Report on tests of Zoll automatic external defibrillator function in hyperbaric heliox conditions.

REVISION STATUS

2	Appendix revised to include testing on Well Enhancer and additional detail on training set-up	24.02.14	SSH		
1	Appendix added. Installation, testing, training	15.07.13	SSH		
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Contents

1. Introduction

An automated external defibrillator (AED) is a portable electronic device that automatically diagnoses the potentially life threatening cardiac arrhythmias of ventricular fibrillation and ventricular tachycardia in a patient and is able to treat them through defibrillation, the application of electrical therapy which stops the arrhythmia, allowing the heart to re-establish an effective rhythm. Many units provide audio and visual commands and are designed to be simple to use by a layman.

The role of an AED is particularly important in remote locations where specialised medical intervention may be many hours away. An offshore worksite will typically have at least one AED and very often several of them located at various locations on the ship or installation.

Divers in saturation conditions live in conditions that impose a further level of isolation. Rapid and effective medical intervention must be provided by fellow divers using equipment already in the chamber or equipment that can be quickly delivered through the medical lock. The situation is made more complicated by the possible efforts of rapid pressurisation and increased ambient pressure on such equipment.

We are aware of some relatively recent incidents in which an AED was locked into a chamber to defibrillate a diver but did not deliver a shock, presumably because the individuals had expired. Examination and testing of the AED after surfacing revealed that it was capable of functioning correctly in surface conditions. There is however no definite proof it would have worked effectively under pressure had the patients' hearts been in fibrillation.

The tests described herein were conducted to provide some assurance that if needed, an AED could be locked into a chamber, applied to a patient and perform its intended function at pressure.

2. Tests

2.1 Protocols

3 test protocols were planned to be performed.

- Test 1. Testing from surface pressure to 250 msw. In these tests the unit was turned on while at surface pressure and remained turned on and delivering shocks as the depth was increased.
  The chamber was filled with air prior to pressurising. The gas used to pressurise the chamber was 2% oxygen, 98% helium. Temperature and oxygen content in the chamber were recorded at intervals

- Test 2. The unit to be locked in and pressurised while turned off and then turned on to give shocks once it had arrived at depth. This test would mimic the likely conditions of use on a diver in a saturation chamber.
  The chamber was filled with air prior to pressurising. The gas used to pressurise the chamber was 2% oxygen, 98% helium. Temperature and oxygen content in the chamber were recorded at intervals

- Test 3. The unit was configured with AED outside a pressure chamber connected to the analyser inside the chamber via a through-hull electrical penetrator. The chamber remained at surface pressure and air-filled throughout.
  The testing was split into 3 discrete tests
  a) Control test. AED directly connected to the analyser on the bench. Patient electrode wire length was kept to standard (as supplied) length of 1.0m
  b) AED directly connected to the analyser on the bench. Patient electrode wire length was increased to 2.0 metres (to mimic length required in a chamber to reach a diver's bunk)
  c) AED connected to the analyser via the hull penetrator. Patient electrode wire length (in chamber) was increased to 2.0 metres (to mimic length required in a chamber to reach a diver's bunk)

2.2 Equipment

The AED was kindly supplied by Zoll Medical. The model provided was their AED Plus. Technical details of the unit are included in appendix 1. Zoll also provided a Fluke Biomedical QED 6 Defibrillator analyser. This device generated a fibrillation signal and analyses the output characteristics of the defibrillator and verifies its current function.

The AED Plus stores data that can be uploaded to a PC using an infra-red data transfer function and Zoll's RescueNet Code Review software.

Figure 1 shows the AED Plus and figure 2 shows the QED 6 Analyser

Figure 1. Zoll AED Plus

Figure 2, Fluke QED - Analyser

Increased ambient pressure was achieved by using the test chamber within Divex' breathing test laboratory. The chamber dimensions are approximately; 90cm diameter and 170cm long with a rated working pressure of 50 bar. Figure 3 shows the chamber in the closed and clamped condition

Figure 3. Test chamber in closed and clamped condition.

The AED was secured in the test chamber and held in place by a fabricated bracket arrangement. A screw-drive was manufactured which allowed the fire button to be depressed by rotating a handle on the outside of the chamber. The signal to and from the QED analyser was transmitted from the AED plus through an electrical penetrator to the analyser situated outside the pressure chamber. A second screw drive drives was installed to push the “on” button for test 2.
Figures 4 and 5 show the set-up in the chamber for test 1

