Hummi Micro Draw Blood Transfer Device

An Important Addition to Your IVH Bundle
Hummi Micro Draw & Micro T Connector
For Infection Control and IVH Risk Reduction

The Next Generation System for Closed Micro Blood Sampling for the Neonate

Also Providing an Important Addition to Your IVH Bundle

This combination of microbial barrier protection utilizing a closed port Micro T and the ability to gain access directly to the catheter hub with a closed Micro Sampling Device providing lower clearance and flush volumes and reduced pressures for sampling, provides both Infection Control and IVH risk reduction characteristics all in the same system. No other system for blood sampling in the Neonate can provide both of these very important clinical advantages.
The Next Generation System for Closed Micro Blood Sampling for the Neonate

continued

- **Waste/holding is reduced by 70%** vs. current methods (0.5mL vs. 1.5mL)
- **Flush volumes are reduced by 80%** vs current methods (0.3mL vs. 1.5mL)
- **Saline values remain more stable** vs. current methods

- **Only 1.3mL total blood / fluid movement** required for blood sampling vs. 4-6mL for current methods

- **The Hummi remains closed to atmosphere during access and blood sampling directly from catheter hub**

- **Waste/holding and sample blood is collected without negative pressure**

- **Flushing the umbilical catheter is completed with only 0.30mL**, and multiple closed flushes (10 with 3mL syringe) are possible without flush syringe change out (inf-ivh)
Complications of Prematurity

Four major complications of prematurity contribute to 90% of all the costs related to the treatment of the premature infant.
Major Complications of Prematurity

1. **RDS** - Respiratory Distress Syndrome
2. **BPD** - Broncho Pulmonary Dysplasia
3. **NEC** - Necrotizing Enterocolitis
4. **IVH / PVL** – Intraventricular Hemorrhage and Periventricular Leukomalacia
What is IVH & PVL?

**Intraventricular Hemorrhage** (IVH) of the newborn is bleeding into the fluid filled areas (ventricles) inside the brain. The condition occurs most often in babies that are born prematurely.

**Periventricular Leukomalacia** (PVL) is a type of brain injury. PVL actually represent small “holes” in the brain due to the death of small areas of brain tissue around the normal fluid filled cavities (ventricles) of the brain.

Often these 2 conditions are referred to as PVH/IVH, or PV/IVH as they are often present together, and have prematurity as a key factor for development.
IVH – Why?

- Primarily attributed to:
  - Increased Vascular Fragility
  - Disturbances to Cerebral Blood Flow (CBF)
  - Possibly, but Not Often Disorder of Platelet Count, Coagulation

Dr. John Golden, D.O. Neonatologist, Pediatrix Medical Group of WA, Tacoma General Hospital, Sept. 2014
What is a Bundle?

- “A bundle is a selected set of interventions or processes of care distilled from evidence-based practice guidelines that when implemented as a group provide a more robust picture of the quality of care provided.”

- The implementation of the bundle is aimed at tracking change in practice and reporting how often these evidence-based interventions are used.

Levy et al. Critical Care Med. 2004
As Part of an IVH Bundle the Hummi Micro Draw has Unique Clinical Implications for Reducing Risk Factors for IVH / PVL

Hummi Micro-Draw Blood Transfer Device has clinical implications for reducing the known risk factors for IVH / PVL development from the use of:

1. Umbilical Arterial Catheters (UAC) and ...

2. Umbilical Venous Catheters (UVC)
Key Neonatal Risk Factors and Clinical Characteristics for Development of IVH / PVL

1. Prematurity
2. Low Gestational Age
3. Low Birth Weight
4. Use of Umbilical Artery Catheter (UAC) or Umbilical Venous Catheter (UVC)
Other Risk Factors

5. Use of Inotropic Agents for hypotension
6. Metabolic Acidosis
7. Development of RDS – Respiratory Distress Syndrome
8. Mechanical Ventilation
9. Development of Sepsis
10. Surgical Procedure
11. Transfusion of Red Blood Cells
## Incidence of IVH / PVL in Premature Infants with Umbilical Catheter Use

<table>
<thead>
<tr>
<th>Catheter Type</th>
<th>Case Group IVH / PVL</th>
<th>Control Group IVH / PVL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Umbilical Arterial Catheter (UAC)</td>
<td>23.7%</td>
<td>7.6%</td>
</tr>
<tr>
<td>Umbilical Venous Catheter (UVC)</td>
<td>27.9%</td>
<td>5.1%</td>
</tr>
</tbody>
</table>

Lee et. al 2010:
The withdrawal and infusion of blood via the umbilical catheter can cause a significant rapid change of cerebral blood flow of preterm infants.

