Medical Disposable Sensors: The Technical Basics

definition

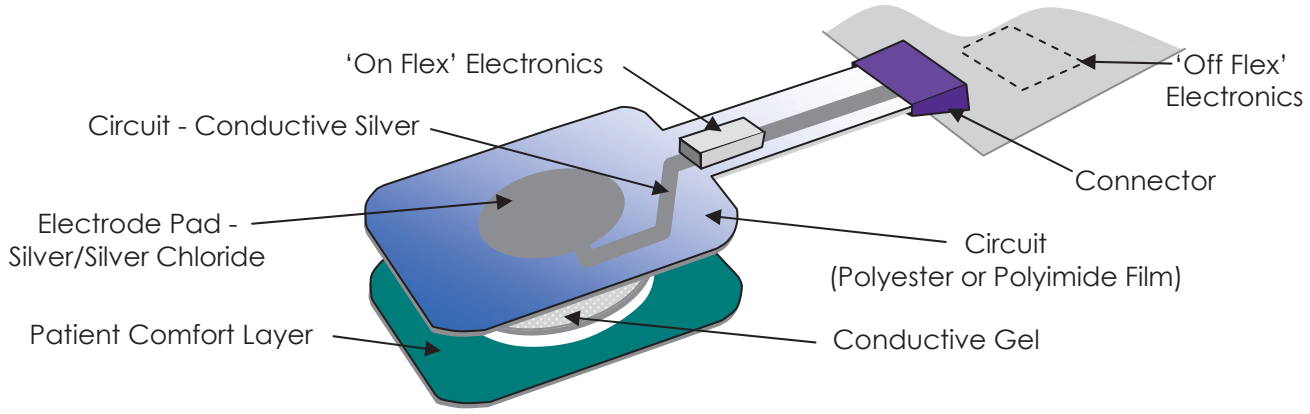
Even among companies that are considered experts in this field, a wide variety of names are being used to describe the products that make up this dynamic industry. Examples of the most popular of these names include:

- Medical Sensors
- Disposable Medical Circuits
- Medical Disposable Sensor
- Medical Electrical Interface

Medical Disposable Sensor—a single use (single patient) device that is used to help detect a physical stimulus (as electrical impulse, heat, light, sound, pressure, magnetism, motion, etc.) for the purposes of helping diagnose, detect and/or monitor a medical or biological condition.

anatomy of disposable sensor

Depending on the application, the medical sensor can be made up of many different components. At a minimum, these devices typically comprise of: a circuit, a patient attachment layer and electronics. In all cases, disposable sensors must adhere directly to a patience's skin. This connection provides an electrical bond and in some instances a mechanical bond, as well. The circuit, which is made of a thin flexible layer of either polyester or polyimide provides the pathway between the individual and the electronics. The electronics includes the proprietary mechanisms for detecting, monitoring and discerning the various human conditions. While medical sensors come in a wide variety of shapes, sizes and configurations, the below model shows some of the various components integrated into these devices.



the market

The medical sensor market is segmented in terms of both application (product) as well as end-user. Product segmentations include biosensors, pressure sensors, image sensors, temperature sensors, accelerometers, SQUID sensors, flow sensors and many others. End-user segments include the following classifications: hospital, nursing home, home healthcare, physician offices and others.

Medical disposable sensor development and usage has experienced extraordinary growth in the last 10 years. It is estimated that this market represents revenue of over $10 billion worldwide. Many studies show that this market will continue to grow by a rate of at least 8% a year, through 2022. By 2022, this global market is expected to eclipse $15 billion in annual revenue.

printed circuit versus FPC

One of the most critical decisions that is made in the design process of a given medical sensor is whether the circuit of the sensor will be made up of a printed silver ink on polyester film or an etched copper on polyimide film (FPC). All things being equal, the cost of the latter can be more than double of the printed silver ink version. Nevertheless, FPC circuits can provide a host of design advantages.

The following two considerations are the most important in determining whether an FPC circuit is favorable.

