# Making sustainable medical devices: five top tips

The need for sustainable manufacturing practices is more pressing than ever and medical devices are no exception. Medical Technology caught up with thought leaders from across the industry to pull together five top tips for manufacturers.

**Look into multiplexing**

The lateral flow test market is a large and growing faction of the overall diagnostics market, worth an estimated $6bn in 2018, and is projected to reach $8.7bn in 2023. More than two billion lateral flow assays are produced each year, but with most tests being single-use and non-recyclable, as well as packaged within plastic, the leftover refuse is typically incinerated or sent to landfill.

At present, multiplex assays are far more common in research settings than clinical ones. A drive amongst clinical manufacturers to multiplex as many lateral flow diagnostic tests as feasible could significantly increase both sustainability and efficiency, by allowing practitioners to test for multiple causes of a condition through just one process.

**Utilise greener materials**

According to the UK Government, plastic waste in the oceans is set to treble within the next decade. Everyday single-use plastics can take over 400 years to biodegrade, which is why it's so important medical device manufacturers look into using sustainable materials in their equipment.

Rowles says: "We must look at different materials, such as reusable plastic cartridges, or even paper or plant-based recyclable.

**Try out 3D printing**

It's not just a final product which should aim to be eco-friendly – the production process should also seek to be as sustainable as possible. Lant says: "The right design and manufacturing processes can significantly reduce waste and reliance on energy, creating a final product with a lower carbon footprint. As a heavily regulated industry we are not always the best at collaboration, yet there is barely an industry not affected by the cry for alternative materials, so it's important to focus on developing solutions."

**Focus on reusables – but keep an eye on the cost of sterilization**

Many medical devices will simply have to be disposed of after to preserve patient safety. However, some pieces of equipment can be designed to be re-used after a process of disinfection between patients.

Devices like surgical forceps and endoscopes can be made in both reusable and single-use formats, and a focus amongst manufacturers to develop the former over the latter can significantly reduce the amount of waste healthcare providers will need to send to landfill.

**Be proactive, hire a consultant**

Sustainable changes can't all be made overnight, but an attitude change can. If development teams begin to foster an understanding of factors like the microbiology, chemistry and material science of a device, they can develop a smarter more eco-friendly end product.

# Catheter Precision gets FDA clearance for VIVO system launch

VIVO is a non-invasive imaging system that offers 3D cardiac mapping to help with localising the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to electrophysiology studies.

The pre-procedure planning tool computer-generates color-coded 3D mapping images of the heart using magnetic resonance imaging (MRI) or a computed tomography (CT) scan along with a standard 12-lead ECG to indicate the area of earliest activation.

