East of England Ambulance Service NHS Trust

Incident date:	28 January 2016
Date of Final Report:	27 April 2016
Investigating Manager:	
Incident Type:	Equipment Failure
Incident Level:	Level 1 Concise Investigation
Report approved by:	

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1. Executive Summary

At 01:39 on 21 January 2016, the East of England Ambulance Service NHS Trust (EEAST) received a call to its Emergency Operations Centre (EOC) to attend a 49 year old male at his home address. This call had been transferred from the 111 service. The patient was reporting pain in the left arm and tightness in the left side of their chest.

A Rapid Response Vehicle (RRV) staffed by a Senior Paramedic was dispatched at 01:40 and arrived on scene at 01:42. This represents a response time of two minutes and is within the timeframe required for a Red 2 category call.

At 01:48 the patient rapidly deteriorated into cardiac arrest. The Paramedic attempted to deliver a shock to the patient using a defibrillator which failed. The Paramedic requested, via the EOC, that the crew bring their defibrillator pads to the patient's side whilst the Paramedic continued with Cardiopulmonary Resuscitation (CPR).

The DSA backup arrived on the scene at 01:54 and the defibrillator pads were changed. A shock was then delivered at 01:58. Resuscitation attempts were successful and the patient was transferred to hospital under emergency conditions.

The patient was taken to the receiving hospital where he sadly died. Following recognition of death the cause of death was identified as:

1(a) Myocardial Infarction
(b) Left Anterior Descending Artery Occlusion

The Trust would like to offer sincere apologies to the patient's family for the incident and to thank them for their patience while this investigation is being concluded.

The investigation has identified the following lessons from this incident:

- It is important that comprehensive Patient Care records are completed
- It is essential that spare equipment is stored in the device in case of failure
- Incorrectly stocked Paramedic bags or equipment can lead to a delay in treatment.
- Lost Vehicle Daily Inspection (VDI) paperwork can lead to gaps in the Trust's own recording, self-assessment and investigations.

The Investigating Officer has made the following recommendations:

- The Trust SLMs to issue a reminder to operational staff of the need to properly store all completed checklists and documentation.
- To communicate to all operational staff the need to ensure that spare defibrillator pads be stored on all defibrillators, as this is not an Ambulance Fleet Assistant responsibility
- A debrief to be held with clinicians referenced on the Patient Care Record(PCR) to ensure that comprehensive PCR notes are completed

2. Main Report

2.1 Concise description of the incident

On 21 January 2016, the patient's wife called 111 to request non-emergency advice for her husband, who was a 49 year old male. The patient was experiencing pain in his left arm and tightness in the left side of his chest.

The call was triaged by the 111 service who coded the call as a Red 2. The 111 service used the automatic transfer system to request a 999 response from the East of England Ambulance Service NHS Trust (EEAST). The request was received by the EEAST Bedford based Emergency Operations Centre (EOC) at 01:39.

It was confirmed during the call that;

- The patient had been experiencing tightness in their chest and pain in their left arm.
- The patient had collapsed and was unresponsive.
- The patient was breathing

A Rapid Response Vehicle (RRV) staffed by a Senior Paramedic was dispatched at 01:40, which arrived on scene at 01:42. This represents a response time of two minutes and within the time required for a resource to arrive at the scene.

Upon arriving at the scene, the Paramedic was met by the patient's wife, who directed the Paramedic to the bedroom where the patient was kneeling over the bed, unresponsive.

The Paramedic began their assessment of the patient and determined from his wife that the patient had woken in the night complaining of chest pain radiating into his left arm and then collapsed. The patient had a history of high blood pressure (hypertension) and raised cholesterol, but was not medicated for either of these.

At 01:43 the Paramedic took his first set of observations and recorded these on the Patient Care Record (PCR):

- Patient position - slumped over bed
- Heart Rate = 30 beats per minute
- Capillary refill - >2 seconds
- Heart rhythm - irregular
- Respiratory rate - 4 breaths per minute
- Chest sounds - Normal
- The Patient was unresponsive
- Glasgow Coma Score - 3/15
- Pupils - Both dilated
- Skin colour - Pale
- Skin moisture - Dry
- Blood sugar level - 8.1 mmol/L

No superficial injuries were noted. The Paramedic's initial assessment revealed that the patient was unresponsive with diminished respiratory effort and a weak bradycardic (slow) radial pulse.

Due to the patient's position, the Paramedic needed to move the patient to the floor to enable ventilation, as their respiratory rate (4) was not effective. Help was sought from the patient's wife. During these attempts the Paramedic became concerned that the patient was no longer making any respiratory effort. Repositioning the patient also required the Paramedic to move some furniture as the space was limited.

The Paramedic then set up his oxygen delivery equipment and administered oxygen and ventilations to the patient via a Bag Valve Mask (BVM). When the patient's breathing was re-assessed, it was found that the patient had deteriorated into cardiac arrest.

The Paramedic prepared his defibrillator and applied the defibrillation pads. At 01:48 the defibrillator confirmed the Paramedic's initial concerns that the patient was in cardiac arrest. The initial rhythm noted to be Ventricular Fibrillation (VF), which is a heart rhythm in which a 'shock' is indicated.

The Paramedic then began to charge the defibrillator. Upon the Paramedic pressing the "shock" button, the defibrillator failed to deliver the shock and the Paramedic noted that the cardiac rhythm was no longer being monitored via the pads. The Paramedic checked that the pads were correctly attached to the patient and that the corresponding connections to

the defibrillator were also intact. No issues were noted and the Paramedic immediately continued treatment (CPR).

The Paramedic contacted EOC to update the patient's condition and requested a "HOT 1" back up. "Hot 1" is EEAST terminology for when a patient has a life threatening condition. At 01:50 the Paramedic contacted the EOC again, this time to determine the estimated time of arrival (ETA) of the "backup" Double Staffed Ambulance (DSA).

The Paramedic determined that the DSA was "moments away" and therefore requested that the back-up ambulance bring their spare defibrillator pads into the patient's house. The Paramedic therefore decided to remain with the patient and continue CPR, rather than return to their vehicle for the spare pads, which were kept within the boot of the RRV.

The Ambulance arrived at 01:54 taking their spare defibrillator pads into the property. The replacement pads were attached to the original defibrillator and two shocks were delivered, the first being delivered at 01:58. Following these shocks there was a Return of Spontaneous Circulation (ROSC). Unfortunately the Patient deteriorated into cardiac arrest again. The time of this was not recorded within the documentation. During this time manual CPR remained ongoing.

A second set of observations were documented at 01:58.