1. Multi-layer circuits. Some designs requiring a number of 'on board' electrical components simply don't have the real estate available for simple, single layer circuit designs. While it is possible to use both sides of a printed silver ink circuit using through-hole vias, this method gets very cumbersome when three or more layers are required.
2. Component attachment. While there are many methods for attaching an electronic component to a polyester based circuit (see page 5), these processes are typically more laborious than those using a FPC circuit. Depending on the type and number of components, the additional labor costs could offset the cost advantage of the circuit itself.

silver/silver chloride

While the electrodes used in early versions of biosensors were made from solid silver or silver coated brass, most sensors today utilize electrodes made of or coated with silver/silver chloride. This is particularly true for biomonitoring devices designed to monitor biopotentials.

Biopotentials are electrical potentials inside the living body that are created by ionic activity in our living cells (For example, the dynamic cells of the heart are the origin of the ECG signal). Because the human body is conductive, many of these potentials can be read on the body's surface. In most cases, silver/silver chloride will come in direct contact with a given hydrogel. Care must be taken to use the proper silver/silver chloride material so it will withstand prolonged exposure to the hydrogel.

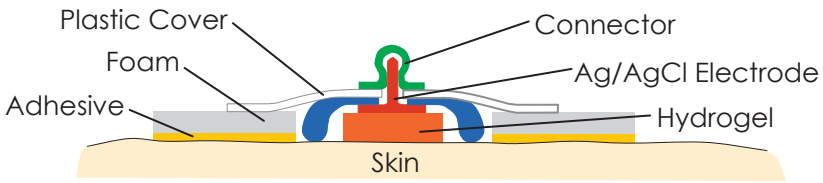
In the case of printed sensors, silver/silver chloride is screen printed in much the same fashion as standard screen printable inks. In most cases, silver/silver chloride will come in direct contact with a given hydrogel. Care must be taken to use the proper silver/silver chloride ink so it will withstand prolonged exposure to the hydrogel.

hydrogels

For the purposes of this writing, medical sensors are generally attached to the human body by using a gel like substance, referred to as hydrogel or conductive gel. Hydrogels are three-dimensional, hydrophilic, polymeric materials capable of absorbing large amounts of water or biological fluids. Due to their high water content, porosity and soft consistency, they closely simulate natural living tissue. Essentially it is this high water content that makes these sticky substances conductive, providing an electrical pathway between human skin and the medical device.

There are two approaches to integrating hydrogel to a given medical sensor. The first is to utilize one of the many off-the-shelf electrodes available from a plethora of manufacturers. Among the most widely known manufacturers include: 3M, Kendall, Conmed, HeartTrace, LeadLok.

Top view of off-the-shelf electrode manufactured by Biomedical Innovations.



Anatomy of a standard disposable electrode.

These electrodes have hydrogel built into them as well as skin-compatible adhesives allowing the electrode to safely attach to human skin. The advantages of using off-the-shelf electrodes is that it makes packaging of the medical sensor more simplistic as it does not need to take in consideration the packaging considerations required for the hydrogel. Additionally, shelf-life of the medical sensor can be extended if it does not incorporate the hydrogel. Perhaps the biggest disadvantage of this method, however, is the need to incorporate a fastening method on the sensor that will interface with the connector on the electrode. While discrete wires can easily be outfitted with a clip that will interface to the snap of the electrode, less options are available for sensors using flexible circuits. Currently, the only options available to utilize the standard medical disposable electrode include:

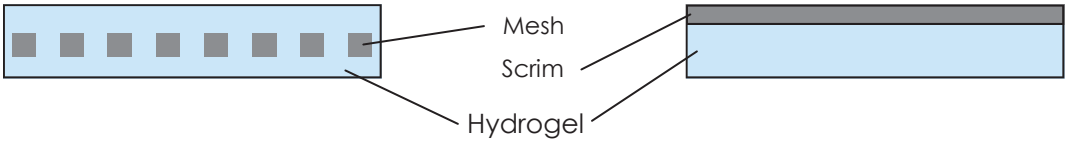
1) **Metal Snap**— This snap (see below, left image) 're-purposes' the fastener often used for clothing. While this snap is widely available, some feel that it lacks a refined look. Additionally, there are safety concerns among some designers about having exposed conductive elements.
2) **Plastic Snap**—These snaps are typically proprietary and allow for a lower profile method for attaching a flexible circuit to an electrode. The snap pictured below is a commercially available snap developed by SSI Electronics (patent pending).

