ARE YOU IN THE MARKET FOR A NEW MANUAL DEFIBRILLATOR?

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So, you are in the market for a new manual defibrillator. Why might you be making a purchase decision at this time? Perhaps you are in the midst of expanding services, such as a new cath lab, and need to plan for a defibrillator. Do all of your defibrillators still employ a monophasic waveform? If so, those who perform cardioversions may be requesting a defibrillator with a biphasic waveform since the scientific evidence shows significantly improved conversion rates for atrial fibrillation. Or do you have a mixed monophasic/biphasic environment, which causes the care providers confusion when selecting the energy setting for shocks? Institutions that have a variety of models of defibrillators in use along with accessories that are not interchangeable may think that now is the time to standardize before a major safety issue arises. Educators may be clamoring for one standard defibrillator with an interactive computer teaching program to make more efficient the competency training and testing.

Practitioners who are familiar with scientific studies showing how poorly cardiopulmonary resuscitation (CPR) is performed may want a manual defibrillator that coaches in proper CPR technique and gives immediate feedback for improvement in performance. Critical care staff may have recently returned from a national meeting and gotten excited about a new product they viewed in the exhibit hall. Perhaps the biomedical engineering personnel have informed the CPR committee that the defibrillators in your institution have reached their "life expectancy" based on capital depreciation and are beginning to show an increased repair record. Has a sales rep gotten his/her foot in the door, found the way to the office of a staff member who has influence on resuscitation practice, and demonstrated a new model?

Whatever reason you may have for purchase of a new manual defibrillator, this newsletter may help you figure out how to get started and what to look for among the various models on the market. I will speak to the basic manual defibrillator that contains capability for ECG monitoring, defibrillation, cardioversion, and external pacing. In the hospital, this manual defibrillator often lives on the code cart and is used during resuscitations by Advanced Cardiac Life Support (ACLS) providers on the CPR team. In addition, manual defibrillators are found in critical care units and specialty units such as the operating room, post anesthesia care unit, stress lab, cardiac catheterization lab, and electrophysiology lab. They may also be used for intra-hospital transport when unstable patients are taken for diagnostic studies, and for inter-hospital transport by air and ground teams. Many of the defibrillators on the market have similar basic capabilities and functionalities, so I will write about what makes the models special, highlighting new features.

What Configuration Meets the Needs of Your Institution?

I would like to emphasize from the outset that each institution should have a long-term plan for standardizing on one make and model of manual defibrillator throughout the institution. Some facilities may have the financial ability to change *all* defibrillators out at one time, knowing that this will simplify the selection process, ease clinician training, and give power to negotiate the best purchase price. Other hospitals, which may only be adding several new defibrillators at this time, should consider the wider view of where they want to be in the future with defibrillator

technology. For example, will automated external defibrillators (AEDs) eventually be added into medical/surgical units, diagnostic and treatment departments, and common areas such as long hallways, the cafeteria, and information desks? If so, then you might also want to investigate the AEDs that are available from the vendors while you are evaluating their manual defibrillators. Ask what other physiologic monitoring capabilities are available so that you can add them to your basic defibrillator in the future.

It is helpful to have the discussion in advance of the purchase decision about whether the institution will switch over to disposable electrode technology, relegating paddles to only a few select locations. In my experience conditions in which paddles are needed include:

- Patients undergoing an exercise stress test due to their diaphoretic skin
- Patients who are diaphoretic due to hemodynamic instability
- Patients with chest and abdominal incisions/wounds
- Patients with a large amount of hair on their chest
- Trauma patients

Since paddles have been used for many years, it is difficult to convince some providers that disposable electrodes are the path to take. Use of pads is much safer for the person performing the actual defibrillation since s/he no longer has to lean over the patient's body trying to apply the necessary 25 pounds of pressure to the paddles. On the other hand, in the noisy chaotic environment of a code, it is important for the person pushing the discharge buttons to loudly inform those around the bed when the defibrillation will occur since it is less obvious with disposable electrodes, making it easier for them to be injured. With paddles there is the problem of the paste smearing over the chest and the potential of electrical arcing if there is not good skin contact. With disposable electrodes the skin must be prepared properly and the pads must be rolled onto the skin so that they adhere well – or energy delivered to the patient will be reduced. Some providers will state that the shock can be provided more quickly with paddles, but if the pads are pre attached to the multi-function cable, and the package is easy to open, they can be applied in very little time. Paddles have a steep one-time cost, so many institutions are eliminating them in areas in which the manual defibrillators have advisory capability and purchasing them only for the select areas listed above. Perhaps a set of external paddles can be brought by the CPR Team for the rare time that they are needed in a code. On the other hand, disposable electrodes are a continuing cost and will need a management plan, so begin discussion with your central supply department.

