

## Philips HeartStart XL Defibrillator/Monitor

### Clinical profile



# HeartStart XL setting new standard at Lutheran General

Named one of the top 100 hospitals in the country, 608-bed Advocate Lutheran General Hospital in Parkridge, Illinois, standardized to the Philips HeartStart XL defibrillator with SMART Biphasic waveform technology. The decision was a result of an extensive planning and evaluation process that spanned two years. Here's the story of how the selection committee at Lutheran General, a recognized leader in cardiology, chose HeartStart XL.

When a patient is experiencing sudden cardiac arrest (SCA), his chances for survival diminish with every passing minute. Taking the time for the ALS team to get up to speed on unfamiliar equipment could cost a life – a chance Advocate Lutheran General Hospital is not willing to take.

“It's critical that the code team has access to external defibrillators that are so intuitive to use, they're second nature. They can't afford the time to figure out what model they're using and how it works,” notes Ms. Barthel, Director of Cardiac and Respiratory Services at Lutheran General. “So we decided that when it was time to replace our external defibrillators, we would standardize house-wide. This would ensure that anyone responding in an emergency would be fully trained and familiar with the same equipment.”

As Ms. Barthel notes, one of the biggest drawbacks to standardization is building consensus. “The downside is that you must bring a lot of opinions to bear. But since we are planning to replace all of our defibrillators, we felt it was important to allow our staff to express their opinions up front.” That’s why, says Ms. Barthel, an extensive evaluation that involved many people was an integral part of the hospital’s decision-making process.

### A brief look back

As a long-time customer of Philips Medical Systems (formerly Hewlett-Packard and Agilent Technologies), Lutheran General had a total of 18 CodeMaster XL+ defibrillators and 64 43100 defibrillators (as well as 30 defibrillators from other manufacturers) in use throughout the hospital. Approximately two years ago, Philips 43100 Series defibs moved out of support after being obsolete for 9 years, providing parts for the equipment on a “best effort” basis only. At the same time, Lutheran General decided it needed to replace its defibrillators. The hospital had used their CodeMasters and 43100s for more than a decade. This, combined with the phasing-out of the 43100s, led the hospital to decide it was time to purchase new equipment. Due to the capital investment required, Lutheran General estimated that it would take three to four years to replace all of its defibrillators. During the transition, those units being replaced would be used for spare parts.

The evaluation process did not begin immediately. Because of its high level of comfort with its existing Philips equipment, the hospital chose to wait for the manufacturer to introduce its new HeartStart XLT biphasic defibrillator/monitor, which was released in early 2000.

The hospital tested the equipment and liked it, but found that the XLT model, with its flat screen, was not ideal for use on a crash cart. The hospital decided to wait for the company to release its crash cart version – the HeartStart XL – which was introduced nine months later in November.

### Biphasic, the new gold standard

A selection committee, which included Dr. David Cooke, Associate Director of Cardiology;

Ms. Barthel; Debbie Raley, Clinical Nurse Educator; and Marcel Trutza, Biomedical Engineer, was formed, and the process of evaluating the leading biphasic defibrillators began. As Dr. Cooke notes: “In addition to Philips, two other manufacturers had introduced new defibrillators based on biphasic waveform technology. After carefully reviewing medical literature and manufacturers’ information, we were convinced that biphasic offered clear advantages over monophasic.” Here’s why, Dr. Cooke explains.

With monophasic waveforms, the heart receives a single burst of electricity that moves from one pad to the other. The monophasic waveform does not compensate for differences in impedance (the resistance of the body to the flow of current). As a result, the waveform can require high energy levels – up to 360 J – to defibrillate effectively.

On the other hand, with biphasic waveforms, electricity moves from one pad to the other then reverses direction. Philips SMART Biphasic technology automatically measures the patient’s impedance and adjusts the waveform dynamically, optimizing it for each shock delivered.

“The principle of monophasic – escalating energy until resuscitation is successful – is a primitive way of dealing with transthoracic resistance,” notes Dr. Cooke. “Biphasic technology takes an entirely different approach. It automatically measures resistance 1/1000th of a second before letting go of the charge, modifying the waveform as necessary to customize it to the patient. As a result, less energy is required, helping minimize such side effects as post-shock dysfunction, skin burns and brain dysfunction.”



## Criteria determined

Based upon its wide range of requirements, the selection committee established an extensive criteria list against which all defibrillators would be evaluated. Topping the list was ease of use. "When the code team is mobilized, they may be asked to respond to an emergent situation in an unfamiliar area within the hospital. They need to feel immediately comfortable with the defibrillator at hand," reiterates Ms. Barthel.

A built-in automated external defibrillator (AED) mode was another key criteria. Says Debbie Raley: "Eventually, as we phase-in the equipment, we plan to train BLS nurses to use the devices. In the event they are the first to arrive on the scene, they can start the machine in the AED mode." Lutheran General also wanted the flexibility to customize the equipment to the area. For example, equipment to be used in areas in which patients are at greater risk – in the ICU, cardiac surgery or the OR – need pacing capabilities, while units used in lower-risk settings don't.

