

# Acquisition of SmartMonitor and NeoPAP portfolio By Circadiance from Philips Healthcare FREQUENTLY ASKED QUESTIONS

### Situation

On July 8, 2015, Circadiance completed the purchase of Philips' SmartMonitor and NeoPAP product lines and accessories, which includes the infant apnea monitoring technologies, nasal CPAP technologies, and related intellectual property.

## Q: Who is Circadiance?

**A:** Circadiance is a medical device company that makes innovative respiratory products. The company's main products are a line of soft cloth facemasks used to treat Obstructive Sleep Apnea (OSA). Circadiance's SleepWeaver CPAP masks are widely viewed as the most comfortable CPAP masks available and have been shown to reduce pressure ulcers in pediatric patients. The company has targeted the pediatric non-invasive ventilation market as a growth area. Circadiance was founded by CEO David Groll, a medical device executive and serial entrepreneur.

## **Q: What did Circadiance Purchase from Philips?**

**A:** Circadiance has purchased two pediatric respiratory products from Philips Healthcare, the Smart Monitor infant apnea monitoring system and the NeoPAP neonatal CPAP System. This acquisition was an asset purchase that included: inventory; production equipment; customer lists with detailed sales history; Supplier list & source of supply for each item, material or service used; manufacturing specifications, packaging, distribution, and service; Regulatory records; Service records and intellectual property.

## Q: What is Circadiance's role with these products going forward?

A: Circadiance has taken over all responsibilities for the SmartMonitor and NeoPAP portfolio, including sales and service.

## Q: When was the transition to Circadiance completed?

**A:** The transition of all assets of the SmartMonitor and NeoPAP portfolio was completed on July 8th, 2015.

## Q: What will Philips role in these products be?

**A:** As of July 8<sup>th</sup>, 2015, Philips has no further role in the production, distribution or service of these pediatric products.

## Q: Why did Circadiance make this acquisition?

**A:** This acquisition complements Circadiance's effort to migrate toward pediatric respiratory care, an underserved market where the company's products provide unique and superior benefits. The key reasons why the transaction is attractive to Circadiance are:



- Home infant cardiorespiratory monitoring is an established market dominated by SmartMonitor's proven technology which offers at-risk infants a smooth transition from hospital to home. We believe this product enhances our position with DME customers who provide home pediatric respiratory care.
- Infant apnea monitors are sold through home care companies, where Circadiance already has a strong presence.
- NeoPAP represents the future of respiratory care in neonatal patients with respiratory distress syndrome. The combination of this machine with our soft cloth mask technology will make a very strong product offering in this underserved market.
- These products provide an immediate source of cash flow and a revenue boost to Circadiance as they have ongoing demand in the market.
- SleepWeaver technology improves NeoPAP. One of the major drawbacks to NeoPAP is the lack of a good interface (face mask). The Circadiance SleepWeaver technology unlocks the value of the NeoPAP product.
- Circadiance's cloth CPAP masks have been shown to reduce or completely avoid pediatric pressure ulcers, a major concern for all pediatric hospitals. Circadiance has experienced demand pull into the pediatric space. However, the company has never directly marketed to this segment of the market. These pediatric products will provide direct access for Circadiance to the pediatric clinicians via products that they already know and use. This access will allow Circadiance to cross sell its SleepWeaver products for approved indications into this space.

## Q: Why did Philips divest the SmartMonitor and NeoPAP product lines?

**A:** After careful consideration and evaluation of the complete Children's Medical Ventures portfolio, the decision to divest the SmartMonitor infant apnea monitoring and NeoPAP nasal CPAP product lines was made in line with Philips' strategy of divesting activities outside of their strategic scope and focusing on expanding their strategic platforms.

# **Q: Will Circadiance be pursing sales of the SmartMonitor and NeoPAP products globally?**

**A:** Circadiance will pursue sales of the SmartMonitor products globally. Circadiance will reregister the product under our name in some countries as Philips is not allowed to transfer some registrations to them. For specific details on countries where SmartMonitor and/or NeoPAP is available, contact Circadiance customer service at 888-825-9640 or +1-724-858-2837.

