Health Technology Review	
Technology Ref.:	**HTA21049**
Technology Name	**The BioIntelliSense System**
Approvals by International Bodies:	**U.S. Food and Drug Administration (FDA)**
Company name:	**Tamouh Health Care LLC**
Agent in UAE:	**Ahmad Mustafa**
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Short Description of the Technology:	The BioIntelliSense System (the System) is a remote patient monitoring solution that is capable of, through a wearable sensor device, continuously obtaining physiological data from patients in healthcare and home settings for up to 30 days. The physiological data collected by the System, depending on the wearable sensor device used for data collection, can include: • Heart rate at rest • Respiratory rate at rest • Skin temperature • EKG waveform Other non-medical data may be collected and reported by the device such as sneezing, coughing and vomiting events, steps and activity levels, gait cadence, body position, fall detection, sleep patterns, and user Identity Management. The BioIntelliSense System consists of wearable sensors (BioSticker , BioButton, or other type of wearable sensor) placed on the body of the user using adhesives and continuously collect physiological data for up to 30 days.

Health Technology Assessment Team Recommendation:	**Approved**

Summary of Review:

BioIntelliSense is a remote patient monitoring (RPM) device, it takes Patients vitals up to 30 days and transfer it to a connected hub which captures and transmits the data back to the care team. The collected data will be filtered and analyzed by the clinical care team to monitor the patients and provide the clinical care.

Advantages	Disadvantages
Simplify the patients experience, provide supports 30 days of continuous passive vital sign monitoring	Since RPM only provides episodic data collection, it cannot help to detect the early signs of chronic conditions worsening nor can it alert providers of a crisis in real time, thus Future studies should focus on the ability to detect patient deterioration.
Leverage a patient-centric approach that captures the multidimensional nature of an individual's health over time	Threats to Confidentiality and Privacy of Patients' Data
Useful tool for clinical care and research for Patients with Chronic diseases.	Proper training is required for doctors, nurses, and IT staff on using the system.

Non- Invasive and easy to wear & use by patients	Concerns in Data not being accurate

We recommend an **approval of using this technology** only with the following conditions:

1. Ensuring the dataset residency and access are compliant to the applicable Laws &Regulations.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and Patient
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "BioIntelliSense System"

- **Population/ Intended User**;
  - Patients with Chronic diseases
  - To monitor patients' heart rate, respiratory rate, skin temperature and EKG waveform when prescribed by a clinician.
- **To be ordered by**:
  - healthcare professionals
- **Clinical Setting:**
  - hospital with outpatient setting
- **Condition of use:**
  - Patients who are able to use the device at home
  - Patients who have access to mobile phone
  - Inpatients and post-hospital care
  - Pre-and post-surgical care
  - Chronic care management
  - Rehabilitation
- **Exclusion criteria:**
  - Patient is less than 18
  - Patients that have medical conditions that would limit their participation with no family assessment
  - The device is not intended for use on critical care patients