PROTOTYPE PRODUCT/
NEWLY COMMERCIALIZED

2022

Continuous positive airway pressure device

Country of origin | India
Primary function | Treatment
Category | Medical device

Commercial information

List price (USD): 3000
Year of commercialization: 2021
Number of units distributed: 0-100
Currently marketed in: India, under evaluation in Ethiopia, Sri Lanka
Brand: InnAccel
Model: Saans Neonatal CPAP

Product description

Saans is an infrastructure-independent, low-skill breathing support system that can provide multiple therapy options (CPAP, HFNC, resuscitation), across multiple settings (hospitals of all levels and transport). The device has an in-built flow generator and air-oxygen blending and incorporates sensors and simple digital controls/displays for flow, FiO_2, and pressure output. In addition, Saans is portable, has an in-built battery backup, and alarm system.

Product details

Accessories: For long-term use, accessories required are: 1. Servo-controlled humidifier 2. Trolley
Consumables: Circuits and patient interfaces
Warranty duration: 1 year
Lifetime: 2-5 years
Energy requirements: Rechargeable battery, Continuous power supply, AC, 110V, 220V, 36W, 6-hour battery recharge cycle, 5-hour battery life
Facility requirements: Specific temperature and/or humidity range, Gas supply (Oxygen), Operating: 0 to 45 C°, Storage: 0 to 50 C° and Humidity: 25-95% non-condensing

Contact: Shaunak Patel | Email: shaunak@innaccel.com | Phone: +91 98 1060 2033 |
Web: https://innaccel.com/products/saans/

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

In 2019, 2.4 million newborns died worldwide, with sub-Saharan Africa carrying the highest neonatal mortality rate at 27 deaths per 1,000 live births, followed by Central and Southern Asia with 24 deaths per 1,000 live births. According to recent estimates, the primary causes of neonatal death include pre-term birth, intrapartum-related complications (birth asphyxia or lack of breathing at birth), infections, and birth defects. Similarly, the highest under-five mortality rate is recorded in the WHO African Region (74 per 1000 live births), around 9 times higher than that in the WHO European Region (8 per 1000 live births). Among under-five children, infectious diseases, including pneumonia and malaria, remain a leading cause of death.

Saans is a breathing support device that aims to address a substantial source of mortality among newborns and children by offering multiple therapy options, including continuous positive airway pressure (CPAP) and resuscitation therapy for newborns and high-flow nasal cannulas for pediatric patients. It requires minimal infrastructure support, has several built-in features, including an air-oxygen blender, digital control of flows and FiO_2, and relevant alarm systems, and can be employed by appropriately trained physicians in secondary or tertiary hospital settings as well as during the transportation.

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WHO specification comparison

At the time of report creation, WHO technical specifications available are related to CPAP and HFNC devices ONLY for adults and paediatric applications, and NOT for neonates/infant. Consequently, the specific requirements cannot be compared to finalize a compliance evaluation.

Regulatory assessment

Pre-market assessment
Post-market assessment
Quality system assessment

Proceed with caution
Not acceptable
Proceed

Pre-market – The manufacturer provided an Oxygen Gas Monitoring test report per ISO 8573, USP, and EP requirements, and EMC/EMI safety test report based on IEC 6100. Three articles were provided to demonstrate clinical performance. However, other significant pre-market assessment data and documents were missing; please see the list below.

Post-market – No data or documents were provided.

QSA – A current ISO 13485:2016 certificate was provided.

The following data and documents were not provided and should be included for the Pre-market assessment and to demonstrate the safety and efficacy of the device:

- IEC 62366: 2007, IEC 60601
- IEC 60601-1-8: 2012, ISO 5356-1 ;2004
- ISO 18562-1;2017
- ISO 18562-2;2017
- ISO 18562-3;2017
- ISO 18562-4;2017

Cleaning and Disinfection of a reusable medical device validation referencing :

- AAMI TIR12
- AAMI TIR30
- ASTM D543
- ASTM EI 837-96
- ISO 17664-1:2021

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact
Medical	⚠	⚠
Safety	⚠	⚠
Economy	→	→
Organizational	→	→
Legal	⚠	⚠
Social	⚠	⚠
Ethical	⚠	⚠
Green environment	✗	✗

Saans is a low-skill breathing support system that can provide multiple therapy options. It provides CPAP and resuscitation therapy with the appropriate oxygen blend in all hospital settings (labor room, NICU, SNCU) and during transport. It is portable, has a built-in battery backup, an alarm system, and is compatible with various oxygen sources such as central oxygen lines, cylinders, and even oxygen concentrators. The device can entrain atmospheric air at high pressures in the absence of oxygen. The device is durable, but the battery and oxygen sensors should be checked annually. Control and alarm software is built-in. Clinical data were mentioned but were not provided. The manufacturer provides evidence on the effectiveness of the technology in general, but not specifically on the submitted device. The manufacturer mentioned several certificates but did not submit them. Given the lack of evidence, the device should be used with caution.

Summary

Innovation		Technology evidence assessment	Recommend with caution
Technology readiness level	7		

Health technology and engineering management

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Domains	Appropriateness	Domains	Appropriateness
Durability	⚠	Ease of cleaning	⚠
Ease of Use	⚠	Ease of maintenance	→
Positive impact on clinical outcomes	→	Infrastructure requirements	→
Affordability	⚠	Local access to sales support	✕
Engineering resources minimization	→	Local access to technical support	✕
Cultural and social acceptability	N/A	Local access to training	✕
Environmental conditions	→	Local access to spare parts	✕
Aesthetics	→	Locations of use within target setting	⚠

Target settings: Primary, Secondary & Tertiary level, Ambulance

This commercially available CPAP device is intended to provide short-term support to babies suffering from RDS who are not in an ICU setting. The product's ease of use and ability to be powered by a variety of power sources (AC, battery, gas, and manually with Ambu bag) is an attractive feature especially for rural settings. Maintenance service is required for addressing, blender parts replacement, battery condition verification, compressor parts, filter condition/ replacement, and oxygen sensor replacement, as with any mechanical product used in critical conditions. The submission includes a description from a paper presented at an Indian conference, but there is no performance data or identification of all maintenance services periodicity. Finally, the submission includes three (3) different versions of the product, each with a different user interface and features, making it difficult to determine which is the actual submitted product. The following information is required to resolve engineering assessment challenges: the final version of the product being offered, maintenance services requirements for the filter, sensors, compressor, other mechanical components (Ambu bag), and valves. Where will the spare parts be available to support servicing in low-resource settings? Recommend inclusion with caution.

Intellectual property and local production

Technology transferability	⚠
Openly access intellectual property	✕
Local production	✕

Intellectual property – The device is patent-protected and it has proprietary software. Clearance is required to use this technology.

Local production – The product is most likely in the field trial phase and will require regulatory approval. Manufacturing know-how is most likely to be with contract manufacturers. The licensee must have experience with electronic assembly/manufacturing and related QMS. Existing manufacturing line is currently in a region suitable for low volume production, this, in addition to low volume of market demand is less likely to provide further commercial advantages through local production.

WHO related guidance material

- Newborns: improving survival and well-being - https://www.who.int/news-room/fact-sheets/detail/newborns-reducing-mortality
- Child mortality and causes of death - https://www.who.int/data/gho/data/themes/topics/topic-details/GHO/child-mortality-and-causes-of-death
- Guidelines on basic newborn resuscitation - https://apps.who.int/iris/handle/10665/75157
- Oxygen therapy for children: a manual for health workers - https://apps.who.int/iris/handle/10665/204584
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - https://www.who.int/publications/i/item/WHO-MCA-17.07