The defibrillator would also have to serve double duty as a transport device. "When a patient needs to be transported from the bedside to X-ray, for example, he or she must be monitored continuously," explains Ms. Barthel. "But we feel there's no sense in monitoring someone at high risk if you can't respond immediately should the patient experience an arrhythmia." With the need for portability, the defibrillator's weight, battery reliability and screen visibility were important considerations.

Ease of maintenance was another primary factor. Once an equipment warranty has expired, Lutheran General has a policy of servicing devices in-house. In fact, the hospital has a full biomedical engineering department responsible for equipment maintenance and repair. Says Marcel Trutza, Biomedical Engineer and member of the selection committee: "As much as we can, we service the equipment in-house. Of course, we buy parts from the manufacturer, but we are really set up to act quickly and cost-effectively."

## Evaluation begins

With its commitment to go biphasic established, Lutheran General invited Philips and the two other

defibrillator manufacturers into the hospital to demonstrate their equipment. Following each manufacturer's presentation, the staff was given the opportunity to evaluate the equipment. The three defibrillators were set up on a table, side by side, for a day. Approximately 20 staff members were asked to rate a variety of product attributes, from ease-of-use to portability.

To ensure that the process was objective, Debbie Raley developed a formal evaluation tool. "At times, the hospital has had seven different types of defibrillators in use. Typically, each staff person has one brand he or she prefers using over another," she says. "So naturally there's some subjectivity. This tool helped eliminate as much of that as possible."

In addition, each of the manufacturers loaned the devices to the hospital for a few weeks. During that time, Lutheran General trialed the defibrillators in the clinical setting of the cath lab. Says Debbie: "Using the devices to perform synchronized cardioversion to resolve non-life threatening rhythm problems was an excellent way to determine how well they met our criteria in a real-world setting. Moreover, we have found that the devices are working wonderfully for cardioversion because the time and energy settings required to shock the patients are reduced," she adds.

The results of the preliminary evaluation, the clinical trials and additional information about the vendors were summarized and presented to the selection committee for review. The HeartStart XL won hands down. Here's why.

## HeartStart XL's true 1-2-3 operation

The HeartStart XL, at just 14 pounds and equipped with a tilted screen, fit the bill perfectly for transport use. In addition, the device was the easiest of the three defibrillators to use. As Amy Vizanko, sales representative for Philips Medical Systems, explains, "It provides true 1-2-3 operation. One, turn the knob on and select the energy; two, press the charge button on the paddle or on the front of the monitor; and three, press the shock button."

Its intuitive 1-2-3 operation will also make it easier for Lutheran General to phase-in the use of equipment by

its BLS trained staff. In the AED mode, voice prompts and text messages will guide BLS nurses through the defibrillation process, while the defibrillator continuously monitors and displays the patient's ECG. By the time the code team arrives, the BLS nurse may be delivering his or her second shock. With just a turn of a knob from AED to manual, the ALS team has immediate access to such advanced therapeutic features as selectable energy (from 2 to 200 J), non-invasive pacing, synchronized cardioversion, SpO<sub>2</sub> pulse oximetry monitoring and ECG monitoring.

### Extensive clinical data provided

Ease of operation, portability and a full feature set were important attributes in the hospital's final decision. But there was another overriding factor that sealed the deal.

Lutheran General was in a tough spot. The hospital had to know exactly how the defibrillators would work in emergencies. "But codes don't happen every day, and a formal trial with data on at least 100 people could take up to a year to complete," notes Ms. Vizanko. As a result, the hospital had to rely on data provided by the manufacturer. And here's where Philips – which had conducted substantially more clinical research than any of the competing vendors – offered a significant competitive edge.

Using a process outlined by the American Heart Association in 1995, the Philips team put the SMART Biphasic waveform through a rigorous sequence of validation studies. Animal studies were first used to test and fine-tune the waveform parameters to achieve optimal performance. Electrophysiology laboratory studies were then used to prove the effectiveness of the waveform on people in a controlled hospital setting. Finally, after receiving FDA clearance for the HeartStart AED, post-market surveillance studies were used to prove how effective the SMART Biphasic waveform is in emergency resuscitation situations outside of the hospital.

In the course of these studies, it was shown that the low-energy SMART Biphasic waveform defibrillator performed as well as or better than traditional monophasic waveform devices. In fact, in the hospital environment, the SMART Biphasic waveform had a first-shock efficacy of 97 percent in one study and 86 percent in another. In addition, in a randomized

out-of-hospital study comparing SMART Biphasic to high-energy escalating monophasic defibrillation, the average collapse-to-first shock time was 12.3 minutes. Of the 54 SMART Biphasic patients, 100 percent were defibrillated – 94 percent on the first shock and 98 percent with three or fewer shocks. This compared to 58 percent and 67 percent respectively with monophasic devices. In addition, the data showed that the SMART Biphasic waveform resulted in better post-shock cardiac function, fewer post-shock arrhythmias and better neurological outcome for survivors.



