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RSPA-04-19296-1

13960-1
2004100025

DOT/RSPA/OHMS
UNIT

04 SEP -7 AM 11: 14

Exemption Request

for

**Lithium Ion Battery,
Contained in Equipment**

04 OCT -4 PM 12: 25

DEPT OF TRANSPORTATION

== 49 CFR §173.185 ==

Terumo Heart, Inc.

August 31, 2004

Terumo Heart, Inc.

6180 Jackson Road, Ann Arbor, MI 48103, U.S.A.



Fax Transmittal

Date: 10/1/04

To: Ms. Sandra Cureton, D.O. Fax Number: 202-366-3308

From: Kay Fuller Regulatory Affair Department
RA Manager

Re: Exemption Request Signatures

Total Pages 2

Dear Sandra,

Thank you for your call this morning. Per your request I'm providing a signed Exemption Request via this fax (pg 2).

Please let me know if I can be of further assistance to you.

Regards,
Kay Fuller

Terumo Heart, Inc.

TERUMO HEART, INC.
 6180 JACKSON ROAD, ANN ARBOR, MI 48103-8300, U.S.A.
 PHONE: (734) 741-6213 TOLL FREE: (800) 292-3304



August 31, 2004

Associate Administrator for Hazardous Materials Safety,
 Research and Special Programs Administration,
 U.S. Department of Transportation
 400 7th Street, SW
 Washington, DC 20590-0001

Attn.: Exemptions, DHM-31

INTRODUCTION

The subject of this exemption request application is the lithium ion battery module contained in a Hospital Console, one component of a prototype critical life support medical device known as the DuraHeart™ Implantable Left Ventricular Assist System (LVAS), manufactured by Terumo Heart, Inc. Due to the prototype status, production of the subject lithium ion battery module runs consisting of not more than 100 lithium cells and batteries¹.

Terumo Heart, Inc. is a wholly owned subsidiary of Terumo Corporation (a leading developer, manufacturer and global marketer of a wide array of medical products) with headquarters and manufacturing facilities in Ann Arbor, Michigan. The company develops and manufactures products to improve the quality of healthcare for heart failure patients.

To support market release of the DuraHeart™ LVAS, Terumo Heart plans to conduct clinical studies in Europe and the US during the coming two years. Terumo Heart respectfully submits this exemption request in order to enable the shipment of the Hospital Console prior to conducting UN T1-T8 testing on the lithium ion battery module². Your consideration and decision on granting such an exemption would be greatly appreciated.

1. **Applicant**

Name: Terumo Heart, Inc.
 Address: 6180 Jackson Road
 Ann Arbor, MI 48103
 Contact: Jun Chen, Regulatory Affairs Specialist (Tel. 734-741-6377)
 Kay Fuller, Regulatory Affairs Manager (Tel. 734-741-6221)

¹ White Paper "Overview of Lithium Transportation Regulations, as of April 2004" issued by Panasonic Industrial Company, Page 9, "Prototype: Lithium and Lithium Ion Transport Concerns – UN Model Regulations Special Provision 310".

² 49 CFR 107.105, "Hazardous Materials Program – Application for Exemption".

Terumo Heart, Inc.

TERUMO HEART, INC.

6180 JACKSON ROAD, ANN ARBOR, MI 48103-9300, U.S.A.

PHONE: (734) 741-6213 TOLL FREE: (800) 262-3304



August 31, 2004

Associate Administrator for Hazardous Materials Safety,
Research and Special Programs Administration,
U.S. Department of Transportation
400 7th Street, SW
Washington, DC 20590-0001

Attn.: Exemptions, DHM-31

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DOT/RSPA/OHMS
INIT

INTRODUCTION

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1. Applicant

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² 49 CFR 107.105, "Hazardous Materials Program – Application for Exemption".