Bray, et.al
Maintaining stable cerebral blood flow is paramount to avoiding damage to premature brain cells due to excessive volumes and pressures created during a blood sampling procedure with umbilical catheters.

The Hummi reduces blood and fluid volume movement by 70% during blood sampling from umbilical catheters and eliminates negative pressures during blood collection, thus reducing the risk of altering cerebral blood flow.
The Risk for IVH Development

Reduction in intra-ventricular hemorrhage by elimination of fluctuating cerebral blood flow velocity in preterm infants ...

Perlman, et.al Have demonstrated that the alteration from auto-regulation to a pressure passive circulatory pattern appears to be an important step in the development of PV / IVH.

New England Journal of Medicine
1988; 309 – 204 - 9
The Risk for IVH Development

Premature infants brains have some ability to regulate pressure and blood flow some of the time but not all of the time.

Since the baby’s brain cells are underdeveloped, excessive movement of blood and fluid in an out of the heart and brain during a blood draw can damage the underdeveloped cells and change them from auto-regulation to a passive state, where no regulation of pressures takes place.

This is a high risk situation for the development of IVH, which is damage to the cells, leading to bleeding in the brain. If severe enough, mental retardation and cerebral palsy can develop.
Changes in cerebral hemodynamics and Oxygenation are thought to be major causes of Intracranial Hemorrhage and Periventricular Leukomalacia in premature infants.

Roll, et.al
Acta Paediatrical 2006; 95: 68 - 73
Decreased oxygen supply (ischemia) and decreased blood flow to the brain are both causative factors for IVH and PVL development according to Roll et al.

When using the Hummi for blood draws, the volume of blood and fluid movement is significantly reduced from current methods, thereby reducing the risk of decreasing blood flow and oxygenation to the brain.

The Hummi only moves 1.3mL in total fluid when doing a blood draw vs. 4-6mL with current methods.

Known de-oxygenation has been reported at 1.8mL of total fluid movement during a blood draw.
The Risk for IVH Development

Umbilical Artery Catheter Blood Sampling Volume and Velocity: Impact on Cerebral Blood Volume and Oxygenation in Very Low Birth Weight Infants

This study demonstrates that blood sampling from an Umbilical Arterial Catheter (UAC) induces an inevitable decrease in Cerebral Blood Volume and Cerebral Oxygenation in preterm infants.

In contrast to our expectations, reducing sampling velocity failed to prevent the reduction of oxygen supply to the preterm infant’s brain associated with the blood withdrawal from a UAC.

Sampling volume appears to be central in determining the magnitude of this decrease.

Roll, et al.
Acta Paediatrica, 2006; 95: 68 - 73
Total sampling volume of blood and flush is now known to be a prime cause of reduced cerebral blood volume and reduced oxygenation during umbilical catheter sampling.

The Hummi Micro Draw reduces the total sampling volumes by 70%, and flush volumes by 80%, thus reducing the risk for reduced cerebral blood volume and reduced oxygenation which is known to be a causative factor for IVH development.
The Risk for IVH Development

Risk Factors for Periventricular – Intraventricular Hemorrhage in Premature Infants

Use of umbilical catheters and infusion and transfusion of blood products are all related to circulatory volume changes directly.

These findings suggest that hemodynamic changes of systemic and cerebral circulation are important for the development of PV – IVH in preterm newborns.

Lee, et.al
Journal Korean Medical Science
2010; 25: 418 - 424
Lee confirms what Roll discovered, but takes it one step further and defines the risk factors even further, implicating the use of Umbilical catheters as a prime causative factor in the development of IVH / PVL.