- Patient Position= flat on back on floor (Paramedic assisted by patient's wife to move some furniture.)
- Heart Rate - 0 beats per minute
- Capillary refill - >2 seconds
- ECG (3 lead) Ventricular Fibrillation
- Heart rhythm - Absent
- Respiratory rate - 0 breaths per minute
- Chest sounds - Abnormal
- The Patient was unresponsive
- Glasgow Coma Score-3/15
- Pupil - Both dilated
- Skin colour - Pale
- Skin moisture - Dry

At this time no further shocks were delivered, as there was an unassisted ROSC and the patient's heart was beating. The patient then deteriorated into cardiac arrested again and five further shocks were given, which resulted in a maintained ROSC.

The DSA left the scene and a “pre-alert” telephone call was made by the ambulance crew to the receiving hospital to alert them of the patient’s imminent arrival and their condition. During the journey to hospital the patient began breathing of his own accord. En-route to the hospital the Patient recovered further respiratory effort which was maintained.

On route to hospital a third set of observations were taken at 03:30.

- Patient Position-Supine (lying on an ambulance stretcher)
- Heart Rate - 68 beats per minute
- Cap refill – 2 seconds
- ECG (12 lead) – STEMI (heart attack)
- Heart rhythm - Irregular
- Repertory rate - 24 breaths per minute
- Chest sounds - Abnormal
- The Patient was unresponsive
- Glasgow Coma Score - 3/15
- Pupils – Normal (both)
- Skin colour - Normal
- Skin moisture - Dry

The ambulance crew correctly identified from the patient’s ECG that he was having a heart attack. This is defined by “STEMI” referring to an ST Segment Elevation Myocardial Infarction.

Drugs administered to the Patient

From the time of the back-up DSA’s, arrival a number of drugs were administered to the patient during resuscitation attempts.

At 02:03 a cannula was prepared and a 10mg flush was then administered at 02:03.

At 02:04 1mg of adrenaline at a ratio of 1:10,000 was administered intra-venously (IV). Starting at 02:10 two litres of 0.9% Sodium Chloride was administered to the Patient. At the same time a further 1mg of adrenaline at a ratio of 1:10,000 was delivered. Further doses of 1mg of adrenaline at a ratio of 1:10000 were delivered to the Patient at 02:15, 02:20, 02:25, 02:34, 02:47 and 02:58.

At 02:27 300mg of Amiodarone was delivered IV followed by a further dose of 150 mg at 02:31. The Amiodarone was diluted using 14ml and 7 ml of 5% Glucose solution respectively. At 02:43 600mg of Atropine was delivered.

The patient was taken to the receiving hospital where he sadly died. Following recognition of death the cause of death was identified as:

1(a) Myocardial Infarction
(b) Left Anterior Descending Artery Occlusion

2.2 Background and context of incident

The East of England Ambulance Trust was created on 1 July 2006 and covers the six counties which make up the East of England - Bedfordshire, Cambridgeshire, Essex, Hertfordshire, Norfolk and Suffolk. The Trust provides a range of services, but is best known for the 999 Emergency Service.

Our diverse area is spread over about 7,500 square miles and contains a mix of rural, coastal and urban areas – from Watford to Wisbech and Cromer to Canvey Island. Our services are tailored to meet the needs of each community's differing environmental and medical needs.

The Trust employs around 4,000 staff and 1,500 volunteers to deal with over 900,000 999 calls every year. In addition the Trust handles more than one million non-emergency Patient journeys to and from routine hospital appointments.

The EOC is the communications centre for all emergency and urgent calls in the area, receiving all requests for ambulance responses and dealing with all communication with operational resources in that area. There are three EOCs in the Trust based in Norwich (covering Norfolk, Suffolk and Cambridgeshire), Bedford (covering Bedfordshire and Hertfordshire) and Chelmsford (covering Essex). Each EOC has a call handling function where it accepts the 999 emergency calls, a dispatch function that sends the appropriate response to the calls received and a clinical desk that provides clinical support via clinician based telephone triage.

NHS111 is the non-emergency medical helpline which operates in England and Scotland and replaced the telephone advice service which was previously operated by NHS Direct. The NHS111 service is available 24 hours a day, 365 days a year.

Each 111 Call Centre is staffed by a team of fully-trained advisers, who are supported by experienced nurses and Paramedics. They ask a series of questions to assess the patient's symptoms, and then give healthcare advice or direct the caller/patient to the local service which can help the best.

Where possible, 111 will book an appointment at a local surgery for the patient to be seen, or they can request the patient takes themselves to A&E, a local Urgent Care Centre, or a late-opening chemist. 111 can also request that the Ambulance Service attends, and can specify whether this is under emergency conditions (blue lights and sirens) or as a normal road conditions attendance (no blue lights and sirens).

If the 111 service triage recommends that an ambulance is dispatched, this requested will be forwarded to the ambulance EOC via an electronic 'data transfer' and the call details are not passed verbally.

EEAST has a range of resources available to it to respond to calls. These include Rapid Response Vehicles (RRV), Double Staffed Ambulances (DSA) and Air Ambulances. The vehicles will generally be staffed by a Paramedic who will be supported by Emergency Medical Technicians (EMT), Emergency Care Assistants (ECA) or Student Ambulance Paramedics (SAP). The Air Ambulances will be staffed with a specialist Paramedic with advanced qualifications in Critical Care, and a Doctor.

Another form of Specialist Paramedic is the Emergency Care Practitioner (ECP). These clinicians have developed their clinical scope of practice to be experts in primary care. They boast advanced clinical assessment skills, further diagnostic ability and a greater range of treatments and referral options available to them.

Call Categories

Life threatening conditions such as cardiac arrest, unconsciousness and breathing difficulties are graded as Red 1 and Red 2. These require an emergency response within eight minutes. Lower acuity medical conditions, such as falls and diabetic problems, grade as either Green 1, Green 2, Green 3 or Green 4. These calls require a response between 20-90 minutes.

Back-Up Requests

Within the EEAST Resource Allocation Policy it is stipulated which categories of call must receive immediate backup for an RRV.

These are:

- All Red 1 incidents – must receive Automatic Hot 1 backup
- Red 2 incidents with the following chief complaints must receive Automatic Hot 2

10 - Chest pain (non-traumatic)
11 - Choking
12 - Convulsion
24 - Pregnancy/Childbirth/ Miscarriage
28 - Stroke (CVA)
29 - RTC
31 - Unconscious

For all other incidents where a Rapid Response Vehicle makes a primary response, the clinician is to expect that no backup is also attending unless they advise the EOC Dispatcher from being on scene with the patient.