2. **Date of application**

August 31, 2004

3. **Citation of the specific regulation from which the applicant seeks relief**

49 CFR §173.185

(c) Cells and batteries also are not subject to this subchapter if they meet the following requirements:

(3) Each cell or battery is of the type proven to be non-dangerous by testing in accordance with tests in the UN Manual of Tests and Criteria, such testing must be carried out on each type prior to the initial transport of that type

4. **Specification of the proposed modes of transportation**

Cargo aircraft and public highway.

5. **Detailed description of the proposed exemption**

5.1 Exemption Proposal

In this request, we are proposing an exemption to the requirement of testing the Lithium Ion Battery Module contained in a prototype medical device, known as the DuraHeart™ Left Ventricular Assist System, in accordance with the UN Manual of Tests and Criteria, prior to shipment.

Although the subject battery module is pending for UN testing T1~T8 (Table I, below), as part of DuraHeart™ LVAS pre-manufacturing studies, various testing has been performed on the battery module contained in the Hospital Console. Many of these tests are similar to the UN test criteria (see Table II for comparison).

Terumo Heart has also conducted additional tests to further verify the safety and stability of the entire Hospital Console including its internal battery module in terms of storing, handling, and distribution (see Table III).

Table I: UN Testing

Test Ref.#	Description
Test T1	Altitude Simulation
Test T2	Thermal Test
Test T3	Vibration
Test T4	Shock
Test T5	External Short Circuit
Test T6	Impact
Test T7	Overcharge
Test T8	Forced Discharge

Table II: Comparison of UN Tests and Similar Tests Performed on Subject Battery Module

UN Tests	Similar Tests performed on the Battery Module contained in DuraHeart™ LVAS	Results
T1 – Altitude Simulation	Altitude Test under US Standard Atmosphere, 1962-National Aeronautics and Space Administration	Pass
T2 – Thermal Test	i) Temperature and Relative Humidity Test (Operating-Battery not charging) Ref. EN45502; DVT (Design Verification Test) §7.5 ii) Temperature and Relative Humidity Test (Operating-Battery charging) , Ref. EN 45502; DVT §7.6 iii) Temperature and Relative Humidity Test (Non-Operating) , Ref. EN 45502; DVT §7.7	Pass
T3 – Vibration	i) Mechanical Vibration -Random Test per AAMI TIR26:2000 & MIL-STD-810E, DVT §7.4 ii) Random Vibration Test per AAMI TIR26:2000 & MIL-STD-810E, DVT §7.16 iii) Vehicle Vibration Test Assurance Level II per ASTM D 4728 – Schedule E, DVT §7.21 iv) Loose Vibration Test Assurance Level II per ASTM D 999 – Schedule F, DVT §7.20	Pass
T4 – Shock	i) Operational Drop/Shock Test , per IEC-601, DVT §7.2 ii) Non-Operational Drop/Shock Test , per IEC-601, DVT §7.3	Pass
T5 – External Short Circuit	Baseline Safety Test , Per IEC60601-1, DVT §3.1~3.7 <ul style="list-style-type: none"> • Dielectric Strength AC Mains to Ground • Dielectric Strength AC Mains to Enclosure • Dielectric Strength AC mains to Secondary • Leakage Current - Earth • Leakage Current – Enclosure to Ground • Leakage Current – Enclosure with Mains on SIP/SOP • Earthing & Potential Equalization Test 	Pass
T6 – Impact	Impact Test , per UL 2601, Sub-Clause 55 (C10), DVT §8.7	Pass
T7 – Overcharge T8 – Forced Discharge	Internal Battery Charging Environment Tests Per ISO 9002 & ISO 14001; ECT (Engineer Confidence Testing) No. 934409-16 ~ 914409-20 <ul style="list-style-type: none"> • Battery Module Protection Test - Primary low voltage cutoff circuitry in pack • Battery Module Protection Test - Overcharging due to excessive voltage applied by the charger • Battery Module Protection Test - Excessive discharge current • Battery Module Protection Test - Over-discharge due to low voltage • Battery Module Protection Test – Over-current due to short circuit or overcharging • Battery Module Protection Test - Over current protection on each battery cell • Battery Module Protection Test – Thermal cutout fuse • Battery Module Protection Test - Over/Under temperature during charging • Battery Module Protection Test – Over current on charger 	Pass

