Portable Medical Devices

Design. In response to the increasing trend for portable medical equipment and care in the home, smaller, lighter, more attractive medical devices are being developed. These must also meet the customer need for user-friendliness. Thanks to their light weight and robustness combined with wide design and manufacturing flexibility, plastics are excellent materials for the production of portable medical devices.

In the mobile x-ray unit from GE Healthcare, the housing is molded from impact-modified, colorable PBT and the transparent storage bins are produced from a PC+polyester blend (photos: Sabic)

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A number of factors are contributing to the boom in portable medical devices. The healthcare industry is trying to control runaway costs by streamlining care in the hospital (e.g., by bringing the device to the patient rather than having to transport the patient to a special area) and moving care out of the hospital to a less-costly setting whenever possible. People are living longer and developing chronic conditions, from diabetes to hypertension, that require long-term management (particularly self-management). At the same time, many consumers seek medical information and have a desire to play a larger role in their own care. Shortages of hospitals and doctors, together with pent-up demand for access to high-quality care in developing nations, are driving new approaches such as telemedicine and field-based care. Finally, sophisticated consumer electronics, particularly wireless connectivity, are making it possible to design devices that can be safely and effectively used in the home instead of requiring operation by a clinician.

Examples of home healthcare devices include continuous positive airway pressure (CPAP) devices, nebulizers, drug delivery devices, digital signal processing hearing aids, glucose monitoring systems and self-test (in vitro diagnostic) devices. The global market for home healthcare devices is set to grow by more than 9 % by 2012 with the market exceeding USD 70 billion in 2012. [1]

Performance Spectrum of Plastics

Advanced materials, such as healthcare resins and composites from Sabic Innovative Plastics, Bergen op Zoom, Netherlands, can make important contributions to a portable medical device throughout its life cycle, from design to manufacturing to everyday use.

Design Freedom: Light weight and ergonomic design are vital to safe, easy op-

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eration and transport of portable devices, particularly when they are being used by elderly, frail or disabled patients. Compared with traditional materials such as metal and glass, plastics offer greater design freedom, particularly when creating small parts, complex shapes and thin walls. Plastics also enable part consolidation to simplify a design and achieve cost and weight savings.

GE Healthcare, Munich, Germany, selected the engineering plastics Valox for the housing and Xylex for the storage bins of its Optima XR220amx mobile x-ray machine **(Title photo, Fig. 1)**, a "radiology center on wheels" that brings diagnostic radiology to the patient's bedside. Valox resins offer significantly greater freedom than metal to create new ergonomic designs. Also, this high-impact polybutylene therephthalate (PBT) blend provides molded-in color as a cost-effective alternative to traditional painted metal.

Fig. 1. The PBT housing for the detector on the mobile x-ray unit from GE Healthcare is a cost-saving alternative to a painted metal housing

Xylex, a transparent blend of polycarbonate (PC) and amorphous polyester, also features molded-in color. This resin is an excellent fit for healthcare applications because of its ability to be water-clear or colorable, biocompatible, lipid resistant and gamma sterilizable, and to maintain a good balance between chemical resistance and toughness. It is a good choice for disposables and device/pump housings.

Manufacturing Efficiency: In the manufacturing phase, plastics offer many avenues for cost and cycle time reduction and consistent quality of miniaturized parts, including the efficiencies of high-speed molding and high flow and rapid release capabilities. Integration of special properties, from custom color to flame retardance, avoids the time and costs of secondary operations and can improve consistency.

Fig. 2. For the housing of this portable device from Multigon Industries, which is used to detect unseen traumatic brain injuries on site, a plastic compound incorporating stainless steel fibers provides a cost-saving alternative to metal-oversprayed plastic, while delivering equivalent electromagnetic shielding performance

For example, Multigon Industries Inc., Yonkers, NY, USA, selected LNP Faradex DS 1003 FR HI compound to shield its Neurovision 500P hand-held Transcranial Doppler (TCD) device **(Fig. 2)**. This portable device allows clinicians to detect unseen, yet traumatic, brain injuries in the field, e.g. at sports fields. The Neurovision TCD requires electromagnetic/radio frequency interference (EMI/RFI) shielding.

Initially, Multigon used a copper overspray to provide shielding, but the time and labor associated with spraying added a significant amount to the cost of producing the housing. There were also concerns about inconsistencies in the copper application that could impact performance. Replacing spraying with LNP Faradex, which incorporates electrically conductive stainless steel fibers in a resin matrix, yielded a better solution that not only cut costs but also provides uniform shielding performance. The compound also provides flame retardance without the use of halogenated additives, as well as high impact performance and low shrinkage.

