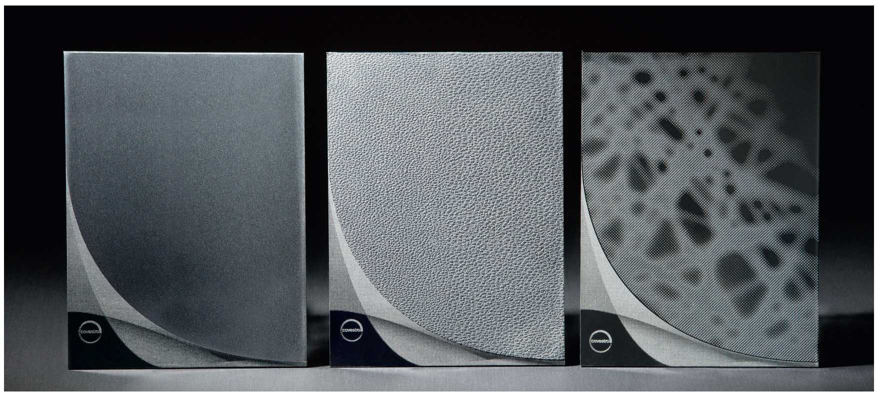
Protection and Attractive Design

Materials for Medical Wearable Housings

Housings not only protect the inner workings of medical equipment, but also protect patients from electric shocks, for example. This function is very important for the increasingly widespread medical wearables, which are often in constant contact with the patient. When designing such devices, it is therefore important to select the appropriate housing material. It must not only be insulating and at the same time well accepted, but also allow an attractive and user-friendly design.



Housings play an important role in medical wearables. They protect their inner workings, but at the same time protect the users of the devices © Covestro

Several trends in the modern healthcare industry are increasing the demand for connected devices that are in direct contact with the patient. Aging populations as well as an increase in chronic diseases represent important trends in healthcare that have brought added pressure to reduce costs and find new solutions. Shifting therapies from clinics or hospitals to the home by using connected therapy systems is an attractive option. For such applications it is necessary to monitor both the patients and their medication remotely. The increased trend of patient monitoring is further exemplified by preventive patient monitoring with connected devices to screen body signals such as ECG, EEG or blood sugar.

The requirements for materials used for wearable devices depend on the function of the components. In less critical cases, such as fitness or wellness trackers, mechanical properties or freedom of design are important. For more critical cases such as for the injection of pharmaceuticals, dosage accuracy and consistency, sterilization and biocompatibility of the materials are additional critical considerations. As such, it is not possible to realize wearable devices with just one technology or one material. In this article the author will summarize important considerations for selecting a housing material and how these can be linked up. In particular, the focus of the article is rigid housings made from polycarbonate (PC), a well-established material in both electronic as well as healthcare industries and therefore a material suitable for the combination of both areas. For all housings in these applications, the following demands have to be met:

- Protect the inner parts of the wearable (i.e. electronics or pharmaceuticals). This includes resisting the outside environment (moisture or chemicals) and the user of the device (e.g. impact resistance),
- protection of the user from direct contact with electronic parts,
- communication between the device and user. The housing can have an active and direct role such as implementing light signals, displays or an indirect role such as signal transmission to other devices like a smartphone,
- provide an attractive and user-intuitive design to the device.

These aspects will be briefly discussed in terms of property requirements and polycarbonate capabilities in the sections which follow.

Protection of the Inner Parts

One of the most common materials from Covestro for electronic housings is Bayblend FR3010. The properties of this flame-retardant PC+ABS blends (polycarbonate + acrylonitrile butadiene styrene) are balanced for performance and productivity and suitable for many electronic applications. It has, for example, a tensile modulus of 2700 MPa, a yield stress of 60 MPa and an Izod impact strength of "no break" at 23 °C. But these numbers about mechanical properties are not enough to specify a good housing material, because protection of the inner parts is more than mechanical stability. The selection should be based on several aspects as mechanical properties, dimension and thermic stability, flame retardancy (i.e. UL listing requirements) and other properties such as processability during the injection molding and assembling.

One good starting point of the material selection process for wearable devices is the definition of the dimensional requirements. How thick can or should be the wall thickness be and how big are the different parts? This, in turn, can be important to selecting a material which is moldable at the chosen thickness. The trend for wearables is to reduce the size and weight to improve the wearing comfort and the user acceptance of devices. In addition to smarter battery concepts, lighter housings with thinner walls are used to reach this requirement. Wall thicknesses for small devices can even be below 0.5 mm, which mean small devices would favor ductile and rigid housing materials that can also fill extremely thin walls during molding.

