Factors Influencing Defibrillator Design Today

Eric R. Gustafson
Senior Product Manager
Professional Defibrillators
ZOLL Medical Corp.

Influences We Will Explore . . .

- Biphasic Defibrillation
- CPR
- Rising Cost of Batteries
- Cost of Maintaining Defibrillator Readiness

Influences We Will Explore . . .

- Biphasic Defibrillation
- CPR
- Rising Cost of Batteries
- Cost of Maintaining Defibrillator Readiness

Defibrillation Waveforms

- Waveforms describe the electrical pulse:
  - Amount of **CURRENT** delivered
  - **TIME** over which it is delivered
  - Direction of current flow
- Three waveforms in use today:
  - Monophasic Damped Sine (MDS)
  - Biphasic Truncated Exponential (BTE)
  - Rectilinear Biphasic (RBW)

Biphasic Defibrillation - AHA 2005

- Energy is a nonphysiologic descriptor of defibrillation despite its entrenchment in traditional jargon
- 1st shock efficacy of MDS is lower than biphasic
- Energy settings for defibs are designed to be the lowest effective energy needed to terminate VF
- Energy levels vary by type of device

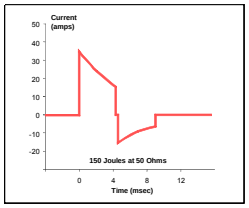
Biphasic Defibrillation – AHA 2005

- With a biphasic defibrillator, it is reasonable to use selected energies… In this context 'selected' refers to the energy dose selected by the operator. With a biphasic waveform device, selected and delivered energies usually differ; delivered energy is typically higher in the usual range of impedance. For example, in a patient with 80Ω impedance, a selected energy of 120J will deliver 150J."

Biphasic Waveforms

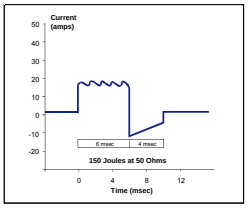
- Developed in Russia during the 1930s
- Used in implantable devices in the 1980s
- First cleared by FDA in 1997 for use in First Responder-style AEDs
- Approved for use in professional defibrillators in 1999/2000

Different Shape



Biphasic Truncated Exponential

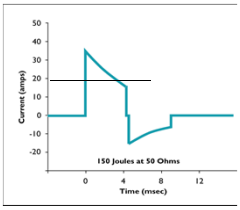
- 1st Generation Technology
- Adapted from low-impedance ICD applications



Rectilinear Biphasic Waveform

- 2nd Generation Technology
- Designed specifically for external use
- Fixed-interval, constant current design

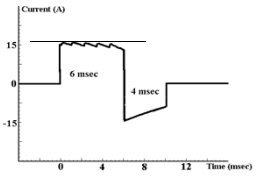
Biphasic Truncated Exponential



The First Generation:

- Adapted from low impedance ICD application.
- Impedance causes waveform to change shape.

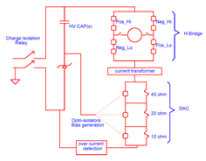
Rectilinear Biphasic Waveform

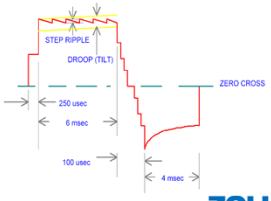


Designed Specifically for External Use:

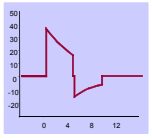
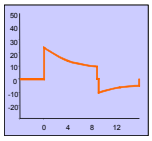
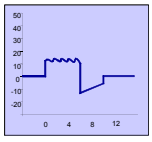
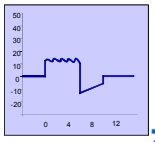
- *Constant Current* eliminates high peaks
- *Fixed Duration* stabilizes waveform in face of varying impedance levels.

Impedance Compensation

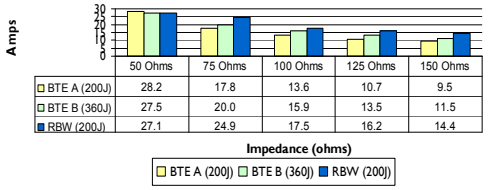




Different Response to Impedance

	Low Impedance	High Impedance
First Generation Biphasic		
Rectilinear Biphasic		

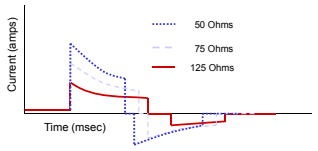
Average Current @ Maximum Energy



	50 Ohms	75 Ohms	100 Ohms	125 Ohms	150 Ohms
BTE A (200J)	28.2	17.8	13.6	10.7	9.5
BTE B (360J)	27.5	20.0	15.9	13.5	11.5
RBW (200J)	27.1	24.9	17.5	16.2	14.4