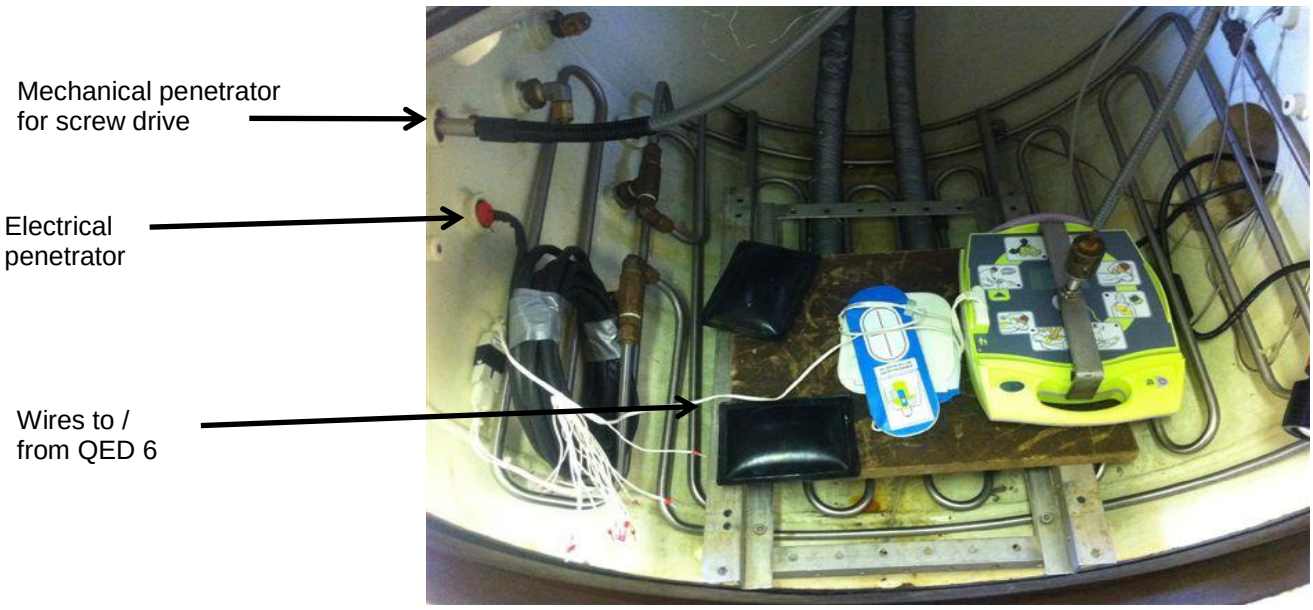


Figure 4. Equipment in test chamber

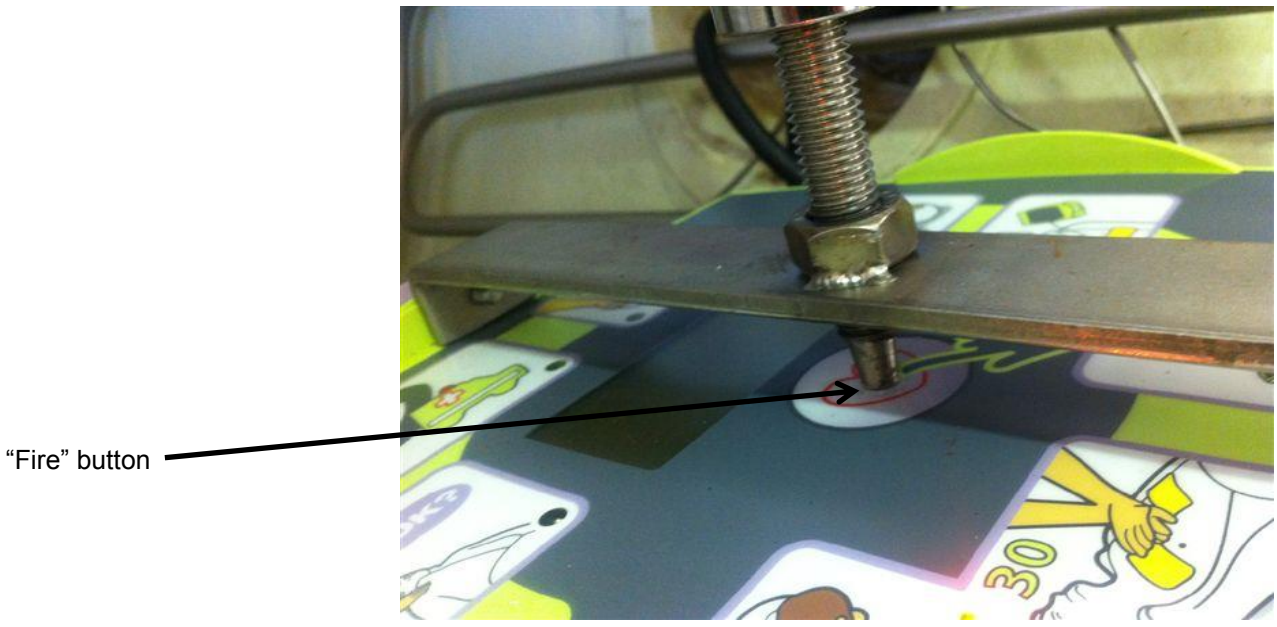


Figure 5. Screw drive activation of AED Plus

Figures 6 to 9 show the arrangements from the outside of the chamber to the analyser inside.