Metal snap attached to flex circuit.

SSI's proprietary Connect-Cap™.

The other approach to integrating hydrogel is applying it directly to the medical sensor. Hydrogels can be procured in roll or sheet form from companies like Axelgaard, Covidien, Katecho, R&D Medical and many others. These hydrogel manufacturers carry standard formulas that have already been developed and validated to perform in various applications. These formulations are typically considered stock items. Alternatively, hydrogels can be customized in a variety of ways including incorporating additives or simply changing the thickness of the formulation. Regardless if they are standard or custom, these gels can be cut to nearly any shape and selectively applied to the disposable sensor.

Because hydrogel in its natural state lacks cohesion, manufacturers typically integrate layers within the gel construction to help support the substances. Sometimes this layer is a mesh-like substance and other times it is separate layer. In the case of the latter, this layer is referred to as "scrim". In either case, this supporting layer helps with processing the hydrogel but also helps prevent residue being left on the skin when medical sensors are removed from the patient.



When choosing this method of utilizing hydrogel, it is important to evaluate the following considerations:

1. **Type of Sensing.** Various hydrogels are best suited for different types of sensing (ECG/EKG) and/or stimulations.
2. **Adhesion Strength.** How much adhesion strength is provided by the hydrogel? Will supplemental medical adhesives (non-conductive) be required to effectively affix the sensor to the human?
3. **Repositionability.** Does the application of the sensor require the gel to allow for multiple placements?
4. **Bio-burden Controls.** For some applications, the FDA may require that the manufacturing facility applying the hydrogel possess bio-burden monitoring capabilities. For some facilities, this can represent a significant increase in manufacturing costs.

attachment of electronics to flex circuits

The electronics, 'the working part' of a medical sensor, can come in a wide variety of formats. One main distinction is whether the electronics are going to sit on the flex circuit itself ('on-flex') or whether they will sit outside ('off-flex') the format of the flex. In some cases, there is a combination of both. Of course, regardless of the format, the flex and the electronics will have an electrical connection.

"Off-Flex" Connections

For 'off-flex' applications, the flex is attached via a connector that interfaces to an electronic module. There are basically 3 approaches to achieving this connection.

1) Standard flex connector

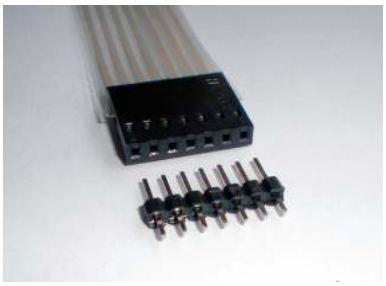
While this may seem like a simple approach, particulary from design perspective, there is unfortunately a limited number of standard connectors that attach directly to flex circuits. Moreover, many of these connectors and the board-level connetors for which they mate, can be bulky (standard trace spacing is: .100").

2) Bare 'tail' on flex

In the last several years there has been a growing trend to connect flex circuits to electronic modules by designing the flex circuit to have a bare cable-end (no connector). When outfitted with a stiffener the tail end can be inserted into a large number of board mounted connectors. These connectors are referred to as "LIF" (low insertion force) or "ZIF" (zero insertion force). The advantages of this approach is lower interconnect costs as well as a smaller connection footprint. The standard pitch sizes for these connections are 1mm and .5mm.

3) Custom connection

Many medical disposable sensors utilize custom designed connectors that allow the flex and the electronic module to interface. This is particularly true in cases where this connection will be visible in the final format of the product. Though this approach requires greater tooling costs, it often can result in a more refined connection point.