Impedance Compensation - BTE

Biphasic Waveform changes voltage and time in response to increased patient impedance. For a given 200J shock:



1450 volts / **50 ohms** = 27.5 amps

1690 volts / **150 ohms** = 9.5 amps

Source: Medtronic Physio Control *Defibrillation with ADAPTIV™ Biphasic Technology* p10

Biphasic Defibrillation (AHA Quotes)

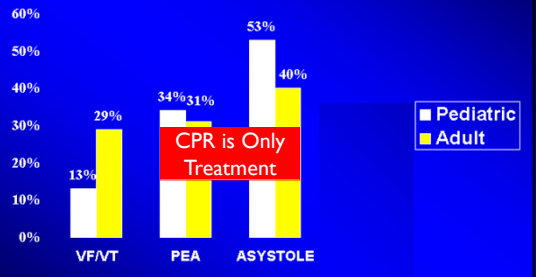
"…Given the high efficacy of all biphasic waveforms, other determinants of survival (eg. Interval from collapse to CPR or defibrillation) are likely to supersede the impact of specific biphasic waveforms or energies…"

Influences We Will Explore . . .

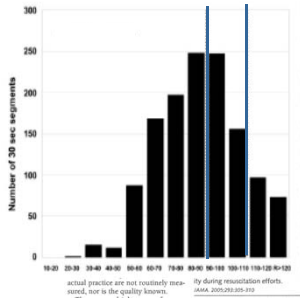
- Biphasic Defibrillation
- CPR
- Rising Cost of Batteries
- Cost of Maintaining Defibrillator Readiness

Initial Rhythms

American Heart Association
Fighting Heart Disease and Stroke



CPR Lacks Consistency in the Hospital



Only 37% of the compressions met recommendations of the AHA.

Survey of Nurse Educators

How important is it for defibrillators to have the following functions?

Function	Educators n = 46
CPR Feedback that ensures quality	4.5
Fully automated self-test that insures readiness	4.5
CPR filter that reduces interruption of chest compressions	3.9
Single cable that simplifies treatment	3.9
Tutorial helps familiarize new staff	3.6
Wireless networking assists nursing	3.3

Rated on a 5 point scale where:
1=Not Useful, 3=Valuable, 5=All Defibs should Have

ZOLL Advancing Resuscitation. Today.™

Survey of Nurse Educators

How important is it for defibrillators to have the following functions?

Function	Educators n = 46
CPR Feedback that ensures quality	4.5
Fully automated self-test that insures readiness	4.5
CPR filter that reduces interruption of chest compressions	3.9
Single cable that simplifies treatment	3.9
Tutorial helps familiarize new staff	3.6
Wireless networking assists nursing	3.3

Rated on a 5 point scale where:
1=Not Useful, 3=Valuable, 5=All Defibs should Have

ZOLL Advancing Resuscitation. Today.™

CPR Aids: Clarifying the Terminology

- **CPR Prompting** – focus on prompting the ***start and stop*** of compression cycles

ZOLL Advancing Resuscitation. Today.™

CPR Aids: Prompting vs. Feedback

	Prompting
"If no pulse, do CPR"	✓
"Stop CPR"	✓

ZOLL Advancing Resuscitation. Today.™

CPR Aids: Clarifying the Terminology

- **CPR Prompting** – focus on prompting the start and stop of compression cycles
- **CPR Feedback** – helps caregiver deliver ***better*** compressions.

ZOLL Advancing Resuscitation. Today.™

CPR Aids: Prompting vs. Feedback

	Prompting	Feedback
"If no pulse, do CPR"	✓	
"Stop CPR"	✓	
"Push Harder"/"Push Deeper"		✓
"Good Compressions"		✓
"Push Faster"/Pacing Metronome		✓
Draw attention to interruptions		✓
Filter CPR artifact		✓
Visual Quality Indicator		✓

CPR Feedback Acceptance Study

Key Findings

1. Code committees are aware of the need to improve the delivery of CPR.
2. First responders (BLS-trained) individuals welcome CPR assistance.
3. ACLS-trained responders questioned the need for CPR assistance.

Influences We Will Explore . . .

- Focus on CPR
- Rising Cost of Batteries
- Cost of Maintaining Defibrillator Readiness

This Got Our Attention . . .


Service Solutions

24/7

Improving Equipment Reliability Through Battery Management

. . . vendors suggest retiring the battery 18-20 months . . . But our data shows them lasting 3+ years. For a large hospital . . . that's significant.

