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GED Electronics Report

1 Introduction

The Judge Rotenberg Educational Center, Inc. employs electronics devices known as a GED in their behavioral plans for some of their students. Use of this "level III intervention" is regulated by Massachusetts Department of Developmental Services. The department's review committee has requested a review of the GED devices. Bay Computer Associates, Inc. has been retained by the Judge Rotenberg Educational Center to provide an external electronics review of their GED devices. This report details the results of that review.

2 Purpose

The Level III Certification report issued by the Massachusetts Department of Developmental Services contains the following charge to the Judge Rotenberg Educational Center (JRC):

> *While the Committee did not review the reliability of the GED apparatus, to ensure the continued safety of the GED interventions, JRC will have both the GED and GED 4 devices reviewed by outside experts with experience in medicine and engineering. JRC shall obtain from these experts a written report on the functioning and safety of the devices, and will submit that report to the Certification Team. This report should include a review of the functioning and safety of the devices providing the application, the triggering devices (both for one application and multiple automatically triggered devices, or devices otherwise not manually triggered) and the mechanisms used to distribute the current to random devices and will submit that report to the certification team.*

This document describes the evaluation of the GED devices with regard to their reliability and safety.

3 Scope

Bay Computer Associates, Inc. (BCA) is a contract electronics and software design firm with significant experience in the area of the design of medical devices. The principal investigator for this investigation is Dr. David A. Durfee the CEO and Chief

Scientist of BCA. Research and testing assistance was by the electronics staff of BCA. Therefore, due to the stated expertise of the engineers involved, the scope of this evaluation will be limited to the function, management, maintenance, and hazards of the electronics of the device proper and not the specific medical or clinical effects of the device's operation.

4 Summary

BCA has reviewed the GED within the confines of the scope listed above. We have found that the device, under normal operation, delivers energy that is within the bounds of that which is allowable for medical nerve and muscle stimulators. We also believe the device is in conformance with the significant electronics related requirements of the present day generally accepted medical device standard. (see references in section 6.1)
Potential hazards have been reviewed for the device and we believe that, with very minor changes to documentation to some procedures at JRC, mitigations are sufficient. Based on the design of the device and the procedures in place at JRC, the likelihood of the device operating outside of its normal operations is very small.
Our recommendations (found in section 8) are predominantly recommendations for improving documentation and some procedures at JRC. Based on the analysis below, we do not see an immediate need to modify the GED3 or the GED4 from the present design.

5 Definitions and Terms

GED	Acronym for Graduated Electronic Decelerator. A device more generally known as an "Aversive conditioning device". This refers to the GED, GED4, or GED3A throughout this report.
CFR	Code of Federal Regulations (http://www.gpoaccess.gov/CFR)
510(k)	A premarket notification where your device is determined by the FDA to be substantially equivalent to an existing device in commercial distribution giving you the ability to commercially distribute you device.
BCA	Bay Computer Associates, Inc. An independent contract electronics and software firm – the author of this document.
JRC	Judge Rotenberg Educational Center
DDS	Massachusetts Department of Developmental Services (formerly known as Department of Mental Retardation)
IDE	An FDA "investigational device exemption"

6 References

6.1 Safety and Regulatory Standards

1) **BS/EN ISO 14971: 2007 Application of Risk Management to Medical Devices**

2) **ANSI / AAMI ES60601-1 2005: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance**

3) **IEC60601-2-10, Particular Standards for the Safety of Nerve and Muscle Stimulators.**

4) **UL1642 revision 3 UL Standard for Lithium Batteries.**

5) **FCC Part 15**

6) **Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**

6.2 JRC Documents

1) **JRC Procedure on Battery Changing**

2) **Graduated Electronic Decelerator User's Manual**

3) **GED Quality Assurance**

4) **JRC Policy on GED Rotation**

6.3 Articles

1) **A transient thermal failure mode in metal film resistors, S V G Vardigans *et al* 1987 *J. Phys. D: Appl. Phys.*** 20 **1454-1456**

7 Review

7.1 GED Overview

The GED devices take direct current energy from their associated battery pack and produce a stimulus waveform that is both AC and DC in nature. This "shock"

waveform is applied to the student's skin with the use of a cable-connected electrode. This waveform is initiated with the use of a radio frequency transmitter that is digitally identified with its associated GED.

JRC uses two versions of their GED device at this time. They are referred to as the GED and the GED4. Both employ virtually identical electronics but different energy sources[1]. The GED uses a battery pack that has a nominal voltage of 12.0 Volts and the GED4 delivers more energy by using a battery pack that has a nominal voltage of 22.2 Volts.

The battery packs are contained in an enclosure that is separate from the electronics enclosure but connected with a cable. The electronics and battery pack form a pair that is attached with Velcro to be put into service. This allows the batteries to be charged separately.

Even though the two systems (GED and GED4) effectively have the same electronics, they reside within different colored enclosures to allow differentiation of the configuration in which they were put into service.

The certification report from DDS mentions "*multiple automatically triggered devices, or devices otherwise not manually triggered".* We have been informed by JRC that, while they may have been considered at one time, no such devices exist. JRC uses multiple GED devices (each with their associated "trigger" transmitter devices) to provide for the possibility of providing "randomness" of shock application. This use is no different than described above with the exception that more than one GED device may be configured on a single student.

There is one version of the GED in which the student is automatically shocked when his or her hands are raised from their side. The GED will continue to be triggered until the student's hands are returned to the "holster". This device, as the others is used under direct supervision of the staff.

To be specific there are three differences between the electronics for the GED4 and GED (beyond the use of a different battery pack). They are:

- A resistor population difference between them to avoid a GED configured device to use a GED 4 battery and visa versa.
- A resistor change so that the low battery circuit will work properly with the associated battery
- A resistor change in the output stage so that the device will provide the output power desired.
- A transistor change to reduce power consumption.

[1] There are small number of minor changes to some discrete components such as resistors and capacitors to compensate for the higher voltage used in the GED4.

These changes have been documented and regression testing has been completed.

7.2 Conformance to Claims

In addition to reviewing documentation, BCA used tests on a GED and a GED4 device selected at random to verify the claims made by JRC.

7.2.1 FDA registration

JRC has stated that their GED device has been registered with the FDA. This is clearly correct as documentation to this fact is located on the FDA website (see section 10.1).
Apparently JRC was considering selling this device as a product to other organizations at one time. In order to legally allow for the commercial distribution of a medical device you need to have your device registered with the FDA.
Subsequent to the creation of the GED device, JRC developed a modified the GED; the GED4. As JRC is no longer considering commercial distribution of either of these products, we have the understanding that this device is used under the FDA's "investigational device exemption (IDE)" (21CFR812) rather than being registered under their premarket notification "510(k)" procedure.

7.2.1.1 Modifications to circuitry since FDA registration.

The GED device has changed slightly from that originally submitted to the FDA for registration in 1994. It is common for device manufacturers to make minor changes to their devices to improve manufacturability or reliability. This is fine as long as those changes have determined to not be significant, have been documented and regression testing has been completed.
The general changes to the GED device since FDA registration are listed below:

- Power up delay added
- Low battery Buzzer indication
- Lower power, pin compatible components added
- Receiver interface updated
- Transformers mounted on printed circuit board
- Updated printed circuit board design
- Linear regulator of same function but higher voltage input (to accommodate the GED4 version)

7.2.2 Energy Delivered

7.2.2.1 2 second shock

Various documents and comments refer to the waveform applied as a two second shock. The calibration procedure tests that the duration is for 2 seconds +/- 10%. For the devices we tested, the duration of the shock did not exceed two seconds and was within 10% of 2 seconds.

7.2.2.2 Output Power

The GED and GED4 are rated with the RMS voltage output and current parameters. These two parameters can be multiplied to get the power output of the device. The GED is claimed to provide the following

- GED 15 mA rms at 60 Vrms +/-10% into a 5K resistance.
- GED4 41 mA rms at 66 Vrms +/- into a 1.6K ohm resistance.

The resistance values used have been reported to us by JRC as representative resistance values for skin contact for these voltages.

Our measurements of the voltage output of the devices we tested using a "true RMS" meter do indeed show an RMS voltages reported above. (GED – 63.5Vrms and GED4 -- 64 Vrms[2])

We do note that an RMS meter does not report on any direct current (DC) voltage, only AC voltages. Therefore, the statements on output power above are correct in that they report on the AC power output of the device. To be more complete, we have measured the DC voltage output to be:
GED – 13.88V
GED4 – 13.38V

7.2.3 Stimulation indication

The device is described to provide an indication that a stimulation output has occurred. This claim is also correct. There is an audible buzzer output that is actuated whenever a significant current flows between the electrodes. There is also a visible LED output that is initiated by current flow and is illuminated for a duration of 120 seconds.