Table III: Additional Tests Performed on Subject Battery Module

Description of the Additional Tests	Results
Shipping & Handling Test (Non-Operational) Assurance Level II per ASTM D 4169-99, DVT §7.17	Pass
Manual Handling Test Assurance Level II per ASTM D 5276 – Schedule A, DVT §7.18 & §7.22	Pass
Vehicle Stacking Test, Assurance Level II per ASTM D 642–Schedule C, DVT §7.19	Pass
Stability and Transportability Test per IEC 601-1, Sub-Clause 24 (C13), DVT §8.6	Pass
Temperature Normal Load Test per IEC 601-1, Sub-Clause 42, DVT §8.22	Pass
Internal Battery Power Test DVT §6.3	Pass
Internal Battery Charging Environment Test DVT §6.4	Pass
Dynamics Test per IEC 60068-2-64	Pass
Distribution Simulation Testing per ASTM D 4169, Assurance Level II	Pass

In summary, Terumo Heart is submitting this request to receive a grant of exemption to the testing required in 49 CFR §173.185 (c)(3), which requires passing UN T1-T8 testing prior to the initial transport of Class 9 lithium ion batteries – in order to conduct DuraHeart™ LVAS clinical studies. The results of the above noted globally recognized testing has provided a reasonable degree of assurance that the Lithium Ion Battery Module used in the DuraHeart™ Hospital Console can be safely transported via air cargo and public highway.

Further, the lithium ion rechargeable cell, Model 18650, the key component of the Hospital Console internal battery module, was UL approved in 1999. Presented in Attachment-1 is the relevant notice of authorization to apply the UL mark along with the test record summary.

5.2 Description of the Subject Lithium Ion Battery, and the Equipment It's Contained In

The Terumo DuraHeart™ LVAS is a third-generation Left Ventricular Assist System engineered to overcome shortcomings of current and previously released implantable circulatory assist devices. DuraHeart™ LVAS is designed to minimize friction between moving parts using magnetic levitation to suspend and rotate the pump's impeller. With no drive shaft to create heat and damage blood cells, Terumo Heart anticipates improved device durability and patient outcomes. The main components of DuraHeart™ LVAS are: the Pump, Inflow and Outflow Conduits, Apical Cuff, Controller, Hospital Console,

Battery¹, Charger and Surgical Tools.

The Lithium Ion Battery Module is contained within the Hospital Console and is the subject of this exemption request. The Hospital Console is a special computer system that connects to the DuraHeart Controller in the hospital setting. It is used to set up, adjust, monitor, and troubleshoot the implantable DuraHeart system. Its internal battery module is utilized as a backup power source for this critical life support device. In the event of an AC power failure or, when transporting a patient within the hospital, the internal battery module can supply power to the DuraHeart system for approximately 1 hour. This battery module consists of two battery packs and one charger PCBA (printed circuit board assembly) housed in a metal enclosure. Details about the battery module and battery pack are presented below, respectively.

Battery Module:

- Operation/Storage Environmental Parameters
- Labeling includes following:
 - A) Serial Number
 - B) Lithium Ion Cells
 - C) Current Rating
 - D) Capacity Rating
 - E) Voltage Rating
- Electrical test data sheets and certificate of compliance are required for each console battery module.
- Shipped Module State Requirements: Module to be shipped in partially charged state, in “Hibernate” and “Sleep” mode.
- Package to prevent damage and ensure safety during shipping & handling: Refer to below **Section 9**.
- Drawing, Ref. #802736, *Attachment-2*

Battery Pack (Quantity of 2):

- General Requirements:
 - A) Chemistry: Lithium Ion
 - B) Pack Size: 16 cells of 18650 Package (18mm D x 65mm L Nominal)
 - C) Charging Method: Constant Current, Constant Voltage.
- Safety Monitoring/Gas Gauging:
 - A) Appropriate protection is provided against over-charge, over-discharge, and over-current.
 - B) A momentary button initiates sleep mode. Sleep mode is terminated by connecting the battery module to a 24VDC charger
 - C) Hibernate mode will be initiated via the SMBUS. Hibernate mode is terminated by depressing a momentary switch. An LED will light confirm hibernation mode termination