In other shielding applications, LNP Faradex compounds are preferable to heavy die-cast metal layers because they reduce the weight of the device and avoid secondary operations. In some cases, thanks to the use of this compound instead of lead, the inserts can be injection molded directly into the part instead of having to be machined and inserted after molding.

Increased Robustness: Everyday usage places major demands on a portable device, which might be banged or bumped in transit through a hospital, dropped on the floor by a patient, sub- →

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jected to harsh cleaning chemicals or even exposed to rugged conditions in the field. The right plastics provide toughness and resistance to abrasion, chemicals, UV light and temperature extremes that extend the useful life of the device and help preserve its optimal performance and appearance.

PWB Health Ltd. from Dumbarton, Scotland, developed the award-winning Breastlight **(Fig. 3)**, a home-use device that makes it easier to perform breast self-examinations. Because the product is typically used in the bathroom where it might drop onto a hard tile floor, the company wanted a tough, impact-resistant resin. For ease of use, PWB Health wanted relatively thin walls (2 mm) to make the housing lightweight, which required a high-flow resin. Cycoloy, a PC+ABS blend, was selected for the housing components of the Breastlight. This specific healthcare grade, which is assessed to the ISO10993 standard for biocompatibility, offers excellent impact resistance for durability and high flow for thin-wall molding.

Molded-in color capability of plastics also contributes to their practicality. In the case of the GE Healthcare Optima device, Valox and Xylex resins with molded-in color avoid the problem of scratches in a painted surface and simplify cleaning.

Improved Aesthetics: As medical devices move into the home, assisted living and long-term care settings, appearance becomes more important. Patients want attractive devices that are unobtrusive and non-threatening. In fact, they are, in many respects, becoming household furniture that needs to blend with home furnishings. In addition, an elegant design and appealing materials may even encourage greater use of the device. Aesthetics such as a clear, easy-to-read interface, a textured surface for better grip or contrasting colors to spotlight key components also can play a role in patient compliance.

When ResMed Medizintechnik GmbH, Höchstadt/Aisch, Germany, created the S9 series of sleep apnea devices **(Fig. 4)**, the goal was a sleek design and outstanding aesthetics for customer appeal. ResMed wanted the devices to blend in at home – looking more like a clock radio or stereo than a piece of medical equipment. The ResMed sleep apnea devices are designed with Lexan (PC) and Cycoloy (PC+ABS blends), which not only provided design freedom but also light weight yet durability.

The PC+ABS blend is used to mold the complex, thin-wall chassis, which is custom-colored dark gray. The resin provides excellent mechanical performance under high-temperature conditions. Further, this material provides flame retardance without the use of hazardous materials, enabling it to meet the requirements of the European Union's Restriction of Hazardous Substances (RoHS) and Waste Electrical and Electronic Equipment (WEEE) directives. PC was chosen for the S9 top case and H5i humidifier flip lid for its exceptional impact properties.

Fig. 3. A lightweight, robust, impact-resistant PC+ABS blend is the material used to produce the housing for the breast self-examination device from PWB Health

Plastics can be enhanced with an almost infinite array of colors, special effects, textures and finishes to blend in with home decor.

Fig. 4. The lightweight, durable chassis for the sleep apnea devices from ResMed is produced from PC and a PC+ABS blend

Service

Sabic has created a comprehensive healthcare product policy that was designed with the intent of supporting OEMs in achieving regulatory compliance. This policy ensures the consistency and biocompatibility of healthcare grades.

This healthcare product policy provides device manufacturers with the following:

- Pre-assessment of biocompatibility according to ISO 10993 or USP Class VI standards;
- U.S. Food & Drug Administration (FDA) or Device Master File listing, with letter of authorization provided if needed;
- healthcare product nomenclature for easy identification; and
- products subject to formula lock and change management process.

Such measures save time and money, since they avoid delays due to repeated qualification processes and – depending on the number of parts involved – can cut costs considerably. ■

REFERENCES

1 "Top 10 Medical Equipment Trends in 2009" available through Aarkstore Enterprise [press release]. March 20, 2009. Available at http://www.prlog.org/10202269-top-10-medical-equipment-trends-in-2009-available-now-through-aarkstore-enterprise.html

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