BENEFITS OF PIEZO-RESISTIVE FORCE SENSORS FOR MEDICAL DEVICE APPLICATIONS

Author: **Sean Gough**
Director, Force Sensor Engineering Group

Contact: **Sean Gough**
Director, Force Sensor Engineering Group
sean.gough@te.com

For more details please also visit:
www.TE.com/forcesensors

BENEFITS OF PIEZO-RESISTIVE FORCE SENSORS FOR MEDICAL DEVICE APPLICATIONS

TE CONNECTIVITY (TE) IS ONE OF THE WORLD'S LARGEST SENSOR COMPANIES. FOR DECADES TE SENSORS HAVE BEEN PROVEN IN MEDICAL DEVICES OF VARIOUS TYPES, RANGING FROM THE MOST DEMANDING APPLICATIONS, REQUIRING FDA-APPROVAL, TO EXTREMELY COST-SENSITIVE DISPOSABLES WITH INTEGRATED SENSORS.

Force sensors are hidden champions in medical devices as they play a key role in many critical applications, most notably infusion pumps. Despite this, the number of players in the force sensor field is limited. TE Sensor Solutions leads in the design and manufacture of force sensors. Proprietary technology is utilized to offer well-proven force/load sensors of the compression type, which offer both, technological and economic benefits. This white paper provides a brief introduction to TE force sensor technology, exemplary application areas and resulting value for customers globally.

CONTENTS

INTRODUCTION

Modern medical treatment would be inconceivable without electronic control functions. Sensors play a key part in this element of medical devices as they provide data on states and processes, which are instrumental in ensuring the quality, safety, and efficiency of patient monitoring, diagnosis, and treatment.

Sensors tailored for medical devices are therefore in wide use. Applications range from implantable sensors to sensors used in catheters and/or body cavities. Other sensors are used externally where they may be exposed to fluids, or other harsh environments (Fig. 1).

As the health sector remains under serious cost pressure globally, sensors are expected to help balance the cost of technology and the desired benefit of a particular device or treatment. Manufacturers of medical devices (OEMs) make targeted use of suitable sensor technology that helps give their products a leading edge in this highly competitive (and in some areas of the world also highly fragmented) market.

Figure 1: Monitoring the flow rate and/or potential occlusion during infusions is an application field for low range compression load sensors.

Use cases and technologies covered

TE experts' broad and deep sensor plus application know-how has been harnessed to develop sensor solutions for medical devices as one large segment within a broad portfolio, currently spanning around 40,000 products and a number of vertical markets. This product range combined with the company's global footprint makes TE one of the largest sensor specialists in the world.

The range of **measurands,** which TE medical sensors covers, includes the detection of air bubbles, force, humidity, liquid levels, position, pressure, pulse, temperature, and vibration/acceleration. Classified according to the **type of medical device**, the list includes interventional therapy, surgical devices, patient monitoring, respiratory and dialysis equipment, hospital infrastructure (medical gas distribution) and medical wearables.

TE sensor technologies, which manufacturers of medical devices can choose from, include:

- capacitive thin film
- foil-bonded strain gage
- linear string potentiometers
- microphones
- NTC thermistors
- piezo-resistive ceramic/polymer
- silicon bonded strain gages
- ultrasonic piezo film/ceramic
- float/magnet and reed switch
- IR thermopiles
- magnetic and optical encoders (MR)
- micro-thermocouples
- piezo-resistive silicon MEMS
- photo optics
- tilt-capacitive fluid
- ultrasonic probes

This white paper focuses on Microfused **force sensors**, which are used in many types of medical devices including infusion pumps.

Various types of **pumps** are used to infuse a fluid, medication or nutrient into a patient's circulatory system. Typically the fluid is infused intravenously, however, infusion pumps are also occasionally used with subcutaneous, arterial or epidural accesses. There are many pump variables which include not only the volume of fluid but also the mode of infusion, which can be continuous, intermittent or patient-controlled. To ensure a correct flow of the fluid, sensors are integrated into the pump to detect possible occlusions. Enhancing and improving patient safety in this way can be understood as an element of abiding by the Hippocratic Oath.

Infusion pump monitoring is highly health-relevant as the correct dosage (= amount over time) can directly impact the effectiveness of a treatment and thus the patient's health. This applies equally to hospitals and to home care: At a medical point of treatment (intensive care unit, hospital, practice) the number of medical staff is typically managed by economic factors so that the time for monitoring infusions on an individual patient level is restricted to certain intervals. Patients who need infusions at home, on the other hand, may not have the combined medical and technological know-how to check an infusion pump without the support of an integrated electronic control function, based on sensor technology.