¹ Specification of the DuraHeart™ external Battery differs from that of the internal battery module of the Hospital Console. The equivalent lithium content of the external Battery is 0.66 gram per cell and 5.28 grams per battery. Terumo Heart is arranging the UN T1-T8 testing to be performed on this external Battery. In view of this, the DuraHeart™ external Battery is excepted from regulations.

- Serial number is assigned to each battery pack and stored in the gas gauge IC. Valid range 0-65535.
- Components are derated.

6. **Specification of the proposed duration for which the exemption is sought**

As aforementioned in the introduction, the clinical studies are scheduled to be conducted during a period of two years; therefore, we request the exemption to be granted for the same length of time. The total quantity of Hospital Consoles to be transported during the two years would be limited to approximately 80 units.

7. **Statement outlining the basis for seeking the exemption**

Basis of this application is mainly rooted on 49 CFR §173.185 - Lithium Batteries and Cells, Item (c), which states "*Cells and batteries also are not subject to this subchapter if they meet the following requirements:*

- (1) *Each cell contains not more than 5 g of lithium or lithium alloy;*
- (2) *Each battery contains not more than 25 g of lithium or lithium alloy;*
- (3) *Each cell or battery is of the type proven to be non-dangerous by testing in accordance with tests in the UN Manual of Tests and Criteria, such testing must be carried out on each type prior to the initial transport of that type; and*
- (4) *Cells and batteries are designed or packed in such a way as to prevent short circuits under conditions normally encountered in transportation.*

- The cell that built up the subject battery module of this application contains 0.66g of lithium ($22\text{Ah} \times 0.3 = 0.66\text{g}^1$), which is much less than 5g as required in 49 CFR §173.185 (c)(1);
- The total lithium content for the entire battery module is 21.12g ($0.66\text{g} \times 16 \text{ Cells} \times 2 \text{ Packs} = 21.12\text{g}$), which is less than 25g as described in 49 CFR §173.185 (c)(2).
- The battery module is a backup power source for the Hospital Console, a component of the DuraHeart™ LVAS device. The battery module is packaged in a metal housing and further contained within the metal Hospital Console case. This dual metal container/package configuration was designed to prevent short circuits and damage to the battery module during transport. (49 CFR §173.185(c)(4))

Therefore, the only regulation we are seeking exemption from is 49 CFR §173.185 (c)(3).

As noted previously in Table III of Section 5.1, the subject battery module has undergone and passed similar and additional shipping safety tests. All packaging, labeling and marking for future shipments will be strictly in compliance with the regulation concerning Class 9 hazardous material (see **Section 9**).

¹ White Paper issued by Ultralife Batteries, Inc. dated December 18, 2003, "Transportation Regulations for Lithium, Lithium Ion and Polymer Cells and Batteries. Page 1 of 8, "Equivalent lithium content for lithium ion and lithium polymer cells and batteries in grams on a per cell basis is calculated as 0.3 times the rated capacity in ampere-hours."

Also, Terumo Heart plans to conduct the UN Tests on the Hospital Console internal battery module, in parallel with this exemption request. The plan includes the communication with the UN testing house, and scheduling the manufacturing of the Hospital Console internal battery modules for the quantity required for UN T1-T8 tests.