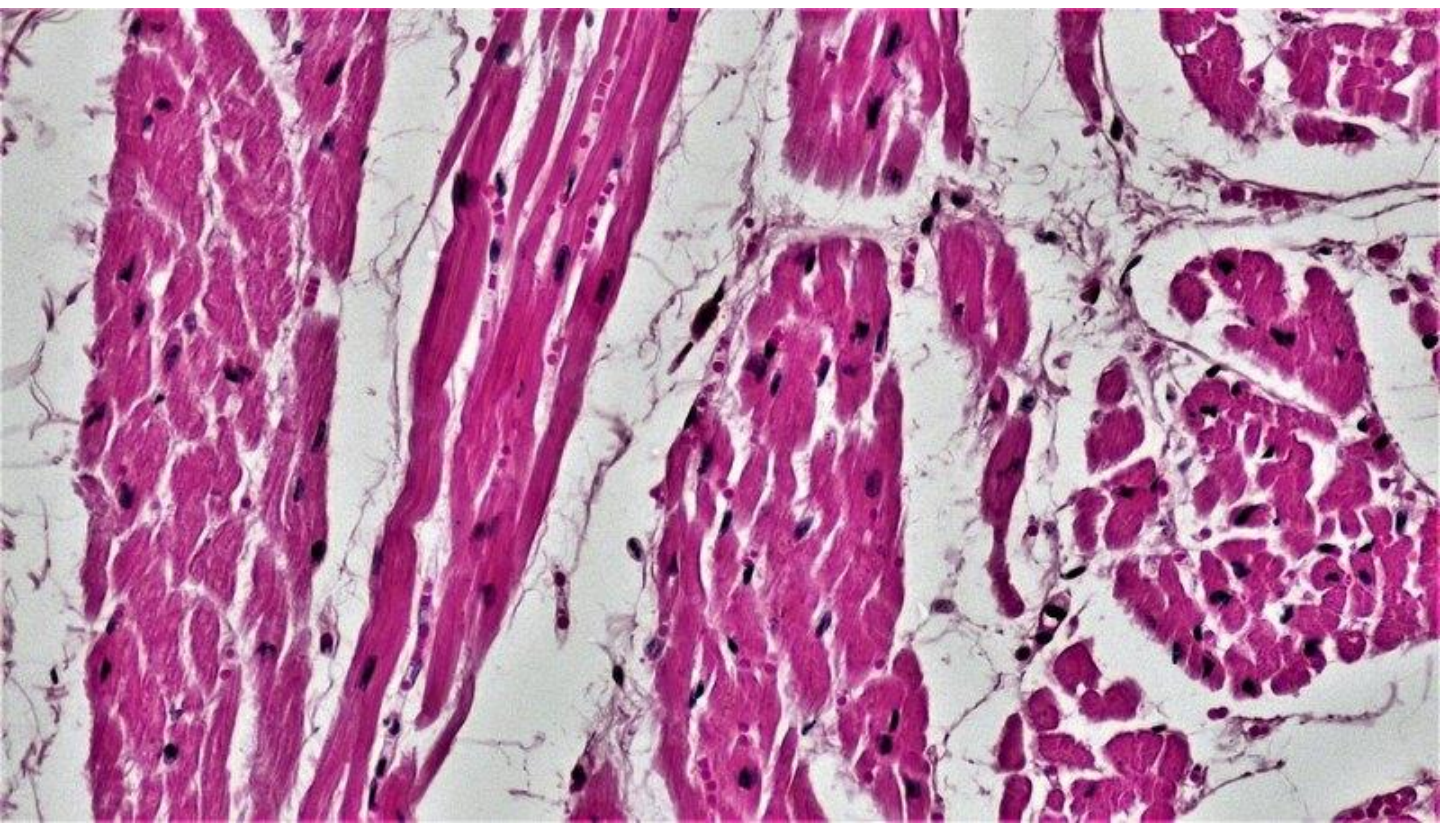
Catheter Precision CEO Steve Adler said: “The FDA clearance of the VIVO system puts an important new tool in the hands of electrophysiologists that allows for highly accurate, non-invasive identification of ventricular arrhythmia origins, displayed on a colorised 3D map.

“VIVO uses a proprietary algorithm based on proven electrophysiology principles to generate an accurate 3D model of the heart with a superimposed electrical activation map. These 3D maps help physicians pinpoint the sites of origin for certain types of rhythm disorders.”

The VIVO system comprises a hand-held 3D camera and an off-the-shelf laptop computer.

With the help of lead positions, the chest photograph, and DICOM data, VIVO will be able to determine the precise spatial relationships involved.

It can then provide new cardiac mapping that a physician can use prior to conducting an electrophysiology study and subsequent ablation.



# Brain stimulation may improve sight recovery after stroke

Non-invasive brain stimulation may help speed up and improve vision recovery for cortically blind patients following a stroke or similar brain injury.

Academics from the University of Rochester collaborated with researchers at the Italian Institute of Technology to study how brain stimulation could impact visual perceptual learning and retention in both healthy individuals and those with brain damage. The results of their study have been published in the Journal of Neuroscience.

Participants in the study were divided into sub-groups and asked to complete a computer-based visual processing task which measured their motion perception. This is what enables people to see movement and avoid or interact with moving objects.

The participants were shown clouds of dots and asked to determine which way they moved across the screen, with each sub-group given a different type of brain stimulation involving a non-invasive electrical current applied over the visual cortex.