Figure 6. AED outside chamber

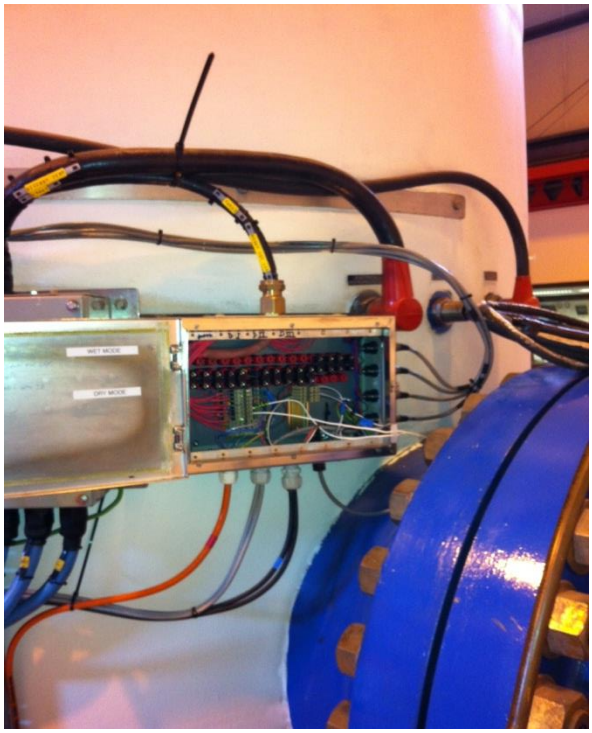


Figure 7. AED External chamber connections

Figure 8. Internal chamber connections

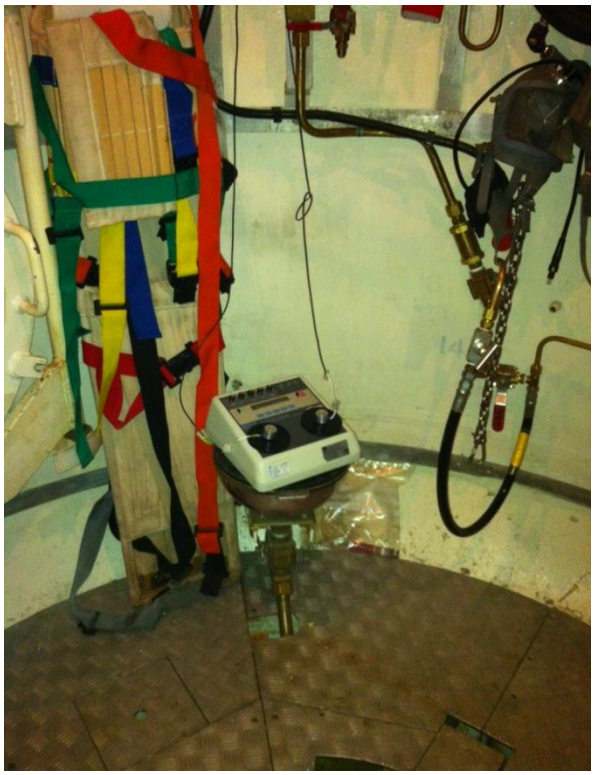


Figure 9. Analyser inside chamber

3. Results

TEST 1. UNIT TURNED ON BEFORE PRESSURISING

TIME	DEPTH MSW	TEMP C	O_2 %	EVENT	COMMENT
09.34	0	8.5	21	Unit in chamber, connected analyser via penetrator. Clamp closed Press shock button. Shock delivered	Shock 1
09.36	0	8.5		Shock delivered	Shock 2
09.37	0			Start pressurising	
09.39	14	35.0		Shock delivered	Shock 3
09.40	30			Voice command to change batteries	
09.42	40	31.0	2.8	Shock delivered	Shock 4
09.44	66			Voice command to release shock button, no shock delivered	Stop pressurising
09.48	66			Shock delivered	Shock 5
09.50	88			Shock delivered	Shock 6
09.52	109	26.0	2.2	Shock delivered	Shock 7
09.55	124	22.0	2.1	Shock delivered	Shock 8
09.55				Change gas supply to second quad	
09.58	122	18.0	2.1	Shock delivered	Shock 9
10.00	130	22.1	2.1	Shock delivered	Shock 10
10.02	155	16.7	2.0	Shock delivered	Shock 11
10.04	180	24.1	2.0	Shock delivered	Shock 12
10.06	204	17.4	2.0	Shock delivered	Shock 13
10.10	226	16.9	2.0	Shock delivered	Shock 14
10.12	245	18.6	2.0	Shock delivered	Shock 15
10.14	250	13.5	2.0	Shock delivered	Shock 16
10.16	250	13.5	2.0	Shock delivered	Shock 17
10.17				Start decompressing	
10.30	150	-16.0		Unit switches itself off	
13.40	0			Download data onto PC via IR port and RescueNet software	
13.50	0	20.0	21	Shock delivered	Checking after surfacing
13.52	0	20.0	21	Shock delivered	
13.55	0	20.0	21	Shock delivered	

TEST 2. UNIT TURNED OFF BEFORE PRESSURISING

TIME	DEPTH MSW	TEMP C	O_2 %	EVENT	COMMENT
09.28	0	6	21	Unit turned off Positioned in chamber Door closed and clamped	
09.30	0	6	21	Start pressuring with 2% heliox	
09.31	43	30		Unit turns itself on	Screw drive was not in contact with On/off button
09.32	80	35		Voice message “Unit failed”	Stop pressurisation
09.33	76	34		Voice message “unit failed” repeated numerous times	
09.33	76	34		Attempt to turn off the unit using the screw drive to push the on/off button	Unit would not turn off
09.37	75	30		Voice message “Unit OK”	
09.40	75			Voice message “Unit OK” repeated numerous times but unit does not appear to be analysing electrical signal and gives no commands to start CPR	
09.41	75			No commands given	Decide to abort trial
09.41	75			Start depressurising chamber	
09.47	0			Unit has turned itself off during depressurisation	Maybe due to cold (-16 C noted)
09.50	0	20		Open chamber door	
09.51	0			Put unit into non-rescue mode and connect IR port on PC to transfer data No data to transfer	Power on was not recorded. Only data was from tests performed the previous day
FOLLOWING DAY					
09.30	0	21		Turn unit on, connect to QED analyser	
09.35				3 shocks delivered	Unit functioning properly

TEST 3. SIGNAL CONDUCTED THROUGH HULL PENETRATOR

TIME	DEPTH MSW	TEMP C	O_2 %	EVENT	COMMENT
3a Control test Set up on bench					
14.35	0	18	21	Power on	
14.36	0	18	21	Shock delivered 120J	
14.39	0	18	21	Shock delivered 150J	
14.43	0	18	21	Shock delivered 200J	
14.46				Download data onto PC via IR port and RescueNet software	
3b On bench, extended leads					
14.58	0	18	21	Power on	
14.59	0	18	21	Shock delivered 120J	
15.01	0	18	21	Shock delivered 150J	
15.06	0	18	21	Shock delivered 200J	
15.10				Download data onto PC via IR port and RescueNet software	
3c. Through hull penetrator, extended leads					
15.18	0	18	21	Power on	
15.20	0	18	21	Shock delivered 120J	
15.23	0	18	21	Shock delivered 150J	
15.25	0	18	21	Shock delivered 200J	
15.30				Download data onto PC via IR port and RescueNet software	

4. Conclusions

The tests revealed that, under certain conditions, the Zoll AED Plus functions as intended in a heliox atmosphere from the surface to 250m. The first test was performed with the power on at the start of pressurisation. The unit appeared to malfunction at 66 msw following pressurisation a rate of approximately 10 m/min. It is probable that the membrane over the shock button was compressed by the external pressure and was therefore pressing down on the shock button. The pressure over this membrane appeared to equalise after a few minutes and the pressurisation to 250m continued and the unit functioned throughout. The rate of compression from 66m to 250m was in a range between 5 to 12 m/min. Faster rates of compression would cause significant temperature rises, especially in the small confines of a medical or equipment lock.