Do not make a purchase decision based mainly on the "futures" being promised by the sales rep. Are the features promised still being trialed by the supplier's R&D department? Is the vendor in the process of seeking FDA approval? If so, the time span needed to obtain FDA approval is not always as short as the supplier hopes. Where in the queue is your institution once the new model starts rolling off the production line? Do you want to receive one of the first devices manufactured, rather than having other institutions use the new model for several months and work out any bugs? If you are waiting to purchase a new model not yet available, realize that you will probably wait longer than promised and your timeline for implementation cannot be defined for a while.

Table 1 is a list of suppliers with their respective models of manual defibrillators that are FDA approved for use in the United States.

Table 1. Suppliers of Manual Defibrillators

Medtronic Emergency Response Systems http://www.medtronic-ers.com/products/ LIFEPAK® 12 LIFEPAK® 20 (As of 1/14/07, they have temporarily suspended US shipment of their defibrillators) **Philips Medical Systems** http://www.medical.philips.com/us/products/resuscitation/ HeartStart MRx HeartStart XL	**Welch Allyn® Inc** http://www.welchallyn.com/medical/products/search/results.asp?NextRecordNumber=0&LastRecordNumber=0&submit=Next&searchstring=AED&location=PRODUCTS&x=28&y=8 PIC 40 PIC 50 **ZOLL Medical Corp** http://www.zoll.com/product_search.aspx?id=103 M Series® R Series™

When considering how to configure the new manual defibrillator for your hospital, review your practice needs and match them with what is available in the various models. All models listed in Table 1 have capacity for ECG monitoring, external defibrillation, cardioversion, and transcutaneous pacing. But what additional needs does your institution have? It is better to determine at the outset of your investigation that the models you are considering have the capabilities that you need. For example, if open heart surgery is performed in your hospital, you will want to make sure that internal paddles are available as well as energy settings for internal defibrillation. If you have an inter-hospital transport service, then you probably want to make sure 12 lead ECG interpretation and communication to the ED is available.

Ask the questions in Table 2 of those who are involved in the selection process to help come up with the configuration you need.

Table 2. Questions to Ask About the Configuration of the Manual Defibrillator

- ECG monitor
  - Do you desire 3-lead, 5-lead, V-lead monitoring?
- Defibrillator/Cardioverter
  - What type of paddles will you need: external (adult and pediatric), internal (what sizes), anterior/posterior, reusable external sterilizable?
  - Do you or will you want to add advisory analysis capacity so that the device can be used by Basic Life Support (BLS) providers?
- Hands-free disposable electrodes
  - Are multi-function electrodes available for ECG monitoring, defibrillation, and external pacing?
  - Do you need electrodes for adults and children? For neonates?
  - Do you desire radiolucent/radiotransparent electrodes?
  - Are sterile disposable electrodes needed?
- Do you desire voice recording during codes?
- Do you desire advanced code documentation?
- Do you desire CPR coaching and/or real-time feedback in the device?
- What physiologic monitoring add-ons will you need?
  - SpO_2
  - End tidal CO_2
  - 12 lead ECG
  - Non-invasive blood pressure
  - Invasive pressure
  - Respirations
  - Temperature
  - Vital sign trending
  - ST segment monitoring

Using the services of ECRI is a good place to start to match up the configuration needs of your institution with the models of manual defibrillators available. ECRI (formerly the Emergency Care Research Institute) is a nonprofit health services research agency and a Collaborating Center of the World Health Organization. It is designated as an Evidence-based Practice Center by the U. S. Agency for Healthcare Research and Quality.