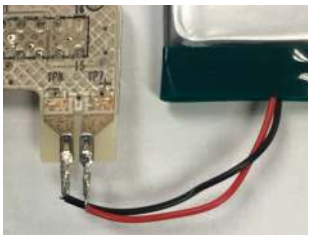
LEFT—Example of a standard flex connector with mating board-level header. MIDDLE—A 1mm pitch bare cable and mating LIF (PCB mounted) connector. RIGHT—A custom, proprietary connector system.

"On-Flex" Connections

As mentioned before, one of the most critical considerations for disposable sensors is whether the design requirements can be accommodated by using a polyester (screen printed silver) substrate for the circuit. The most limiting factor of this type of circuit involves the electronic component assembly options that are available. Following is a breakdown of the various assembly/attachment methods that are currently available:

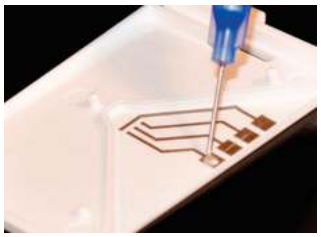
1) Solder Tabs

This process involves stitching metal solder tabs to the flexible circuit in order to provide a traditional (hand) soldering point. The main limitation to this technique is that soldering tabs can only be placed at .100" centers. Additionally, this method requires hand soldering and is technique sensitive in order to prevent overheating of the tab and melting of the polyester substrate.



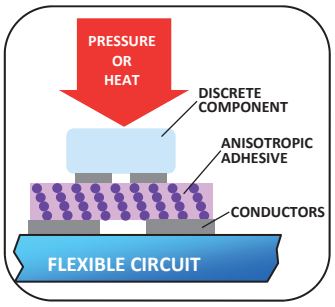
2) Conductive Epoxy

For years, conductive epoxy has been the preferred means of adhering discrete SMT components onto polyester-based flex circuits. This method is particularly effective for small, light components but can lack adhesion strength for larger components. Often, additional non-conductive encapsulates are utilized to add adhesion strength between the circuit and the discrete component.



3) Anisotropic Pressure Sensitive Adhesives

These pressure sensitive adhesives can be applied across many conductors making their placement much less exacting than with epoxy. While very versatile, these adhesives have only moderate holding power. Furthermore, a minimum pad size is required for these adhesives to effectively provide an electrical conduit between flex and component.

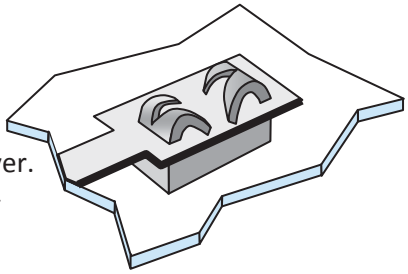


4) Anisotropic Heatset Adhesives

Like their pressure sensitive "cousins", these anisotropic adhesives can be applied over multiple conductors without risk of electrical shorting. These heat activated adhesives don't require as large of a pad so tighter pitch components can be considered. The largest challenge, however, is being able to efficiently get enough heat to the adhesive area while the component is in place.

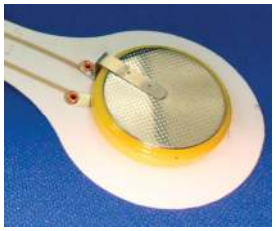
5) Crimping Method

This method requires that a component be customized so that it integrates sharp contacts able to pierce through the flex and crimp on the underside of the circuit layer. While there may be limited applications for this method, the attachment point is extremely robust.



6) Rivet Attachment

This method utilizes micro-rivets to provide both a mechanical and electrical connection to a flex circuit.

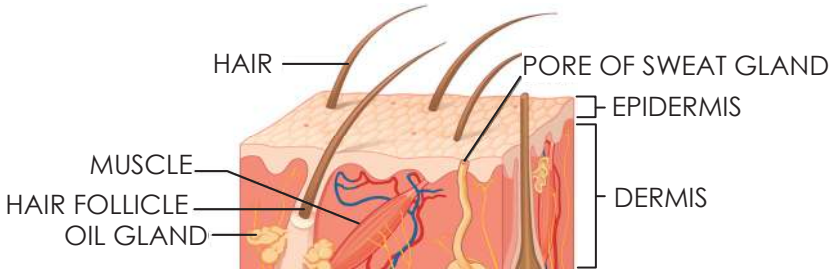


The following table summarizes some of the advantages and disadvantages of these attachment methods.