7.2.4 Electrodes

There are descriptions in JEC literature regarding the two types of electrodes. They are a concentric electrode and a "spread electrode. It is our understanding that the spread electrode is being used because it is harder for the student to defeat. Electrodes are made of a stainless steel to avoid any reaction with sensitive skin. We note that the smaller contact of the concentric version is the same diameter as the contact of the spread electrode so the power density at the contact area does not change based on which electrode is used.

[2] These measurements were conducted with a Fluke Model 189 Digital Volt Meter.

7.3 Analysis of Risk and Risk Management

7.3.1 General

Regulatory agencies have recognized the importance of risk management in the development of medical products. We have included risk analysis information loosely based on the ISO 14971 Risk Management standard.
There is a standard list of questions that are generally used to elicit questions regarding the safety of a device. We have provided a table of that list of questions and the associated answers as they relate to the GED in the appendix. (See section 10.3)
Normally a risk analysis is done from a "top down" point of view (Hazards Analysis) and a "bottom up" point of view" (Failure Modes and Effects Analysis).

7.3.1.1 Hazards Analysis

The hazards analysis lists all potential hazards and determines if they could happen with the device and discusses the mitigations to prevent the hazards. Here again, there is a standard list of hazards and we have provided this list and the mitigations in the appendix. (See section 10.4) Many of the hazards have a statement of "does not apply". We kept these entries for completeness but we believe these hazards to not apply to the GED devices.
This is known as a top down analysis as the hazards that could cause harm are listed and then their cause is considered.

7.3.1.2 Failure Modes and Effects Analysis (FMEA)

The FMEA is considered a "bottom up" analysis since sub circuits and, potentially, individual components are reviewed to determine if a hazard could occur upon its failure. Here again, mitigations to avoid the hazardous condition are listed as well. The FMEA is provided in the appendix. (See section 10.5)

7.3.2 Risk Management

The standards also recommend that procedures be in place to reduce the possibility of policies and procedures introducing risks into the device and/or the operation of the device.
JRC has a GED Quality Assurance document outlining the roles and responsibilities for the QA functions related to the device.
JRC has a "good manufacturing practices" (GMP) documentation process and procedure in place to help provide checks and balances in any potential modifications to the device and to provide for maintenance/calibration procedures.

If a device fails to perform properly, the device is returned to the JRC electronics staff. They log the issue and maintain documentation for each device individually.

Once a quarter, statistics regarding GED operation are tabulated by the Director of Clinical Services so that a historical trend view of operation is reviewed.

7.4 Conformance to Standards

The FDA website does not list any "Recognized Consensus Standards" for the appropriate product code (HCB) nor for the regulation number associated with this product.
While there are no particular standards for this device, we feel it is helpful to search for standards that may provide some helpful information with regard to the GED.
The last comparison of the GED to standards was done in 1994 using tests found in the AAMI (ANSI) "Safe current limits for electromedical apparatus" (EB1-1993) and UL544 "Standard for Safety medical and Dental Equipment" 1994. At that time, the device was found to comply with the risk current and isolation requirements of those standards. The device has not changed significantly since that evaluation.

We have done a review of today's standards and believe that elements of the following standards are helpful in evaluating the GED and GED4.

- IEC 60601-1 (see reference 2) This is the newest version of the medical device standard.
- IEC 60601-2-10 (see reference 3) This is a standard for "the application of electric currents via electrodes in direct contact with the PATIENT for the diagnosis and/or therapy of neuromuscular disorders". Note that it does not directly apply to this application but has information useful for evaluation of the GED.
- UL1642[3] (see reference 4)

7.4.1 General Medical Device Standard

It is out belief that this device conforms to the significant electronics oriented requirements of the standard. Note, this standard does not specify any limits for currents that are intended to produce a physiological effect.
We list issues with respect to electronics performance found in the standard and discuss them below.

7.4.1.1 Single fault safe

The standard expects an electrical medical device to remain free of unacceptable risk during its expected service life under single fault conditions. This would be a case where a single abnormal condition (such as a component failure) is present.
This topic is discussed in section 7.3.1.2 of the risk management portion of this document and also in section 7.4.2 of this portion of the document.

[3] While there are IEC standards related to Lithium batteries, they do not apply to rechargeable batteries.

7.4.1.2 Power Input

Since the device is designed to operate with battery power and has no provision to be operated from an AC wall outlet connection, most of the requirements regarding power input do not apply to the GED.

7.4.1.3 Reverse battery polarity

The circuit board has a diode on the input to prevent reverse current. Also, the cable to the separate battery enclosure is "keyed" to prevent reverse polarity connections.

7.4.1.4 Leakage Currents

The device complies with the leakage current requirements of this standard. This is mainly because it has a BF-type isolated (floating) connection.

DC Battery Isolation

Upon measuring the patient auxiliary current (the current that flows between the two patient leads that is not intended to produce a physiological effect) per IEC60601-1 Figure 19, it was found to be 0.0uA (limit = 10uA).

AC Mains Isolation:
Since the GED device doesn't connect to the AC mains (other than when charging the battery packs), there is very little risk of patient leakage to earth ground due to the inherently large creepage and clearance distances involved. Conventional patient leakage to earth ground per Figure 15 of IEC60601-1-2005 3rd edition was found to be 0.0uA. Additionally, patient leakage of devices with floating outputs, such as the GED, must be tested additionally per Figure 16 of IEC60601-1 2005 3rd edition. Per Figure 16, AC mains voltage is applied to the floating patient connections and leakage to earth is measured. Only 5.9uA was measured with the AC mains in either polarity. This is well below the allowable limit of 5,000uA. Additionally, the GED was tested with the patient leads grounded to earth and 120VAC applied to a foil wrap placed around the GED (battery enclosure and stimulus unit). In this case, only 27.0uA of leakage was measured.

7.4.1.5 Creepage and Clearance

Note for the purposes of the 60601 standards, the output voltage is not considered "high voltage"[4]
The GED is powered from a DC battery that has a worse case high voltage of 25V. Per Table 12, for two means of patient protection, 4mm (158 mils) of creepage and 2mm (79 mils) of air clearance must be provided. It is unclear if that 4mm of creepage distance has been allowed for between the transformer output traces and

[4] "**HIGH VOLTAGE:** Voltage over 1,000 V a.c. or over 1,500 V d.c. or over 1,500 V peak value."

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the four electrolytic capacitors that connect to the transformer input. Environmental Influences
The GED is designed for the environment it is intended for. There is a section in the staff training manual with procedures for the device to avoid getting wet in the instances where a student continues to have a GED when showering[5].

7.4.1.6 Batteries

The battery housing is not airtight which fulfills the venting requirementof the standard.
The connection to the device is with a "polarized" connection (in that the connector can only be inserted in the proper orientation).
Nickel Metal Hydride (NiMH) batteries are generally only considered to have a hazard due to an internal gas buildup if over charged. The Panasonic NiMH battery of the GED is vented to prevent this hazard[6]. Potential heating hazard due to an over-current condition is mitigated by the addition of a fuse within the GED battery pack. The Lithium Ion GED4 battery pack is protected with specific protection circuitry for overcharge, over discharge, over drain, and short circuits. A 2 amp fuse is part of this protection provided by the battery pack manufacturer.
Charging is not done in an area where students are located. JRC uses commercially available battery chargers. The GED4 battery pack is charged with a device that is CE listed.

7.4.1.7 Indicators

The standard requests an indication that the device is ready for normal use. If it is otherwise apparent to the operator then an indicator light is not required. We note that the device is ready for normal use when the battery is connected which is obvious to the operator.

7.4.1.8 Transformers

The GED uses the same transformer that was specified in 1994 when it was shown "to withstand 10 times the expected secondary voltage".

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[5] Staff Training Manual text -- "The student will have one electrode placed on the lower arm (below the elbow) with the wire running away from the body to the GED fanny pack/backpack which will be hung on the wall completely outside the shower stall.
The student will be in a standing position (shower) or seated (bath) with his/her arm raised. A GED wrap/towel is then wrapped around the arm and the electrode to ensure the electrode remains dry."

[6] "When the internal pressure of these batteries rises due to overcharge, short-circuiting, reverse charge, or other abuse or misuse, the self-resealing safety vent is activated to prevent battery damage. From "http://www.panasonic.com/industrial/battery/oem/images/pdf/Panasonic_NiMH_Overview.pdf"

7.4.1.9 Software

There is no programmable device within the GED so many parts of the standard don't apply.

7.4.1.10 Auditory alarm signal

The sound pressure level (volume) was measured at 0.5 meters on the A weighted scale. A sound pressure level of 81dB was recorded using a Radio Shack Sound Level Meter (catalog number 33-2055). This is below the 120dB recommendation given in IEC60601-1 2005 3rd edition in Section 9.6.2.1 Note 2. (A limit suggested for children.)