EEAST staff use terminology for backup categories to advise the EOC Dispatcher under which circumstances they require, or don't require, additional support.

There are five categories of Back-Up:

- "Hot 1" = For patients who present with an immediately life-threatening or limb-threatening condition, which will result in a medical "Pre-Alert" to the nearest receiving hospital
- "Hot 2" = For patients who have other serious medical conditions which require an emergency response, but which may be diverted to a Hot1 / Red1 or Green1 call
- "Cold" = For patients who have non-serious conditions which require normal road speed (non-emergency) backup, which can be diverted to patients of higher priorities
- "Urgent" = For Paramedics to reprioritise the call to receive an ambulance response within 2 hours, allowing the Paramedic to leave the scene and for the patient to wait for the ambulance to arrive
- "None Required" = No backup required, the Solo Paramedic does not require any assistance from a Double Staffed Ambulance.

Vehicle Daily Inspection

The Paramedic who attended the incident has informed the IO that prior to the call their Vehicle Daily Inspection (VDI) was completed on the day of the incident stating "*It always is*".

The Paramedic has recalled that*, "As this job occurred in the early hours of the morning, the VDI was certainly completed before then."*

The IO confirmed that the Paramedic began their 12 hour shift the evening before the call at 17:45, this would have meant the Paramedic was ready and available to receive calls from 18:00 after they had their 15 minutes of protected time to ensure that a Vehicle Daily inspection was complete.

The IO requested the Dispatch sheet from the Control Room Records to confirm this. This sheet details the time the Paramedic started and finished their shift and confirmed that the Paramedic's shift began at 17:45. By cross referencing this with the Paramedic's call records, the IO confirmed that the Paramedic had sufficient time to complete their VDI before their first call of the shift. The Paramedic and his documentation confirm that the VDI was completed.

After liaising with the Paramedic's DLO the IO has been informed that the Paramedic "completed his VDI checklist and submitted this with his daily running sheet, which is now in medical records". At the end of the shift the Paramedic attached his run sheet to the VDI form, and all documentation was returned to the Trust's Medical Records department for archiving.

This sheet has been requested from medical records but at the time of writing this report the Paramedics VDI sheet has not been located. This is because the Paramedic, by their own admission, had not been filing the VDI sheets correctly. After completing a thorough search the Paramedic informed his DLO that the VDI sheet was placed in a folder with the Paramedic's Patient Care Records (PCR's) for the day.

Equipment

The Paramedic has reported that he was not aware of any previous issues with this particular defibrillator or monitor. The Investigating Officer (IO) has also ascertained that the Corpuls device, which is used by the Trust, completes a "self-test" every time the unit is turned on; however it does not produce any evidential receipt or print-out of the self-test. The previous defibrillator equipment used by the Trust did produce a 'receipt' to evidence the machine was working correctly.

The Paramedic involved in this incident confirmed that the Corpuls completed a self-diagnostic when it was switched on and no abnormalities or errors were detected. Furthermore, the defibrillator had been used throughout the shift and no errors or

abnormalities had been detected. If the defibrillator had reported an error then it would have been detected, quarantined and replaced.

The Paramedic went on to confirm: "*There are no additional checks I could have completed. As it was, no error messages appeared on the machine, not even when the pads failed."* The Paramedic's line manager has also informed the IO that when a piece of faulty equipment is detected "*Crews will inform DLO, attach a faulty equipment label and place into a quarantine area to ensure the device is not used. A Datix is not always submitted depending when the fault was discovered. A datix would always be submitted if this was during patient assessment... All crews are fully aware of the procedure locally*." Please see appendix 1-4 for evidential images.

The Paramedic confirmed that they informed their DLO of the fault; however the rest of the procedure was not followed. The IO questioned the Paramedic and Station Manager about the reason for this and was informed that the Paramedic "*was fully aware of his requirement to keep the pads to enable further diagnostic tests to determine why they had failed. Unfortunately due to the complexity of the patients' condition and the scene [being] chaotic, it is believed the pads were placed into a clinical waste bag when removing equipment at the scene. There were a number of contaminated items within the clinical waste and we would not encourage staff to remove/examine such contaminated equipment*." The pads therefore could not be recovered for further examination as part of this investigation.

The area's Senior Locality Manager has reported that "the machine itself was not taken off of the road, as when the new pads were attached to the Corpuls [during the incident] it worked perfectly well and delivered the shock as desired every time."

As part of this investigation, the IO has contacted the Senior Locality Manager for the county, a Duty Locality Officer for a different area, and the Business Support Manager, who have all advised that there have been no further reports of faulty equipment with regards to machines not delivering a shock to the patient.

The IO investigated the contingency planning for faulty equipment when in the patient-facing environment. The IO discovered that there are in fact three sets of adult defibrillator pads stored on the RRV. One is kept with the Corpuls defibrillator, one with the Automated Emergency Defibrillator (AED) and one spare set on the vehicle.

Within the Trust individual Paramedics are responsible for ensuring defibrillators are properly stocked. Organisation and storage of defibrillator pads is therefore the responsibility of the individual Paramedics. On this occasion there were no spare adult pads stored with the

defibrillator itself, or in the defibrillator equipment bag. The kit bags, which are carried by Paramedics from their vehicles to the patient's side are standardised and do not contain a spare set of pads.

The defibrillator itself, has both adult and child pads stored within it as shown below. In addition to the pouches shown on the side of the monitor (image below) a pouch is also attached to the back of the monitor.

The station Duty Locality Officer (DLO) confirmed that there "*is a make ready system at [the station] where the Paramedic operates from. The modules and bags placed on the vehicle would be prepared by an Ambulance Fleet Assistant (AFA) operating from the make ready standard operating procedures (SOP's). Due to the defibrillator being assigned to the response car, and the response car being in 24 hour use, the clinician would be responsible for stocking and checking the defibrillator on a shift by shift basis. It is not current practice to hold spare defibrillator pads with the machine. The pouch is fairly small and currently holds one set of adult pads, and one set of paediatric pads. Spare pads would be held in the response car should they be required. Should the defibrillator be the source of the fault, the AED would also be held in the response car.*" [Furthermore, at the time of the incident] *"the Corpuls machine was in [service] date and due to expire at the end of January 2016."*

A copy of the document which was provided by the Trust's Clinical Engineering department and completed by local management when the Corpuls units were received and prepared for clinical use has been attached at appendix 5.