In both cases, **force sensors** of the compression type serve to **detect a possible occlusion** of the infusion tube which necessitates immediate corrective action. Irrespective of this core function, load sensors have to meet tough cost and quality/reliability levels.

FORCE/LOAD SENSORS

Although medical sensors for **external use,** e.g. in pumps, tend to pose less of a technological challenge than, for instance, implantable sensors, they have to meet tough requirements nonetheless. Force measurement provides an example of why this is so.

Force sensors (referred also to as "load cells") are used in a variety of applications including infusion pumps, for example. Other applications include physical therapy, hospital beds (patient weight), surgical staple guns, cardiopulmonary-resuscitation (CPR) assist machines for emergence medical treatment, and oxygen tank monitoring.

TE has been supplying **load cells** for many years to medical device OEMs in Europe and also to the large and highly competitive US market (Fig 2).

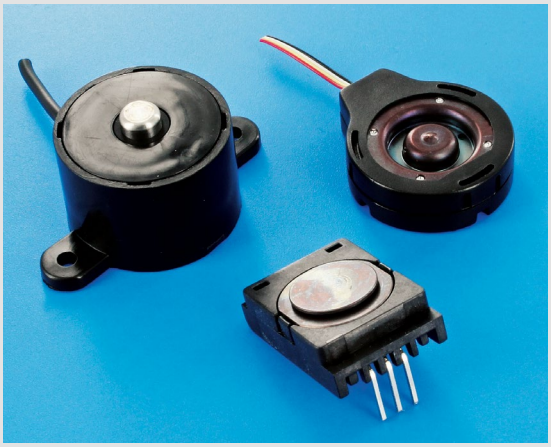

Figure 2: TE miniature force sensors

Miniature force sensors of the **FS20** type offer a particularly attractive combination of electromechanical and economic features, many of which are based on proprietary TE technology (Fig. 3). FS20 cells use the **piezo-resistive effect** for their measurement.

Principles of operation

The piezo-resistive effect is widely used in sensor technology. The following description is therefore brief and focuses on medical load cells. Two product examples are given to illustrate principles of operation:

In the **FS20 force sensor** (Fig. 3), a disc-shaped load collector at the top of the cell is exposed to the mechanical stress caused by the fluid pressure in the pump. The metal load collector acts as a working point. It is deflected by up to 0.05 millimetre at rated load. A **silicon piezo-resistive strain gage** is fixed underneath the load collector. When the strain gage is exposed to stress by the elastic bending of the load collector, the resistance of the strain gage structure changes.

This change is processed in an IC and is fed forward to the output lead. Zero and span of the cell are normalized to ensure interchangeability of the sensor. Temperature influences are compensated. Fig. 4 depicts the connections and block diagram of the FS20 cell.

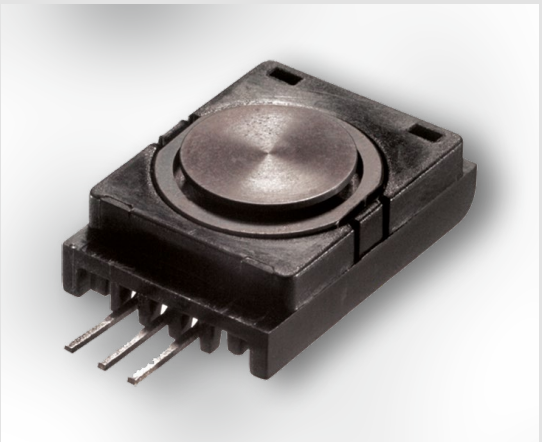

Figure 3: FS20 Microfused low range force sensors are employed to monitor infusion pumps

The RoHS compliant FS20 cell is available in two versions with either up to 750 grams of force or with up to 1500 g of force range. A high-level output, low noise, low off-center errors, and high over-range capability (up to x2.5) in combination with fast and accurate results (± 1% of span) plus temperature compensation for a range between 0° C and 50° C make the cell an excellent choice for pump monitoring.

As the load collector deflection is very small, the cell has an essentially unlimited cycle life expectancy. The cell's compact design (25.1 x 17.27 x 8.26 mm) allows for use in a broad range of applications with space constraints.