IEC60601-1-8 Section 201.3.3.2 discusses how loud an auditory alarm should be. The A-weighted background noise level is to be at least 10dB lower than the alarm level. Section AAA.201.3.3.2, where the rational for this requirement is discussed, states that alarm levels between 45dB and 85dB are generally audible in most situations without being too obtrusive. As discussed above, the GED alarm was measured to be 81dB at 0.5 meters from the GED enclosure

While the device does not have the spectral quality specified in IEC60601-1-8 the requirement for several frequencies was developed to avoid confusion in an emergency environment. Given the environment this device is to operate in, we do not expect this to be an issue.

7.4.1.11 Emissions and Susceptibility

Electronics devices are tested for emissions and susceptibility. Proper testing of this type must be done in FCC approved facilities. Because of the 4 layer construction of the GED device, the fact that it is battery operated, it does not contain a programmable device, and does not have an intended radiator, we believe it is highly likely to pass any emissions test.
Emissions and Susceptibility are related so the same reasons that the device is unlikely to emit excessive radio frequency energy are the same for why it would show immunity to the same. In addition, the radio receiver uses a unique identifier (in the sense that it only responds to one of approximately 60 thousand possible codes that further reduces the susceptibility of the GED. We have exposed the devices to several separate radio frequencies with no spontaneous activations occurring (145MHz, 223MHz, 445MHz, 2.4GHz-WiFi).

Electrostatic Discharge (ESD)

ESD was tested Per IEC60601-1-2 Section 36.202.2

- air discharges +/-2KV, +/-4KV and +/-8KV
- contact discharges +/-2KV, +/-4KV and +/-6KV.

The GED's LED, which is designed to illuminate for two minutes after a stimulus is delivered, is triggered by air discharges of +/4KV and +/-8KV. No output stimulus

was observed at any air discharge level. Air discharges occur at the battery input of the stimulus unit and to the metal screws of the enclosures.

The GED's LED also illuminated for +/-4KV and +/-6KV contact discharges to the stimulus unit battery connector and the stimulus unit's enclosure screws. No false output stimulus was observed.

Intended Radiation

The manufacturer of the transmitter and the receiver electronics subsystems used with the GED has provided documentation that these subsystems conform to US Federal Communications Commission requirements.

7.4.2 Specific Nerve and Muscle Stimulator Standard

We note that this specification is for the safety of therapeutic nerve and muscle stimulators. In addition, it excludes body-worn equipment. Despite the restricted scope of this standard we feel that it is helpful to provide some guidance as there is no particular standard for an aversive conditioning device.

This standard provides a table of "limitation of output parameters" for therapeutic applications.

7.4.2.1 Current Limit

The medical device standard uses a 500 ohm load when performing this current limit test. We have performed this test on the GED and GED4 devices under normal conditions for the devices and the currents measured are compared against the standard in the table below.

	GED	GED4	Standard Limit
DC	12.0 mA	45.1mA	80mA
RMS	20.4 mA	26.2mA	50mA

Note that there are a couple of theoretical fault conditions that could result in higher output conditions.

1- If the output resistor is shorted on the GED or GED4, additional current would be delivered. We physically shorted this part out for our tests. For the GED it was measured to be 29.2mA DC and 42mA AC. For the GED4 it was measured to be 48mA DC and 92mA AC.

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Given that the output resistors are of a metal film resistor type, it is almost a certainty that the resistor would fail in an open condition resulting in no current to the patient[7]. (In fact, metal film resistors are sometimes used as fuses.)

2 – If U5 pin 10 (see GED Type 1 Mod GED4 Rev E Schematic) were to become stuck in the logic high state, approximately 47VDC is placed across a 500Ω load resistor for approximately 2 seconds. This corresponds to a load current of 94mA, which is above IEC60601-2-10 recommendations for DC current listed in Section 51.104 (80mA). The AC voltage applied across the 500Ω load in this fault condition is less than 1Vrms. The probability of U5 malfunctioning in this manner is highly unlikely.

This "single fault" behavior of the device was presented to the medical consultant at JRC for evaluation. His opinion is that as long as the device is applied in a manner that avoids the heart the resulting risk could be considered a "low severity" using the definitions of the FMEA[8]. In addition, our recommendation is to increase the calibration frequency of the GED4 to further reduce the risk.

7.4.2.2 Voltage Test

The standard also imposes a limit of 500V on the output of the device when the electrode is not connected (open-circuit condition).

	GED	GED4	Standard Limit
Peak O.C. Volts	426V	452V	500V

It is the very nature of this test that the value would not change even if the output resisters were shorted.

7.4.3 Rechargeable Lithium Battery Standard

The manufacturer has tested individual cells using tests from the UL1642 Standard. It is not uncommon for the complete battery pack to be sold without proof of conformance to standards as they expect that the purchaser would handle testing to show conformance. The pack itself is protected by a circuit board that is designed to mitigate the significant hazards potentially presented by the pack.

7.4.4 FCC Part 15

Because the transmitter is an "intended radiator", it must conform to the requirements of the Federal Communications Commission. The manufacturer of the

[7] A transient thermal failure mode in metal film resistors. S V G Vardigans et al 1987 J. Phys. D. Appl. Phys. 20 1454-1456

[8] Email correspondence with Dr. James Miner, Associate Professor of Emergency Medicine, UMN Twin Cities.

subsystem used for the communications part of the device has provided documentation that their product is FCC compliant.

8 Recommendations

After evaluating the documentation provided to us we have the following recommendations.

8.1 GED Labeling

The labeling for the GED3 contains text appropriate for a device registered with the FDA. The GED4 has the same text but it is being used under an IDE. To completely conform to the CFR regulations the labeling for the GED4 should add the following - "CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use."

8.2 Procedures

8.2.1 Service procedures

JRC should document when batteries should be removed from service. In particular, the Panasonic NiMH batteries used in the GED3 are recommended to be taken out of service within 2 years.

Also the service personnel should be informed of the need to dispose of batteries in accordance with all applicable federal, state and local regulations.

It should explicitly be part of the service procedures that a documented calibration procedure be performed on units taken out of service before it is put back in service.

Also, the devices and their electrodes should be cleaned at some regular interval. JRC needs a cleaning schedule/procedure.

8.2.1.1 Calibration instructions.

Calibration of GED4 devices should be more frequent then GED3 devices. In addition, the results of the calibration and any components that are replaced to conform to the calibration should be documented.
In addition to its present tests, the calibration procedure should:

- Should have an explicit inspection of the enclosure for cracks or weakening.
- Should have an explicit inspection to see if their was any evidence of liquid ingress)
- Should verify output voltage and current (both DC and AC-rms) is in compliance.
- Verify the 2 minute LED output

- Update to include a leakage test (since creepage and clearance distances on the circuit board are not obvious). We recommend that the patient auxiliary current be measured and confirmed to be less than 10uA at every regular calibration interval.
- Check if the power up reset circuit is operating.
- Verify patient auxiliary current (see 7.4.1.5 and 10.4.1.1)
- Verify both 2- second shutdown circuits are working.

Due to the potential single fault condition mentioned in section 7.4.2.1 we recommend the calibration cycle for GED4 be every three months.

8.3 Documentation

Avoid relying on personal knowledge and more on documentation.

8.3.1 Engineering Change Orders (ECO)

While there is a process in place for documenting changes to the GED we feel that it should be improved.

BCA found it difficult to ascertain from the paperwork exactly the changes reflected by an ECO, what root cause it was trying to resolve, and what documents were updated as a result.

We recommend that the ECOs not be approved unless they contain:

- information describing the problem to be solved
- what is believed to be the root cause of the problem
- what the solution is (as well as testing to show the solution is valid)
- the revision number of the current documentation and what that revision number is being changed to for the updated documentation.

There was not enough evidence for us to ascertain if an electronic engineer reviewed each of the previous changes to the GED itself. We recommend that an electronic engineer with a minimum of a 4 year degree at an accredited institution and medical device design experience (or equivalent experience) review all ECO's pertaining to the GED.

In addition, documents related to the operation and use of the GED should be "controlled documents". What we mean by this is that the documents should be provided with a revision number and should only be modified using a change order process that requires management approval. It is possible that changes to the device would result in changes being necessary to procedures in the documents. This should be considered when approving ECOs.

8.3.2 GED Operator Procedures

BCA has already conveyed to JRC corrections to the User's Manual. None of those changes resulted in any significant procedural modifications. Emphasis was on incorporating more differentiation regarding the GED and GED4 and making the document more readable. The desire was to explain to the operator what behavior to expect and inspect rather than a detailed explanation of how the device was designed electronically.
There are several documents that JRC uses to train its staff. Because the label specifically states that the user's manual should be read, the user's manual should, at a minimum, refer to those other documents by reference.
The documents that govern the procedures used with the GED devices should be reviewed annually to validate that they continue to contain accurate information and match the actual usage of the device by staff.