After consulting with one of the Trust Area Clinical Lead's (ACL), familiar with the Corpuls defibrillator, the IO has been informed that the individual Paramedics are responsible for the organisation of the defibrillator pouches. In the ACL's experience it is possible to fit the "dots", which are attached to the patient, in the left pouch with one set of adult pads in the right pouch. A spare set of adult pads and one set of paediatric pads can then be stored in the rear pouch.

After conferring with a member of the Ambulance Fleet Assistance team the IO confirmed that clinicians are responsible for ensuring the vehicle is stocked with the correct Corpuls equipment on both RRV's and DSA's. When stocks on the vehicles need to be replenished, the clinicians will obtain them from the open stores. It is therefore the responsibility of the clinicians to ensure they have all the correct Corpuls defibrillator equipment, including spare equipment.

By properly organising defibrillator equipment, it is possible to store a spare set of adult defibrillator pads with the Corpuls monitor

Patient Care Review

One of the Trust's Area Clinical Leads (ACL) was asked to comment on the Paramedic's assessment and treatment of the patient on scene and whether the Paramedic's actions were appropriate on detection of the faulty pads.

The Clinical Lead reviewed the evidence available and reported that, "*As Paramedic's we always start by ensuring a patent airway and if the airway is not patent [we] correct this before moving on to the next stage of the assessment*". The ACL has reported that the Paramedic has demonstrated good practice in this area.

The ACL continued in their review that "*appropriate initial management of this patient was carried out. On recognising the arrest [the Paramedic] informed EOC of this and quickly attached the defibrillator pads and commenced resuscitation protocols. This is documented to have been at 01.48*."

The Corpuls information shows that at 01.48 there was a VF/VT alarm and the defibrillator was activated at 01.51, but no shock was delivered. This is when the fault with the defibrillator occurred. The ACL has commented that "*Whilst defibrillation is the key to survival from cardiac arrest, good quality chest compressions also support this. By not interrupting his compressions to fetch some more defibrillator pads, he was able to provide continual compressions whilst waiting for the arriving crew*."

The DSA crew arrived at 01.54 and the pads were changed and a shock delivered at 01.58. This is 10 minutes after the cardiac arrest was recognised. The ACL noted in their review that "*This prolonged period without defibrillation may have been of detriment to the outcome for the patient. Ideally a shock should be delivered as soon as possible after recognition of an arrest*." However the "*evidence provided shows good clinical practice by the Paramedic and appropriate actions on recognition of faulty pads. A second set of pads stored within the Corpuls unit would have minimised the delay in providing a shock to this patient*."

The nature of defibrillator pads is such that they are single patient use pieces of equipment, and therefore cannot be individually tested prior to deployment. Furthermore anomalous manufacturing errors can be minimised but not completely removed. This raises the conclusion that the only means of further minimising risk to patients is to carry spare defibrillator pads with the defibrillator rather than storing them in the vehicle.

Paramedic Training and Experience

The Paramedic joined the Trust in 2008, qualified as a Paramedic in 2012 and at the time of the incident had been a senior paramedic for 18 months. The Paramedics last Professional Update date as of the 21 January 2016 was 9 and 10 October 2014. They are scheduled to undertake their next Professional Update on 21 and 22 June 2016.

The Paramedic did not take part in a Professional Update in 2015. An update was scheduled but was cancelled by the Trust due to demands on the service. However, when the Corpuls was released, the Paramedic took part in an internal training session which covered all elements of the operation of Corpuls defibrillator. Those taking part in the training were deemed either "competent" or" not competent" in the use of the defibrillator. The Paramedic was deemed to be competent in all areas of the defibrillators operations.

2.3 Terms of reference

- Review the process of quarantining and reporting faulty medical devices, and the crew's understanding of this process
- Determine whether an alternative defibrillator (AED) was available to RRV
- Establish whether a second set of pads was available on the Corpuls and if, not why not
- Review the assessment and treatment provided to the Patient, to include what action was taken when the faulty pads were detected.
- Establish what VDI was undertaken with regard to the Corpuls monitor and could the fault have been detected prior to this call

- Determine if the Corpuls monitor was within the service date
- Determine if previous issues had been reported with this monitor
- Establish if any other similar problems have been reported since the introduction of the Corpuls monitor

2.4 Investigation Lead, Team and experience

This investigation was led by [redacted], supported by an Area Clinical Lead and D.L.O.

This investigation was led by [redacted], Investigating Officer with the East of England Ambulance Service NHS Trust assisted by [redacted] DLO. The Investigating Officer has completed an LLB (Bachelor of Laws) and the Legal Practice Course, both of which have modular requirements focusing on research and analysis. He has also worked in the private sector as a Paralegal investigating and reviewing claims and for the NHS in a litigation team investigating claims and inquests.

[redacted] joined the Ambulance Service in 2006 as a Trainee Technician and became a registered Paramedic at the start of 2009. She is a qualified Clinical Field Operations Trainer (CFOT) and has experience teaching Professional Update's to other Paramedics for the Trust as well as qualifying as a Level 6 Mentor and providing support and assistance to colleagues and peers. She completed a secondment as a Clinical Operations Manager in 2011 and then spent 3 years working as a Clinical Coordinator in Bedford EOC before moving to a DLO position last year. She joined the Clinical Directorate as an Area Clinical Lead in January 2015 after completing a 3 month secondment working as an SLM. [redacted] now works closely with her Area Clinical Lead colleagues in driving forward the clinical agenda of the Trust.

[redacted] joined the East of England Ambulance Service Trust in 2001 and registered as a Paramedic is 2006. He was appointed Logistics Manager for the West Sector in 2011. [redacted] then became a Duty Locality Officer in 2014. During this time he has undertaken a variety of investigations and is scheduled to undertake an RCA training course is scheduled for April 2016.

2.5 Scope of investigation

This is a Level One Concise investigation, this investigation focuses upon an equipment failure.

