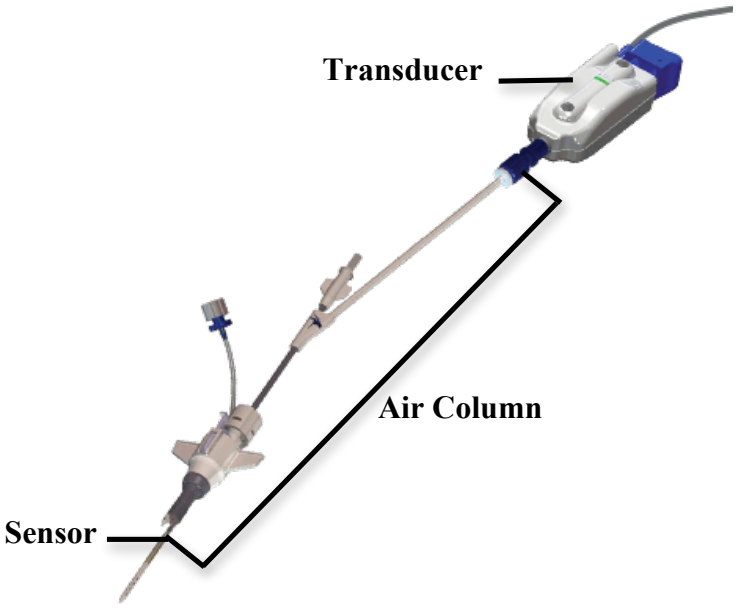
AirPulse ICP eliminates the hardware requirements of traditional parenchymal sensing technology as it uses a patient cable that connects directly to the patient monitor. The AirPulse Air Management System (AMS) patient cable integrates and utilizes a state-of-the-art pressure transducer that translates the physiologic pressure waveform to the patient monitor.

Recalibrate In Situ

AirPulse ICP provides the ability to recalibrate the transducer at any time during the procedure because the transducer is placed within the cable and external to the patient. At any time, the cable can be decoupled from the patient and the transducer calibrated to atmosphere, eliminating transducer drift (an inherent problem for fiber optic and strain gage catheters) and ensuring precise and accurate measurements.

No Leveling Required

AirPulse ICP utilizes an air column to measure pressure. Unlike fluid, air is less dense and is insensitive to the position of the transducer relative to the patient's cranial anatomy nor patient or line movement induced errors. The result is a high fidelity pressure waveform trace without the need to level or re-level.



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Parenchymal ICP Sensor

The AirPulse ICP sensor is placed in the parenchyma providing accurate and stable ICP measurements regardless of whether the catheter is within the ventricle or if the ventricular catheter is occluded.

AirPulse ICP Principle of Operation

The AirPulse System is comprised of the AirPulse AMS patient cable connected to a Hummingbird catheter. The Hummingbird catheter utilizes an air column in the catheter to transmit ICP pressure.

The AMS is designed to inject a defined aliquot of air into the catheter sensor. The AirPulse system changes volume in response to pressure changes within the brain according to Boyle's law ($P_1V_1=P_2V_2$). The air column in the catheter transmits pressure events within the brain to the external transducer housed in the AMS cable. The system is directly analogous to a pressure transducer within the ventricular drainage set, wherein a water-filled tube is connected to an external transducer. The water column in the set serves as a coupling media that transmits pressure information from the brain to the transducer. Similarly, the air column in AirPulse ICP serves as a coupling media that transmits pressure to an external transducer.

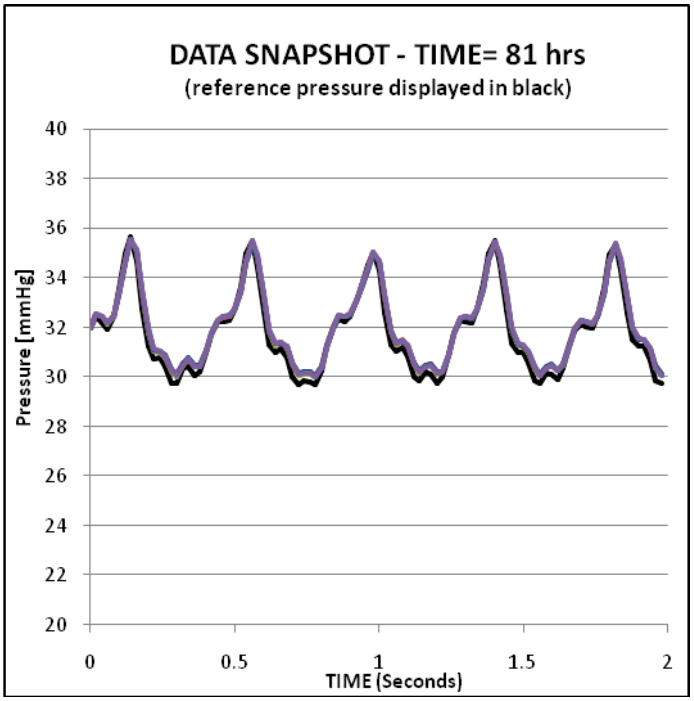
AirPulse ICP Bench Top Results – 6 Day Study (life test)

Objective: Evaluate the accuracy of the InnerSpace AirPulse ICP for 6 days measuring mean pressure and pressure amplitude.

Methods: In order to simulate clinical use, samples were placed into a fluid-filled test chamber with the following additions:
Oxygenator - reduce the partial pressure within the fluid test chamber to simulate the venous return system
Pressure waveform generator- to provide pulsatile pressure
Temperature control mechanism- set to 37 °C ± 2 °C to simulate core body temperature.

Pressure data from the Innerspace AirPulse ICP units and a reference transducer were collected at 50 samples per second for the duration of the test and compared relative to a reference transducer (GE NPC-100T).

Results: AirPulse ICP was able to accurately display mean pressure and pressure amplitude for 6 days. The results demonstrated superior pressure performance to the pressure accuracy requirements of ANSI/ AAMI standard NS28:1988 (R) 2010 of better than ±2 mm Hg in the range of 0 to +20 mmHg and better than ±10 percent from +20 to +100 mmHg.



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Technology Matrix

Technology	Capital Hardware	Accuracy	Re-zero In Situ	Leveling Required
External Strain Gauge (EVD)	NO	YES, if leveled, de-bubbled, and in ventricle	NO	YES
Internal Strain Gauge	YES	YES, if in ventricle	NO	NO
Internal Fiber optic	YES	YES, if in ventricle	NO	NO
AirPulse ICP	NO	YES	YES	NO

The quotes and information referenced in this white paper were selected from independent third party publications and are not intended to suggest that such third parties have reviewed and/or endorsed InnerSpace, Inc. products.

Works Cited

Brain Trauma Foundation. *Guidelines for the Management of Severe Traumatic Brain Injury* . Vol. 3rd Edition. Brain Trauma Foundation, Inc., 2007.

Piper IR, Barnes A. *Re-assessment of the Camino intracra- nial pressure sensor: a bench test study after catheter removal from the patient.* . Vol. 13. Br. J Neurosurg, 1999.

See instruction for use for full prescribing information.

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