8. **Identification and description of the hazardous materials planned for transportation under the exemption**¹

Hazardous Material Description and Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Lithium batteries, contained in equipment	9	UN3091	II

9. **Description of each packaging, including specification to be used in conjunction with the requested exemption**

Terumo Heart has the following packaging related items planned for shipping the DuraHeart™ Hospital Console, once this exemption request is granted and received:

9.1 Packaging – Will use only packaging that meets “Packing Group II” performance standards, and not exceeding 35 kg (for the internal battery module) in gross weight for cargo aircraft per shipment. In specific, there will be a total of five layers of packaging (from the inner to the outer) for the subject lithium ion battery module:

- Metal Enclosure No.1 (the two battery packs are housed in a case made of Aluminum 6061-T6), see Drawing #809543 in Attachment-3.
- Metal Enclosure No.2 (The housed battery module is then stalled inside of the console, of which the outer shell is made of metal); Refer to Sheet 1 of 6 of Drawing #802734, Attachment-4.
- Anti-static Polyethylene Bag (Place the console in the plastic bag, seal and fold bag to fit the unit and fasten using clear adhesive tape before placing in foam set); Refer to Sheet 5 of 6 of Drawing #802734, Attachment-5.
- T-48 Double Wall Cardboard Inner Box (Then, the console will be placed in this inner box); Refer to drawing #808355 & #808358, Attachment-6.
- T-44 Single Wall Cardboard Outer Box (Lastly, the whole inner box to be packed in the outer box); Refer to Drawing #808356, Attachment-7.

9.2 Marking – The following markings will be applied to the packaging (see draft in Attachment-8):

- Shipping name: *Lithium Batteries, contained in equipment*
- Identification number: *UN 3091*
- Weight of package: *Weight of Hospital Console (including Internal Battery Module)*

¹ 49 CFR §172.101 “Purpose and Use of Hazardous Materials Table”

- Shippers name and address: *Terumo Heart, Inc. (6180 Jackson Road, Ann Arbor, MI 48103, USA)*
- Name and address of the consignee (varies per clinical study site)



9.3 Labeling – The following Class 9 label will be used:

9.4 Shipping Papers – The following information will be included on shipping papers:

- Proper shipping name, hazard class, identification number, and packing group in the following order: *Lithium batteries contained in equipment, 9, UN3901, PG II)*
- Number of and type of packages
- Weight
- Page number and total number of pages
- Emergency telephone number: 800-262-3304
- Shipper's certification: See draft in Attachment-9.
- Signature of shipper

In case of shipping by air, the following additional information would be added to the shipping papers:

- Air Waybill Number
- Indication of "Cargo Aircraft Only"
- Airport of Departure
- Airport of Destination
- Shipment Type: *Non-radioactive*
- Place and date of signing of shippers certification

10. **Justification of exemption proposal**

As mentioned earlier in this application, the subject battery module is used as a back-up power source for the Hospital Console of the prototype life-saving device known as the DuraHeart™ Left Ventricular Assist System. The innovation and improvements that Terumo Heart has with the DuraHeart™ LVAS is opening a brand new page of the history for this type of device, such that we truly believe the benefit of introducing the DuraHeart™ LVAS to heart failure patients much outweighs the risk of shipping the subject battery module prior to finalizing the UN tests.

Terumo Heart is not aware of any incident concerning shipping the subject battery module. The subject battery module is made of ICR 18650 Lithium Ion Rechargeable Batteries, a model that has been well validated as a model that can be safely transported via air cargo and public highway. The Material Safety Data Sheet (MSDS) for ICR 18650 is presented in Attachment-10.

Terumo Heart does not anticipate increased risk to safety or property that may result if the exemption is granted. As previously mentioned in **Section 5.1**, although the subject battery module is pending testing in accordance with the UN tests T1 ~ T8, as part of pre-manufacturing testing for the DuraHeart™ LVAS, various tests have been performed on the battery module contained in the Hospital Console. The acceptable test results have indicated a reasonable degree of assurance that this battery module can safely withstand the conditions normally encountered during air cargo and public highway transport.

CONCLUSION

As the quality policy of Terumo Heart states, “We strive to provide products for end-state heart failure patients including circulatory support products that are safe and effective, meet all government regulations and applicable standards, and fully satisfy the needs of the customer.”