Information about their valuable product comparison service can be found at http://www.ecri.org/Products_and_Services/Products/Healthcare_Product_Comparison_System/Default.aspx. A *Product Comparison for Defibrillators, External, Manual; Defibrillator/Pacemakers, External* is available from July 2005. In addition to a Product Comparison Chart, you will find content about the basic principles of operation of a manual defibrillator, reported problems, purchase considerations, related standards and guidelines, and supplier information. Investigate whether your institution is already a member of ECRI or you will need to purchase this comparison document.

In their June 2005 issue of *Health Devices*, ECRI presents descriptions, specifications, test results, and ratings for ten models of defibrillators available at that time.[1] There is also a helpful discussion of the pros and cons of purchasing "advanced" monitoring capabilities such as SpO2 and 12-lead ECG with defibrillators. Their criteria used for evaluating monitor/defibrillator/ pacemakers should help you determine whether the model you favor matches these essential criteria, though several of the newer models possess futuristic features not yet incorporated into these descriptions.

I will write about the newest features in some of the manual defibrillators on the market. I have asked the vendors: What makes your defibrillator special? What are the features you point out when trying to sell your defibrillator? What puts your product on the leading edge of technology development in this field?

Philips Medical Systems

Figure 1. Philips HeartStart MRx

The HeartStart MRx is the top-of-the line manual defibrillator for Philips. The MRx is designed around ease of use, with the 1, 2, 3 function being very intuitive. The measurements and waveforms on its large 8.4" (diagonal), 4-wave color display screen can be organized to a user's preferences. The same "ready-for-use" indicator icon seen on their AED is now on the front of the manual defibrillator. One knob is used to turn the device on and to select all therapies. Automated self tests are performed hourly, daily and weekly, and routine operational checks can be run by the provider from screen prompts.

Sensors in the external paddles' electrodes assess paddle-to-patient contact and display their readings in the Patient Contact Indicator on the sternum paddle's handle. If paddle contact is poor, the provider can push on the chest with more force, remove the patient's hair, or add more electrolyte paste. With Philips's Quick Shock capability, approximately 5 seconds to analyze and shock in the AED mode, pauses in compressions can be minimized.

There is much discussion among the various vendors about the characteristics and efficacy of their biphasic waveforms. See table 3 for several web sites that present detailed content about delivery of electrical shock therapy, the difference between monophasic and biphasic waveforms, biphasic waveform designs, energy settings and current delivery.

Table 3. Web Sites of Defibrillator Manufacturers about Biphasic Waveforms

From Philips Medical Systems: www.medical.philips.com/biphasic

From ZOLL Medical Corporation: http://www.zoll.com/page.aspx?id=287

Published, peer-reviewed studies have shown that with Philip's patented SMART truncated exponential biphasic waveform and low energy settings up to 200 joules, conversion of tachyarrhythmias is successful. Their waveform automatically measures a patient's impedance and then delivers the appropriate amount of current needed for conversion. They have shown that their high peak current is efficacious, yet their lower energy causes less cardiac dysfunction.[2] "Contrary to common perceptions, patient impedance is not closely linked to patient size or weight"[3], so higher energy is not needed for conversion of larger patients and it causes myocardial dysfunction.

With Philip's Q-CPR™ a sensor is placed on the sternum to measure and provide feedback on compressions. Data is transmitted back to the HeartStart MRx, where it is interpreted and displayed. See Figure 2 for Philip's screen display of Q-CPR. Compression rate and depth are presented as a wave graph: wave height depicts compression depth, while the interval between waves indicates rate. The displayed "No Flow" time calls attention to the number of seconds when compressions are not being administered. A calculated compressions-per-minute value (cpm) is shown as a numeric above the waveform. Compressions are analyzed in real time, contrasting actual performance with established American Heart Association (AHA) guidelines. If either depth or rate drifts outside its target range, the MRx displays on-screen signals and provides audible feedback for correction.

