TRUST AND RELIABILITY FOR IN-HOME MEDICAL SENSORS

Quality of life might mean different things to different people. However, when it comes to healthcare, quality of life takes on a more specific meaning. Medical professionals must prove or quantify actions to determine and justify treatment. Testing, measuring, and other processes are done with devices that must deliver reliable data repeatedly. This paper will review how the medical industry is working to provide accurate robust devices to improve quality of life with a focus on mobility and at-home care.

To manufacture a consistent product, it is imperative to control the materials and processes. There are techniques such as Six Sigma that guide product design and manufacturing. There are also standards such as ISO13485 which set requirements for medical devices' quality management systems.

Often there must be documentation proving that the materials and components are trusted, and that the processes were controlled to validate a device's outputs. Whether a medical device is in a professional medical facility or at home, it must deliver the same quality and accuracy. The ability to monitor or treat patients at home reduces healthcare costs and frees up hospital resources. While at-home care introduces several benefits there are many challenges OEMs must overcome.

Benefits and Challenges in Medical Devices for At-Home Care

The following are only a few examples to provide a brief overview of the benefits modern devices can provide, and the challenges manufacturers must deliver to ensure homecare meets the same standards and quality of care as a medical facility.

- **Benefit:** Remote monitoring provides doctors data from between visits for a more complete picture of the patient's overall health.
- **Challenge:** Connectivity and security to receive medical data from the remote patient to the doctor while following regulations such as HIPAA. Also, remote devices make it more difficult to monitor device health. It is necessary to ensure proper calibration or prove the data collected is accurate.
- **Benefit:** Portable devices can offer patients new levels of mobility and quality of life.
- **Challenge:** Low energy consumption for mobile medical devices is important so patients do not have to travel with a heavy battery, need to recharge regularly, or lose power.
- **Benefit:** Patients with chronic health needs can automate medication management with devices that provide continuous monitoring and drug administration to improve quality of life.
- **Challenge:** Administering drugs automatically must ensure the data received is accurate and verify the amount was delivered to the patient. This can require constant power for monitoring with multiple sensors which increase the energy consumption and complexity of the device.

Applications of Medical Devices for At-Home Care

In general, many medical applications are to collect data for health care providers. At-home devices can help nurse practitioners (NP) and physician assistants (PA) validate writing prescriptions or make more informed decisions. Health information is often only collected at a doctor's office. However, wearables and other monitoring devices can provide a complete view of the patient's wellbeing between visits.

Home care also includes more critical care equipment, such as respiratory equipment or dialysis equipment. Adding connectivity to these devices can confirm the patient is using the equipment as prescribed. Quality of life is improved when a patient can be at-home or on the go for care. The challenge for medical devices is measuring accurate data in a variable environment while being operated by a patient. Some applications include:

- Battery powered oxygen concentrators that make it easier for patients with asthma and chronic obstructive pulmonary disease (COPD) to be mobile.
- Travel continuous positive airway pressure (CPAP) machines let patients continue therapy while away from home.
- Smart insulin pumps communicate with glucose sensors to automatically regulate insulin delivery.
- Smart inhalers help patients comply with dosage requirements and reduce ER visits.

Improving quality of life through at-home care hinges on the accuracy and reliability of the components which make up these devices. Manufacturers are tasked to deliver user-friendly, quality devices that are no longer operating in controlled medical facilities by trained staff. Adding to the list of challenges is the lifecycle of at-home devices. Products that will be used in the home need to withstand heat, humidity, rapid changes in temperature, being dropped, vibration and others while providing accurate and repeatable measurements or treatments. Addressing these challenges requires proven design and manufacturing experience.

How Medical Sensors are Expanding At-Home Care

Five common vitals that help determine patients' health are temperature, pulse, respiratory rate, blood pressure and blood oxygen level (SpO2). The ability to measure a patient's blood oxygen levels can be used to adjust the flow of oxygen delivered to the patient.

Oxygen concentrators can use pressure sensors to determine when a patient is exhaling and inhaling. Previous solutions would simply provide a constant flow of oxygen which led to patients being tethered to, or having to carry around, large oxygen tanks. This method wasted much of the oxygen because the flow would not stop between breadths.

With digital or analog pressure sensors that can detect extremely low full scale pressure ranges, it is possible to deliver oxygen only when the patient is inhaling. This reduces the amount of oxygen needed which reduces the time the machine runs. In oxygen concentrator applications, this technology reduces the load on the equipment which extends the machine's battery life and its overall lifecycle.

To add value to respiratory devices, efficient sensors must detect small changes in pressure. For example, pressure sensors such as TE Connectivity's (TE) **LMI** and **LME** sensors offer an extremely low full scale pressure range to monitor a patient's respiration accurately enough to only dispense oxygen when they are inhaling. Accurate low-pressure devices also provide monitoring for patients with shallow breathing and pulmonary problems.