Most Important for Biomeds

In rank order, list the 3 most important aspects of effectively maintaining defibrillators:

Capability	1	1,2	1,2,3
Finding problems before a code	64%	75%	79%
Simple, cost effective battery management	7%	32%	68%
Troubleshoot from any PC on the network	11%	46%	64%
Configure defibrillators from a central location	11%	29%	54%
Locate any defibrillator within the hospital	7%	14%	25%

n = 92

Source: Survey Conducted at AAMI Annual Meeting 2007

Most Important for Biomeds

In rank order, list the 3 most important aspects of effectively maintaining defibrillators:

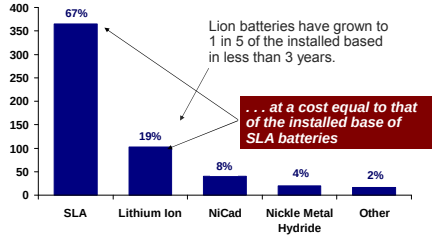
Capability	1	1,2	1,2,3
Finding problems before a code	64%	75%	79%
Simple, cost effective battery management	7%	32%	68%
Troubleshoot from any PC on the network	11%	46%	64%
Configure defibrillators from a central location	11%	29%	54%
Locate any defibrillator within the hospital	7%	14%	25%

n = 92

Source: Survey Conducted at AAMI Annual Meeting 2007

Current Battery Practices

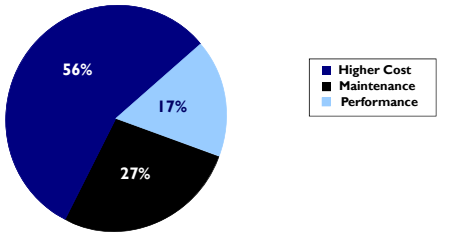
Battery Chemistries in Use



Source: Survey of Battery Practices 2007
Barbara Malanga (E3 Solutions)

Conversion to Lithium Ion

What is your biggest concern related to a switch to lithium ion batteries?

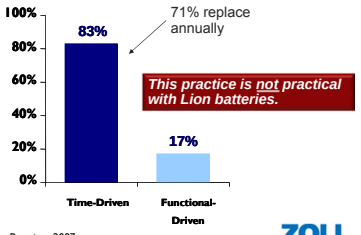


Source: Survey of Battery Practices 2007
Barbara Malanga (E3 Solutions)

ZOLL
Advancing Resuscitation. Today.™

Battery Replacement Practices

How do you decide when to replace your defibrillator batteries?

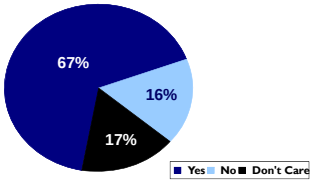


Source: Survey of Battery Practices 2007
Barbara Malanga (E3 Solutions)

ZOLL
Advancing Resuscitation. Today.™

Battery Replacement Practices

Do you feel you discard batteries that probably still have sufficient capacity?



Source: Survey of Battery Practices 2007
Barbara Malanga (E3 Solutions)

ZOLL
Advancing Resuscitation. Today.™

Battery Maintenance Practices

Functional Testing

- **Batteries tested during PM Inspections.**
- **Typical testing is superficial:**
  - –Charge & discharge defibrillator on battery power
  - –Measure charge time to maximum energy (<15 seconds)
  - –Verify energy delivery (±10%)

Source: Survey of Battery Practices 2007
Barbara Malanga (E3 Solutions)

ZOLL
Advancing Resuscitation. Today.™

State of Battery Management

It is easier to replace all batteries on a schedule than try to identify the "weak" ones because the right tools don't exist ***to make it practical***.

As a result batteries . . .

1. Are prematurely discarded.
2. Represent the highest annual out-of-pocket cost of ownership.

ZOLL
Advancing Resuscitation. Today.™

Conventional Battery Systems Inadequate

Shortcomings

1. Conservative Pass-Fail thresholds that drive replacement cycle

ZOLL
Advancing Resuscitation. Today.™

Optimize Replacement to Demand

Solution

From: ZOLL SurePower Battery Manager Software

Provide the ability for the hospital to select an appropriate replacement threshold.

Why Would I Change the Threshold?

The Lion Paradox

	Seal Lead Acid	Lithium Ion
Capacity When New	2.5 Ah	5.8 Ah
x Pass/Fail Threshold	60%	60%
Remaining Capacity	1.5 AH	3.5 AH

Why Would I Change the Threshold?