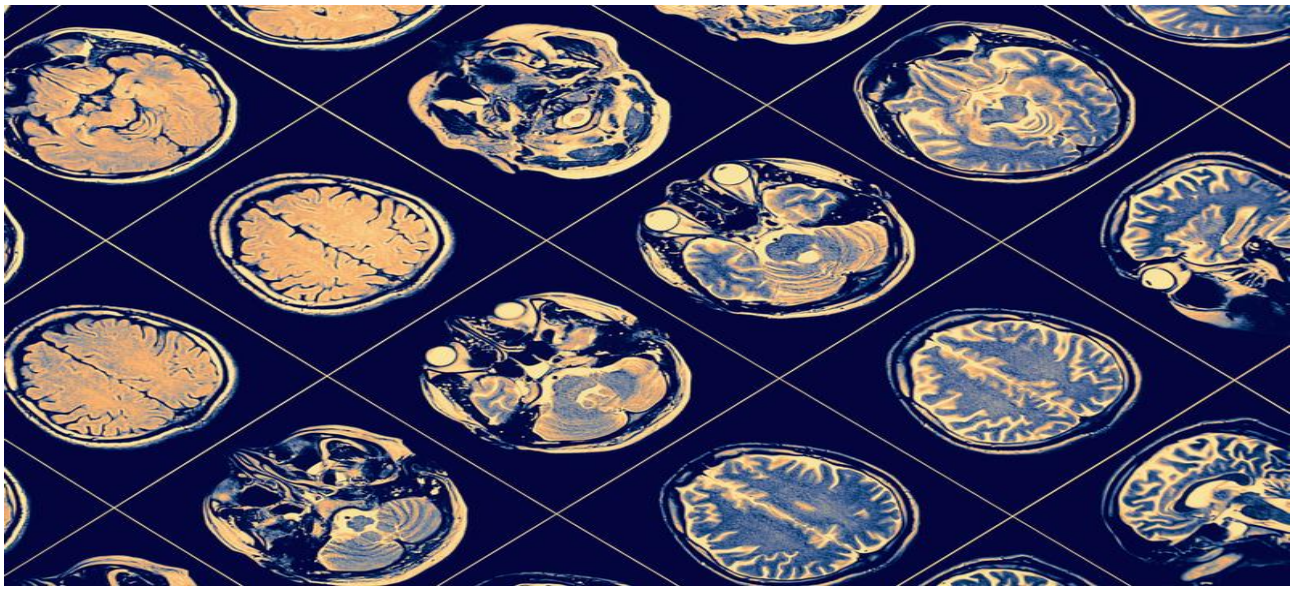
A type of stimulation known as transcranial random noise stimulation (tRNS) significantly improved participants' motion integration thresholds when they performed the task. All groups got better with practice, but the tRNS group improved twice as much and was able to learn the motion task more successfully than other groups.

When participants were re-tested six months later the participants in the tRNS group were found to have retained what they had learned and were still able to perform better on the motion task than other groups. The researchers said it is unclear why exactly tRNS has this impact on the brain.

University of Rochester professor of brain and cognitive sciences Duje Tadin said: "It appears that tRNS helps put the brain in a more plastic state, which makes it more amendable to training-induced change, or learning. What we hope to learn with future work is why this happens."
The team then extended its research to include patients who had suffered a stroke or other traumatic brain injury which had affected their visual cortex and rendered them partially blind.

These patients were subject to tRNS while using an eye-training system designed to assist stroke patients with recovering vision. This consisted of a set of exercises designed to stimulate the undamaged portions of the visual cortical system, through which the undamaged areas learn to process visual information that would normally be processed by the damaged parts.The patients experienced an improvement in visual processing and function after ten days. Re-learning visual perception lost due to neurological damage typically requires months of training.

University of Rochester professor in ophthalmology Krystel Huxlin said: "This fast improvement is something we've never seen in this patient population."
This two-pronged approach of eye-training and tRNS could lead to more efficient therapies to treat brain damage-associated sight loss in the future.