Figure 2. Q-CPR Display on Philips HeartStart MRx

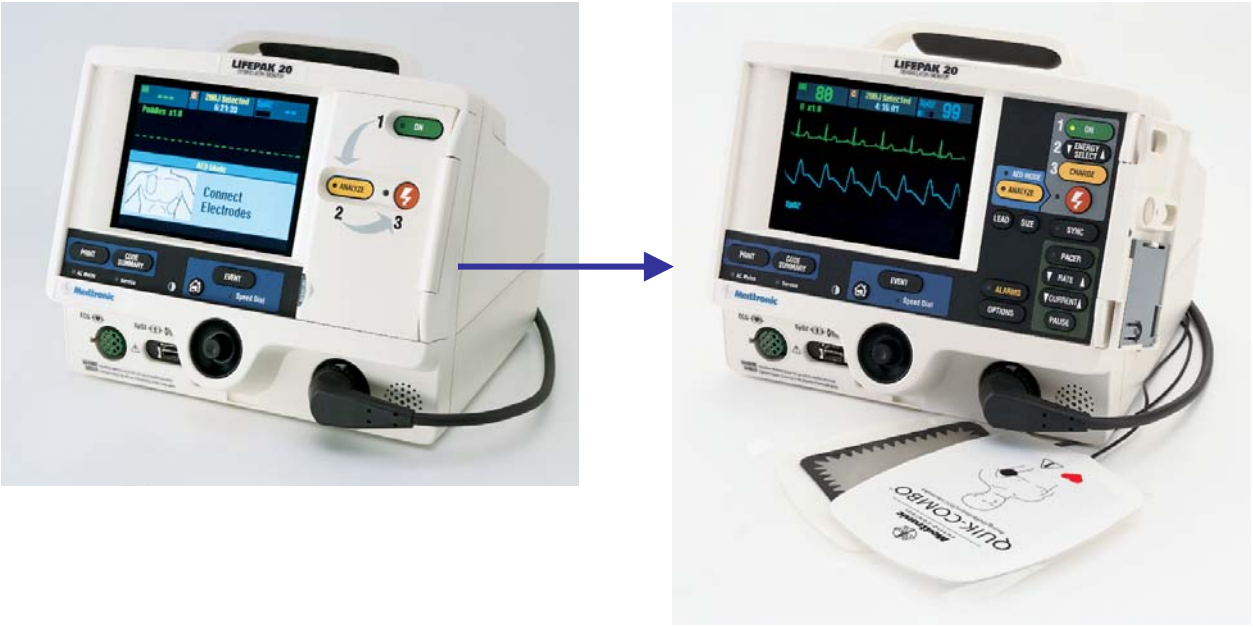
Ventilation data is collected with the same pads used for defibrillation. Attached to the patient's chest, the pads detect changes in chest impedance, which are interpreted by the MRx

and then displayed as lung volume and ventilation rate on-screen. Just above the compression wave, the ventilation indicator shows lung volume. The calculated ventilations-per-minute (vpm) value appears next to the lungs indicator.

Medtronic Emergency Response Systems (Physio Control)

One of the unique features of the LIFEPAK 20 defibrillator/monitor, designed for use on arrest carts, is that it provides simple 1-2-3 button operation, along with voice and display prompts, for the BLS-trained responder. Then with the push of a latch, a door opens uncovering the more sophisticated controls and waveform display for the ACLS-trained user. See Figure 3. A docking station enables the device to be firmly attached to the code cart for safe and rapid transport, or easily released. The docking station swivels so that the colored graphics can be easily viewed from many angles. Their singular selection knob allows the provider to easily move between menus.

Figure 3. LIFEPAK 20 Defibrillator/Monitor with Advisory View and then Manual View



With Medtronic's ADAPTIV™ biphasic technology, the impedance-compensating waveform tailors both voltage and shock duration to individual patient impedance and provides shocks at optional, escalating energy settings up to 360 joules. Several studies have shown that dosages up to 360 joules are beneficial for some patients who need more than one shock, and that repeating the initial dosage is inferior to a strategy of increasing dosage.

When the LIFEPAK 20 defibrillator is placed in the *Archive Mode*, the operator can access records of previous patients for review, transmission, printing, editing or deletion. The educator may choose the *Inservice Mode*, where simulated waveforms are available for demonstration purposes.