# **Q:** How do we contact Circadiance for ordering devices or accessories, service and technical questions?

**A:** All inquiries regarding ordering devices or accessories, service and technical questions can be directed to Circadiance at (888)-825-9640 or +1-724-858-2837. You can also visit <u>www.circadiance.com</u>.

# Q: Where can I find a list of all the products, repair parts and accessories used with the SmartMonitor and NeoPAP products that are impacted by the transition?

**A:** Circadiance will maintain the existing part numbers for all items. A list of all the products, accessories and repair parts impacted by this transition can be provided upon request.



## Q: Will Philips continue to offer repair parts and accessories for existing customers?

**A:** Philips had ceased service and support of all SmartMonitor and NeoPAP products on July 8th, 2015. All customer service requests to Philips will be directed to call Circadiance for service.

### Q: Will Philips accept SmartMonitor and NeoPAP complaints from current customers?

A: Philips customers will be directed to Circadiance to file complaints.

# **Q**: For devices that are still under the manufacturer's warranty, will Circadiance continue to honor the warranty?

A: Yes, Circadiance will continue to honor all devices in the installed base that are currently under warranty.

### Q: What is happening with customer installed base and complaints data?

**A:** Complaints and installed base records have been transferred to and will be maintained by Circadiance.

### Q: What is happening with remaining inventory?

**A:** All commercial inventories of the products and their associated accessories have been transferred to Circadiance.

## Q: Will Philips continue to service the existing installed base of SmartMonitor devices?

**A:** After July 8th, 2015 Circadiance will accept all service orders on the SmartMonitor. Circadiance has all of the installed base records.

## Q: Will training (Service and Clinical) still be offered for these products?

A: Circadiance will establish training and service programs for these products.

### Q: Will there be any changes to the current repair strategies?

**A:** Circadiance is offering "fixed price" repairs. This allows the customer to know the cost of any repair before it is returned for service, eliminating the need to await an estimated quote and provide authorization to proceed. This will allow Circadiance service to quickly turn around repairs.

### **Q: What is SleepWeaver?**

**A:** Circadiance produces and sells the SleepWeaver soft cloth CPAP mask line of products which is used to treat OSA and other respiratory conditions in children and adults.

## Q: How can SleepWeaver Masks benefit children?

**A:** In children, the most common cause of obstructive sleep apnea is enlarged tonsils and adenoids. During sleep there is a considerable decrease in muscle tone, which affects the airway and breathing. Many of these children have little difficulty breathing when awake; however, with decreased muscle tone during sleep, the airway becomes smaller, and the tonsils and adenoids block the airway, making the flow of air more difficult and the work of breathing harder.

Sleep apnea is more common in children who are overweight; however, some children with enlarged tonsils and/or adenoids may even be underweight. Other children who are at high risk



for sleep apnea include those with a small jaw, craniofacial syndromes, muscle weakness or Down syndrome.

Obstructive sleep apnea (OSA) is present in 2%–3% of children, and peaks at 3–6 years of age—which is also the peak age for enlarged tonsils and adenoids. The presentation depends on the age of the child: In the infant, it might present as sudden infant death syndrome (SIDS). Toddlers with OSA will have hyperactivity, school-age children will have failure to thrive and poor school performance, and adolescents may present with obesity and excessive daytime sleepiness.

Due to the difficulty getting children to adhere to their CPAP therapy and the importance of the child getting that therapy, there is a strong demand in the market for a better mask. SleepWeaver masks have been shown to work with children 66 pounds and up and to reduce the incidence of pressure ulcers in these patients.

## **Q: What is Smart Monitor?**

**A:** SmartMonitor 2 is an apnea monitor for newborn infants discharged from the hospital. Apnea monitoring is typically prescribed by a physician and delivered by a homecare provider for home use. A hospital version is also available. SmartMonitor 2 is portable and easy-to-administer. The data from SmartMonitor 2 can be easily downloaded using SmartMonitor Synergy 4.0 software. Hospital alarm and/or oximetry versions are available. The product's revenue streams include capital purchases, annuity consumables and a service component.