The Lion Paradox

	Seal Lead Acid	Lithium Ion
Capacity When New	2.5 Ah	5.8 Ah
x Pass/Fail Threshold	60%	60%
Remaining Capacity	1.5 AH	3.5 AH

Using the same Pass/Fail Threshold means we would discard batteries that have 40% more capacity than brand new SLA packs.

Conventional Battery Systems Inadequate

Shortcomings

1. Conservative Pass-Fail thresholds that drive replacement cycle
2. Inadequate charging & testing tools

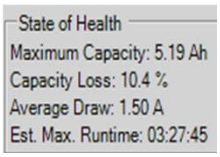
State of Charge is Not the Answer

Today's Charger's are Limited

A simple charge indicator does not discriminate between a new battery and one that is approaching end of life.

Focus on State of Health

Solution



From: ZOLL SurePower Battery Manager Software

Lets one change from a time-driven to a function-driven approach.

Influences We Will Explore . . .

- Focus on CPR
- Rising Cost of Batteries
- Cost of Maintaining Defibrillator Readiness

Let's Ask Ourselves . . .

What is the most frequent use of a defibrillator in hospitals today?

The daily/shift check

Let's Ask . . .

What is the second most frequent use?

Scheduled Preventative Maintenance

These are activities designed to insure the readiness of a defibrillator to respond to a code . . .

. . . that come at a cost.

Is it Worth the Cost?

1. Defibrillators rarely fail.
2. Typically find them when you are trying to save a life.
3. The circumstances of a defibrillator's use are stressful.

Cost of Defibrillator Readiness - 2007

Activity	Annual Cost
Preventive Maintenance	$135

Cost of Defibrillator Readiness - 2007

Activity	Annual Cost
Preventive Maintenance	$135
Service & Repair	$75

Cost of Defibrillator Readiness - 2007

Activity	Annual Cost
Preventive Maintenance	$135
Service & Repair	$75
Battery Replacement	$100 to $350

Cost of Defibrillator Readiness - 2007

Activity	Annual Cost
Preventive Maintenance	$135
Service & Repair	$75
Battery Replacement	$100 to $350
Daily/Shift Check	$2,000 to $8,000

Cost of Defibrillator Readiness - 2007

Activity	Annual Cost
Preventive Maintenance	$135
Service & Repair	$75
Battery Replacement	$100 to $350
Daily/Shift Check	$2,000 to $8,000
Total	$2,310 to $8,560

Survey of Nurse Educators

How important is it for defibrillators to have the following functions?

Function	Educators n = 46
CPR Feedback that ensures quality	4.5
Fully automated self-test that insures readiness	4.5
CPR filter that reduces interruption of chest compressions	3.9
Single cable that simplifies treatment	3.9
Tutorial helps familiarize new staff	3.6
Wireless networking assists nursing	3.3

Rated on a 5 point scale where:
1=Not Useful, 3=Valuable, 5=All Defibs should Have

Survey of Nurse Educators

How important is it for defibrillators to have the following functions?

Function	Educators n = 46
CPR Feedback that ensures quality	4.5
Fully automated self-test that insures readiness	4.5
CPR filter that reduces interruption of chest compressions	3.9
Single cable that simplifies treatment	3.9
Tutorial helps familiarize new staff	3.6
Wireless networking assists nursing	3.3

Rated on a 5 point scale where:
1=Not Useful, 3=Valuable, 5=All Defibs should Have

Most Important for Biomeds

In rank order, list the 3 most important aspects of effectively maintaining defibrillators:

Capability	1	1,2	1,2,3
Finding problems before a code	64%	75%	79%
Simple, cost effective battery management	7%	32%	68%
Troubleshoot from any PC on the network	11%	46%	64%
Configure defibrillators from a central location	11%	29%	54%
Locate any defibrillator within the hospital	7%	14%	25%

n = 92

ZOLL Advancing Resuscitation. Today.™

Most Important for Biomeds

In rank order, list the 3 most important aspects of effectively maintaining defibrillators:

Capability	1	1,2	1,2,3
Finding problems before a code	64%	75%	79%
Simple, cost effective battery management	7%	32%	68%
Troubleshoot from any PC on the network	11%	46%	64%
Configure defibrillators from a central location	11%	29%	54%
Locate any defibrillator within the hospital	7%	14%	25%

n = 92

ZOLL Advancing Resuscitation. Today.™

Automated Testing

ECRI Described Shortcomings - June 2005

- . . . involves ***more*** than discharge testing.
- . . . ***is not*** a suitable substitute . . .because it ***does not test*** the ***paddles*** or the reusable pads ***cable***.