In addition to the specific information that is already in the documentation, we believe the documentation should also:

- Give guidance regarding taking into account what the student is doing before applying a stimulus (to make sure the distraction of the application will not cause harm).
- Include the importance of proper GED electrode placement on the body (Pertains to all documents regarding the GED).
- Ask the operator to check if the LED is on if they believe a spontaneous event happened. (This would differentiate that event from a low battery condition setting off the audible alarm).
- More explicitly inform operators not to expose the GED to fluids.
- Have a more explicit description of operator inspection for damage to enclosure or liquid ingress.
- State what the JRC cleaning procedure for GED, cables and, electrodes is.
- Although the potential for the battery to overheat is extremely small, the battery pack should not be placed near flammable materials.

8.3.3 Quarterly Report

If not already part of JRC's process, we believe the quarterly report on the GED performance should be provided to the JRC electronics manager.

8.3.4 BOM

The JRC electronics staff should go though its most current documentation for the GED3 and GED4 to ensure it is correct and consistent. We request this as we noted one inconsistency between part description and part number in the bill of materials provided to us. As all of the GED devices are presently modified to reflect the

current revision we see no need for scrutiny of documentation regarding previous versions of the device.

8.4 Emissions and Susceptibility

As we have said above, we do not expect the device to have any difficulty passing the emissions and susceptibility requirements of the standards but we recommend that JRC have the appropriate tests performed.

8.5 Future design changes

If JRC is to make any design changes to the GED, we suggest that they follow a design process more closely aligned with the ISO 14971 and ANSI 60601 standards. The use of a hazards analysis and failure modes analysis is key to determining safety related design requirements. In addition, it will make sure that mitigations that are presently in place will not be ignored in future designs.
As a very specific case, JRC should not change the output current limiting resistors from metal film resistors without a supporting risk analysis.

9 Conclusion

BCA has reviewed the GED within the confines of the scope of this document. We have found that the device, under normal operation, delivers energy that is within the bounds of that which is allowable for medical nerve and muscle stimulators. We also believe the device is in conformance with the significant electronics related requirements of the present day generally accepted medical device standard. (see references in section 6.1) Based on the design of the device and the procedures in place at JRC, the likelihood of the device operating outside of its normal operations is very small.

Potential hazards have been reviewed for the device and its use. Based on the information provided to us and our visit to the JRC campus, BCA believes that the usage of this device and the device itself does not provide an unreasonable risk to the operator or the student.

That being said, there is room for improvement in the documentation of the procedures for use of the GED and for the keeping of device related design and maintenance information. Some of the documentation has been written some time ago and should be reviewed for correctness and completeness. Some of the electronics documentation provided to us made it difficult to track and understand the changes that were implemented that resulted in the current design. (The necessary information was provided and the inconsistencies were resolved.). BCA has also requested additional testing and inspections of the device to provide mitigations for potential faults that we have isolated in our failure modes analysis.

We have been in conversation with JRC regarding the majority of these issues through the course of our investigation. In addition, our recommendations regarding the documentation and procedures at JRC are found in section 8. Most of our recommendations are to reinforce documentation methods and procedures to reduce the potential for personnel changes to have an affect on future operation.

Based on the contents of this report, we do not see an immediate need to modify the GED3 or the GED4 from the present design.

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10 Appendix

10.1 FDA Classification for the GED

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR882.5235]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 882 -- NEUROLOGICAL DEVICES
Subpart F--Neurological Therapeutic Devices

Sec. 882.5235 Aversive conditioning device.

(a)*Identification.* An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics.

(b)*Classification.* Class II (performance standards).

10.2 Devices listed by FDA as related to Aversive conditioning

Device Name	Company	Date Approved	**Device or Consumer Information/Instructions**
GED (GRADUATED ELECTRONIC DECELERATOR	BEHAVIOR RESEARCH INSTITUTE, INC.	Dec 05, 1994	Available from the Company
SIBIS REMOTE ACTUATOR	HUMAN TECHNOLOGIES, INC.	May 29, 1987	

SIBIS SELF INJURIOUS BEHAVIOR INHIBITING SYSTEM	OXFORD MEDILOG, INC.	Feb 28, 1986	
ELECTROSTIMULI AVERSION MACHINE	MICHAEL R. KISS	Apr 09, 1982	
HABITSABATER	JACKSON ENT.	Jun 20, 1979	
STIMULATOR, SONIC CONTROL (AS-1)	FARRALL INSTRUMENTS, INC.		

10.3 Identification of Device Characteristics

The section below provides a general overview of all of the hazards associated with the usage of the GED. All information related to predicate devices will be italicized.

Item #	Questions To Ask	Factors To Consider	Device Specific Analysis
1.0	What is the intended use and how is the device to be used?	Intended user: mental and physical abilities required skill and training of user: environment it is to be used by whom it will be installed: whether the patient can influence the use of the device:	The user is a trained staff member. Device is to be generally used indoors or during transport between locations. Trained staff member "installs" the device. There are no settings on the device.
1.1	Is special intervention required in case		The operator is expected to take the device out of service.

	of device failure?		
2.0	Is the device intended to contact the patient or other persons?	Surface contact: invasive contact: period and frequency of contact.	There are stainless steel electrodes and woven fabric that has contact to the patient's skin. This electrode is in contact with the patient for extended periods of time but is moved between different locations.
3.0	What materials and/or components are incorporated in the device or are used?	Applicator materials Battery materials. Enclosure materials. Areas of concern are fluid path and tissue contact materials, and proper disposal.	Batteries: Hazardous ingredients for Lithium Battery Aluminum Foil 2-10% Metal Oxide (proprietary) 20-50% Polyvinylidene Fluoride (PVDF) <5% Copper Foil 2-10% Carbon (proprietary) 10-30% Electrolyte (proprietary) 10-20% Stainless steel, Nickel and inert materials Remainder * Lithium content : 0.66g MSDS says that the RCRA Waste Code is "nonregulated". Hazardous ingredients for Nickel Metal Hydride (NiMH) Battery (Panasonic) – data sheet says: "All Panasonic NiMH batteries are classified by the federal government as a non-hazardous waste…" **Battery Disposal:** Dispose in accordance with all applicable federal, state and local regulations. **Tissue contact materials – Stainless steel and woven fabric** Enclosure – ABS with UL 94HB rating
4.0	Is energy delivered to and or extracted from the patient?	Type of energy transferred and its control, quality, quantity, and time function.	Electrical energy applied across the skin. Device output characteristics are described in section 7.2.2
5.0	Are substances delivered to and or extracted from the patient?	Maximum and minimum transfer rates and control:	No substances delivered or extracted.

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6.0	Are biological materials processed by the device for subsequent re-use?	Type of process and substance processed such as dialyzers or autotransfusion.	No biological materials processed.
7.0	Is the device supplied sterile or intended to be sterilized by the user or are other microbiological controls applicable?	Intended for single use or reusable: packaging: shelf life: limitation on number of re-use cycles: type of sterilization process to be used:	There is no requirement for sterilization for this product. The device is re-usable.
8.0	Is the device intended to be routinely cleaned and disinfected, or routinely tested by the user.	Cleaning and disinfecting agents: Cleaning cycles: Mechanical design for maintenance: User test logging: User test issues:	JRC needs a cleaning schedule/procedure. It is routinely tested by the user as well as tested by electronics technicians.
8.1	Application site disinfection and maintenance.	Cleaning and disinfecting agents:	JRC needs a cleaning schedule/procedure
9.0	Is the device intended to modify the patient environment?	Temperature: Humidity: atmospheric gas composition and pressure:	No
10.0	Are measurements made?	Variables measured, accuracy, precision	No
11.0	Is the device interpretative?	Whether conclusions presented by the device from input or acquired data, algorithms used, and confidence limit	No
12.0	Is the device intended to control or to interact with other devices or drugs?	Identity of other devices and drugs which can be involved and the potential problems associated with such interactions.	No
12.1	Is the device	Potential problems are:	Yes

	remote controlled?	loss of remote interference or jamming of RF communication security issues	The remote control is housed in a "sled" that is attached to the operator. "Jamming" would result in no application of a stimulus and the operator would be aware of that. A transmitter with a unique digital code is used to avoid security issues.
13.0	Are there unwanted outputs of energy or substances?	Noise: Vibration: Heat: radiation (UV, infrared, visible, ionizing, non-ionizing): contact temperatures: leakage currents: electrical and magnetic fields: unwanted substances:	Noise- a buzzer sounds but is within appropriate limit Vibration: no Heat – Battery shorting hazard that is mitigated with fuses Radiation: none Contact temperatures: all items at room temperature Leakage currents: tested within limits E & M fields: Construction and design suggests there would be no issue.
14.0	Is the device susceptible to environmental influences?	Operational: transport and storage environment: spillage: power: cooling supplies:	The device could be susceptible to liquid ingress.
15.0	Does the device influence the environment?	Effects on power and cooling supplies: Emission of toxic materials: Generation of electromagnetic interference:	No
16.0	Are there essential consumables or accessories associated with the device?	Specifications for consumables or accessories: restrictions placed upon users in their selection:	The accessories are the battery packs that are to be replaced periodically, a transmitter, and an electrode. The transmitter has an alkaline battery that should be replaced periodically. There are no "consumables".
17.0	Is maintenance and/or calibration necessary?	Requires user or specialist: Special equipment or substances required:	A specialist calibrates the device. The user performs daily testing.
18.0	Does the device	Whether software is	There is no software in this device.