2.6 Investigation type, process and methods used

The following processes were undertaken:

- Review of this information of Datix including
    - Computer Assisted Dispatch information
    - Witness statements
    - Patient Care Records
    - Emergency Operations Centre call audit
    - Electrocardiogram (ECG) readings from the Corpuls defibrillator
- Review of the Portal
- Liaison with the following personnel
    - Paramedic
    - Area Clinical Lead
    - Duty Locality Officer
    - Senior Locality Manager
    - EEAST Locality Business Support Manager
    - Area Clinical Lead
    - Ambulance Fleet Assistant

2.7 Time Line of Events

Date / Time	Event	Supplementary Information	Notable Practice	Care and/or Service
21 Jan 2016				
	111 call received	111 calls will be redirected to the EOC in order to allocate an emergency resource		
01:39:47	Call received by EOC			
01:39:47	Call picked up by the Call Handler		Call pickup immediately	
01:39:58	Dispatcher used CAD system to identify community defibrillators and their distance from the scene	An automated external defibrillator or AED is a portable electronic device that automatically diagnoses the potentially life threatening cardiac arrhythmias. AEDs are designed to be simple to use for the layman, and the use of AEDs is taught in many first aid, first responder and basic life support (BLS) level CPR classes. Many communities operate a volunteer service where trained lay persons are called upon to deliver emergency support	Had the RRV been unable to respond within the agreed time frame this would have allowed basic emergency care within the community.	
01:40:10	RRV dispatched		Resource assigned within 1 second	
01:40:44	RRV mobile		Resource mobile within 1 second	

01:42:56	RRV on scene	Patient unresponsive on arrival. Agonal breathing identified. Bradycardic with week radial pulse. Fixed and dilated pupils. The Patient was given breathing assistance of 100 % oxygen via BMV on arrival by the Paramedic	RRV on scene within 2 minutes and 8 seconds (required response 8 minutes)	
01:48	Patient deteriorated into cardiac arrest (ventricular fibrillation)	Paramedic contacts EOC for Hot 1 Back up request		
01:48:37	Back up request passed to DSA			Defibrillator pads fail to deliver shock to patient
01:48:42	DSA dispatched		DSA mobile within 1 second	
01:50	Paramedic updates EOC to confirm cardiac arrest	Paramedic contacted EOC to confirm cardiac arrest and to request DSA crew bring spare adult defibrillator pads to the scene	Paramedic reacted calmly in the face of defibrillator failure and made a sound clinical judgment to remain with the patient while awaiting back up	
01:54	DSA on scene			
01:58	First defibrillator shock delivered to patient		DSA Crew respond quickly and effectively to request for back up defibrillator pads	
02:03	A cannula flush of ten mg is delivered to the Patient (IV)			
02:04	1 mg of adrenaline at a ratio of 1:10000 was delivered (IV)			
02:10	2 litres of 0.9% Sodium Chloride was administered to the patient throughout the			

	cardiac arrest (IV) 1 mg of adrenaline at a ratio of 1:10000 was delivered (IV)			
02:15	1 mg of adrenaline at a ratio of 1:10000 delivered (IV)			
02:20	1 mg of adrenaline at a ratio of 1:10000 delivered (IV)			
02:25	1 mg of adrenaline at a ratio of 1:10000 delivered (IV)			
02:27	300 mg of Amiodarone and 14 mg of 5% Glucose solution were delivered			
02:31	150 mg Amiodarone and 7 mg of 5% Glucose solution were delivered			
02:34	1 mg of adrenaline at a ratio of 1:10000 delivered (IV)			
02:43	600 mg of Atropine were delivered			
02:47	1 mg of adrenaline at a ratio of 1:10000 delivered (IV)			
02:58	1 mg of adrenaline at a ratio of 1:10000 delivered (IV)			
03:27:59	DSA departs scene conveying the patient to hospital			
04:29:58	DSA arrives at hospital destination			
04:50:47	Patient handover complete		Three sets of patient observations complete	Patient handover information not complete

2.8 Involvement of patient / relatives

The Trust would like to offer condolences to the patient's family on their loss, and offer a formal apology for not providing the Patient with the care which was expected. The Trust contacted patient's wife by telephone on 7 March 2016

The patient's wife raised a number of questions which she hoped the investigation would cover.

The hospital informed the patient's wife that the patient had been starved of oxygen to his brain for approximately 70 minutes. She is not sure if this is correct but "it has always troubled" her. The patient's wife was in attendance throughout the incident and does not recall the Paramedics putting an oxygen mask on in the house or in the back of the ambulance. She has asked that this information be confirmed.

With regards to the specific question that the patient's wife raised surrounding potential oxygen starvation, although this is included within the Main Report above, the Investigating Officer can confirm, and summarise here, that oxygen was delivered "on arrival" by the attending Paramedic via the Bag Valve Mask, which is the correct route in a cardiac arrest situation.

The patient's wife was very upset but stated that she is coping. She is grateful for the service for carrying out an investigation and hopes that it may set her mind at ease regarding some of the questions surrounding this incident.

A meeting was offered but the patient's wife has declined a meeting at this time.

The IO explained that she could request a meeting or call him at any time. A follow up letter was sent to the patient's wife on 11 March 2016.

Should the patient's family wish to meet with the Investigating Officer on receipt of this final report then the Investigating Officer would be pleased to do so.

2.9 Involvement and support of staff concerned

All staff involved in the incident have been notified that a Serious Incident investigation is underway. The crew members attending the scene or otherwise involved were asked for a

statement and will receive feedback following the completion of the report and have the opportunity to receive a copy.

2.10 Notable practice

- 999 call pickup immediately
- The first responding Paramedic reacted calmly and professionally in the face of an equipment failure.
- Resource assigned within one second
- Resource mobile within one second
- RRV on scene within two minutes and eight seconds (required response 8 minutes)
- DSA mobile within one second

2.11 Detection of incident

This incident was reported by the Paramedic, via the Trust's internal incident reporting system (datix) and initial fact-finding actions were put in place immediately.

2.12 Care and service delivery problems

Care delivery:

- The defibrillator pads failed to deliver a shock when required
- A replacement piece of equipment, although stored on the Paramedics vehicle, was not readily available when the primary piece of equipment failed. This delayed the delivery of the first shock.

2.13 Contributory Factors

Equipment

- Integrity
    - Poor working order (defibrillator pads)
- Positioning
    - Incorrectly stored (defibrillator pads)
- Usability
    - Not designed to make detection of problems obvious (defibrillator pads)

2.14 Root Cause Analysis

In considering all of the facts obtained during this investigation, it is reasonable to assume that there was a fault with the disposable defibrillation pads. This unfortunately cannot be confirmed as the pads were not kept for further investigations.

There have been no other faults reported in the area / Trust since this has occurred.

2.15 Lessons learnt

- It is important that comprehensive Patient Care records are completed
- It is essential that spare equipment is stored in the device in case of failure
- Incorrectly stocked Paramedic bags or equipment can lead to a delay in treatment.
- Lost Vehicle Daily Inspection (VDI) paperwork can lead to gaps in the Trust's own recording, self-assessment and investigations.