	Advantages	Disadvantages
Solder Tabs/Solder	• Strong, reliable connection	• Lack of versatility: Solder tabs must be place on edge of part at .100 centers.
Conductive Epoxy	• Can accommodate unique connection configurations • Can connect very small contacts	• Low mechanical strength • Fairly laborious
Anisotropic (ADF) Pressure Sensitive Adhesive	• Fairly quick when connecting many contacts	• Minimum contact overlap of .005 sq. inches (.070" x .070") • Moderate holding power
Anisotropic (ADF) Thermoset Adhesive	• Fairly quick when connecting many contacts • Tighter pitches/smaller pads feasible.	• Limited to situations where you can access with heat bar.
Rivet Method	• Firm, strong mechanical connection	• Slow process (one connection at a time) • Limited applications
Crimping	• Firm, strong mechanical connection	• Requires a custom component integrating crimping feature.

attachment of medical sensors to humans

A critical consideration in medical sensor design is how the sensor will be attached to the human. In nearly all cases this is done via medical adhesives. More specifically, the use of medical pressure sensitive adhesives (MPSP) are used extensively in medical sensor applications. What may seem a fairly innocuous consideration, choosing the proper adhesive is paramount in the success of the medical device. Whether the function of this adhesive is purely mechanical (non-conductive) or whether it is required to make an electrical connection (conductive), the challenging dynamics of the human skin must be considered.



The physical characteristic of human skin make it a challenging substrate for which to adhere.

Here is summary of the items that make the human skin such a challenging substrate for which to adhere.

1– **"Contaminated" Surface**. Human skin often contains water, salt, oil, cream, lotion and miscellaneous loose debris. In short, the chemistry of the surface of skin is highly variable.
2 - **Replenishable Surface**. The entire epidermis (uppermost layer of skin) rejuvenates every 45-75 days and the very top portion of the epidermis 'sloughs' off every 14 days. This ever changing environment provides a unique environment for pressure sensitive adhesives.
3 - **Rough/Uneven Surface.** A magnified view of the surface (see above) reveals the fact that skin contains a plethora of crevasses, creases, pores and hairs. Moreover, As humans age, there skin gets rougher by nearly 3 fold.
4. **Elasticity.** The fact that skin is designed to move as our bodies move provides yet another challenge.
5. **Allergen Concerns.** Because skin is a live organ, concerns over possible allergic reactions need to be considered.
6. **Low Surface Energy.** The human skin has a low surface energy. For those familiar with adhesion properties to various substrates, they understand that the lower the surface energy, the more challenging it is for which to adhere. Luckily, pressure sensitive adhesive chemistry continues to advance and thus more and more suitable adhesives are being developed all the time.

Material	Surface Tension (dyne/cm)
Stainless Steel	50+
Polycarbonate	46
Polyester	41
Polyethylene	38
HUMAN SKIN	25-29
Silicone	21

Adhesive Performance Characteristics

When choosing a medical pressure sensitive adhesive, there are many performance factors to consider. Perhaps the most critical of these is **skin compatibility**. Evaluating skin compatibility requires evaluating the likelihood of skin sensitivity as well as the possible toxicity of the adhesive. Skin sensitivity is

typically measured by conducting either the Primary Skin Irritation (PSI) test or the Repeat Patch Insult (RPI) test. Toxicity of a given adhesive is usually evaluated by the technique of dermal injections into animals.

Proper adhesion represents another key performance criteria. Not only does the adhesive have to adhere well to a rough, elastic surface but it also must remove in a way that does not cause damage to the skin. This can be a challenging balance.

Flexibility and **breathability** are other key performance attributes that medical device manufacturers should consider.

A wide variety of chemistries are used to address these performance characteristics. Below is a table which shows how these adhesive families compare to one another.