The LIFEPAK 12 defibrillator/monitor provides full therapy and monitoring capabilities for the highest-acuity areas (i.e., ED, critical care, operating room, cath lab, EP lab), for transport, and for procedural sedation, with a platform that enables the hospital to add on other parameters such as SpO2, EtCO2, non-invasive BP, ST trending, and vital signs trending.

LIFENET BLUE wireless data transfer enables 12-lead ECG data from a Bluetooth®-enabled LIFEPAK 12 defibrillator to be wirelessly transmitted to a Bluetooth-equipped cell/mobile phone and then to the LIFENET RS receiving station, which is usually located in the ED. The LIFENET RS is designed to redirect the 12-lead ECG report to a number of predetermined PDAs, computer e-mail, cardiology management systems, faxes or other LIFENET RS systems. If the hospital uses the GEMS MUSE® or Infinity® MegaCare system, the 12-lead record may be integrated into its records.

The LIFEPAK 12 defibrillator/monitor provides continuous monitoring and sets off an alarm if it detects VF or VT. The device provides alarm signals, both audible and on the screen. At the top of the LIFEPAK 12 screen is displayed a battery icon indicating the presence of the batteries. A discharged battery condition is indicated by a flashing arrow until the battery is replaced. When a low battery is detected, the device automatically switches to a second battery. Thus, more prolonged operation via battery power is available when transporting patients. A full line of batteries is available to meet varied usage requirements.

In both the LIFEPAK 12 and 20, the provider can use the EVENT key to enter code events and medications into the CODE SUMMARY™ Report. The device automatically captures and stores patient data, events (including waveforms and annotations), user test results, pacing waveforms and continuous ECG waveform records in internal memory. The user can select and print reports and transfer the stored information via an internal modem through landline or mobile phones.

EDGE System™ electrodes by Medtronic offer a patented design that distributes the current density evenly over the entire surface of the electrode, rather than concentrating it at the edges – with less skin burn reported.

Note: Shipment of Medtronic defibrillators produced at the Redmond, WA, plant has been temporarily suspended as of January 14, 2007, voluntary in conjunction with FDA.

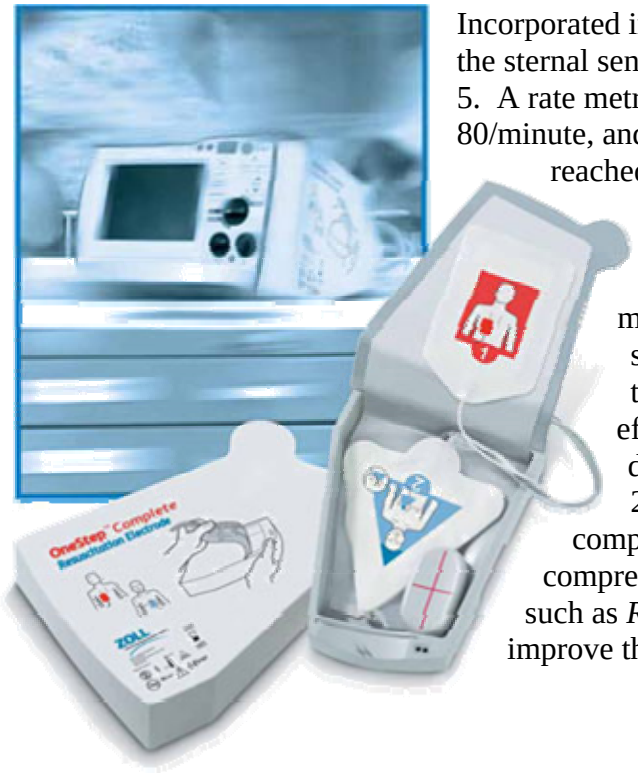
Figure 4. ZOLL R Series

ZOLL Medical Corporation

The R Series by ZOLL is the latest defibrillator to be released on the market; see Figure 4. The front of the R Series will look familiar since it's built using the same standard operating interface as in their previous defibrillators. If you have ZOLL M Series defibrillators in use, providers will readily adapt to the R Series without "missing a beat."