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	contain software?	intended to be installed, modified, or exchanged by the user and/or operator	
19.0	Does the device have a restricted shelf life?	Labeling or other indicators and the disposal of the device.	There is no restricted shelf life beyond that of the battery pack accessory. Battery packs are required to be recharged and tested when being put into service.
20.0	Possible delayed and/or long term use effects?	Ergonomics and cumulative effects	Complaints and user feed back should be tabulated in a product history file.
21.0	To what mechanical forces will the device be subjected?	Whether the forces to which the device will be subjected are under the control of the user or controlled by interactions with other persons	Mechanical stresses are due to the student wearing the device. These stresses would be something the operator would be aware of.
22.0	What determines the lifetime of the device?	Aging: Battery depletion:	The device itself is mostly electronic. The lifetime would be mostly affected by mechanical abuse, transmitter keypad wear, and the battery replacement. An increasing mean time between failure would suggest the need for decommissioning.
23.0	Is the device intended for single use or re-use?	Single or re-use	Re-use
24.0	Is safe decommissioning or disposal of the medical device necessary?	Contains toxic material:	The only special "decommissioning" would be with respect to the batteries getting disposed of under proper guidelines.
25.0	Does installation or use of the medical device require special training?	Is "commissioning" necessary by skilled personnel:	User Manual will indicate necessary training for use of the device.
26.0	Will new manufacturing processes need to be established or introduced?	New technology: Different scale of production:	No new processes are required.

27.0	Is successful application of the medical device critically dependent on human factors such as the user interface? See human factors related questions below.		See items 27.1 through 27.4
27.1	HF1. Does the medical device have connecting parts or accessories?	Wrong connections: Differentiation: Similarity to other products' connection: Connection force: Feedback on connection integrity: :	Connections are keyed so they cannot be put in backwards. The two connections are keyed differently so that you can't plug the accessories into the unit improperly. The user is warned not to connect to any other devices in the manual. The device is tested by the user daily so connectivity is validated.
27.2	HF2. Does the medical device have a control interface?	Spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, and whether the controls are continuous or discrete, and the reversibility of settings or actions	There are only the two buttons for activation. Either button causes it to activate.
27.3	HF3. Does the medical device display information?	Visibility in various environments, orientation, populations and perspectives, clarity of presented information, units, color coding, and the accessibility of critical information.	The device has a very simple "display". It has a buzzer and an LED.
27.4	HF4. Is the medical device controlled by a menu?	Complexity and number of layers, awareness of the state, location of settings, navigation method, number of steps	There is nothing complex about this interface.

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		per action, and sequence of clarity and memorization problems, and the importance of control function relative to its accessibility.	
28.0	Is the medical device intended to be mobile or portable?	Consider necessary grips, handles, wheels, brakes, mechanical stability and durability.	Yes, the device is located in a "fanny pack" strapped to the student. It is small enough to fit within that pack completely.

Table 1 – Questions Used To Identify Device Characteristics That Could Impact Safety

10.4 Potential System Level Hazards

10.4.1 Energy Hazards

10.4.1.1 Electricity and/or Electric shock

1. Exposure to live electronics

Battery operated – no exposure to AC
General isolation for student due to the device being enclosed in a plastic case. Case inspected for damage on each use.
Note that all voltages in either GED are below 24V when the device is not activated.
Output verified in normal operation to conform to nerve and muscle stimulator standards (see section 12).
Output

2. Leakage current

Per IEC60601-1 2005 3rd edition, Section 8.5, medical equipment shall have two means of protection to prevent applied parts from exceeding the leakage current requirements of the specification. Table 12 specifies the amount of creepage and air clearance distance required for one or two means of patient protection.

AC Mains Isolation:

Since the GED device doesn't connect to the AC mains (other than when charging the battery packs), there is very little risk of patient leakage to earth ground due to the inherently large creepage and clearance distances involved. Conventional patient leakage to earth ground per Figure 15 of IEC60601-1-2005 3rd edition was found to be 0.0uA. Additionally, patient leakage of devices with floating outputs, such as the GED, must be tested additionally per Figure 16 of IEC60601-1 2005 3rd edition. Per Figure 16, AC mains voltage is applied to the floating patient connections and leakage to earth is measured. Only 5.9uA was measured with the AC mains in either polarity. This is well below the allowable limit of 5,000uA. Additionally, the GED was tested

with the patient leads grounded to earth and 120VAC applied to a foil wrap placed around the GED (battery enclosure and stimulus unit). In this case, only 27.0uA of leakage was measured.

DC Battery Isolation

The GED is powered from a DC battery that has a worse case high voltage of 25V. Per Table 12, for two means of patient protection, 4mm (158 mils) of creepage and 2mm (79 mils) of air clearance must be provided. It isn't clear that 4mm of creepage distance has been allowed for between the transformer output traces and the four electrolytic capacitors that connect to the transformer input on the printed circuit board used. Upon measuring the patient auxiliary current (the current that flows between the two patient leads that is not intended to produce a physiological effect) per IEC60601-1 Figure 19, it was found to be 0.0uA (limit = 10uA). Clearly within the limits required.

To ensure that leakage requirements are continued to be met, the patient auxiliary current will be measured and confirmed to be less than 10uA at every regular calibration interval. Note that even if the isolation were completely compromised, the leakage would not exceed the limits of the nerve and muscle stimulator specification.

10.4.1.2 Emissions of electromagnetic interference

1. Interference with other equipment –
2. Excessive exposure to EMI –

These issues were dealt with in section 7.4.1.11

10.4.1.3 Heat

1. Generation of excessive heat, fire, and explosion

Heat would only be generated by excess current from the battery pack in the event of some unknown malfunction. Both battery pack types are protected with 2A fuse. Regarding fire the ABS enclosure is rated UL94-HB.

10.4.1.4 Mechanical force

Does not apply.

10.4.1.5 Ionizing radiation (x-rays, gamma rays, cosmic rays, alpha particles, beta particles)

Does not apply.

10.4.1.6 Non-ionizing radiation (microwaves, ultrasound, visible light)

Does not apply.

10.4.1.7 Moving parts

10.4.1.8 Unintended motion

Does not apply.

10.4.1.9 Suspended masses

Does not apply.

10.4.1.10 Failure of support device

Does not apply.

10.4.1.11 Pressure

Does not apply.

10.4.1.12 Acoustic Pressure

Only due to the audible alarm. Meets the standard as discussed in section 7.4.1.10

10.4.1.13 Magnetic fields

Does not apply

10.4.2 Biological Hazards

This section includes hazards related to the material in applied parts (parts that make contact with the body of the patient).

10.4.2.1 Bio-contamination

Does not apply.

10.4.2.2 Bio-incompatibility

Does not apply

10.4.2.3 Incorrect formulation

Does not apply.

10.4.2.4 Toxicity

1. Battery Toxicity and warnings –
2. Battery disposal –

The GED NiMH battery pack does not contain hazardous materials and the manufacturer suggests that it can be thrown away. (Although recycling is recommended.).

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The GED4 LiION pack does contain some hazardous materials but there is no symptoms of exposure under routing handling and use. In addition, the battery is contained in an additional enclosure.

JRC will dispose in accordance with all applicable federal, state and local regulations.

10.4.2.5 Allergenicity, Mutagenicity, Oncogenicity, Teratogenicity, Carcinogenicity, Pyrogenicity

The enclosure is made of ABS and is housed in a "fanny pack" so it is not in contact with the student. The electrodes have been selected of a stainless steel to avoid a skin reaction.
Batteries have no symptoms of exposure under routine handling and use.[9]

10.4.2.6 Re- and/or cross-infection

JRC follows a cleaning procedure for cables and electrodes.

10.4.2.7 Inability to maintain hygienic safety

JRC follows a cleaning procedure for cables and electrodes.

10.4.2.8 Degradation

The electronic components are not overstressed electrically so there would be no degradation of the components due to the very low duty cycle of most of them. The only degradation would be in the battery system and due to mechanical abuse. The batteries are replaced to avoid degradation over time and charging cycles.

10.4.3 Environmental hazards affecting operation of the device

These hazards may occur during normal use or during transport and storage or as a result of misuse.

10.4.3.1 Susceptibility to electromagnetic interference

These issues were dealt with in section 7.4.1.11

10.4.3.2 Electrostatic Charges

These issues were dealt with in section 7.4.1.11

10.4.3.3 Humidity

1. Exposure to water –

The staff is instructed not to expose the GED to fluids. The device is normally enclosed in a "fanny pack". In particular cases, the student may have a GED

[9] From battery MSDS information

while showering. Special instructions are provided to the operator if the student is to take a shower[10].