	ADHESIVE 'FAMILY'					
	ACRYLIC	NATURAL RUBBER	SYNTHETIC RUBBER	POLYOLEFIN	POLY-URETHANE	SILICONE
INITIAL TACK	low to high	high	high	medium	low	low to high
ADHESION (LONG-TERM)	medium to high	high	high	medium	low to medium	medium
COHESIVE STRENGTH	low to high	high	high	low	low to medium	high
STABILITY UPON AGING	poor	poor	poor	medium	medium	excellent
PRASTICIZER RESISTANCE	low to medium	low	low	low	medium	good
SOLVENT RESISTANCE	high	fair	fair	fair	high	excellent
PERMEABILITY TO SKIN	poor	poor	poor	poor	poor	excellent
REPSOTIONABLITY ON SKIN	poor	poor	poor	poor	fair	excellent
LOW SKIN SENSITIVITY	good	poor	good	good	good	excellent
LOW SKIN TRAUMA	poor	poor	poor	good	good	excellent
COST	medium	low	low	medium	high	high

packaging

Perhaps even more critical than with other industries, a broad array of factors must be considered when designing packaging for medical disposable sensors. These considerations go well beyond simply ensuring that the disposable sensor gets to the medical site in the proper condition. Below is a list of some of these important considerations:

- **What are the protection requirements of the device?**

Does exposure to light, humidity, oxygen, moisture, temperature, shock, vibration negatively impact the device? Can packaging be designed to mitigate the impact of these factors?

- **Is it easy to open?**

Unlike in other industries, the packaging of medical sensors is typically opened up by professionals (physicians, nurses, etc.). Among these users, efficiency of operation is paramount and packaging that is viewed as too cumbersome to open could hinder product adoption.

- **How much leftover waste is created?**

More and more hospitals are concerned over generating waste. Can the packaging be designed to create as little leftover waster (by volume) as possible?

- **What is intended shelf life?**

What packaging details need to be considered to prevent premature aging of the sensor?

- **Sales unit configuration?**

Should device be single packed, multipacked or bulk packed. Does the unit of configuration comply with the inventory limitations of the end-user (shelving, racks, etc.)

- **Is packaging density maximized?**

Is the product packaged to maximize possible transit methods such as: air, pallet, container (ocean).

- **Labeling/identification requirements?**

Does the packaging allow for easy recognition of critical aspects of the device (name, use instructions, etc.)? Are the labeling requirements of the appropriate regulatory bodies being considered?

- **Is the packaging visually pleasing?**

While these aesthetic issues may not impact device performance, they are proven to affect the end-user's perception of the device.

- **Is sterilization required?**

If so, are packaging materials being considered that can allow for the chosen sterilization technique (materials porous enough to utilize gas processing)?

sterilization

There is a wide variety of sterilization options offered by a multitude of qualified US-based companies. While it is recommended to discuss the most appropriate options with the suppliers themselves, the following table offers a brief list of the various types of available sterilization and some of where they best apply.

Type	Explanation	Attributes
Gamma Irradiation	Utilizes Cobalt 60 radiation to kill microorganisms	• High penetration capabilities • Quick turnaround time
Electron Beam	Also known as "e-beam". Uses high energy electrons to sterilize product.	• Quick turnaround time
X-Ray Irradiation	Utilizes x-ray exposure to sterilize.	• High penetration capabilities • Quick turnaround time • Some products could be adversely effected.
Ethylene Oxide	Also known as EO or EtO, this method involves exposing products to ethylene oxide gas in a vacuum sealed chamber.	• Packaging must be breathable.

about SSI Electronics

SSI is a US-based manufacturing company that was founded in 1983. SSI has been working with medical device manufacturers for over 30 years and has manufactured medical disposal circuits for nearly 15 years.

SSI possesses both domestic and offshore manufacturing capabilities that are ISO13485 compliant. Its extensive experience in this dynamic field as well as its broad array of critical manufacturing capabilities make SSI an excellent partner in your quest to develop medical disposable sensors.