The new One Step™ Complete electrode, when placed in the anterior/posterior position, provides pacing and defibrillation without the need for additional ECG leads. The cassette with pre-connected electrodes is stored directly on the side of the R Series, and the one cable folds easily into a quick-release sleeve that avoids dangling and tangling of wires. These electrodes provide *See-Thru CPR*™ functionality, which filters out CPR artifact so the clinician can view the underlying filtered rhythm on the monitor screen without stopping chest compressions. Paddles, which also plug into this one cable, have all the controls needed by the user: energy selection, charge, record printing.

Figure 5. ZOLL One Step™ Resuscitation Electrode with CPR Sensor



Incorporated into the One Step™ Resuscitation Electrode is the sternal sensor that provides *Real CPR Help*™; see Figure 5. A rate metronome beeps when compressions fall below 80/minute, and stops beeping as soon as the correct rate is reached. In addition, user selectable audible prompts, i.e., "push harder" and "good compressions", coach the provider. Once 10 seconds have elapsed, a CPR idle time is noted on the monitor screen, displaying how long it has been since the last compression. A CPR Index™ on the screen provides a visual indicator of CPR effectiveness related to compression rate and depth; see Figure 6. The CPR Index takes about 20-25 good quality compressions to become completely full, but empties rapidly when compressions fall below target zones. Screen prompts such as *RATE* and *DEPTH* coach providers on how to improve their technique.

Figure 6. CPR Index on ZOLL R Series

The R Series automatically tests more than 40 measures of readiness, including the internal circuitry, presence of the correct cables and electrodes, and the gel condition and expiration date of the electrode set – without disconnecting the paddles or pads – and then prints out a report with a PASS status. A green checkmark in the window on the front indicates that the

defibrillator is fully ready for use. All interactions with the defibrillator are recorded internally and retrievable in order to differentiate between technical matters and user issues. With the addition of WiFi communication in 2007, biomedical engineering will be able to receive notification of compromised defibrillators via pager or email. System-wide clock synchronization, configuration management and remote troubleshooting from a central location will become a reality.

ZOLL's constant current, constant duration Rectilinear Biphasic™ waveform is different from others on the market. They believe that it is important to deliver the appropriate amount of *average* current while minimizing peak current. The average current delivered to any patient is higher with the ZOLL device than with any other defibrillator's waveform, no matter the patient impedance. During defibrillation, once patient impedance is calculated, equipment resistance is either maintained or decreased to adjust for patient impedance, so the total impedance (equipment + patient) stays relatively constant.

The new SurePower™ lithium ion battery indicates run time instead of the state of charge. With the SurePower Manager Software, biomedical engineering can review the status of all batteries and plan the appropriate time for replacement rather than replacing them every 1-2 years on a set schedule – thus saving on cost.

ZOLL's 40 millisecond, constant current pacing waveform has been effective at achieving electrical capture at lower mA settings, with less patient discomfort. Pushing the 4:1 button enables the provider to determine the patient's underlying rhythm since it delivers a pacing spike only every 4th beat.

For providers who don't often use a defibrillator, there is a built-in tutorial for quick review, which encourages interaction with the controls. In the spring of 2007, there will be an interactive, web-based training and competency testing module.

CodeNet® is ZOLL's total information management system for resuscitations; see Figure 7. During a code, the documenter enters interventions and patient assessment data onto a pocket PC by tapping programmed prompts on the screen or entering voice comments. At the end of the resuscitation patient demographic and pre-code data are entered along with signatures/names of providers and quality issues. ECG data and CPR performance information is downloaded from the defibrillator to the pocket PC using a wireless or serial connection. The pocket PC is docked at a computer so the data can be reviewed/completed and then transmitted all on one synchronized timeline to the CPR committee representative for quality assurance and training purposes. For hospitals who submit data to the National Registry of CPR, data need only be entered once into CodeNet, thus saving on resource time.

Figure 7. ZOLL CodeNet Resuscitation Management System

What Else should be Evaluated?

When evaluating manual defibrillators, there are several additional features that you will want to explore. As you identify where the new manual defibrillators will be located, look at the footprint to make sure that the model will fit in the designated space. This is especially important if the defibrillator will be used in a tight space, such as a transport helicopter. If the manual defibrillator will be transported to other areas of the hospital for resuscitations, the carrying case and weight are important to evaluate. The quality, dependability, and charging time of exchangeable batteries, along with clear indication of battery status, are very important if the manual defibrillators will be used for transport.