The Hummi addresses the concerns that Lee has about Umbilical Catheter use for blood drawing by reducing the required volumes to do a blood sampling procedure by 70% and eliminates negative pressures during sampling, thus reducing the risk for the development of IVH / PVL.
“As the survival rate of extremely preterm infants has remarkably increased recently, more delicate hemodynamic balancing has come to be more essential than any other perinatal factors that have been proposed in previous studies for the prevention of PV-IVH”.

Lee et. al 2010, The Korean Academy of Medical Science

The goal of maintaining hemodynamic balance in the neonate is paramount in reducing the risks for the development of IVH (Intraventricular Hemorrhage) and PVL (Periventricular Leukomalacia), which are the primary causative factors in the development of Mental Retardation and Cerebral Palsy in the premature infant.

Lee et. al 2010, The Korean Academy of Medical Science
Lee summarizes by stating that **upsetting the delicate balance of the blood flow to the premature infants brain is a major factor in the development of IVH / PVL**.

Keeping this balance of blood flow, pressure changes and oxygen imbalance during blood sampling procedures is **one of the most important perinatal factors for the prevention of IVH / PVL in premature infants**.

As we now know, the Hummi provides the opportunity to reduce these risk factors as demonstrated by Roll, Perlman, Bray and Lee.

The Hummi represents the next generation system for reducing Infection Risk and at the same time reducing the significant risk for the development of IVH / PVL in the premature infant when drawing blood from Umbilical Catheters.
# Volume of Fluid Movement as a Percentage of Total Blood Volume during Umbilical Catheter Blood Sampling