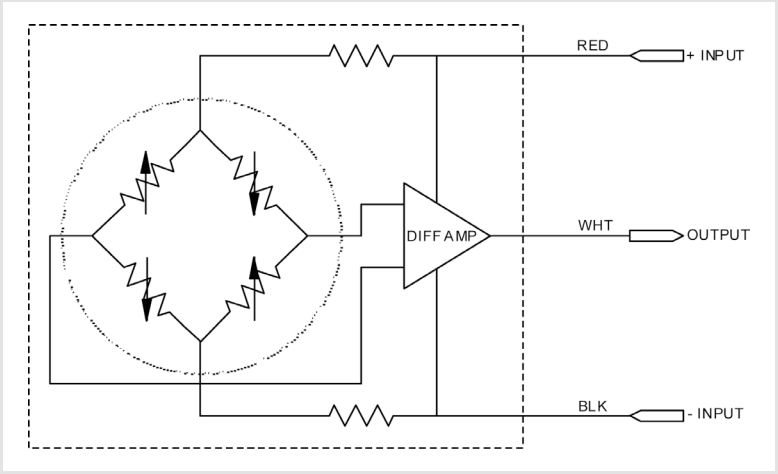

Figure 4: Block diagram and connections of the FS20 low force range compression load cell with amplified output

Figure 5: FC22 miniature low force range compression load cell

The **FC22** miniature force sensor is based on the same operating principle, however the working area is smaller to facilitate point load measurement. The cell's form factor and cable connection offer different integration options, Fig. 5.

The FC22 cell is also available in a millivolt bridge version, which is depicted in Fig. 6.

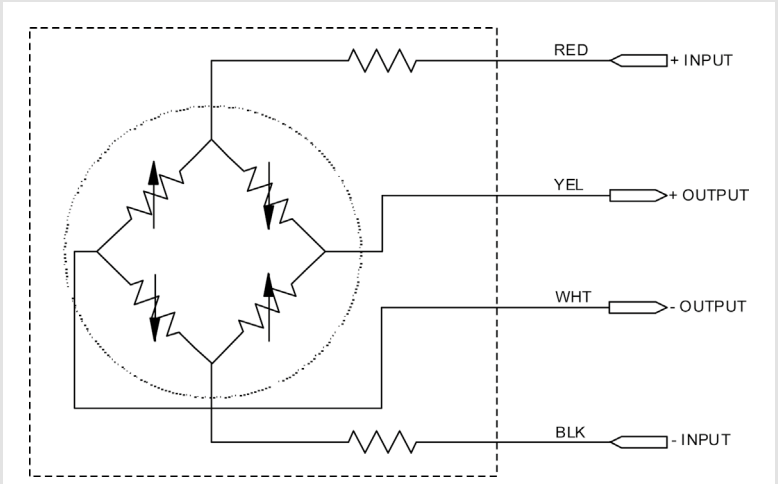

Figure 6: Millivolt bridge version of the FC22 miniature low force range compression load cell

Fig. 7 provides an example of a load sensor for higher force ranges. The FX1901 RoHS compliant compression sensor is used, e.g., in physical therapy, to measure patient weight (scales), and in chiropractic and exercise equipment.

Five measurement ranges span maximum loads from up to 10 lbf to up to 200 lbf (equals around 5 to 100 kg). The analog output signal is of the 20mV/V type. This 1% accuracy load cell is based on a particularly economic structural design (Fig. 8).

Figure 7: FX1901 compression load cell

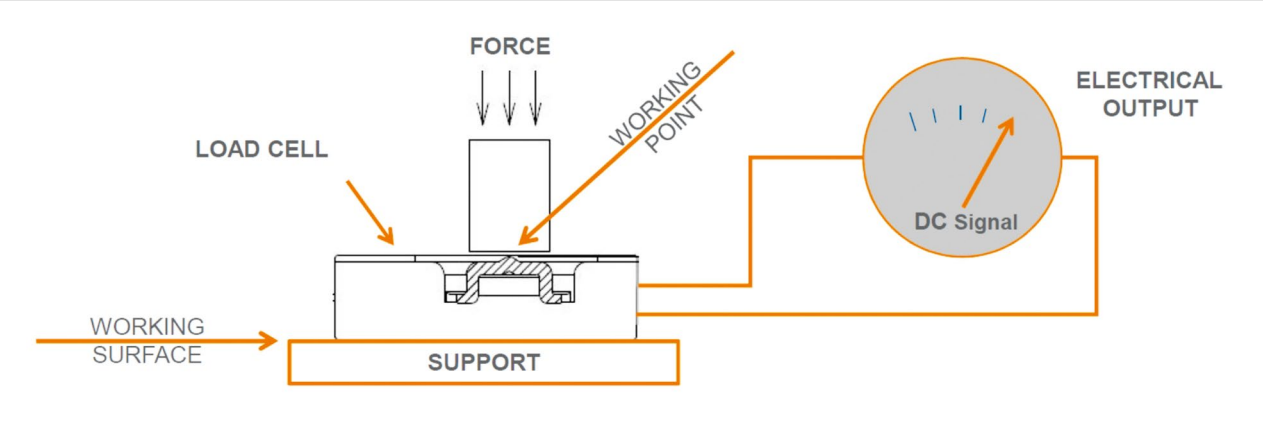

Figure 8: Functional principle of the FX1901 compression load cell with piezo-resistive strain gages

Microfused technology

A common feature of the FS20, FC22 and FX1901 compression load cells is the proprietary TE **Microfused** manufacturing technology in the medical market, which increases service life and at the same time facilitates an economic cost level of the cells.