10.4.3.4 Inadequate power supply

Device is tested on each use and batteries are rotated into service.
Power on is recognized by the operator by the cable between the battery pack and the GED being connected.
An instability in the power supply when the battery is first connected (potentially causing a miss-fire) has been avoided with the use of circuitry specifically for this purpose.

10.4.3.5 Inadequate supply of coolant

Does not apply.

10.4.3.6 Storage or operation outside of prescribed environmental conditions

There should be no adverse effects as long as the device is calibrated before going back into service, as is currently done

10.4.3.7 Incompatibility with other devices with which it is intended to be used

Does not apply.

10.4.3.8 Mechanical damage (can be accidental or wear and tear)

The device is sometimes exposed to abuse from the student. The enclosure has its corners reinforced with hot glue. The device is inspected each shift for mechanical damage as well as when calibrated.

10.4.3.9 Vibration

Does not apply.

10.4.4 Hazards resulting from incorrect output of energy and substances

[10] Excerpt from the staff training manual

- The student will have one electrode placed on the lower arm (below the elbow) with the wire running away from the body to the GED fanny pack/backpack which will be hung on the wall completely outside the shower stall.
- The student will be in a standing position (shower) or seated (bath) with his/her arm raised. A GED wrap/towel is then wrapped around the arm and the electrode to ensure the electrode remains dry.

10.4.4.1 Electricity

Discussed in energy hazards section above

10.4.4.2 Radiation

Does not apply.

10.4.4.3 Supply of Medical Gases, Anaesthetic Agents, Etc.

Does not apply.

10.4.4.4 Volume

Does not apply.

10.4.4.5 Pressure

Does not apply.

10.4.4.6 Application of inappropriate substances

Does not apply.

10.4.4.7 Overflow

Does not apply.

10.4.4.8 Spillage

Does not apply.

10.4.4.9 Leakage

Does not apply.

10.4.4.10 Accuracy of operating data

Does not apply.

10.4.5 Hazards related to the use of the medical device and contributory factors

10.4.5.1 Inadequate labeling

1. Labeling per FDA requirements.

10.4.5.2 Inadequate operating instructions

1. Labeling refers to users manual so that more extensive information can be provided.

10.4.5.3 Use by untrained personnel

The device is not allowed to be used by untrained personnel.

10.4.5.4 Reasonably foreseeable misuse

There are a number of potential misuse scenarios. An examples is attaching electrodes to inappropriate areas of the body.
This misuse would be due to operator not following training procedures. Penalty for this is job termination.

10.4.5.5 Insufficient warning of side effects

Potential side effects are described in the user's manual.

10.4.5.6 Inadequate warning of hazards associated with re-use of single use medical device

Does not apply.

10.4.5.7 Incorrect measurement or dosages

Does not apply.

10.4.5.8 Incompatibility with consumables, accessories/ other medical devices

Does not apply.

10.4.5.9 Sharp edges or points

The enclosure has no sharp edges or points. The operator is instructed to look for damage to avoid any potential for sharp edges due to damage. Also the device is enclosed in the fanny pack.

10.4.5.10 Cleaning

JRC needs a cleaning schedule/procedure

10.4.5.11 Sterilization

1. Device does not need sterilization.

10.4.5.12 Disinfection

JRC needs a cleaning schedule/procedure.

10.4.6 Inappropriate, inadequate or over-complicated user interface (man/machine communication)

This section is designed for devices with complex user interfaces. This device has a very simple interface so most of these items to not apply.

10.4.6.1 Mistakes and judgment errors

There should not be judgment errors with respect to the user interface.

10.4.6.2 Lapses and cognitive recall errors

Does not apply.

10.4.6.3 Slips and blunders (mental or physical)

The transmitter device is enclosed in a "sled" with the student's picture on it and it provides additional mechanical protection from inadvertently hitting the activation button.

10.4.6.4 Violation or abbreviation of instructions, procedures, etc

Device is a simple button press actuation so it is unlikely to have abbreviated instruction.

10.4.6.5 Complex or confusing control system

1. Does not apply

10.4.6.6 Ambiguous or unclear device state, or presentation of data

Buzzer and light inform the user if the device actuated. Buzzer alone informs the user that there may be a low battery indicated. (Although this is unlikely with the battery rotation program JRC has implemented).

10.4.6.7 Misrepresentation of results

User could assume that a low battery was a spontaneous application of a shock if they did not note the LED output. This is included in the training.

10.4.6.8 Insufficient visibility, audibility, or tactility

Audible alarm tested to standards, LED continues to stay lighted for two minutes.

10.4.6.9 Poor mapping of controls to action

Does not apply

10.4.6.10 Modes or mappings that vary from existing equipment

Does not apply

10.4.6.11 Communication security violation

Someone trying to violate the "security" of communication would have to be able to select an appropriate code from one of approximately 60,000,, use the exact FM frequency and be within a relatively short distance from the device in question.

10.4.7 Hazards resulting from functional failure, maintenance and aging

10.4.7.1 Erroneous data transfer

Does not apply

10.4.7.2 Inadequate maintenance and functional checks

Because it is a simple device a functional check is done each time the device is put into use.
This test helps show that the only main maintenance necessary has been completed (changing the battery pack).
A periodic calibration makes sure that the safety circuitry and current limiting circuitry is operating properly.

10.4.7.3 Inadequate specification for maintenance

The calibration procedure should be a sufficient specification.

10.4.7.4 Lack of adequate end of life determination for the device

The device would fail one of the various tests it is put through. It is improbable that it would create an energy hazard to the student.

10.4.7.5 Loss of electrical or mechanical integrity

1. Key stuck conditions

If the key is truly stuck as if it is "pressed", the electronics does not allow repeatedly activating the shock output.

2. Erroneous key press

The enclosure for the key fob (the "sled") is designed to reduce this possibility.

3. Redundancy

The output has redundant circuits to keep the output restricted to two seconds. These circuits are checked on each calibration cycle.

10.4.7.6 Inadequate packaging

The device is not sold to others so there is no "packaging" per se.

10.4.7.7 Re-use and/or improper re-use

There are no restrictions on re-use.

10.4.7.8 Deterioration in function as a result of repeated use

The only deterioration in function would be due to battery deterioration or mechanical abuse. These issues have been dealt with in JRC's procedures.

10.5 Failure Modes and Effects Analysis

10.5.1 Purpose

This section contains the Failure Mode, Effects and Criticality Analysis for the GED3/4 PCB, Rev E. This FMECA serves as a tool to help show fulfillment of the single-fault-

safety requirement stated in IEC 60601-1. The analysis is a bottom-up analysis which complements the top-down hazards analysis.

10.5.2 Scope

The components covered by this FMECA include the GED3/4 PCB and corresponding electronics including the battery packs.

10.5.3 Reference Documents

10.5.3.1 GED Type 1 Mod 3A Rev E Schematics (Schematic Type 1 Mod GED4 Rev E was also referred to).

10.5.3.2 IEC 6060812 Analysis Techniques for System Reliability – Procedure for failure mode and effects analysis (FMEA)

10.5.4 Definitions, Acronyms, and Abbreviations

Table 2 – Definitions, Acronyms, Abbreviations

Term	Definition
ALARP	As Low As Reasonably Possible - This term is used to indicate that the criticality rating is acceptable but should be lowered further if possible.

10.5.5 FMECA Procedures

The FMECA for the GED will be performed at the system level. At the system level each functional sub-circuit is treated as a separate component. Failure modes are determined at the functional level. If it is determined from the system level that a particular sub-circuit requires a component level analysis, then the component level analysis will also be performed on the sub-circuit in question.

The following rankings shall be used in the FMECA table (see reference 4.3 for detailed descriptions):

Table 3 – Severity Level Ranking

Ranking	Level	Description
1	Negligible	severity is negligible if the hazard would not be expected to result in any injury to the patient, operator and/or others. However, it is possible that discomfort could be experienced.
2	Moderate	The severity is moderate if the hazard can

		potentially result in non-serious injury to the patient, operator and/or others, or if it indirectly affects the patient operator, and/or others (e.g., through the action of a care provider) where incorrect or delayed information could result in non-serious injury of the patient, operator and/or others
3	Critical	The severity is critical if the hazard directly affects the patient, operator and/or others with the potential for death or serious injury to the patient, operator and /or others, or if the hazard indirectly affects the patient, operator and/or others(e.g., through the action of care provider) such that incorrect or delayed information could result in death or serious injury of the patient, operator and/or others.

Table 4 – Occurrence Ranking

Ranking	Level	Description
1	Improbable	Not probable; not likely to happen; unlikely to occur during the life of the unit.
2	Remote	Slight; faint; a remote chance of occurring during the life of the unit.
3	Occasional	Of an irregular occurrence; happening now and then; infrequently occurring during the life of the unit.
4	Probable	Likely to occur; can reasonably but not certainly be expected to occur during the life of the unit.