2.16 Recommendations

- The Trust SLM's to issue a reminder to operational staff of the need to properly store all completed checklists and documentation.
- To communicate to all operational staff the need to ensure that spare defibrillator pads be stored on all defibrillators, as this is not an Ambulance Fleet Assistant responsibility
- A debrief to be held with clinicians referenced on the Patient Care Record(PCR) to ensure that comprehensive PCR notes are completed

2.17 Arrangements for shared learning

The report will be shared with the CCG, the Trust Board, and sent to senior managers within the organisation for dissemination to all staff.

Appendixes

1-Image of faulty equipment quarantining site

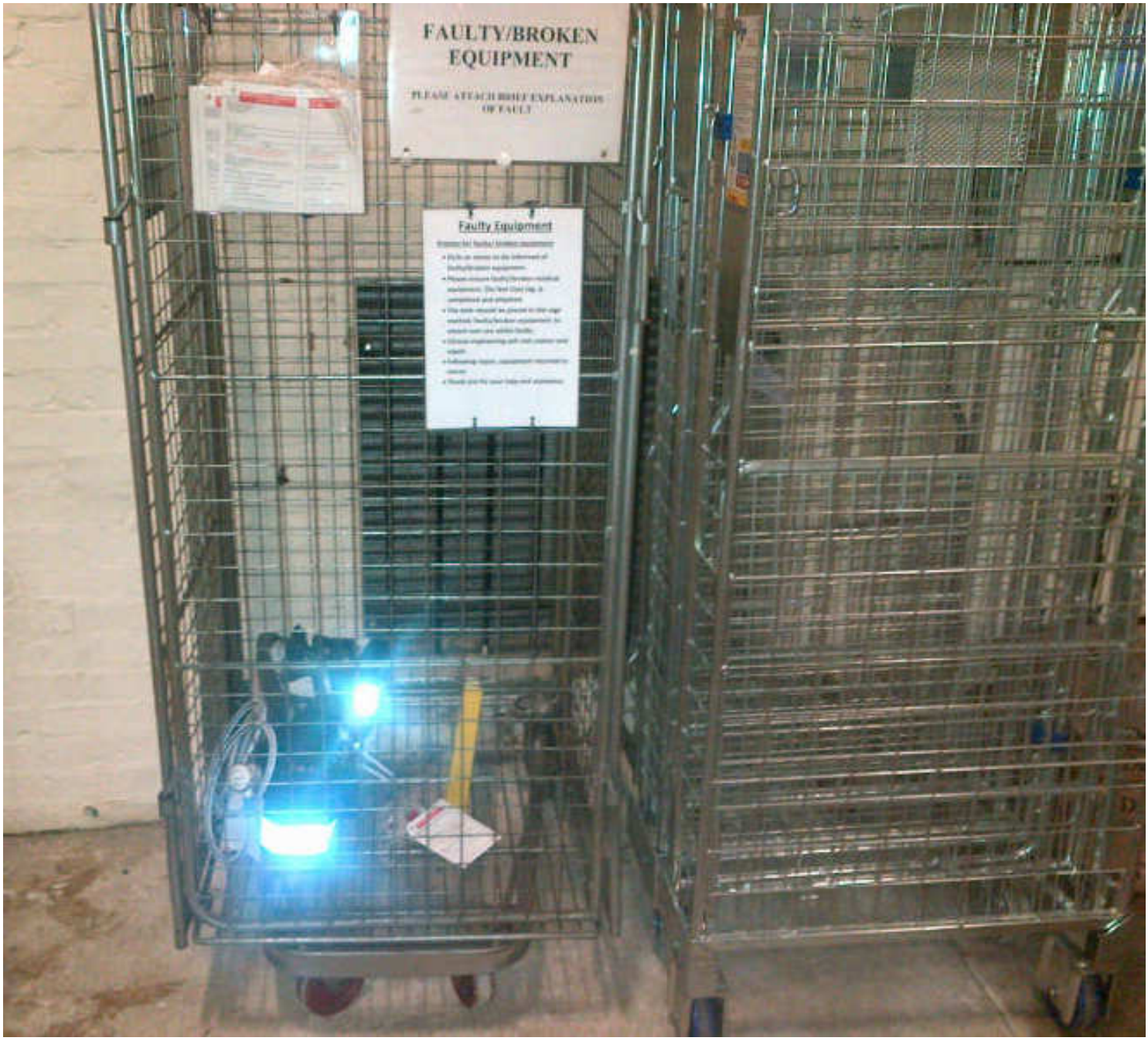
2-Image of engineering tags attached to faulty equipment identifying fault

3-Enlarged image of equipment quarantine sign

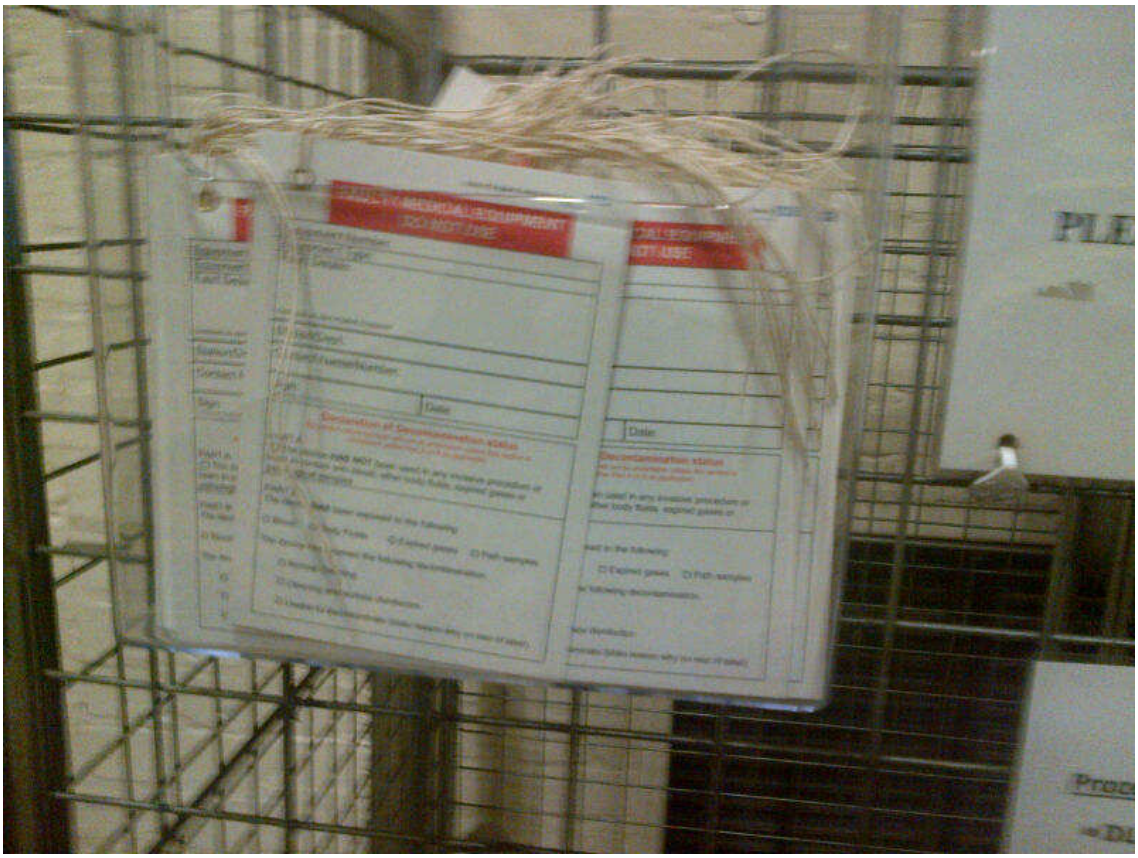
4- Enlarged image of sign attached to equipment quarantine area outlining quarantine process