This technology is based on **micromachining silicon piezo-resistive strain gages** and fusing them in a **high-temperature glass-bonding process** to a high **performance stainless steel substrate.** This very mature and reliable process has delivered many millions of force sensors, which are well proven in medical devices of diverse types.

Microfused technology eliminates age-sensitive organic epoxies, used in traditional load cell designs, thus **providing excellent long-term span and zero stability** because potential problems with resin ageing are avoided.

The cells **measure direct force** and are therefore not subject to lead-die fatigue failure common with competitive designs, which use a pressure capsule embedded within a silicone gel-filled cavity. Operating at very low strains, Microfused technology provides an essentially unlimited cycle life expectancy, superior resolution, high frequency response, and high over-range capabilities. Microfused force sensors have therefore proven to be particularly **rugged and durable** in medical devices.

Customization support

To transform product concepts into smart creations, TE Sensor Solutions provides full support of application-specific, standard, and custom requirements. Depending on the individual device, the sensor cell will typically be chosen from a range of existing and fully approved cells.

Medical device manufacturers can verify the measurement properties of the load cells by testing standardized sensors. In contrast to many other sensor companies, however, TE offers **customization support,** once the OEM decides to integrate the TE cell in a particular device.

The experts which take part in application processes include sensor technology experts from different locations, technical sales engineers, and medical application engineers.

In the case of load cells, off-the-shelf semiconductor strain gages can be adapted to individual product needs with the stainless steel part of the cell body. This facilitates fast sample delivery. As the number of illnesses and respective treatments is so vast, this option of adapting the cell body to individual treatment approaches by OEMs helps to create smart cost-effective devices.

Sensor, cable and connector: EVERY CONNECTION COUNTS

Its background as a leading global developer and supplier of electrical/digital interconnection technology puts TE in a special position when it comes to comprehensive sensor solutions: As the integration of cables and/or connectors can have a great influence on the reliability and robustness of a medical device, TE offers the additional benefits of a consistent solution, which extends from the sensor cell itself right through to the rugged electrical interconnection. Medical device OEMs can leverage TE as a one-stop shop for sensors plus interconnection.

APPLICATION FIELDS FOR FORCE SENSING

Medical device OEMs are seeking products that provide reliability, appropriate size (miniaturization), lower cost, and overall performance. The many application areas of force sensing include:

- Ambulatory drug dispensing systems, many of which rely on force sensing as the primary sensor technology for feedback control.
- Surgical procedures are also rapidly improving, as low cost, high reliability force/torque sensing enables precise measurement; staple machines and ocular surgery devices are being equipped with force sensors to enable quicker, more precise surgical procedures.
- Pumps used to irrigate and saline-flush sites for knee and shoulder surgeries increasingly use force sensing to optimize flow rate.
- Load cells are now widely used in saline drip weight measurement.

CONCLUSION AND OUTLOOK

TE force sensors help to bring a new level of functionality and reliability to medical devices. Proven technology, a multitude of successful applications and stable processes make Microfused force sensors a technology of choice for many measurement requirements. The sensors' combined technological properties and economic benefits provide exactly the features needed to improve the functionality of medical devices while meeting the applicable cost limitations of the medical device industry. The global footprint of TE puts the company in the position to offer global support in all relevant markets.

While medical devices are currently typically wired to avoid the large effort of getting wireless connectivity software FDA-approved, it would be a great benefit to patients and hospital staff likewise if the number of cables leading to a patient and his/her bed were reduced. TE is ready to support wireless connectivity in medical devices. The company's expertise in this area comes from the global trend of wireless networking which TE supports in many industries.

ABOUT TE CONNECTIVITY

TE Connectivity (NYSE: TEL) is a $12 billion global technology leader. Our connectivity and sensor solutions are essential in today's increasingly connected world. We collaborate with engineers to transform their concepts into creations – redefining what's possible using intelligent, efficient and high-performing TE products and solutions proven in harsh environments. Our 75,000 people, including 7,300 design engineers, partner with customers in close to 150 countries across a wide range of industries. We believe EVERY CONNECTION COUNTS – www.TE.com.

TE Connectivity Germany GmbH
Ampèrestrasse 12-14
64625 Bensheim
Germany

www.te.com