# FDA warns of risks when shunt implants, hearing devices mix

**Dive Brief:**
Magnetic interactions between devices can cause complications for patients who have both a programmable cerebrospinal fluid shunt (CFS) and a hearing implant, FDA said in a letter Tuesday to healthcare providers.
The magnetic field interference may cause unintended changes to the shunt valve settings, resulting in over- or under-drainage of the cerebrospinal fluid, the agency said.
Altered shunt valve settings could lead to a host of problems, ranging from altered mental status and headache to difficulty walking. If untreated, the symptoms could progress to loss of consciousness, seizures, hemorrhage or even death, FDA cautioned.
**Dive Insight:**
FDA wants to increase awareness of the potential risk for magnetic interference when patients have both a shunt and an implanted hearing device. The agency has determined there is a risk of unintended changes in a programmable CSF shunt valve setting due to magnet interference, but it's unknown how frequently they occur.

The shunts are used to treat hydrocephalus, a buildup of fluid in the brain that has many causes, including head injury, stroke, infection, tumors and bleeding. The risk is to the shunt patient who also has a hearing implant that contains magnets. Devices that could cause magnetic interference with a programmable shunt include cochlear implants, bone conduction hearing devices and middle ear hearing devices.

FDA conducted an analysis between January 1998 and October 2012 of the possible interaction between programmable CSF shunt valves and external sources that use magnets, such as cell phones, electronic tablets, cordless power drills, headphones and earbuds. The agency found a risk of experiencing an unintended change in valve setting when exposed to strong magnetic fields.

The agency said the studies showed the risk of change to the shunt system rapidly diminishes the farther away the magnetic source is from the CSF shunt. Although the findings were not comprehensive, they can be used as a basis for suggested safe distances between externally programmable CSF shunt valves and magnetic sources, the agency said.

FDA recommends keeping products that contain magnets two or more inches away from the location of magnetic externally programmable CSF shunt valves. Patients are advised to use the ear opposite the shunt for devices such as cell phones and earbuds.

Healthcare providers are advised to consider placing a programmable CSF shunt valve on the contralateral side of a cochlear implant or implantable bone conduction hearing device. For patients requiring bilateral hearing implants, which use magnets and a programmable CSF shunt, the implanting physician should position the shunt valve and the ipsilateral hearing implant at a maximum distance from each other.

If a magnetic interaction inadvertently changes a shunt’s valve settings, patients may experience symptoms that initially include altered mental status, headache, lethargy, irritability, vomiting, change in vision and difficulty walking. Symptoms may become more serious if unchecked.

# Margin for error 'almost zero' in testing pediatric devices

The limited market for pediatric devices has long stymied medical device development for children, prodding regulators, researchers and companies to rethink how to commercialize the devices.

Congress recognized those challenges with passage of the Pediatric Medical Device Safety and Improvement Act in 2007. The law, pushed for by the American Academy of Pediatrics, created a research agenda and bolstered postmarket surveillance for devices used in children.

Despite the market challenges, pediatric device approvals have inched up during the last decade. Of the 66 devices FDA authorized through the premarket approval and humanitarian device exemption (HDE) pathways in 2017, only 18 were indicated for use in a pediatric population, according to former FDA Commissioner Scott Gottlieb, a marginal increase over past years.

But most pediatric disorders do not represent a large enough pool to lure big manufacturers' research and development dollars.

"With pediatric markets, that margin for error is almost zero," James Wall, co-investigator and biodesign lead at the UCSF-Stanford Pediatric Device Consortium said. It is one of five FDA-backed partnerships bringing together health systems and academic or research institutions to support medical devices for children through all stages of development, an idea born from the 2007 legislation.

"If you're going after heart disease or diabetes or even asthma, you can afford to spend a little bit of money and maybe even lose your way a little bit, pivot back, and you still have a big enough market that there's opportunity for technology to be developed on a reasonable amount of capital," Wall told MedTech Dive.

Medtech giant Medtronic is among those able to carry out necessary clinical trials to expand certain product approvals into younger age groups, particularly in the case of its insulin pump system.

"We know based on our current results, kids are not just small adults; they do show different kinds of responses to our therapies," Robert Vigersky, chief medical officer in Medtronic's diabetes group, said in an interview with MedTech Dive.