Study the defibrillator's screen display to see how easy the information is to locate and read. Are the numbers large enough to see from across a patient bed? Is the presentation of the information logical? When in synchronization mode, is the sync marker clear above the QRS?

Will the defibrillator be used for bedside monitoring where V-lead ECG monitoring would be useful? Can ACLS interventions be added to the resuscitation record produced by the defibrillator?

In the recent *2005 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*, the AHA stresses the importance of good quality compressions that are continued with few interruptions.[4] While the defibrillator is charging, providers most often stop compressions, so it is important to note the charging time on the manual defibrillators you are evaluating. ECRI recommends that the ideal charging time to the highest energy setting on battery power be under 10 seconds.[5] In addition, they recommend that the display should recover the ECG image so that it is readable within 5 seconds of maximum energy discharge.

Review the published literature regarding the efficacy of the various biphasic waveforms in conversion of both atrial and ventricular tachyarrhythmias. Compare first shock efficacy and average number of shocks needed for conversion.

There are subtle differences in the self tests with the various defibrillators. So investigate the operational components which are evaluated by the self test. Does the defibrillator have to be set up for this self test in a manner that is different than when used for actual defibrillation? What further testing is required by the care providers on a daily or regular basis?

It is important for hospitals to collect data on resuscitations, both individual and aggregate, so carefully review the software management programs offered by the various vendors. What data is stored in the defibrillator for how many patients and for how long? How is the data downloaded to a computer, and what are the software requirements for loading the vendor's program? It is ideal if you can view a demonstration of the data management program so that you can evaluate how intuitive it is to use. Review the reports to see how well they match the 'Utstein' style recommended by the AHA[6] and meet the specific needs of your institution.

As you compare cost, do not forget to request pricing for all the accessories that you will use. Look at the shelf life of the disposable electrodes, and how it is determined when batteries will

need to be replaced. Explore whether the supplier will offer trade-in discounts for the defibrillators that you will be taking out of service. Compare the warranties and service contracts. What is the cost of the data management program and the educational materials?

Review training materials that are available, e.g., competency checklists, written tests, and sample hospital protocols so that you won't have to "reinvent the wheel." How much support does the vendor provide during the initial training, and are defibrillators available on loan for educational programs?

The ERCI can provide a list of health device alerts and recalls over the past years for defibrillators. Prior to making a purchase decision, learn how the problems have been corrected so that they will not reoccur.

Finally, always ask the vendors for user contact names and telephone numbers at other institutions. Call and ask what strategies they used to educate practitioners about the manual defibrillator, what were the major practice changes and obstacles they had to consider during implementation, and if they have had any problems with this model.

Conclusion

All the manual defibrillators on the market have the basic functionalities needed for hospital resuscitations and are reliable. So the decision comes down to what advanced or new or unique features are available that match the path your hospital desires to take for standardizing on a make and model. What model is intuitive to use, easy for instructors to teach, and supports quality resuscitations according to the *2005 Guidelines*? Which vendor has a manual defibrillator that supports resuscitation practice with leading edge technology that makes it easy for the CPR team leader to view information on the screen and for the CPR team member to perform defibrillation and external pacing competently and without delay? The defibrillator can be a key device in saving a patient's life, not only by promptly shocking, but also by coaching CPR. In addition, the defibrillator can provide physiologic information while you are caring for a gravely ill patient, and aggregate data using the vendor's data management program to support the quality improvement work of the CPR committee. So take the time to review the defibrillator models available and choose wisely based on the direction your hospital wants to go for the future.

References

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2 Tang, W. et. al. The effects of biphasic waveform design on post-resuscitation myocardial function. *Journal of American College of Cardiology* 2004;43:1228-1235.

3 Philips Medical Systems. SMART Biphasic Technology, http://www.medical.philips.com/us/products/resuscitation/biphasic_technology/biphasic_intro.html

4 American Heart Association. 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* 2000; 112:IV-1-IV-211 (Suppl).

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6 American Heart Association. Recommended guidelines for reviewing, reporting, and conducting research on in-hospital resuscitation. The 'Utstein style'. *Circulation* 1997;95:2213-2239.