ZOLL Advancing Resuscitation. Today.™

FDA Confirms the Need

February 2007

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | A-Z Index | Questions?

FDA > CDRH > Medical Device Safety > Tips & Articles > Safety Tip: External Defibrillators With "Hands-Free" Capability: Recommendations for Maintaining Their Cables and Connectors

Safety Tip: External Defibrillators With "Hands-Free" Capability: Recommendations for Maintaining Their Cables and Connectors

(Article reprinted from Medical Product Safety (MedSun) News, Volume 7, Issue 2 (February 2007), p. 24.)

ZOLL Advancing Resuscitation. Today.™

Two Types of Automated Testing

- ***Defibrillator Discharge Testing*** – Evaluates the capacity to charge and deliver energy.
- ***Code Readiness Testing*** – Evaluates the preparedness for the code, includes:
  - Defibrillator
  - Cables
  - Therapy Delivering Electronics
  - Accessories.

ZOLL Advancing Resuscitation. Today.™

Two Types of Automated Testing

Recommended in FDA Safety Tip (February 2007)	Defib Discharge Testing	Code Readiness Testing
. . . test unit on battery power only.	✓	✓
Test the defibrillator system with an external load making sure to include the interface cable.	≈	✓

ZOLL Advancing Resuscitation. Today.™

Two Types of Automated Testing

Recommended in FDA Safety Tip (February 2007)	Defib Discharge Testing	Code Readiness Testing
. . . test unit on battery power only.	✓	✓
Test the defibrillator system with an external load making sure to include the interface cable.	≈	✓
Be sure that all accessories . . . . are present.		✓

Two Types of Automated Testing

Recommended in FDA Safety Tip (February 2007)	Defib Discharge Testing	Code Readiness Testing
. . . test unit on battery power only.	✓	✓
Test the defibrillator system with an external load making sure to include the interface cable.	≈	✓
Be sure that all accessories . . . . are present.		✓
Check for expiration date on disposable products . .		✓

Two Types of Automated Testing

Recommended in FDA Safety Tip (February 2007)	Defib Discharge Testing	Code Readiness Testing
. . . test unit on battery power only.	✓	✓
Test the defibrillator system with an external load making sure to include the interface cable.	≈	✓
Be sure that all accessories . . . . are present.		✓
Check for expiration date on disposable products . .		✓
Keep records of these tests.	≈	✓

Two Types of Automated Testing

Recommended in FDA Safety Tip (February 2007)	Defib Discharge Testing	Code Readiness Testing
. . . test unit on battery power only.	✓	✓
Test the defibrillator system with an external load making sure to include the interface cable.	≈	✓
Be sure that all accessories . . . . are present.		✓
Check for expiration date on disposable products . .		✓
Keep records of these tests.	≈	✓
Report within your facility any failures . . .		✓

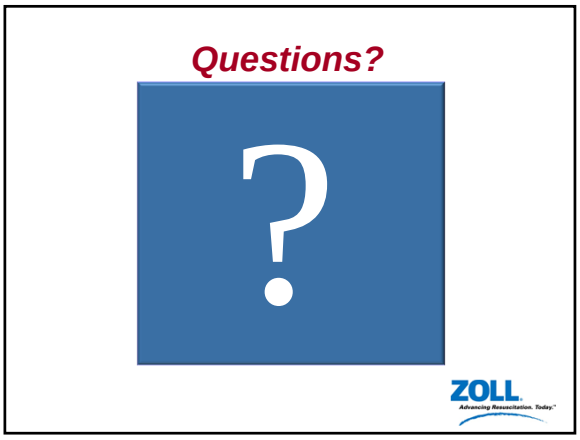
Defibrillator Workstation

- **Practical Tools** – Eliminate guesswork and helps quickly distinguish between user issues or technical matters requiring more detailed investigation.
- **Rapid Troubleshooting** – Trouble shoot defibrillators from any PC on the hospital's network.
- **Remote Technical Support** – Interface directly with support personnel for rapid answers to questions.

Summary

Factors Influencing Today's Design

- Biphasic Energy
  - It's about the current and duration!
- CPR Feedback Mechanisms that:
  - Work to improve compressions
  - Reduce interruptions
  - Do Not Add Steps for the Caregivers
- Battery Management Tools that Drive Replacement based on Functional Capabilities:
  - State of Health
  - Estimate Runtime
- Code Readiness Testing
  - Allow user to see a problem before the code
- Asset Management Systems that:
  - Report compromises to Code Readiness
  - Simplifies & Streamlines response to problems


Questions?
?
ZOLL
Advancing Resuscitation. Today.