The rigidity and toughness of the housing material is a special challenge since the first impression is that thick walls can withstand mechanical stresses better than thin walls. The standard DIN EN 60601–1 is specialized for medical equipment with power supplies, but the mentioned tests methods for mechanical properties can give a roughly guiding value for the mechanical requirements, which are needed for medical devices. Standard DIN EN 60601–1 mentions three different tests that assembled devices should be able to meet without significant damage.

First, an impact test with a continuous force of 250 N for 5 s; second, an impact test with a 0.5 kg steel ball dropped from at least 1.3 m on the housing and, third, a drop test of the housing itself from at least 1 m height. One material property which is related to the mechanical stability of the device is the notched impact strength at different temperatures. Materials such as Makrolon 2458 or Bayblend FR3010 do not break at 20 °C during this test and would be expected to satisfy this requirement at ambient conditions. Even more stringent impact requirements such as low-temperature multi-axial impact performance are more likely to require the impact performance offered by PC.

As mentioned earlier, designs with thin walls can also present a challenge from the manufacturing perspective. To fill a device with a wall thickness of below 1 mm, it is necessary to use polymers with low melt viscosity. For example, the flow path of Makrolon 2458 polycarbonate for walls with 0.5 mm is only a third of the flow path for walls with 1 mm thick- »

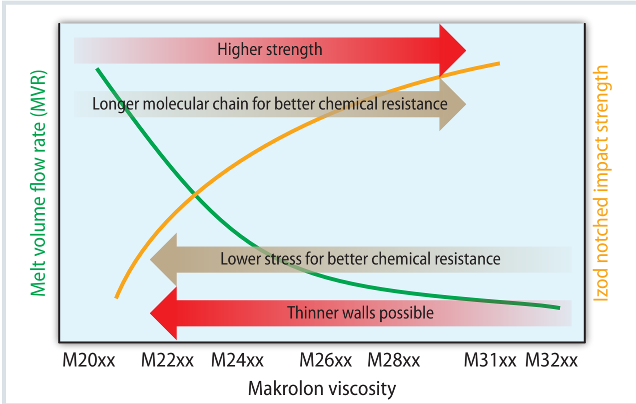


Fig. 1. Mechanical properties such as notched impact strength also depend on the viscosity of a polycarbonate (PC). PC with a lower viscosity also has a lower notched impact strength Source: Covestro, graphic: © Hanser

ness. Although polycarbonates with low viscosity, and therefore a low molecular weight, could easily fill injection molding tools with low stress in thin-walled devices, there is a trade-off in terms of mechanical performance. The relationship between molecular weight (and therefore viscosity) and mechanical properties of polycarbonate is shown in **Figure 1**. A decrease in the viscosity will lead to a decrease of the mechanical properties, as represented with the Izod notched strength. For low molecular weight materials, increasing the wall thickness would be necessary to compensate for the lower performance. Therefore it is important to find the right balance between flow and robustness of the material and to combine this with adjusted injection molding process parameters.

Furthermore, the chemical properties of polycarbonate are also dependent on the molecular weight. Polycarbonates with longer polymer chains are more resistant against chemical attack. Simultaneously, internal stress (i.e. molded-in stress) has a significant influence on the chemical resistance of polycarbonate. Lower overall molded-in stress levels of the materials in the devices favor better chemical resistance. This means that the viscosity of a polycarbonate should be chosen wisely to get suitable mechanical properties without increasing the internal stress.

Wearables can often be exposed to a huge variation of chemicals such as skin lotions or disinfectants for cleaning. In addition to the nature of the chemical exposure, contact time and temperature are important. Long contact times, either due to a long product life or intensive exposure, or high temperatures can be challenging conditions for housing materials. But depending on polycarbonate

Material	Dk (at 5.0 GHz)	Df (at 5.0 GHz)
PC	2.7	0.005
PA66	3.2	0.02
PA6	3.2	0.03
PBT	2.9	0.006
PP	2.2	0.0002
ABS	2.7	0.005

Table 1. Dielectric constant and dissipation factor for low frequencies of several polymers
Source: Covestro

grade, a low stress level and circumstances (contact time, composition, etc.) most typical disinfectants as alcohols, bleach, hypochlorite, peroxides and aldehydes should work.

For optimum resistance a low stress level (either applied or molded-in) helps ensure resistance to most liquids encountered by wearables, as e.g. sweat or lotions. However, many are complex formulations with changing compositions and therefore every individual liquid/polycarbonate material might behave different. Critical mediums for condensation polymers such as polycarbonates are mediums with high pH value (>10) and/or amines/ammonium salts. For applications that require better resistance to chemicals than PC or PC+ABS, combination of polycarbonate with semicrystalline resins (e.g. PC/polyester blend Makroblend) offer high resistance to oils and most cleaners.

