

MEDICAL DEVICE WARRANTIES: FINE PRINT, MAJOR TOTAL COST IMPLICATIONS

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Hospitals are facing well-documented pressures to reduce their costs while still being held accountable to provide quality care.

One path to cost reduction is to ensure hospitals have an accurate understanding of the real cost of medical equipment. The upfront purchase price for a piece of capital imaging equipment is one obvious factor—but what about the true cost of owning this equipment?

In the last article, we discussed ways to gain a better understanding of the true total cost of ownership as a means of making informed decisions when purchasing capital equipment. As hospitals are facing thinner and thinner margins it is crucial that the distinction is made between the initial purchase price and the true cost of owning the equipment over its useful lifecycle. These ongoing costs of ownership can be strikingly different between vendors. This delta can be attributed to differences in costs such as training, service and repairs, replacement parts, software updates, trade-in value, and the impact of down time—several of which are directly influenced by the equipment's warranty coverage.

Simply put, warranties are meant to mitigate the risks related to ownership. For the purchaser they provide an insurance policy of sorts, intended to control additional expenses associated with the items listed above. On the flip side, warranties are a way for vendors to express confidence in the product they are selling. Yet some of these offerings are simply a reaction to market dynamics (in particular the trend of providing generous warranties). Just as all products are not created equal, all warranties are not created equal. It is paramount to consider the quality and durability of the equipment in conjunction with the length of the warranty and the associated scope of coverage. One question to consider is whether the warranty offered aligns with the reliability of the product being considered. If something doesn't seem right, it usually isn't.

Broadly speaking, hospitals need to perform extensive due diligence not only on the warranty coverage, but also on the ability of the equipment and vendor to live up to the promise of managing risk and cost. Prospective buyers should pay special attention to the frequency with which organizations have had to invoke warranty provisions and the response from the vendors in question. One good way to make this assessment is to pull historical records on problem reports and costs incurred which were not covered under the warranty. The amount of additional outlay on a product is often surprising, especially on equipment that has the lowest cost upfront. Quite often, what appears to be the

least expensive alternative ends up costing the hospital more in the long run.

Important questions to ask include:

- What exactly is covered by the warranty? More importantly, what isn't?
- What happens when my equipment fails during the warranty period?
- How do you help sustain my clinical operation while the equipment is inoperable?
- What is the historical frequency of failures reported during the warranty period?

These questions are essential but not sufficient. The following list describes the aspects of a medical device warranty's "fine print" that hospitals should scrutinize before entering into a relationship with a vendor for the purchase of imaging equipment.

1. Beware the Exceptions – i.e. what isn't covered by the warranty?

This is one of the most important areas to unveil, especially with equipment that carries a multi-year warranty. Is the five-year warranty really a five-year warranty? Or is the value diminished due to a long list of limitations or exceptions? Just as vehicle warranties carve out exceptions for high-use items like wiper blades or automatic window controls, medical equipment warranties often contain exceptions that significantly change the calculus on "total cost of ownership." (In fairness to the vendors it should be understood that certain consumables and actions such as abuse, negligence, or intentional damage are items not typically covered.)

In the case of point-of-care ultrasound, transducers are often excluded from the warranty coverage. Some vendors implicitly acknowledge the likelihood that a transducer will need to be replaced by including some minimal coverage or a limit to the number of times a transducer will be replaced over a given period. As clinicians and sonographers know, though, transducers are quite prone to drops and cable damage, especially in a highly mobile environment. Limitations to transducer replacements can and should be a point of comparison when evaluating the proposals across multiple vendors, as their effect on the total cost of ownership over the life of the product can be substantial. Case in point, there are hospitals whose outlay on replacement transducers has surpassed the cost of the original system. A warranty that covers the replacement of transducers can have a significant influence on the bottom line.

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2. Evaluate Vendor Relationships

A warranty is a contract that defines the obligations of the buyer and the seller. It goes without saying that the longer the warranty, the more invested those parties become. Hospitals count on vendors to keep the equipment running for several years at a minimal cost to the hospital (and the closer to zero, the better). When these expectations are met, the chances the hospital will remain loyal to that vendor increase exponentially. On the other hand, when hospitals consider switching vendors, it can be assumed that the relationship was unsatisfactory in some way. Quantifying that dissatisfaction—in terms of the loss of perceived savings on the upfront purchase price, for instance—becomes an important factor when considering future purchases.

3. Quantify the Costs to Invoke the Warranty

When equipment is under warranty hospitals often believe, accurately or not, that if the device needs repair it will be fixed quickly and at no cost to them. This may or may not be the case, depending upon the warranty's service levels and exclusions. But whenever equipment goes down and is not available for use, there are costs involved—not just the obvious and direct costs of shipping, but also opportunity costs in terms of lost revenue due to impeded workflow, clinical downtime, rescheduling, and patient time (which influences satisfaction). Stopping a procedure midway due to equipment failure has a host of ramifications (including for a patient's safety) that go well beyond direct costs, for example. The effect these issues have on the bottom line cannot be ignored.

The goal, of course, is to choose equipment in which the quality and durability are commensurate with the warranty offered. Just because a manufacturer offers a five- or ten-year warranty does not mean the equipment will not fail. It is important to ask about the mean time between failures, and the frequency of repairs during the period. What good is a five-year warranty that must be invoked with great frequency? Downtime is downtime!

For plug-and-play medical devices such as ultrasound, vendors may supply loaner devices, which can help reduce the amount of downtime while the hospital awaits repairs or a permanent replacement unit. In the case of large imaging equipment such as CT or MRI, the loaner scenario is more

challenging. For this equipment, many hospitals require vendors to keep spare parts onsite or at a local depot. This too can help mitigate the amount of downtime and associated costs to the hospital. These are things that should be considered upfront when choosing an equipment and vendor.

4. Quantifying Recurring Costs

Equipment such as MRI and CT imaging devices require a field service organization to perform preventive maintenance on the equipment at regular intervals. Many also need upgrades or software updates over the course of their life. Knowing whether recurring maintenance and upgrade costs are covered by the warranty is important when calculating the total cost of ownership. To make an accurate calculation, hospitals should also quantify those same costs after the warranty period is over.

Conclusion

According to the McKinsey report on “The Value of Good Quality in Medical Devices,” “routine external quality failures represent 0.4 to 1.6 percent of annual sales,” and “these failure costs primarily relate to warranty costs.”¹ In other words this failure rate is accounted for. Reading the fine print in medical manufacturers' warranties—and understanding how that fine print relates to those vendors' confidence in their products—can reduce these hidden costs and the obvious headaches of owning poor quality equipment.

¹<https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/capturing-the-value-of-good-quality-in-medical-devices>