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Grams / Pounds</td>
<td>NICU Practice</td>
<td>Total Fluid Volume Movement (mL)</td>
<td>NICU Practice</td>
<td>NICU Fluid Volume Movement Per Blood</td>
<td>NICU Fluid Volume Movement Per</td>
<td>NICU Fluid Volume Movement Reduction</td>
</tr>
<tr>
<td>and Approximate</td>
<td>NICU Total Fluid</td>
<td>NICU Percent of Neonate’s Total Blood</td>
<td>NICU Total Fluid</td>
<td>NICU Percent of Neonate’s Total Blood</td>
<td>NICU Percent of Neonate’s Total Blood Movement Reduction</td>
<td>NICU Percent of Neonate’s Total Blood Movement Reduction</td>
</tr>
<tr>
<td>Total Blood</td>
<td>NICU Percent of</td>
<td>NICU’s Total Blood Movement (mL)</td>
<td>NICU’s Total Blood</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
</tr>
<tr>
<td>Volume</td>
<td>NICU’s Total Blood</td>
<td>NICU’s Total Blood Movement (mL)</td>
<td>NICU’s Total Blood</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
</tr>
<tr>
<td>Grams</td>
<td>NICU’s Total Blood</td>
<td>NICU’s Total Blood Movement (mL)</td>
<td>NICU’s Total Blood</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
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<tr>
<td></td>
<td>NICU’s Total Blood</td>
<td>NICU’s Total Blood Movement (mL)</td>
<td>NICU’s Total Blood</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
<td>NICU’s Total Blood Movement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grams</th>
<th>Pounds / Ounces (1g = 0.035 oz)</th>
<th>Approx. Total Blood Volume (mL)</th>
<th>Current NICU Practice NICU Total Fluid Volume Movement (mL)</th>
<th>Current NICU Practice NICU Percent of Neonate’s Total Blood Movement (mL)</th>
<th>HUMMI Fluid Volume Movement Per Blood Draw (mL)</th>
<th>HUMMI Percent of Neonate’s Total Blood Movement (mL)</th>
<th>HUMMI vs. Current NICU Practice Overall Fluid Volume Movement Reduction (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,000</td>
<td>2.25 lb = 36 oz</td>
<td>75.0</td>
<td>4.50</td>
<td>6.0%</td>
<td>1.30</td>
<td>1.7%</td>
<td>4.3%</td>
</tr>
<tr>
<td>950</td>
<td>2.14 lb = 34.2 oz</td>
<td>71.3</td>
<td>4.50</td>
<td>6.3%</td>
<td>1.30</td>
<td>1.8%</td>
<td>4.5%</td>
</tr>
<tr>
<td>900</td>
<td>2.03 lb = 32.4 oz</td>
<td>67.5</td>
<td>4.50</td>
<td>6.7%</td>
<td>1.30</td>
<td>1.9%</td>
<td>4.7%</td>
</tr>
<tr>
<td>850</td>
<td>1.91 lb = 30.6 oz</td>
<td>63.8</td>
<td>4.50</td>
<td>7.1%</td>
<td>1.30</td>
<td>2.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>800</td>
<td>1.80 lb = 28.8 oz</td>
<td>60.0</td>
<td>4.50</td>
<td>7.5%</td>
<td>1.30</td>
<td>2.2%</td>
<td>5.3%</td>
</tr>
<tr>
<td>750</td>
<td>1.69 lb = 27.0 oz</td>
<td>56.3</td>
<td>4.50</td>
<td>8.0%</td>
<td>1.30</td>
<td>2.3%</td>
<td>5.7%</td>
</tr>
<tr>
<td>700</td>
<td>1.58 lb = 25.2 oz</td>
<td>52.5</td>
<td>4.50</td>
<td>8.6%</td>
<td>1.30</td>
<td>2.5%</td>
<td>6.1%</td>
</tr>
<tr>
<td>650</td>
<td>1.46 lb = 23.4 oz</td>
<td>48.8</td>
<td>4.50</td>
<td>9.2%</td>
<td>1.30</td>
<td>2.7%</td>
<td>6.6%</td>
</tr>
<tr>
<td>600</td>
<td>1.35 lb = 21.6 oz</td>
<td>45.0</td>
<td>4.50</td>
<td>10.0%</td>
<td>1.30</td>
<td>2.9%</td>
<td>7.1%</td>
</tr>
<tr>
<td>550</td>
<td>1.24 lb = 19.8 oz</td>
<td>41.3</td>
<td>4.50</td>
<td>10.9%</td>
<td>1.30</td>
<td>3.2%</td>
<td>7.8%</td>
</tr>
<tr>
<td>500</td>
<td>1.13 lb = 18.0 oz</td>
<td>37.5</td>
<td>4.50</td>
<td>12.0%</td>
<td>1.30</td>
<td>3.5%</td>
<td>8.5%</td>
</tr>
<tr>
<td>450</td>
<td>1.02 lb = 16.0 oz</td>
<td>33.8</td>
<td>4.50</td>
<td>13.3%</td>
<td>1.30</td>
<td>3.9%</td>
<td>9.5%</td>
</tr>
<tr>
<td>400</td>
<td>0.90 lb = 14.4 oz</td>
<td>30.0</td>
<td>4.50</td>
<td>15.0%</td>
<td>1.30</td>
<td>4.3%</td>
<td>10.7%</td>
</tr>
<tr>
<td>375</td>
<td>0.84 lb = 13.5 oz</td>
<td>28.1</td>
<td>4.50</td>
<td>16.0%</td>
<td>1.30</td>
<td>4.6%</td>
<td>11.4%</td>
</tr>
<tr>
<td>350</td>
<td>0.79 lb = 12.6 oz</td>
<td>26.3</td>
<td>4.50</td>
<td>17.1%</td>
<td>1.30</td>
<td>5.0%</td>
<td>12.2%</td>
</tr>
</tbody>
</table>
UAC Single Blood Sampling using Hummi Micro-Draw
Clinical Implications from Reduced Saline Flush

- 80% Reduction in Saline Flush Volume per UAC Blood Draw
- 0.30mL Flush vs. 1.5mL Flush
- Reducing the Impact of Flush Volumes on Body Water and Sodium Values
- Allows fluid and electrolyte changes in the low gestational age infant to occur more appropriately during the first week of life
- Reduced risk for alteration of Cerebral Blood Flow during Umbilical Catheter Blood Sampling, a known risk factor for IVH development
Saline Flush Reduction

