



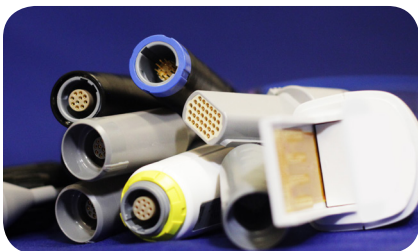
New devices may reduce your reprocessing savings due to irrelevant “locks”

The speed of innovation in the electrophysiology area is very high, and when rapidly adopting new technologies without carefully evaluating whether such devices represent performance improvement, hospitals risk out-of-control device costs without any beneficial impact.

Increasing device costs from new device launches do not just present themselves in the form of higher priced items. When Biosense Webster recently launched SoundStar eco, a next-generation ultrasound catheter to replace the SoundStar 3-D, it was launched with a chip in the handle that prevents reprocessing of the device, yet the description of change listed in the Biosense Webster submission states that the “modified SoundStar eco 10F and SoundStar eco 10FG Catheters are **identical to the currently cleared SNDSTR10F and SNDSTR10FG Catheters** in terms of: Indication for Use, Material, Manufacturing methods, **Operating principles, Fundamental Scientific Technology, Performance**, Array and Sensor specifications...”. This new chip provides no improvement to the overall performance of the device.

In addition, Biosense Webster has started rolling out a software upgrade to the Carto system, which disallows the use of reprocessed devices.

It is important to note that there is no evidence this chip or the software update have any other function than to remove the ability of the hospital to save money through reprocessing. If the hospital starts using the SoundStar eco, they cannot achieve savings by reprocessing the devices.



New SoundStars cost the hospital around \$2,500, but the hospital can acquire reprocessed SoundStars for around \$1,250 – savings of \$1,250 per catheter. An average sized EP Lab that uses SoundStar, may use as much as 8 catheters per week, equivalent to savings of \$10,000 per week – if all catheters used are reprocessed.

Adopting this new technology could cost the hospital as much as \$1/2 Million per year.

However, the cost of being a Biosense Webster customer may be even higher than this.

Out of the three major systems on the market, Biosense Webster Carto system is the only “closed” system – the only system that only works with Biosense Webster devices. Competing systems (St. Jude and Boston Scientific) are open – all devices can be used with them. In other words, the industry as such affords the EP lab and the Electrophysiologist a great deal of freedom to select what devices they think are best for the case.

As an exception, the Carto system locks in the EP lab and the Electrophysiologist to ONLY use Biosense Webster devices.

This leaves the hospital in a vulnerable situation, where they may commit to investments in capital equipment or computer software that dictates buying evermore expensive devices from the manufacturer – devices that cannot be reprocessed.



Ask this to protect your savings when a new technology or device is introduced:

- Is there any documented evidence of improved patient outcomes from the technology?
- Does the “upgrade” allow you to continue savings through reprocessing?
- What are the implications on capital equipment, computer systems or other devices used?
- Does the technology prohibit you from using certain devices during a procedure?

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