Table 5 – Detection Ranking

Ranking	Level	Description
4	Very high	End user will certainly detect a device failure, has plenty of time to react and should have the presence of mind of what is to be done to mitigate the hazard. -or- The hardware/software automatically detects the failure and provides direct mitigation.
3	High	End user should detect a device failure, has time to react and should have the presences of mind of what is to be done to mitigate the hazard. -or- The hardware/software detects the failure and provides an audible and visible alarm.
2	Moderate	End user should detect a device failure, but time to

		react is limited. The end user should have the presence of mind of what is to be done to mitigate the failure. -or- Hardware automatic detection only on power up and during periodic self-test (failure not immediately detected)
1	Low	End user not likely to detect a device failure or to have time to react. End user cannot detect a device failure. Hardware cannot detect a device failure.

The following risk control chart will be used to determine the acceptable criticalities:

Table 6 – Risk Control Chart – Acceptable Criticality and RPN Values

	Low(1)	Moderate(2)	Critical(3)
Probable (4)	ALARP (4)	Intolerable (8)	(12)
Occasional (3)	ALARP (3)	Region (6)	(9)
Remote (2)	(2)	ALARP (4)	(6)
Improbable (1)	Broadly (1)	Acceptable Region (2)	ALARP (3)

Any "Criticality" numbers above 4 must be reduced through mitigation, where

$$Severity \times Occurance = Criticality\ .$$

Any criticality values of 4 and 3 are acceptable but should be reduced if possible.

Residual Risk Evaluation – this is estimated by factoring in the effects of the control measures on the criticality estimates. The likelihood of the hazard may decrease as a result of the applied mitigation. In addition the detectability is factored in such that a Risk Priority Number (RPN) can be calculated as follows:

$$Severity \times \frac{Likelihood}{Detectability} = RPN$$

The detectability factor must be applied carefully in order to avoid improper usage. The detectability can only reduce the probability of occurrence of the hazard, but it cannot reduce the severity. The detectability is used to calculate a new probability factor that must remain within the original probability scale of 1 to 4. That is, the ratio of probability/detectability will be rounded up to 1.0 if the ratio is less than 1. Note that the risk control chart remains the same for RPN estimates and criticality estimates.

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10.5.6 FMECA Table (System Level)

Note: Failure modes at the system level are based on the system function (not component function).

Table 7 – System Level FMECA

ITEM #	SUB-CIRCUIT	FUNCTION	FAILURE MODE	CAUSE OF FAILURE	EFFECT OF FAILURE	SEVERITY	OCCURANCE	DETECTABILITY	INITIAL RPN	RECOMMENDED ACTION(S)	SEVERITY	OCCURANCE	DETECTABILITY	NEW RPN
1.0	+5V Regulator Circuit: R45, R46 D1, C5-C8 C2-C4 U2	+5V regulator for therapy gate, low battery detector, various logic.	Supplied circuits could malfunction if operating from an out of spec supply voltage.	IC failure. Open/shorted capacitor, resistor or diode.	A shorted bypass cap on the input or output of U2 could cause a large current to flow from the battery. **Present Mitigations:** The NiMH battery pack has a 2A fuse. The LI-Ion battery back has a 2A poly-fuse. IC failure could reduce U2 output to 0V. In this case the therapy gate signal will be inactive resulting in no therapy. **Present Mitigations:** Operator will notice that there was no activation and take	1	2	1	2					

					device out of service. IC failure could place 12V on the output of U2. This would lead to the therapy being disabled. **Present Mitigations:** Operator will notice that there was no activation and take device out of service. .									
2.0	Pulse Duration/Therapy Gate Circuit U3A R41-44 R8,13,16 D11-13 C16,31-33	Produces an approximate 2S pulse width signal to time the stimulus application.	Duration of the stimulus could be incorrect. Stimulus may not occur.	IC failure. Open or shorted capacitor, resistor or diode.	If the therapy gate fails to be asserted, there would be no stimulus. **Present Mitigations:** Operator will notice that there was no activation and take device out of service. Discrete component failure would result in a different duration of the output of this part of the system. **Present Mitigations:** Operator will notice that there too short a duration and the secondary 2 second timer will prevent too long a duration. These two 2 second	1	2	1	2	A tolerance analysis should be performed to establish that the asserted trigger signal at U6.1 will reliably be of a sufficient voltage to cross the logic "1" threshold of U6.				

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					timers are tested in calibration. . (Segments of U5 and U6 form a backup 2S gate signal which will deassert the stimulus.) The signal from U3.5 (timer output) is connected to U6.1 via a voltage divider and acts as an enable to stimulus signal. The divider is formed by R13, R6 and R7. If the logic "1" U3.5 output is low enough, there is a chance that the signal at U6.1 may not get high enough to trigger the stimulus. This would result in no stimulus being delivered. **Present Mitigation:** The lack of the audible alarm would inform the attendant of the malfunction.									

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3.0	Battery voltage Switched Circuit. Q1,2 R1,3,6,7 C14	Enables power for the output stimulus circuit.	DC power applied to the output transformers at the wrong time, or not at all.	Transistor failure	Applying DC power to the output transformers alone will not cause inadvertent stimulus. The modulating signals from Q4/Q5 are also necessary for output to occur. **Present Mitigations:** If stimulus is not provided, this will be noted by the attendant.	1	1	1	1					
4.0	+5V Switched Regulator U1 C1	Provides power for logic that generates the modulation therapy signal.	Stimulus signal not generated	IC failure. Capacitor shorted.	Failure of this regulator would likely result in open or short failures of the logic. This would result in no stimulus from being applied. **Present Mitigations:** If stimulus is not provided, this will be noted by the attendant.	1	1	1	1					
5.0	LED Trigger Circuit U3B LED1, Q7,9 R23-25,39 R31-33 C20,21	Illuminates for 60S after stimulus is delivered.	Visible indication of stimulus is missing, or is stuck on, or is asserted for the wrong duration.	IC failure, discrete component failure	If the "two minute" LED doesn't stay illuminated. **Present Mitigation**: Attendant will notice that the LED isn't illuminated for the expected period of	1	1	2	1					

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	D7				time and take the device out of service.									
6.0	Stimulus Waveform Generator U5, U6 C24-26 C28-30 R26,28,30 R34-38	Generates the modulated waveform that is applied to the output transformer low voltage input.	Stimulus not generated. Incorrect stimulus generated.	IC failure. Discrete component open or short.	No stimulus provided. **Present Mitigation**: The attendant will note that there was no audible alarm upon delivery attempt. Also, the LED will not illuminate. Incorrect stimulus provided. Worse case in U5.10 stuck high, which delivers approximately 94mA into a 500Ω load (GED4). This is above IEC60601-2-10 recommendations for DC current listed in Section 51.104. **Present Mitigation**: Calibration every three months. Two-second gate circuit becomes stuck on. **Present Mitigation**: One shot circuit U3A acts as a backup circuit to stop the stimulus after 2 seconds. These two circuits "watch" each other and are both	1	2	1	2	Frequent calibration testing will verify that the GED is delivering the desired stimulus. These readings should be made once with the meter set to AC volts and again with the meter set to DC volts. Failing units should be removed from service and investigated until the root cause of the failure has been determined. For severity see section 7.4.2.1	1	2	1	2

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					checked at calibration time.									
7.0	Low Batter Detect Circuit U4 R5,14,18 R10,12,20 RW C17 Q3,10 BZ1	Informs attendant of low battery by sounding an alarm.	No alarm generated. False alarm generated.	Open or shorted discrete component. Failed transistor.	Failure of this circuit can't cause inadvertent or erroneous stimulus delivery. **Present Mitigation**: Low battery condition should not happen because procedures are in place for battery replacement.	1	1	1	1		1	1	1	1
8.0	Transformer Input Drive Circuit Q4-6, C18, R15,19	Applies modulated waveform to the low voltage side of the output transformer.	No stimulus provided.	Open or shorted discrete component. Failed transistor.	Since the transformer input must be modulated in order to produce an output, interrupting this signal path would lead to no stimulus being delivered.	1	1	1	1					

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9.0	Output Transformer circuit C9-C12 T1,2	Steps up the low voltage transformer input.	Incorrect or no stimulus provided.	Transformer insulation failure. Cap open or short.	A short circuited cap would either blow a battery pack fuse or destroy Q1, leading to the inability to deliver stimulus. If the transformer failed, you would not get a stimulus. The DC output resulting would be well below the output allowed. **Present Mitigations:** If stimulus is not provided, this will be noted by the attendant. Also would be noted by calibration.	1	2	1	2					
10.0	Output Rectifier, Filter and Clamp Circuit D4-6,8 R21,22 C19, D9, RV1	Rectifies output waveform	Incorrect or no stimulus provided.	Discrete component open or short.	A shorted or open bridge diode will lead to less energy delivered. C19 open has a small effect on the output stimulus. C19, R21 or RV1 shorted causes a greatly diminished stimulus. R21 open has a very small effect on the delivered stimulus.	1	2	1	2					