## **Q: What does Smart Monitor do?**

**A:** Home apnea monitors like SmartMonitor 2 measure respiratory effort and heart rate, and are typically utilized to monitor central apnea of prematurity in newly discharged at-risk or high-risk premature infants (infants are at increased risk of cardiorespiratory events until 43 weeks' post-gestational age). An alarm will sound if there is respiratory cessation (central apnea) beyond a predetermined time limit (e.g., 20 seconds) or if the heart rate falls below a preset rate (bradycardia) to notify the parent that intervention (stimulation, mouth-to-mouth resuscitation, or cardiac compression) is required.

Infants who may benefit from home monitoring include those who have experienced an apparent life-threatening event (ALTE), have tracheostomies or other anatomic abnormalities that make them vulnerable to airway compromise. They may have neurologic or metabolic disorders affecting respiratory control, including central sleep apnea or chronic lung disease, including bronchopulmonary dysplasia). Monitoring is especially helpful for those individuals requiring supplemental oxygen, continuous positive airway pressure or mechanical ventilation.

## Q: What is NeoPAP?

**A:** The NeoPAP Continuous Positive Airway Pressure (nCPAP) System is designed to provide respiratory support to spontaneously breathing neonatal and infant patients less than 5kg in weight. Premature infants typically require either invasive ventilation and/or non-invasive respiratory support because they often lack the lung infrastructure to maintain adequate lung volume following exhalation. NeoPAP is designed for less severe infants that require respiratory



support. The product's revenue streams include capital purchases, annuity consumables and a service component.

## Q: What does NeoPAP do?

**A:** Neonatal CPAP is used with babies that have poor respiration because it supplements the baby's natural breathing rhythms. It also helps to counteract airway resistance, pushing the air through to the lungs despite minor obstructions or congestion. The pressurized air and steady rhythm of the breathing that is regulated by the machine also helps to develop lung function in the babies and promote the development of healthy breathing naturally, a neonatal CPAP is far less invasive or problematic for small babies than intubation soon after delivery. Because neonatal CPAP has had such positive results being used in this capacity, there are continuing adaptations and modifications that are being developed to make this treatment option and medical support system better and better for these small patients.

Neonatal CPAP machines function essentially the same way as the traditional CPAP because the design and function of the machines are basically the same. CPAP stands for Continuous Positive Air Pressure. Its primary function is to pump pressurized air into the lungs of the patient , ensuring that an adequate oxygen supply reaches the lungs and body at all times. This has been a great treatment for sleep apnea sufferers because the disorder is characterized by momentary episodes of no breathing due to a collapsed or obstructed airway. The pressurized stream of air supports the walls of the airway, enabling the airway to remain open.

Because most neonatal babies do not suffer from sleep apnea, neonatal CPAP operates in a different capacity. It is used primarily with premature babies or babies who are born with complications, especially those in the respiratory system. In addition to providing adequate oxygen to the baby just as a breathing machine would, Neonatal CPAP also has other positive effects.

In premature babies, CPAP is delivered through a set of nasal prongs or through a small mask that fits snugly over a baby's nose (newborn babies are obligate nose breathers). CPAP is used to deliver constant air pressure into a baby's nose, which helps the air sacs in the lungs stay open and helps prevent apnea. CPAP can deliver more pressure than a basic nasal cannula, so it is often used in babies who are breathing well enough on their own that they do not need mechanical ventilation, but who need more support than the cannula offers. CPAP can also be used to deliver higher concentrations of oxygen to premature babies who have trouble maintaining good oxygen levels in their blood.

In some preterm infants whose lungs have not fully developed, CPAP improves survival. It also can reduce the need for steroid treatment for the lungs.

In some infants, CPAP prevents the need to insert a breathing tube through the mouth and into the windpipe to deliver air from a ventilator. CPAP treatment is less invasive than ventilator therapy. Research suggests that CPAP is an appropriate first line treatment for some preterm newborns.