<table>
<thead>
<tr>
<th>Q4 - Every 4 hours - ABG / LAB Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>UAC mL Fluid</td>
</tr>
<tr>
<td>Volume Movement</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>24 hrs</td>
</tr>
<tr>
<td>48 hrs</td>
</tr>
<tr>
<td>72 hrs</td>
</tr>
<tr>
<td>96 hrs</td>
</tr>
<tr>
<td>Q 4 hr Current Protocol per procedure</td>
</tr>
<tr>
<td>4.50 mL</td>
</tr>
<tr>
<td>27.0 mL</td>
</tr>
<tr>
<td>54.0 mL</td>
</tr>
<tr>
<td>81.0 mL</td>
</tr>
<tr>
<td>108.0 mL</td>
</tr>
<tr>
<td>Q 4 hr Hummi per procedure</td>
</tr>
<tr>
<td>1.3 mL</td>
</tr>
<tr>
<td>7.8 mL</td>
</tr>
<tr>
<td>15.6 mL</td>
</tr>
<tr>
<td>23.4 mL</td>
</tr>
<tr>
<td>31.2 mL</td>
</tr>
<tr>
<td>Hummi Fluid</td>
</tr>
<tr>
<td>Total Volume Reduction per procedure</td>
</tr>
<tr>
<td>3.2 mL</td>
</tr>
<tr>
<td>19.2 mL</td>
</tr>
<tr>
<td>38.4 mL</td>
</tr>
<tr>
<td>57.6 mL</td>
</tr>
<tr>
<td>76.8 mL</td>
</tr>
<tr>
<td>Reduction in Saline Flush</td>
</tr>
<tr>
<td>1.2 mL</td>
</tr>
<tr>
<td>7.2 mL</td>
</tr>
<tr>
<td>14.4 mL</td>
</tr>
<tr>
<td>21.6 mL</td>
</tr>
<tr>
<td>28.8 mL</td>
</tr>
</tbody>
</table>
Saline Flush Reduction

Hummi Micro Draw vs. Current Methods
Q4 - UAC Blood Draws
Cumulative Volume Reduction Over Time (96hrs)
Reduction in Saline Flush Volumes & Overall Volume

Volume mL

Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2 Day 1 Day 2

Hosp. Protocol 4.5mL
4.5 9.0 13.5 18.0 22.5 27.0 31.5 36.0 40.5 45.0 49.5 54.0 58.5 63.0 67.5 72.0 76.5 81.0 85.5 90.0 94.5 99.0 103.5 108.0

Humm Protocol 1.3mL
1.3 2.6 3.9 5.2 6.5 7.8 9.1 10.4 11.7 13.0 14.3 15.6 16.9 18.2 19.5 20.8 22.1 23.4 24.7 26.0 27.3 28.6 29.9 31.2

Reduction in Saline Flush mL
1.2 2.4 3.6 4.8 6.0 7.2 8.4 9.6 10.8 12.0 13.2 14.4 15.6 16.8 18.0 19.2 20.4 21.6 22.8 24.0 25.2 26.4 27.6 28.8

Total Fluid Volume Movement Reduced
76.8 mL
Benefit for IVH Bundle
Hummi Micro Draw
Reducing the Risk Factors for IVH / PVL
Associated with Umbilical Catheter Use

The Hummi Micro-Draw represents a new closed method for doing umbilical catheter sampling that reduces the total movement of blood and fluid during the draw procedure by 70% for every blood draw vs current methods.

This reduction in blood and fluid movement significantly reduces the risk for alteration in cerebral hemodynamics, including cerebral blood flow alterations and cerebral de-oxygenation which can lead to the development of IVH / PVL.
The Hummi Micro-Draw and Micro T T-Connector System

a simple, closed, yet effective solution to reducing the risk factors for the development of IVH / PVL and Infection in the premature infant when using umbilical catheters.

Why not use the product for your IVH bundle that provides for reduced infection risk and the lowest possible blood / fluid movement in and out of the low birth weight baby, when it has been demonstrated that current methods definitely pose a higher risk in use for UAC blood sampling?
Hummi Needleless Micro-Draw Blood Transfer Device

Approximate Residual Fluid Volumes

S Sample Microbore Tubing Volume – 0.045 mL
W Waste Microbore Tubing Volume – 0.045 mL
Blunt Tubing & “Y” Hub Volume – 0.080 mL

Approximately 0.17 mL
Total Residual Volume

PAL Clean Blood Clearance Point

Approximately 0.080 mL
Residual Volume

0.045 mL
Residual Volume

0.17 mL
Total Residual Volume
Hummi Needleless Micro-Draw Blood Transfer Device

Questions?