Another parameter which is influenced by the wall thickness is the flame retardency. Standard DIN EN 60601–1 mentioned a necessary flame protection of V2 or better (UL94 V rating) for the thinnest wall thickness, but this standard is for medical devices with a permanent connection to a power supply. A new standard for wearables (DIN IEC 63203–101–1) is at the moment in preparation, but currently it is still unknown if any flame-retardancy requirements will be mentioned in this standard. If flame protection is necessary, it will depend on the power supply and the risk of damages for patients during a failure of the device. Fortunately, polycarbonate already has some inherent self-extinguishing characteristics (e.g. most grades can easily meet a V2 UL listing).

Further important material properties are the thermal stability and the dimensional stability. Thermal stability of a material can be important for production processes as well as for conditions of use of the device. Is it for example possible that the device could be forgotten inside a car at a hot summer day where temperatures as high as 80 °C can be reached. But also for solder reflow, often used to join electronic components on a circuit board (e.g. plastic camera lenses), can involve heating entire assemblies in ovens where temperatures as high as 150 °C can be reached. A thermally stable material can prevent warping or deformation during the solder reflow process. Makrolon polycarbonates are suitable up to 100 °C for permanent use and 121 °C for short time use and can easily meet such requirements. A material with high dimensional stability is important to maintain precise tolerances and stay together during the use of the device as temperatures fluctuate. Generally, a materials' CLTE behavior is used to calculate potential dimensional changes and Bayblend and Makrolon have a low CLTEs of 0.75 x 10^{-4}/K and 0.65 x 10^{-4}/K, respectively. The high heat resistance of polycarbonate means that Makrolon's low CLTE is maintained up to almost the glass transition temperature of 145 °C.

Thus, is highly advisable to select the material for the wearable housing at an early stage of the design process and to incorporate all aspects of the application, including manufacturing to help choose the housing material.

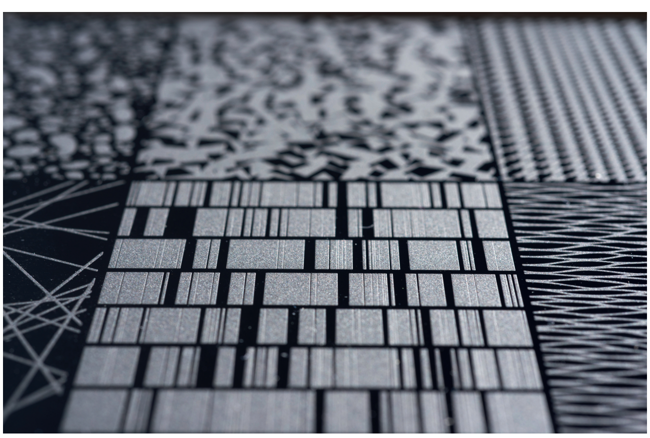


Fig. 2. With medical wearables, it is not only the function of the housing that plays an important role, but increasingly also its appearance © Covestro

Protection of the User

As implied by the word "wearables" these devices are in contact with the user and their skin. Therefore the task of the housing is not limited to protecting the inner components of the device, but should also protect the wearer from substances such as colorants, residual catalysts, leachable substances or other additives that could migrate from the housing. One of the relevant standards for the material selection for materials used in medical devices is ISO standard 10993. This standard describes the assessment of the biocompatibility of materials and divides the devices in different groups depending on the type and duration of contact with tissue.

For medical devices which contact only unharmed skin, it is necessary to test the cytotoxicity, which determines whether materials are toxic to biological cells (ISO 10993–5). The sensitization is also evaluated to detect the allergenic potential of a test article and if the material could generate any skin irritation (ISO 10993–10). Although these tests have to be done with the final device, it is useful to use materials which are known to already fulfill these biocompatibility requirements. Even wearables which might be classified as "wellness devices" and are not intended to be considered as medical devices are best designed with materials that minimize potential risk to the wearer (e.g. avoid potential allergic reactions). Thus, resins that are able to meet biocompatibility requirements of ISO 10993–5 and –10, such as Makrolon 2458 are advisable when designing new wearable devices.

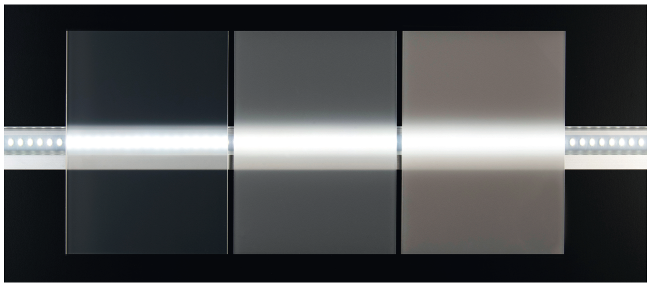


Fig. 3. LED covers should be translucent, but also have a certain degree of diffusion so that the individual LEDs are not visible © Covestro