Says Dr. Cooke: "We found that while there's a large body of literature published about the SMART Biphasic waveform, there's very little published research from the other manufacturers. Philips invested the time and resources to prove that its SMART Biphasic technology is clearly superior to monophasic. Moreover, the company was an excellent steward of the research effort, continuing their clinical studies uninterrupted despite transitions in ownership."

Another major consideration that guided the hospital's final selection was its relationship with Philips. Says Ms. Barthel: "We have had a long history of product dependability and good service from Hewlett-Packard Medical Product Group, Agilent Technologies Healthcare Solutions Group, and now Philips Medical Systems. We know that if our staff needs training or our biomed have a problem, we'll get a reasonable response in a timely manner." Marcel Trutza, Biomedical Engineer, agrees: "Philips people are highly professional, knowledgeable and responsive. Overall, we have been very happy with the service they've provided."

The selection of the HeartStart XL is also making the process of transitioning from the older equipment to the new easier. The HeartStart XL's user interface, keys, energy selection knob, paddles, alarms and prompts are very similar to the CodeMaster's and 43100's. Even the recorder paper is the same. Says Ms. Barthel: "One of Hewlett-Packard's claims to fame, long before it spun-off Agilent (now Philips), is that each subsequent generation of product would be similar to the previous version. There are new attributes, but it isn't like starting over. It's a familiar product, with a familiar look and feel."

### Changing mindset

Replacing the defibrillators was complicated by the change to biphasic technology, which required more than education and hands-on training. Because monophasic was the gold standard for more than two decades, it would take a change in mindset as well. To facilitate hospital-wide acceptance of biphasic technology, Lutheran General worked extensively to educate physicians and nurses. Every clinician was given a letter announcing the change, accompanied by an information sheet explaining the difference between biphasic and monophasic. In addition, pink stickers are placed on all of the HeartStart XLs as a quick reminder that the devices utilize the biphasic technology. Says Ms. Vizanko: "For the next few years, both monophasic and biphasic devices will be used. During this time, the hospital does not want a situation in which one clinician has to explain biphasic technology to another – especially in an emergency. The pink stickers provided an instant reminder that this is a new defibrillator with a new type of technology."

In addition, Philips conducted extensive training sessions, educating the "super users" first, who, in turn, are training the rest of the staff. They also brought in product and technology experts to help round out the staff's understanding of biphasic technology and equipment use. Says Ms. Raley: "Because of the effort we made, supported by the training provided by Philips and Amy's personal dedication, we found that there has been very little resistance to using the devices." Philips also provided sample protocols, prepared by top practitioners in the field. "This was a huge timesaver for us," she adds. "When you are trying to change a product

of this magnitude throughout the whole campus, having such outstanding support and resources makes a huge difference in terms of acceptance and proper use."

### Greatest risk replaced first

The defibrillators in the ICUs, where the equipment is used extensively, were the first to be replaced."

We don't have the resources to replace all of the defibrillators throughout the hospital in one year's time," says Ms. Barthel. "So we looked carefully at the age and clinical performance of each device, and submitted capital requests for purchasing blocks of equipment at a time. We are also planning to replace all equipment in one department at once, so that there aren't two or three different models in use in that area. This strategy allows us to replace equipment used on patients with the greatest risk first and budget expenses appropriately."

To date, the hospital has also replaced the majority of units in its medical surgery departments, as well as in Pediatric ICU. The next tier, scheduled for 2002, will include the OR suites. Approximately three years from now, the majority of clinical departments within Lutheran General will have been transitioned over to the HeartStart XL. "It was time to replace our equipment, and with the introduction of the SMART biphasic HeartStart XLs, there was no better time to undertake this hospital-wide effort. We are very pleased with our decision. We have already had numerous comments from staff regarding its ease of use, as well as comments about fewer problems with skin burn and other post-shock conditions," concludes Dr. Cooke.



For more information on the HeartStart XL biphasic defibrillator, contact Philips Medical Systems at your local Philips sales office or Philips regional office.

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### On the web

[www.philips.com/heartstart](http://www.philips.com/heartstart)

### Via email

[medical@philips.com](mailto:medical@philips.com)

### By fax

+31 40 27 64 887

### By postal service

Philips Medical Systems  
3000 Minuteman Road  
Andover, MA 01810-1085

### Asia

Tel: +852 2821 5888

### Europe, Middle East and Africa

Tel: +31 40 27 87246

### Latin America

Tel: +1 954 628 1000

### North America

Tel: +1 800 934 7372

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