**REVISION HISTORY**

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# Strategy and Overview

## Goals and Objectives

The product Revive is aimed at providing whole body cooling as treatment for Neonates with Hypoxic Ischemic Encephalopathy. This therapy currently is provided as part of a controlled protocol within an Neonatal Intensive Care Unit (NICU) supported by monitoring of critical body parameters. The objectives for the Revive device are the following –

1. It should operate in the following setups.
2. Neonatal Intensive Care Units (Level 2 and Level 3)
3. Ambulances while the Newborn is being transported to an NICU
4. Low resource care settings where the Newborn was delivered and while waiting to be transported to a better Hospital.
5. It should have the ability to monitor the treatment continuously through Cerebral Function Monitoring

## Strategic Road Map

This product is part of the company’s vision to provide a complete solution to effectively diagnose, monitor and treat Hypoxic Ischemic Encephalopathy in Neonates while being Affordable. The Revive device is aimed at providing therapy and monitoring of the HIE condition. The products that will follow Revive, will address the need to effectively and quickly Diagnose HIE. This will enable Sensivision to provide a comprehensive HIE management solution.

The products that diagnose and treat Birth Asphyxia complications like HIE, can also be extended for addressing complications resulting from Cardiac or brain surgeries.

# Business Model

## Value Proposition

Revivewill provide one of the most effective treatments for HIE. This is backed by research studies conducted the world over. Its servo-controlled mechanism of providing whole body cooling with in a controlled range of temperature throughout the treatment duration ensures that the treatment is effective. Existing devices either cannot provide an effectively controlled therapy or even if they can, are prohibitively expensive. The unique value propositions of this product would be the following –

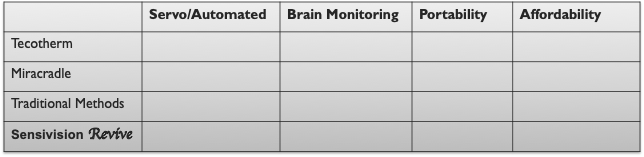
1. **Servo-Controlled,** for maximum effectiveness with temperature control at least within +/- 0.5oC
2. **Fully Automated,** for precise treatment while reducing the need for constant clinical attention and monitoring.
3. **Cerebral Function Monitoring** enabled, for early Diagnosis of the condition and continuous monitoring of the Treatment.
4. **Transport enabled,** providing Portability to treat during transport in an Ambulance.
5. **Battery backup,** enables use in low resource setting or during power interruptions.
6. **Whole Body Cooling** made possible by finely fabricated Body Wrap providing effective heat extraction.

## Market Segment

The market segments that Revive will target are –

1. Level 3 Hospitals (Hospitals in Tier 1, Tier 2 cities)
2. Level 2 Hospitals (District Hospitals, Special New Born Care Units or SNCUs)
3. Ambulance networks. Our initial focus will be Level 3 hospitals since currently these are equipped to provide comprehensive monitoring and treatment for conditions with co-morbidities like HIE.

## Competition





## Value Chain Structure





## Cost Structure

Target manufacturing cost of Device : Rs. 1.5 Lakhs.

Target manufacturing cost of Wrap : Rs. 2000

# Configurations

Revive device will be available in two variance or configurations. Depending on what configuration the Customers opts for, the Device can be configured through a software switch. Configuration will be set prior to the Device being shipped. The two configurations in which the Revive will be available are –

1. Revive
2. Revive Plus with CFM

Revive Plus will have the capability to acquire, process and display Amplitude Integrated EEG also called Cerebral Function Monitoring.

# Forecast

The planned roll out for the product will be as follows –

1. In the first two years, Revive will be piloted in the 5 southern states of Karnataka, Kerala, Tamilnadu, Telangana and Andra Pradesh.
2. Subsequently roll out will be done Nationally.
3. International roll out will begin with South Asian countries like Srilanka, Bangladesh and Nepal.

Forecast for the number of Devices and Wraps are as follows.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **1st year** | **2nd year** | **3rd year** |
| **Revive device** | 50 | 100 | 200 |
| **Body Wrap** | 800 | 3000 | 8000 |
|  |  |  |  |

# Distribution

Distribution of Revive will be through selected Distributors in the Neonatal domain as well as Sensivision’s Sales team. For the heterogenous market as India with the type of Customers and their geographical spread, this would be the better approach.

# Servicing

Servicing responsibility will be shared between the Revive device Distributers and Sensivision’s Sales & Service group. In general, the organization that engaged with the Customer during sales and support will own the servicing function with that customer.

# Manufacturing

Manufacturing of the Device and the Wrap will be handled between external contract manufacturing and in-house facility. The device will be assembled by external contract manufacturer while the Wrap manufacture will be done through the in-house fabrication facility.

# Required Features

**Temperature Control System Requirements**

1. Ability to bring the Core body Temperature to the range of 33 to 34 oC in 30 minutes with a tolerance of +/- 10%
2. Ability to maintain the Core body temperature in the desired range for up to 72 hours.
3. Minimize fluctuations to the Core body temperature to not more than +/- 0.5 oC.
4. Ability to warm the Core Body temperature back to Normo-therm in 5 to 8 hours.
5. The system produces audio and visual alarms for critical events requiring Clinician attention.
6. The system should automatically make the adjustments to correct the CBT changes.
7. The system should automatically detect the Rectal probe slipping.
8. The system should switch to a safe mode or default mode when servo-mode operation is impacted.

**Body Wrap Requirements**

1. With the Wrap on, the baby’s body should still be accessible for measuring parameters like Saturation, Heart Rate, Respiration Rate etc.
2. The abdomen should be visible/accessible to observe breathing pattern and also color.
3. The wrap should be sterilizable to prevent cross-infections.