Communication with the User

Wearables are often connected with other devices as smartphones or special diagnostic devices. For this connection it is necessary to transmit signals through the housing, with minimal loss in signal. The quality of signal transmission depends on the material which is located between signal transmitter and signal receiver and the frequency of the signal. To describe the transmission quality through a material it is necessary to know the dielectric constant (Dk) and dissipation factor (Df) of a material at a certain frequency, which is given for several materials at 5.0 GHz in **Table 1**. The quality of signal transmission generally improves with low values of Dk and Df. Polycarbonate has low Dk and Df values and is therefore a good choice to maintain high signal transmission. This benefit is especially the case for higher frequencies (over 30 GHz) that are foreseen for big data transmission. As mentioned previously, » weight reduction of wearables to improve customer satisfaction is highly desirable. Because low frequencies need less power but are also suitable for transmission of a low data volume, they are typically used for wearables. The frequency used will determine the reachable distance for signal transmission. For signal transmissions over several kilometers (e.g. for a tracker), frequencies below 1 GHz are possible. In contrast to that is Bluetooth at a frequency of 2.4 GHz is only able to achieve near-field communication.

Signal transmission with low frequencies and low power consumption need long antennas, which can be a challenge for small wearable devices. One option for these antennas are PCB or Chip antennas, which are placed inside the device. Both technologies need sufficient ground clearance, keep-out areas and no enclosure on-top, which is clearly impractical for compact consumer electronics devices.

In addition, internal structure features will occupy available space for antenna and complicate the pattern design. An innovative solution to this challenge is to integrate the antenna in the housing and to increase the size of the antenna pattern as well as save space for battery or other functions. One state-of-the-art technology for electronic integration is laser direct structuring (LDS) technology. For LDS, the device is molded out of a specially formulated resin, where the areas for the electric elements are integrated and activated by a laser on the housing surface. These activated parts can be afterward selectively coated with different metal layers.

An alternative technology is injection molded structural electronics (IMSE). For this technology the electronic circuits are first printed on a thin film. In a second step these films are reshaped and over-molded with the housing material to produce circuits embedded in the housing. A benefit of polycarbonate for IMSE is its high thermal stability, where connecting electronic components as chips or camera lenses with solder reflow can mean processes temperatures of over 150 °C.

Design Flexibility

For the design of wearable devices, including those with active interaction with the user, are many options possible with polycarbonate. The most basic elements are colors and surface structures on the housings. These basic elements have a huge influence on the first impression of the device and can even be critical in understanding how it should be used. Polycarbonate has a high gloss surface, which can help create a premium look. Furthermore polycarbonate allows for easy incorporation of additional surface features besides high gloss. **Figure 2** shows examples of surfaces which are producible with polycarbonate. Structured surfaces can be useful to create intuitive design with tactile features for patients with impared vision, or to simply create an attractive appearance.

With modern technology several other design and communication elements are possible to integrate in device housings. For example, integration of LED technology can permit direct communication between the device and the user. For LED covers, it is important to have a high light transmission to make the LED light as visible as possible. At the same time, however, it is necessary to have a high degree of diffusion to minimize hot spots and keep the single LES lamps invisible (**Fig. 3**). Polymers with high transparency, such as polycarbonate, blended with special colors and light diffusers can achieve this effect. With these kinds of special colors it is furthermore feasible to create materials which are transparent at certain wavelengths. Such materials appear black, yet are transparent to infrared light and allow designers to conceal a sensor without limiting its usability. Other color effects, such as fluorescence, are furthermore possible and shown in **Figure 4**.

To cover elements with a smooth surface until they are used is one further potential of transparent polymers. Beside LEDs and sensors it is also possible to cover displays as a uniform black panel. This means that the display remains a uniform black surface until the display element is switched on. For these sophisticated displays, a combination of materials and processing know-how is necessary. The freedom of design with large uniform surfaces, however, is huge, and enables the creation of 3D formed displays and integration of functions such as touch panels into the housing. With these kinds of technologies it is possible to convert a simple housing in an active interface with the customer. This technology is particularly appealing for wearables and medical devices, because smooth surface without edges mean a device that is easier to clean and to disinfect.

Fig. 4. Colors in housings are not only used for purely visual design, but can also take on additional functions © Covestro

Conclusion

A housing material for a wearable device is more than a simple plastic cover. With modern technologies such as integrated electronics or displays it is possible to create housings which represent the surface of the device and the interface to the user. The foundation to this result is the correct material selection which fulfills the basic requirements as biocompatibility, mechanical properties and chemical resistance and maximizes the possibilities of different designs. To select the correct material based on the many requirements is a challenge, which has to be implemented in the development process of the device in an early stage and where experts are needed. ■

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