Compression of the unit while its power was off caused malfunction at approximately 43 metres following compression at approximately 11m/min. The unit did not seem to recover from this malfunction and the test had to be abandoned.

In a cardiac emergency situation, rapid intervention is of course critical and the reaction of personnel would be to try to get the AED to depth as soon as possible to make it accessible to the divers in the chambers. We believe that the tests performed have shown that there is significant doubt over the unit's ability to perform as required following pressurisation. It could be argued that the unit could remain in the saturation chambers at all times and so be immediately accessible to the divers. If this was the case it would only see gradual and controlled pressure changes (following the same profile as the divers). However the unit contains 10 x 3V lithium batteries and in view of the industry's current concern about the possible consequence of lithium battery malfunction, it may not be deemed prudent to keep such a number permanently in the chamber. Furthermore, to offer reasonable accessibility to the unit, one would have to be kept in each DDC to accommodate split level saturation and decompressing chambers.

It is suggested that the preferred solution is to provide at least one unit outside the chamber complex. Each chamber is to have an external plug connected to an electrical penetrator which has a corresponding plug internally onto which the Stat Padz II electrodes can be connected. The penetrator needs to conduct signals through 2 isolated conductors. Our tests have shown that the Zoll AED can deliver the required energy at the electrodes when transmitted through the penetrator and with an additional length of wire included in the circuit. Zoll's technical division have analysed the data from the trials through the penetrator and have confirmed there did not appear to be any interference on the cyclic ECG signal being generated by the simulator tester. Nor was there any loss of energy during the delivery of defibrillation therapy to the tester, nor, was there any increase in measured 'Patient' impedance within the circuitry and extended leads when the shocks were delivered.

This preferred solution minimises the risk of significant numbers of batteries in the chambers, removes the doubt over the possible effects of pressure on the unit, leaves it accessible to use on any chamber, test and maintain and allows easy and rapid

replacement if necessary. Patient electrodes could be permanently connected and stored within the DDC or at least kept available inside for rapid connection.

Certain sensible precautions should be observed: the penetrator should not be expected to carry other signals (such as communications or video) while the AED is in use; significant power is conducted during the defibrillation process (albeit for only approximately 10 milliseconds) which may affect other equipment; measures should therefore be in place to isolate circuits that may share the same penetrator.

Good communications and a rigid protocol must be in place between the operators of external AED and those inside treating and attending the patient. Training drills and familiarisation are essential for divers and surface personnel. Routines should be established to ensure the equipment outside and inside the chambers undergoes regular inspection and testing.

5. Acknowledgements

We extend our thanks to Zoll Medical UK Ltd for their generosity and support with the provision of equipment and for their patience in responding to the numerous queries we raised.

We also thank the National Hyperbaric Centre Ltd for yet again offering the use of their remarkable facilities and expertise for the final part of the test program

Appendix 1. Technical information on Zoll AED Plus.

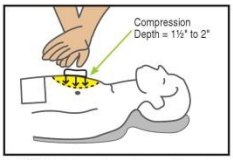
AED Plus Technical Application Note

Automated External Defibrillator with Real CPR Help

ZOLL
Advancing Resuscitation. Today.™

Measuring Chest Compression with Real CPR Help

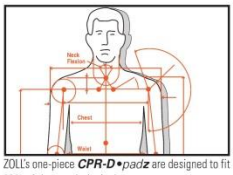
Failure to adequately compress a victim's chest is a common error during CPR.[1,2,3] The force required to properly compress a victim's chest 1½ - 2 inches varies depending on the patient's build and anatomy. Until now, only force and pressure sensors have been available. Real CPR Help technology in ZOLL's ***CPR-D•padz***® includes a hand-placement locator, an accelerometer, electronics, and a sophisticated processing algorithm. This technology accurately measures chest compressions and converts the motion of the accelerometer over time into distance moved. Only Real CPR Help can help an infrequent rescuer correct and improve compressions in real-time as CPR is performed during the rescue.



Real CPR Help® provides unique assistance to rescuers with real-time feedback on CPR compression depth and rate.

One Electrode Size Fits All

A one-piece electrode design must account for anatomical variation in the patient population. The design of ZOLL's ***CPR-D•padz*** is based on extensive human anthropometric data and studies designed to accommodate the wide range of patient sizes and shapes and to ensure that a one-piece electrode meets the needs of emergency AED use. The design developed for the ***CPR-D•padz*** meets the anthropometric characteristics of 99% of human chest anatomy. A special feature lets the rescuer separate the apex (lower) electrode to cover the other 1% of the population whose anatomical variations require special adaptation.



ZOLL's one-piece ***CPR-D•padz*** are designed to fit 99% of the population's chest anatomy.

Simplified Electrode Placement

Simplifying electrode placement is critical to widespread use of AEDs. Labeling helps but is often overlooked or discarded in an emergency that is sudden and unanticipated. The infrequent rescuer is easily confused when looking at a victim as to "left," "right," "up," and "down." Two separate electrodes cause concern over incorrect placement and technical complications if electrodes stick together before being placed correctly on the patient. The unique one-piece design of ZOLL's ***CPR-D•padz*** addresses these problems by orienting the design to the head while using the easily remembered CPR landmark (the sternum) as the key placement cue. The backing of the electrode is then removed by a simple pull after positioning. Because this is the same placement taught for CPR hand position, AED users benefit from having to remember only one easy landmark for both interventions.