5- Copy of documentation completed when Corpuls defibrillators received

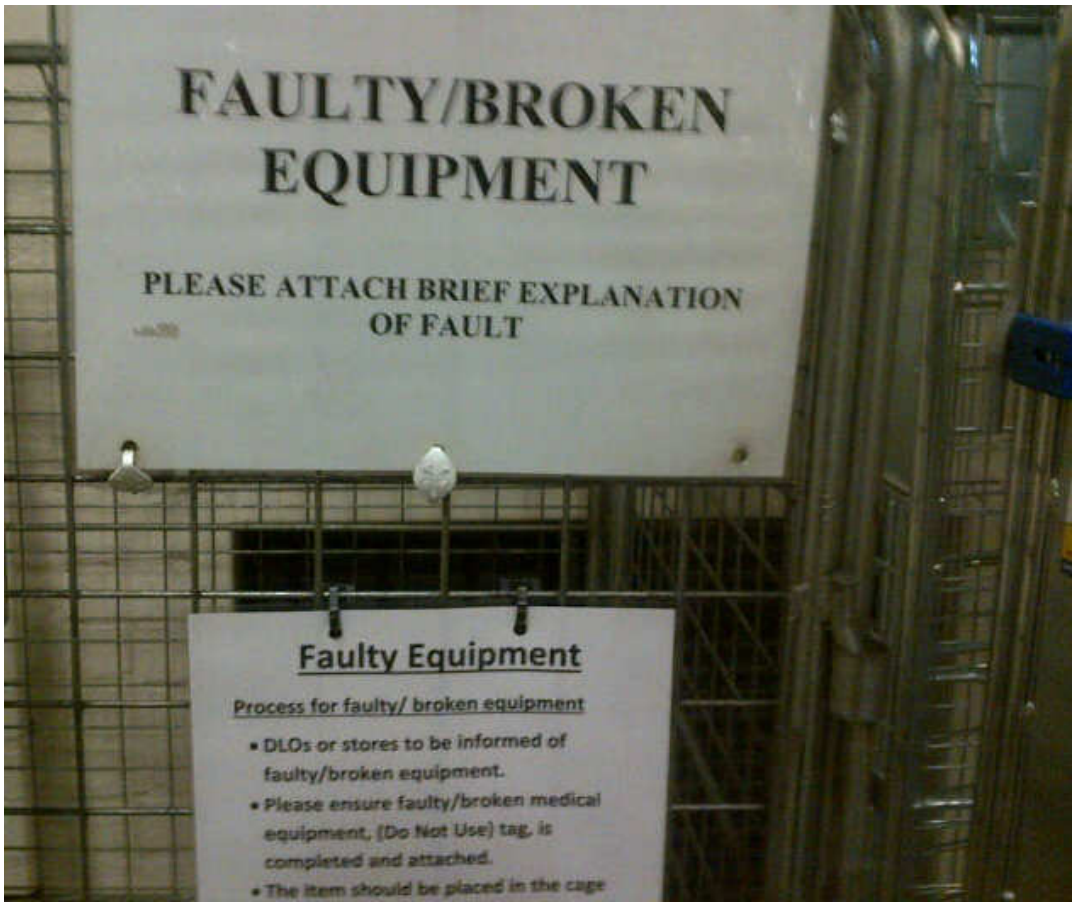
1)



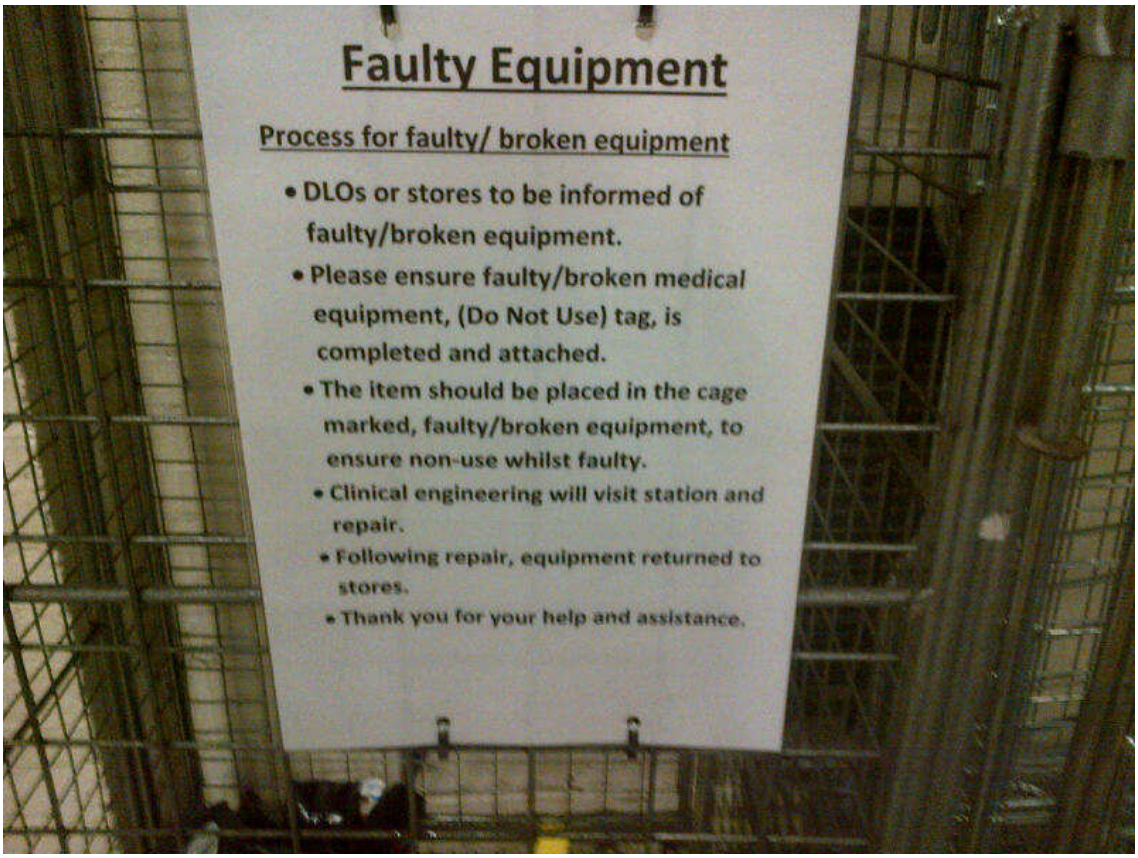
2)



