Researchers probing how magnets may disable medical devices

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Researchers and regulators are working quickly to learn more about

potentially dangerous interactions between implanted medical devices and an ever-widening array of consumer gadgets that contain powerful magnets.

The concern follows research published earlier this year that found an iPhone 12 temporarily deactivated a defibrillator when held to a patient's skin just above the implant. Though the chances of this happening by mistake seemed low, the news spurred researchers in Minnesota and around the world to action.

"We believe the risk to patients is low. … However, the number of consumer electronics with strong magnets is expected to increase over time," Dr. Jeff Shuren, director of the Food and Drug Administration's medical device division, said in a statement following a broad study by the agency in May.

A pacemaker uses mild electric pulses to keep a heart beating in normal rhythm. An implantable cardioverter defibrillator also can deliver major electric shocks for sudden cardiac arrest. Both are implanted just under the skin in the upper chest, on the right or left side.

All pacemakers and defibrillators contain magnetically controlled switches that doctors can deactivate during surgery, MRI scans and medical emergencies. That's why magnetic inference has long been a risk with heart devices.

While the risk of occurrence may be low, the consequences could be serious. If a patient unknowingly puts their heart device into "magnet mode," a defibrillator could fail to treat a fast heartbeat condition called ventricular tachycardia, which can be deadly. A pacemaker could lose its ability to sense the heart's rhythm while pacing.

Patients are coming into contact with ever-stronger magnets, journal

articles warn, from the magnetic bands in FitBits and Apple Watches to e-cigarettes to special cases that charge wireless headphones. Jewelry and brooches with magnetic attachments have been known to affect heart devices, as have hospital communication badges with magnets in them.

The iPhone 12, released late last year, has been the subject of particular scrutiny because the phone model contains a circular array of powerful magnets that help align it with Apple's new MagSafe wireless charging pads and other accessories.

Reports about the iPhone 12 prompted an updated warning from Apple and rising concern among the public.

"We have received numerous calls from patients, because they are quite aware of these reports," said Dr. Jay Sengupta, an electrophysiologist and researcher with the Minneapolis Heart Institute Foundation.

The independent, nonprofit research organization is working with the med-tech industry to test the effects of magnets in cellphones and other devices on implantable heart devices, though officials declined to say which devices are being tested or when the work will be published.

Sengupta said he agrees with Apple and device makers like Medtronic, who say heart-device patients can safely use an iPhone 12 as long as they follow the guidance to keep it 6 inches from the implanted device—guidance that applies to all consumer electronics with magnets.

Cardiac patients are routinely told not to put cellphones of any model in a shirt breast pocket on the same side of the body as the implant, Sengupta said. They're also advised to hold cellphones to the ear on the other side of the body and to avoid putting other magnet-containing devices such as headphones and trackers with magnetic-clasp bands near

their implant.

The FDA has confirmed that some phones and consumer devices can temporarily disable implanted heart devices like pacemakers and defibrillators, by tripping the magnetically controlled switch inside the devices. The announcement didn't specifically mention the iPhone 12, but it cited journal reports that do.

After the Star Tribune pointed out a half dozen reports of potential problems, an FDA official said the agency would continue to examine its database of adverse event reports, which are unproven reports of patient harm or device malfunctions.

At the request of the Star Tribune, Minneapolis-based Basil Systems used its proprietary research software to scan the FDA's public database and turned up reports of potential magnetic interference with several different devices.

There were no reports of an iPhone 12 disabling a heart device outside of controlled experiments, but the search turned up other problems, some involving several devices from Medtronic, which is run from offices in Fridley.

The search found two reportssince 2019 of Medtronic heart devices that were possibly affected by magnetic interference. There were two more reports involving motor stalls in Medtronic's SynchroMed II implantable drug pump, which is designed to shut off when exposed to the magnetic field of an MRI scanner.

The search also turned up a report of an iPhone 12 allegedly changing the settings on a San Francisco patient's implanted Medtronic shunt, causing the device to drain too much cerebrospinal fluid and triggering severe headaches and other health problems.

But the database is not comprehensive.

"Many medical device industry experts believe that only a small fraction of adverse events actually get reported to the FDA," Basil Chief Commercial Officer Ross Meisner said.

The dust-up over the iPhone 12 began when cardiologists with the Henry Ford Heart & Vascular Institute in Detroit followed a hunch and, after getting ethics-board approval, held an iPhone 12 to the skin above a patient's implanted Medtronic Cobalt cardiac resynchronization therapy defibrillator. The phone temporarily suspended therapy functions, and normal function resumed when the phone was removed.

They published their findings in a letter published in the journal *Heart Rhythm* in January. A follow-up letter in April said, "We have shown for the first time that a ubiquitously used smartphone is capable of interacting with [an ICD] at clinically relevant distances."

The report kicked off research around the world, as concerned patients called their doctors and more letters from researchers began appearing in the *Heart Rhythm* journal.

Subsequent results have been inconsistent. One group in the United Kingdom reproduced the effect on nonimplanted devices, while another in Los Angeles could not reproduce it in real patients.

One letter cautioned that the Detroit group's report could arouse undue concern because "critical problems are quite rare." But the Detroit researchers responded that it was important to highlight issues that could lead to even brief disruptions.

The Detroit team is at work on a broader study that will include dozens of patients and a variety of different brands and consumer devices. Dr.

Gurjit Singh, one of the researchers, said data from those experiments likely will be published in the coming months. He's also been meeting with the FDA and industry standards-setting officials.

Apple issued a support article emphasizing the 6-inch guideline and acknowledging that magnets in a list of devices "might" interfere with medical devices. The iPhone 12 was the only phone on the list.

A Medtronic spokeswoman said the Detroit researchers appeared to bring strong magnets closer than 6 inches to the device, despite the device's labeling not to do that.

It's not clear whether or when other solutions will be developed that don't require patients to remember to keep their phones away from their chests.

Dr. Fred Kusumoto a Mayo Clinic electrophysiologist and president of Heart Rhythm Society, said it would take years to develop new strategies that are accepted industrywide like magnetic switches are today.

So for now, the burden will remain on consumers.