CPR-D•padz offer clear anatomical placement illustrations and a CPR hand positioning landmark.

Five-Year Shelf Life

Infrequently used AEDs need electrodes that do not require frequent replacement. Most AED electrodes will expire before they are used. Corrosion of the electrode element due to long-term contact with ionic gel is the main limitation of electrode shelf life. ZOLL's ***CPR-D•padz*** protect the electrode elements with a novel design that sacrifices a non-critical element in the electrode to control the corrosion process and allow an unmatched five-year AED electrode life. ZOLL's ***CPR-D•padz*** reduce electrode replacement costs, facilitates AED readiness and maintenance, and decrease the probability of an AED's failure due to electrode expiration.

CPR-D•padz come complete with rescue essentials including a barrier mask, a razor, scissors, disposable gloves, and a towelette.

Specifications

DEFIBRILLATOR

Waveform: Rectilinear Biphasic

Defibrillator Charge Hold Time: 30 seconds

Energy Selection: Automatic preprogrammed selection (120J, 150J, 200J)

Patient Safety: All patient connections are electrically isolated.

Charge Time: Less than 10 seconds with new batteries.

Electrodes: ZOLL ***CPR-D•padz***, ***pedi•padz***® *II* or ***stat•padz***® *II*.

Built-in Defibrillator Self Test: Included

CPR: Metronome Rate: Variable 60 to 100 CPM

Depth: 1/2" to 3"; 1.3 to 7.8 cm.

Defibrillation Advisory: Evaluates electrode connection and patient ECG to determine if defibrillation is required. Shockable Rhythms: Ventricular fibrillation with average amplitude >100 microvolts and wide complex ventricular tachycardia with rates greater than 150 BPM for adults, 200 BPM for pediatrics. For ECG Analysis Algorithm sensitivity and specificity, refer to AED Plus Administrator's Guide.

Patient Impedance Measurement Range: 0 to 300 ohms

Defibrillator: Protected ECG Circuitry

Display Format: Optional LCD with Moving Bar

Size: 2.6" x 1.3"; 6.6 cm x 3.3 cm

Viewing Time: 2.6 seconds

Display Sweep Speed: 25 mm/sec; 1"/sec

Battery Capacity: Typical new (20°C) = 5 years (300 shocks) or 13 hours continuous monitoring. End of life designated by Red X (typical remaining shocks = 100, 5 hours continuous monitoring).

PC Minimum Requirements For Configuration And Patient Data Recovery: Windows® 98, Windows® 2000, Windows® NT, Windows® XP, IBMcompatible PII with 16550 UART (or higher) computer. 64MB RAM. VGA monitor or better. CD-ROM drive. IrDA port. 2MB disk space.

DEVICE

Size: (H x W x D) 5.25"x 9.50" x 11.50"; 13.3 cm x 24.1 cm x 29.2 cm

Weight: 6.7 lbs.; 3.1 kg

Power: User Replaceable Batteries. 10 -Type 123A Photo Flash lithium manganese dioxide batteries.

Device Classification: Class II and internally powered per EN60601-1

Design Standards: Meets applicable requirements of UL 2601, AAMI DF-39, IEC 601-2-4, EN60601-1, IEC60601-1-2.

ENVIRONMENT

Operating Temperature: 32° to 122°F; 0° to 50°C

Storage Temperature: -22° to 140°F; -30° to 60°C

Humidity: 10 to 95% relative humidity, non-condensing

Vibration: MIL Std. 810F, Min. Helicopter Test

Shock: IEC 68-2-27; 100G

Altitude: 300 to 15,000 ft.; -91m to 4573m

Particle and Water Ingress: IP-55.

CPR-D • padz

Shelf Life: 5 years

Conductive Gel: Polymer Hydrogel

Conductive Element: Tin

Packaging: Multilayer foil laminate pouch

Impedance Class: Low

Cable Length: 43 in (1.1 m)

Sternum: Length: 6.1 in (15.5 cm); *Width:* 5.0 in (12.7 cm); *Length, conductive gel:* 3.5 in (8.9 cm); *Width, conductive gel:* 3.5 in (8.9 cm); *Area, conductive gel:* 12.3 sq in (79.0 sq cm)

Apex: Length: 6.1 in (15.5 cm); *Width:* 5.6 in (14.1 cm); *Length, conductive gel:* 3.5 in (8.9 cm); *Width, conductive gel:* 3.5 in (8.9 cm); *Area, conductive gel:* 12.3 sq in (79.0 sq cm)

Complete assembly: Folded Length: 7.6 in (19.4 cm); Folded width: 7.0 in (17.8 cm); *Folded height:* 1.5 in (3.8 cm)

Design standards: Meets applicable requirements of ANSI/AAMI/ISO DF-39-1993.

[1]Moser DK, Dracup K, Guzy PM, Taylor SE, Breu C. Cardiopulmonary resuscitation skills retention in family members of cardiac patients. American Journal of Emergency Medicine. 1990;498-503.
[2]Kern KB, Hilwig RW, Berg RA, Ewy GA. Efficacy of chest compression-only BLS CPR in the presence of an occluded airway. Resuscitation. 1998;39;179-188.
[3]Handley AJ, Handley JA. The relationship between rate of chest compression and compression:relaxation ratio. Resuscitation. 1995;30;237-241.1Moser DK, Dracup K, Guzy PM, Taylor SE, Breu C. Cardiopulmonary resuscitation skills retention in family members of cardiac patients. American Journal of Emergency Medicine. 1990;498-503.
[4]Kern KB, Hilwig RW, Berg RA, Ewy GA. Efficacy of chest compression-only BLS CPR in the presence of an occluded airway. Resuscitation. 1998;39;179-188.
[5]Handley AJ, Handley JA. The relationship between rate of chest compression and compression:relaxation ratio. Resuscitation. 1995;30;237-241.

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Specifications subject to change without notice.