3)


FAULTY/BROKEN EQUIPMENT
PLEASE ATTACH BRIEF EXPLANATION OF FAULT
Faulty Equipment
Process for faulty/ broken equipment
• DLOs or stores to be informed of faulty/broken equipment.
• Please ensure faulty/broken medical equipment, (Do Not Use) tag, is completed and attached.
• The item should be placed in the cage

4)


Faulty Equipment
Process for faulty/ broken equipment
• DLOs or stores to be informed of faulty/broken equipment.
• Please ensure faulty/broken medical equipment, (Do Not Use) tag, is completed and attached.
• The item should be placed in the cage marked, faulty/broken equipment, to ensure non-use whilst faulty.
• Clinical engineering will visit station and repair.
• Following repair, equipment returned to stores.
• Thank you for your help and assistance.

5)

Corpuls3 Defibrillator Pre-rollout Checklist for Devices

Please complete this checklist prior to rollout of each batch of corpuls3 devices and save the completed copy.

<table>
<tr><th>Item No</th><th>Description</th><th>Complete?</th></tr>
<tr><td colspan="3"></td></tr>
<tr><td>1</td><td>User Training</td><td></td></tr>
<tr><td>1.1</td><td>All Staff in local area have been trained and signed off on use of Corpuls3</td><td></td></tr>
<tr><td>1.2</td><td>Staff advised how to access further help/advice on the use of the Corpuls if required (Trainers, Datix, and Corpuls3Support Inbox)</td><td></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td>2</td><td>Risk Assessment</td><td></td></tr>
<tr><td>2.1</td><td>Trust Operational Risk assessment has been completed.</td><td></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td>3</td><td>Vehicle Installation</td><td></td></tr>
<tr><td>3.1</td><td>Confirm Corpuls mounting bracket has been installed in vehicle</td><td></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td>4</td><td>Consumables Stock</td><td></td></tr>
<tr><td>4.1</td><td>Check that local station stores has sufficient stock of all consumable items as per list below:
<table>
<tr><th>Stock number</th><th>Description</th></tr>
<tr><td>M713</td><td>Pulse oximeter sensor – Paediatric – Corpuls3 Defib – Single patient use</td></tr>
<tr><td>M714</td><td>Airway adaptor – Mainstream – Corpuls3 Defib</td></tr>
<tr><td>M715</td><td>Airway adaptor – Naso-oral – Corpuls3 Defib</td></tr>
<tr><td>M716</td><td>Defibrillator Pads – Adult – Corpuls3 Defib</td></tr>
<tr><td>M717</td><td>Defibrillator Pads – Paediatric – Corpuls Defib</td></tr>
<tr><td>M718</td><td>CPR Sensor – Corpuls3 Defib</td></tr>
<tr><td>M719</td><td>Printer Paper – Corpuls3 Defib</td></tr>
</table></td><td></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td>5</td><td>Device Readiness</td><td></td></tr>
<tr><td>5.1</td><td>Final check all accessories loaded onto Corpuls – ECG limb leads, ECG check leads, pulse probe (adult), nibp hose, nibp cuffs x 3, ETCO2 sensor, CPR cable</td><td></td></tr>
<tr><td>5.2</td><td>Final check all consumables loaded onto device – ECG dots, defib pad adapter, defib pads (adult and paediatric), airway adaptors, razors, paediatric pulse ox probe, paper in recorder</td><td></td></tr>
</table>

5.3	Batteries full charged	
6	Vehicle Readiness	
6.1	Spare consumables loaded onto vehicle – defib pads, ECG dots, airway adaptors, CPR sensor, paediatric pulse ox probe, paper	
7	Installing on vehicle	
7.1	Defib mounts and demounts easily on bracket	
7.2	Confirm battery charge light illuminates on defib when unit in bracket	
7.3	Switch unit on and check that unit passes self-test satisfactorily	
7.4	* Undertake pre-use checks as per user manual	
7.5	Remove Zoll from Vehicle.	
7.6	Record Equipment number(s) and Vehicle reg and update Clinical Engineering – Please complete form below and send it to: XXX	

Corpuls3 Vehicle Register

Corpuls3 Equipment Number (on front of machine)	Location	Assigned to Vehicle Registration	Date Assigned

Glossary of Terms

A&E	Accident and Emergency
AED	Automated External Defibrillator
AF	Atrial Fibrillation
ALS	Advanced Life Support
BVM	Bag-Valve-Mask
CPR	Cardiopulmonary Resuscitation is a lifesaving technique useful in many emergencies, including heart attack or near drowning, in which someone's breathing or heartbeat has stopped.
DSA	Double Staffed Ambulance - the conventional ambulance vehicle used to convey ill patients to places of definitive care. They are fitted with blue lights and sirens, and marked accordingly. They will usually have two ambulance staff members on board
ED	Emergency Department
EEAST	East of England Ambulance Service NHS Trust
EOC	Emergency Operations Centre - the Trust's control rooms where 999 calls are answered and where our dispatch staff communicate with our vehicles and staff. The Trust has three EOC's; One in Norwich (covering Norfolk, Suffolk and Cambridgeshire), one in Bedford (covering Bedfordshire and Hertfordshire) and one in Chelmsford (covering Essex)
ETA	Estimated Time of Arrival
GP	General Practitioner
IO	Investigating Officer
OA	On Arrival
PCR	Patient Care Record-the systematic documentation of a single patient's medical history and care
SCAS	South Central Ambulance Service
VDI	Vehicle Daily Inspection
VF	Ventricular Fibrillation