Efficient features are reducing cost for at-home care, but devices that require maintenance or replacement can impede ROI. Selecting the right technology and design for a robust device is increasingly important to address concerns around drift, fatigue, and while maintaining cost-effective manufacturability. Modern piezoelectric, board mounted MEMS technology, such as the **LMI** and **LME** designs from TE are capable of producing cost-effective mass production, low power medical sensors with high-pressure sensitivity and reduced drift.

Pressure sensors also provide air flow, respiration control, and filter cleanliness monitoring. For example, board mounted MEMS pressure sensors **SM9000** and **SM7000** provide ultra-low pressure ranges down to 125 Pa to detect minimal pressure changes. When it comes to manufacturing system integration, mounting orientation, and other factors are important. The SMI sensors from TE provide a 16-bit digital or analog output interface, simplified signal read-out, easy system integration, and are insensitive to mounting orientation. While pressure sensors work together to improve respiratory devices, other factors may jeopardize a patient's ability to absorb oxygen into the bloodstream.

Blood Oxygen Sensors use optical sensors to detect oxygen in the bloodstream. A simple to use non-invasive finger clamp is able to house a light source, commonly LEDs, and a photodetector to monitor a patient's pulse rate, oxygen saturation, blood flow, and more. This is a simple device that patients can use at home. Regular monitoring of oxygen saturation and other vitals help health care providers understand what is causing a change. This additional data collected can also help determine if a patient needs to visit a provider and what tests to order before the patient arrives. Digital trends are increasing the adoption of connected devices. With the right sensor technology, a low energy connection such as Bluetooth Low-Energy (BLE) can send data to a phone, or intermediary device, to securely send data to a doctor online. This can help doctors collect more information while improving mobility and quality of life for the patient.

Using photo optic sensors in oxygen saturation devices requires a small size, low-power consumption, and fast response times in addition to common concerns such as drift and fatigue. For example, the **EPM series** of optical sensors is designed specifically for medical applications. The EPM sensor design uses a silicon planar diffused photodiode with dual drive to deliver a small, power-efficient sensor capable of detecting blood oxygen saturation. For improved manufacturability and to eliminate compatibility issues, the EPM is matched with TE's **ELM series** of photo emitters and others that operate at 660 nm. The ELM's 660 nm ±3 nm peak wavelength red LED and three IR wavelength work well in pulse oximetry, SpO2 Finger/Ear Reusable Probes, and SpO2 Disposable Strip or Butterfly Probe applications.

As devices expand further into the home, it is possible to use data to dynamically change treatment to best fit a patient's needs in real-time. Accurate monitoring can drive automation in at-home devices to improve quality of life by helping to automate manual monitoring and treatment. For example, Type 1 diabetics must monitor their glucose levels and inject themselves with insulin throughout the day. Small wearable devices are not only monitoring but administering treatment with accurate sensors and infusion pumps.

Infusion Pumps are used in many medical applications. Sensors including force, ultrasonic, position, and temperature can work with infusion pumps to monitor and deliver nutrients and medications to the patient automatically. For some applications, technology is small and power-efficient enough so the patient can wear the pump throughout the day.

For diabetics a glucose sensor must precisely monitor sugars in the bloodstream and communicate with the infusion pump. However, ensuring the right dose is delivered properly is essential. Position sensors can track the displacement of the pump, but blockages or bubbles can occur.

In some applications bubbles are deadly. Fortunately, piezo-electric transducers paired with a receiver are able to detect bubbles. Ultrasonic waves, emitted by the transducer, travel through liquids differently than gases. For example, the **AD-101 ultrasonic sensor** can detect a break in the flow of a liquid and can work with infusion pumps to keep the patient safe.

Force sensors are also commonly added to infusion pumps to detect blockages or resistance in the flow of nutrients or medications. Too much resistance or a blockage can expand the tubing running to or from the pump.

Sensors such as the **FS20 series** are an example of how medical technology is changing. The easy to integrate board mounted sensor delivers low compression force sensors with normalized zero and span for interchangeability, and thermal compensation for changes in zero and span with respect to temperature. The FS20 offers an operating temperature range of -40°C to +85°C, and in percent of FS the zero and sensitivity shift (in CTR) is ±.05.

More sensors can provide features or options that may solve challenges medical device OEMs run into during development. Devices are becoming more complex as home care increases and continues to drive demand for accurate, reliable sensors. Additionally, the increase in complexity reiterates the need for small, power-efficient sensors.

Trends in Medical Devices

As healthcare costs, demands, and regulations increase, it is imperative to reduce the time patients need to spend in medical facilities. However, moving to at-home care must be done with equal or better quality. OEMs will need to find manufacturers with experience designing and manufacturing accurate sensors built with compatibility and manufacturability for medical applications. These sensors will monitor and aid in the delivery of treatments in addition to confirming the success of these at-home medical devices.

MEMS and connectivity trends are increasing the need for manufacturers to interact with and deliver more digital options. Digital and connected devices could accelerate as more standards and regulations are passed for wearables and at-home care devices. Technology and manufacturing capabilities will continue to enforce strict standards and regulations to document and prove that medical devices are working properly.

To learn more about how medical sensors are improving quality of life visit **TE's Medical Sensor Applications and Solutions page**.

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