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Appendix 2. Installation on MSV Seawell

The trials at the National Hyperbaric Centre confirmed the viability of conducting to and from the defibrillator through chamber hull penetrators. Accordingly arrangements were put in place to provide this facility on the 3 living chambers on MSV Seawell.

Figure 10 shows the arrangement on the outer side of the chamber hull. The defibrillator is connected by a non-reversible 2 pin plug

Figure 10
Defibrillator connected outside of DDC

Figures 1l and 12 illustrates the connection inside the DDC.

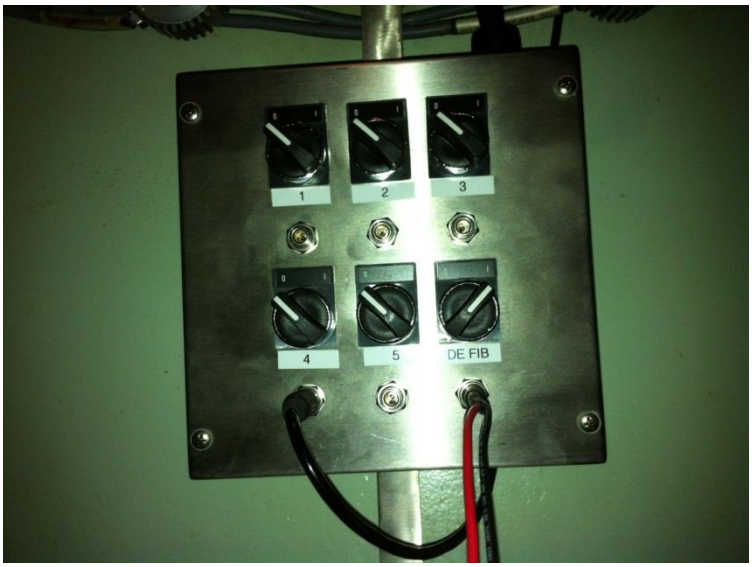

Figure 11. Internal connection box

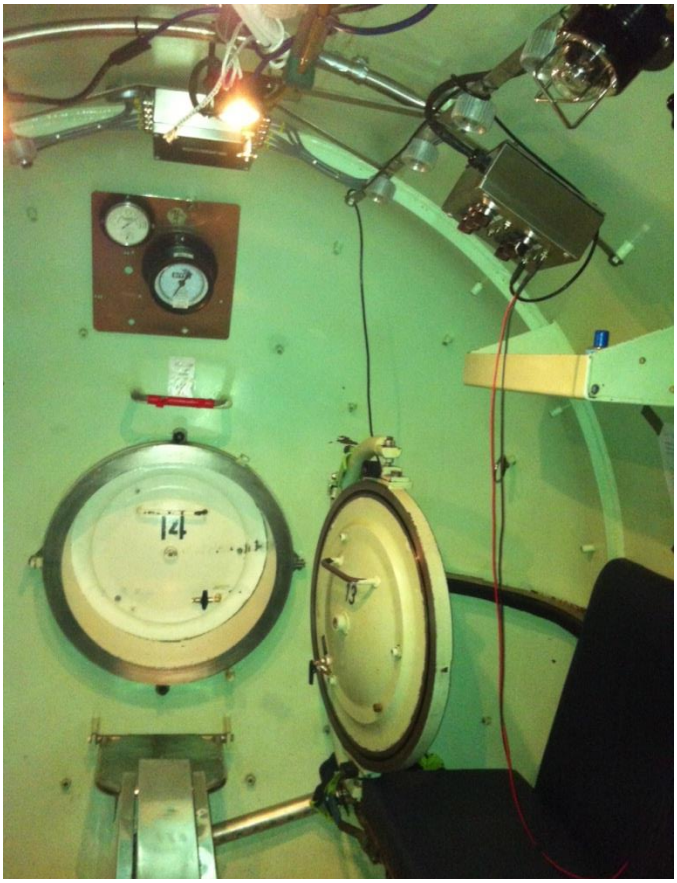

Figure 12.
Wires to electrode pads from internal junction box

Conduction to and from the defibrillator to an ECG simulator (mimicking a “patient” suffering a heart attack) was tested on each chamber. The data file for each test was submitted to Zoll Medical technical department for analysis. Figure 13 shows examples of the ECG trace over 3 shock deliveries at increasing energy levels.