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					RV1 threshold voltage is not reached during normal operation **Present Mitigations:** This would be noted by calibration. Failure of R22 will have a direct impact on the stimulus delivered since this component is in series with the load. R22 is a metal film resistor, which will almost certainly fail as an open circuit. In the case of an open circuit, no stimulus will be delivered. Since the GED is enclosed in a plastic box, the probability of R22 being "bridged", causing a short circuit, is very remote. D9 open will prevent the application of the stimulus. D9 shorted will disable the audible alarm, but only have a very small effect on the delivered stimulus (1.2V zener). **Present Mitigations:**									

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					If stimulus isn't provided, there will be no audible alarm, which will be detected by the attendant.									
11.0	Audible Alarm Generator ISO1 C22,23,27 CRW R27,29 Q6 BZ1	Generates an audible alarm for the duration of the delivered stimulus.	Audible alarm stuck on or off.	Open or shorted discrete component. Failed transistor.	**Present Mitigation**: In either the stuck on or off case, the attendant will notice that the alarm is malfunctioning.	1	2	1	2					
12.0	Lithium Battery Pack for the GED4	Provides power for the GED4	Excessive heat2 in the case of a defective battery pack potentially creating a fire. Improper delivered stimulus, in the case of an improperly charged battery.	Defective Battery, improperly charged battery	**Present Mitigation:** Lithium battery pack has a protective circuit provided from the manufacturer (has a 2 amp fuse).MSDS says that the cell itself is not flammable[11]. Battery compartment is vented. Using commercial charging equipment and device is not on a student when charged.	3	1	2	3	Recommending not to put the battery pack near flammable materials. Mitigation included to make risk ALARP. This issue is indicative of Lithium batteries in general.	3	1	2	3
13.0	NiNH Battery Pack for use with the GED3.	Provides power for the GED3	Improper delivered stimulus, in the case of an	Defective Battery, improperly charged battery	**Present Mitigation:** NiMH battery pack has	1	1	1	1					

[11] MATERIAL SAFETY DATA SHEET -Model Battery LG ICR18650A2 Lithium Ion, LG Chemical LTD.

			improperly charged battery. NiMH batteries are generally considered much more stable that Li-Ion.		a 2 amp fuse. The batteries themselves are quite safe and generally only provide reduced service when they see adverse conditions. Battery compartment is vented.									
14.0	Connectors HD1, TB1, HD10	For power, RF receiver and stimulus interfaces.	Incorrect or no stimulus provided.	Loose, shorted or opened connections	Loose connections from the receiver will lead to the inability to deliver stimulus. Broken power or output connections will also lead to the inability to deliver stimulus. **Present Mitigation**: The attendant will notice that stimulus is not being delivered (lack of audible or visual indication).	1	1	1	1					
15.0	Power On Reset Circuit U7	Ensures there are no inadvertent stimuli delivered upon power	Stimulus could potentially be delivered upon power-up.	IC failure.	A single inadvertent stimulus could be delivered upon power up if U7 fails. **Present Mitigation**:	2	1	1	2					

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		up.			The attendant will hear the audible alarm if an inadvertent stimulus is delivered. The device should be removed from service. Will be checked in calibration.									

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10.6 CURRICULUM VITAE

DAVID A. DURFEE Ph.D.
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SUMMARY

David A. Durfee has worked as a systems design engineer for several companies. From 1983 to 1992, he has simultaneously attended graduate school and worked as a commercial design engineer. He co-founded and is currently the President and Chief Scientist for Bay Computer Associates, Inc. a contract design firm in Cranston, Rhode Island. He is also an adjunct professor at Brown University. Commercial design interests include medical devices, embedded systems, analog electronics, and systems design.

PROFESSIONAL EXPERIENCE

BAY COMPUTER ASSOCIATES — *Providence, R.I.*
Director - Systems Engineering — *1990 to Present*
Bay Computer Associates is a contract design firm specializing in custom electronics and software. These systems include custom analog and high speed digital designs, PC based systems, and ASICs. Projects include industrial monitoring devices, patient applied medical devices, communications equipment, laboratory equipment, and consumer products as well as software oriented business/web products. At this time, the firm permanently employs 20 engineers. This position is a "hands-on" management job that requires technical engineering expertise in addition to project and business management skills. Customers range from fortune 500 companies to new startups.

BROWN UNIVERSITY
Adjunct Professor -- Electrical Engineering — *1999 - present*
Graduate course "Introduction to Data Communications and Computer Networks" as well as an innovative product design course taught on behalf of both the Rhode Island School of Design and Brown University. Also a member of the Division of Engineering's "Program in Innovation, Management, and Entrepreneurship (PRIME) faculty.

UNIVERSITY OF RHODE ISLAND
Adjunct Professor – Computer Science — *1994 -2000*
Graduate course "Introduction to Data Communications and Computer Networks"

DESIGN LAB — *Providence, R.I.*
Senior Engineer — *Jan., 1989 to Jan.,1991*
Design Lab is a contract design firm. Was responsible for dental, consumer, communications, and advertising products. Research was performed in the areas of custom LCDs, low power systems, hand held terminals, infra-red transmission/detection. Involved in all phases of embedded controller system development including design, assembly, firmware, packaging and contract manufacturing supervision. The most notable product produced during my tenure was the Bausch and Lomb Periodontal Probe.

TSS Ltd. — *Providence, R.I.*
Senior Engineer — *Dec., 1987 to Jan., 1989*
The need for a novel coupon dispensing terminal for retail stores required my involvement in all aspects of development. This includes the hardware design of a new PC based IO/thermal printer controller and controller/PC software development as well as dealing with systems design, board fabrication, mechanical design, scheduling, and vendor selection issues.

BROWN UNIVERSITY — *Providence, R.I.*
Systems Hardware Mgr. — *July, 1985 to Nov., 1987*
Senior Research Engineer — *July, 1983 to July, 1985*
Research Engineer — *Sept., 1982 to July, 1983*

Early in my tenure I performed the duties of facilities administrator for the computer and graphics systems for Brown's Computer Science Department. These duties included the creation of the Foxboro Educational Laboratory, the first computerized educational facility of its kind. Later work for Brown included the supervision of the maintenance of all of the electronic and computing equipment owned by the Dept. of Computer Science.

In addition to the maintenance and management tasks I designed and developed custom electronic hardware. Firmware I wrote for graphics editing was used by both the Brown and MIT Graphics Labs. Software systems programming tasks included work on VAX, Sun and Apollo computers under the UNIX operating system. TCP/IP interface code which I co-wrote was incorporated in an Apollo computer OS release.

CODEX CORPORATION — Mansfield, MA
Engineer — *Feb., 1981 to Aug., 1982*
Associate Engineer — *July, 1980 to Feb., 1981*

Performed duties of both a hardware and software engineer for this leader in data communications. Participated in all phases of research and development of state of the art network products.

EDUCATION

BROWN UNIVERSITY
Ph.D. for studies in EE/CS. — *1985 to 1992*

Research oriented towards the use of VLSI circuits for the implementation of neural networks and in the use of Fowler-Nordheim tunneling for analog storage.

Research in VLSI and computer architecture — *1987 Sc.M. - Computer Science*

Masters research involved the design of a VLSI based coprocessor system used to solve a subset of partial differential equations. This work required knowledge in computer architectures well suited for VLSI implementations and methodologies for design and simulation of integrated circuits.

Magna Cum Laude graduate — *1980 Sc.B. - Electrical Engineering*

NORTHEASTERN UNIVERSITY
Attended graduate courses in electrical engineering. — *1980 - 1981*

OTHER EXPERIENCE

DURFEE HARDWARE, INC., Cranston, RI. — *1976 to Present*
On the board of directors for this family owned business employing over twenty persons.

STANLEY DAVIES ELECTRIC,*Cranston, R.I.* — *1976 to 1980*
Formerly a licensed Journeyman Electrician and licensed Alarm Agent in the State of Rhode Island.

HONORS AND MEMBERSHIPS

Member IEEE
Secretary of the Rhode Island Technology Council – 1998
Treasurer of the Rhode Island Technology Council -- 1999

GRANTS

1. "Toys and Technologies for Rehabilitation.", Rhode Island Science And Technology Council (STAC) PI: Crisco J, Co-investigators: Kerman K, D'Andrea S, Nichols K, Durfee D. ($199,967). 01/01/07 – 12/31/07
2. "Launching Rhode Island as the R & D Nexus for Next Generation Hearing Devices", Rhode Island Science And Technology Council (STAC) PI: Bradford K, Co-investigators: Heller L, Durfee D. ($200,000). 01/01/08 – 12/31/08

PUBLICATIONS

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David A. Durfee, "Review of A Neural Chip Based on Pulse-frequency Activation", Neural Network Review, Lawrence Erlbaum Associates, no. 4, vol. 3, 1989
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David A. Durfee and F. S. Shoucair, "Low Programming Voltage Floating Gate Analog Memory Cells in Standard VLSI CMOS Technology", Electronics Letters, no. 9, April 1992

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