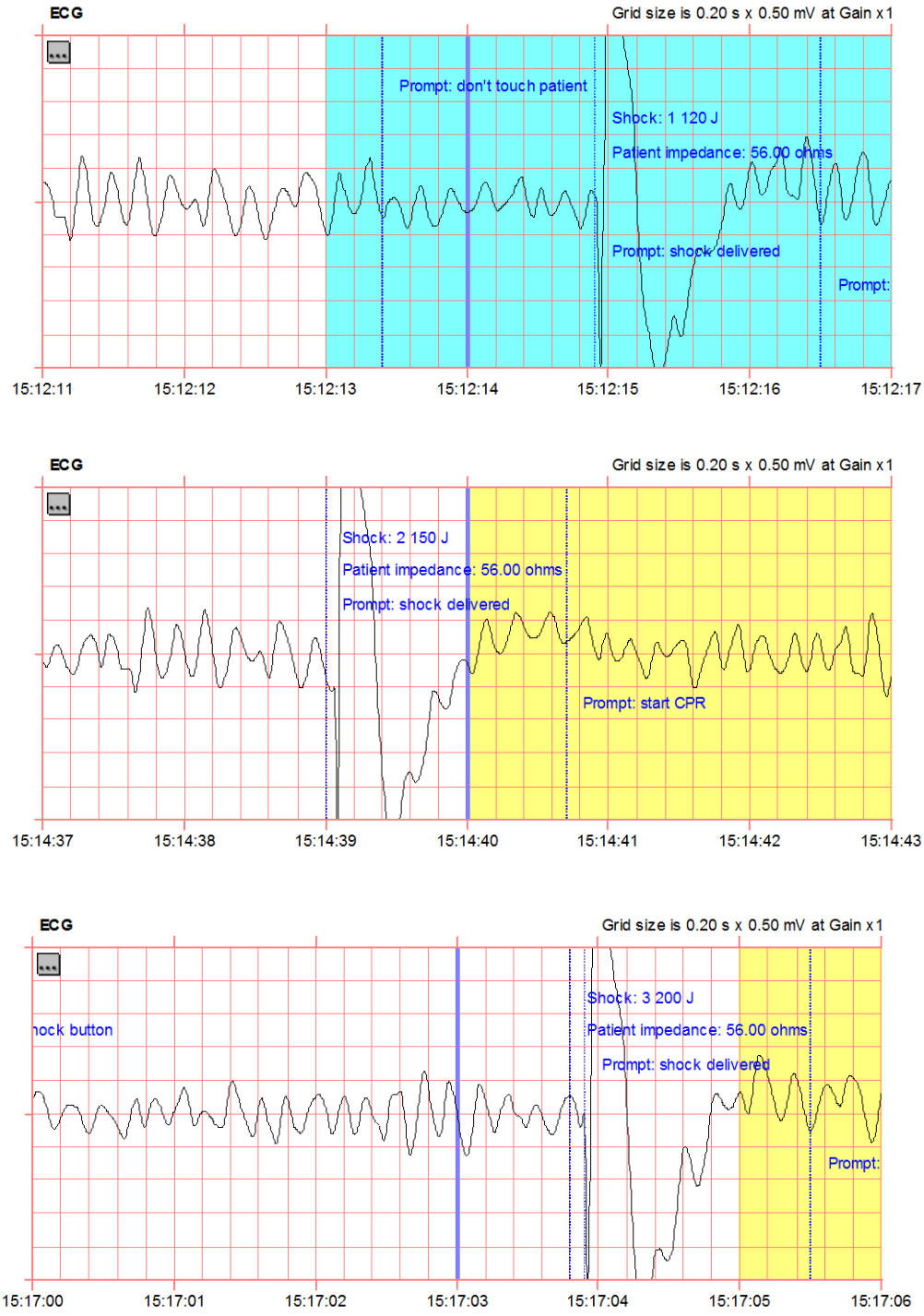

Figure 13. Extracts from downloaded data showing shock delivery through penetrator on chamber 3 on Seawell

It is important to have measures in place to train the users of the equipment and to ensure the equipment remains in a state of readiness and to perform periodic testing of the "quality" of the conduction through the hull penetrator. The provision of an ECG simulator will ensure that these requirements can be met. Figure 14 show the simulator connected directly to the defibrillator. This is the configuration that would be used for training on the defibrillator unit. An alternative configuration is that used for the testing described herein where the defibrillator is connected to the plug on the outside the DDC and the simulator connected to the electrode leads inside the DDC. Good voice communication routines must be in place between the position of the defibrillator and the inside of the DDC.

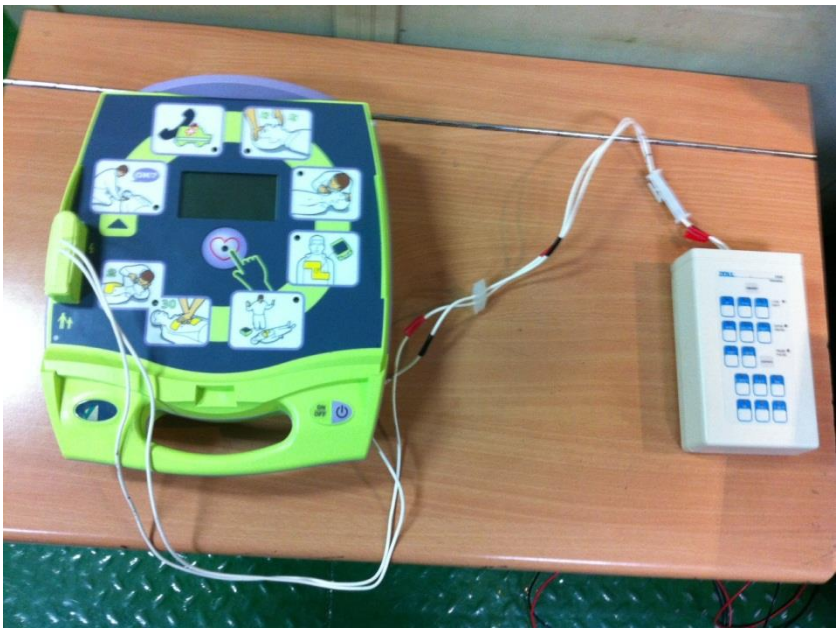

Figure 14. Defibrillator connected to ECG simulator.

The defibrillator and associated peripherals required is as follows

Zoll AED Plus
Zoll ECG Simulator (8000-1629)
Zoll Stat padz electrodes (8900-5002)

The components used for the external and internal connection plugs and sockets are as follows. Numbers in brackets referrer to RS part numbers

Inside DDC.
Bulkhead restrained Socket (RS 705-1525)
Plug:- (RS 705-1519)

Outside DDC
Pins (RS 236-3230)
Sockets (RS 236-3246)
Male holder (RS 236-3066)
Female holder (RS 36-3117)
Crimper (RS 501-045)

Appendix 3. Installation on Well Enhancer

Installation of the dedicated penetrators, internal and external circuits was complete during a dry-dock period in January 2014. Each of the 4 chambers has an external plug in point (EO type connector) and an internal connection point for the defibrillator electrodes contained within a steel box. The electrodes are left connected and stored within the box. Adequate length of wires between the connector plugs and the electrodes allows use of the electrodes on any of the bunks.

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Connection point from AED

Fig 15. Connection point outside chamber

Fig 16. Electrodes stored in box

Fig 17. Electrodes available for use

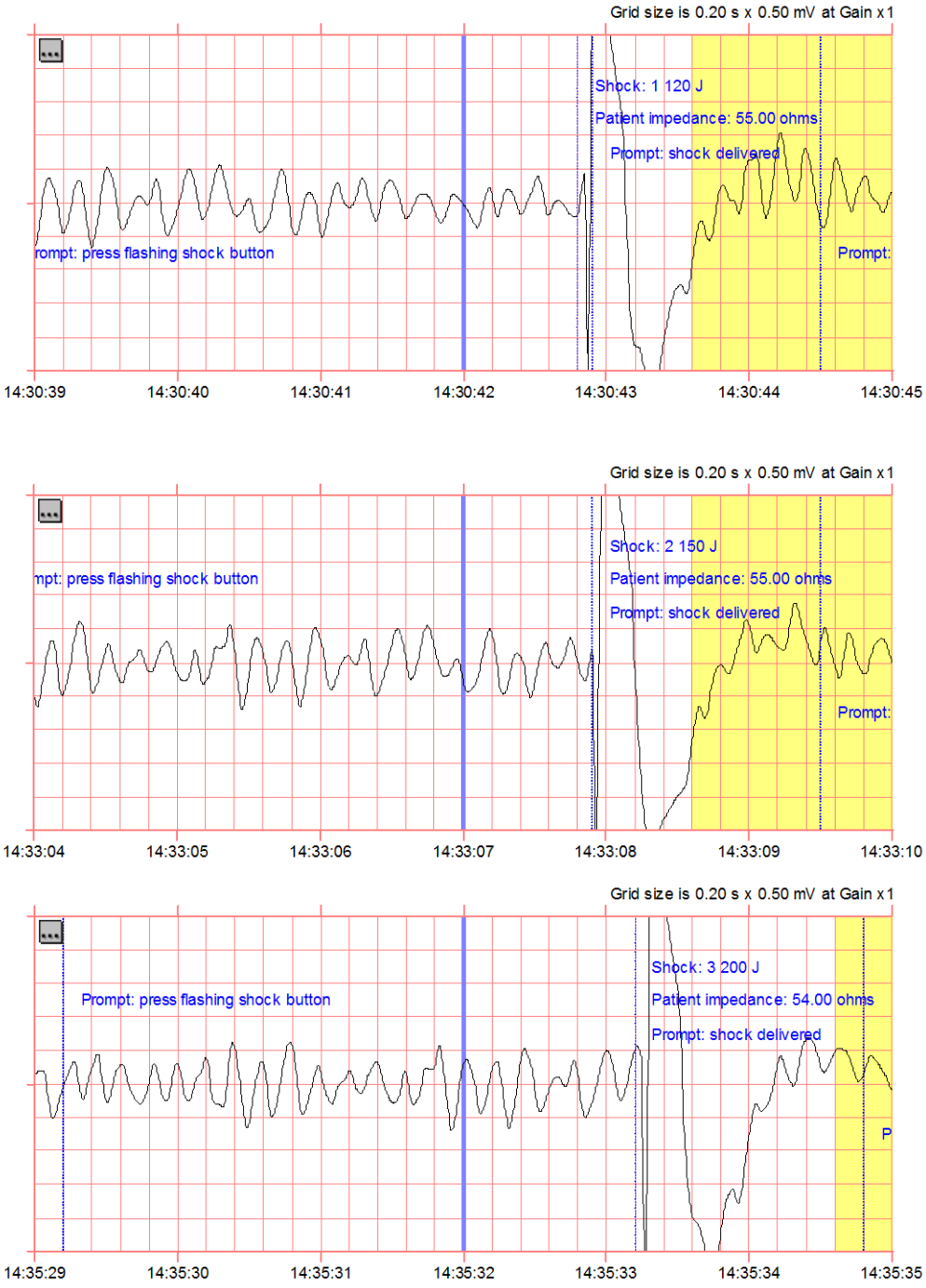

Fig 18. Examples of 3 sequential shocks delivered to electrodes (chamber 4)

Appendix 4. Testing and training configuration

The AED and ECG simulator can be connected without going through the chamber penetrators for training exercises. Figure 19 below illustrates the configuration for performing CPR training using the AED, ECG simulator and manikin. The ECG simulator should be set to the “VFIB” mode and reset to this mode after each shock delivery.

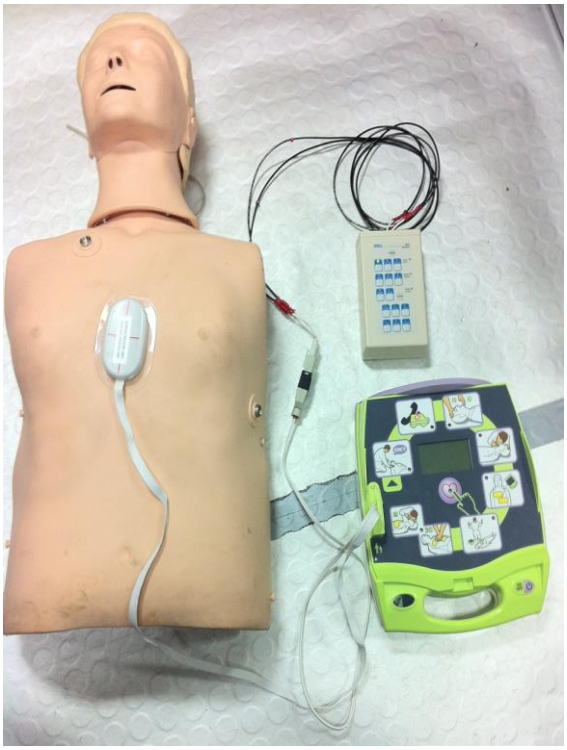

Fig. 19, CPR and defib training configuration