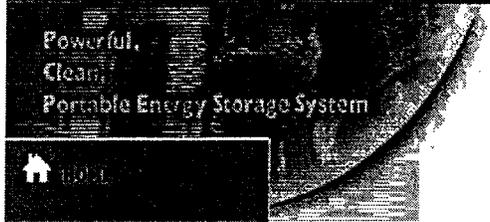
Being a medical device developer and manufacturer, Terumo Heart believes it has a duty to introduce devices that help improving the quality of patient’s life, and is confident that DuraHeart™ Left Ventricular System will become one of these devices. Terumo Heart plans to conduct clinical studies to support its market release. Due to the existence of lithium ion battery within one of the system components, Terumo Heart considers the relevant transportation safety issue as an important aspect, and hence is submitting this exemption request to be in compliance with the specific regulations. Your granting this request would enable Terumo Heart to contribute to relieving the suffering for patients with heart failure worldwide. Therefore, in advance we hereby express our sincere gratitude for your review and consideration of this exemption request.

~ End ~

Attachment

1

Clean & Green Energy



News >>>

UL approved LG Chem's Battery.
1999-08-26 2:57PM from 150.150.120.14
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UL(Underwriters Laboratory) approved LG Chem's Lithium Batteries.
- 1400mAh,1600mAh and 1800mAh for cylindrical 18650 model and 1300mAh for prismatic 103448 model.



MH19896, 99SC45899

June 16, 1999

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Ultrad... County, CA 95001
4150 385-3000
FAX No. 415 385-3255
ul@ul.com

LG Chemical Ltd.
Taejeon, KOREA

Fax No: 82-42-863-2934

Attention:

Reference: Project 99SC45899

Subject: Addition of New Lithium Battery Model ICR13650-W1

Dear Mr. Kim:

NOTICE OF AUTHORIZATION TO APPLY THE UL MARK

We have completed our engineering investigation under the above project number and find the product complies with the applicable requirements.

This letter temporarily supplements the UL Follow-Up Services Inspection Procedure and serves as authorization to apply the UL Recognized Marking to the above product which is constructed as described below:

Identical to Model ICR13650-W1, which was submitted to UL for this investigation. The UL records covering the product will be in the Follow-Up Services Inspection Procedure, File MH19896, Volume 1.

Model ICR13650-W1 is Recognized as User-Replaceable with a maximum charging current of 1800 mA.

To provide the manufacturer with the intended authorization to use the UL Mark, the addressee must send a copy of this Notice and all attached material to each manufacturing location.

This authorization is effective for 90 days only from the date of this Notice. Records covering the product are now being prepared and will be sent to you in the near future.

Products produced which bear the UL Mark shall be identical to those which were evaluated by UL and found to comply with UL's requirements. If changes in construction are discovered, authorization to use the UL Mark may be withdrawn and products that bear the UL Mark may have to be revised (in the field or at the manufacturer's facility) to bring them into compliance with UL's requirements.

Very truly yours,

Andrea Cote
ANDREA COTE (Ext. 32940)
Engineering Group Leader
Engineering Services
Section 315T

Reviewed by:

John Marke
JOHN MARKE (Ext. 33120)
Associate Project Engineer
Engineering Services
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UL Underwriters Laboratories Inc. ©

MB19896,99SC44581

July 15, 1999

LG Chemical Co., Ltd.
Taejeon, KOREA

Fax No.: 082-042-863-2934

Attention: [Redacted]

Reference: Project 99SC44581

Subject: Addition of New Lithium Prismatic Cell, Model ICP103448

Dear Mr. Kang:

NOTICE OF AUTHORIZATION TO APPLY THE UL MARK

We have completed our engineering investigation under the above project number and find the product complies with the applicable requirements.

This letter temporarily supplements the UL Follow-Up Services Inspection Procedure and serves as authorization to apply the UL Recognized Marking to the above product which is constructed as described below:

Identical to ICP103448, which was submitted to UL for this investigation. The UL records covering the product will be in the Follow-Up Services Inspection Procedure, File MB19896, Volume 1.

Prismatic Cell Model ICP103448, similar in chemistry to Model ICR18650, is
Recognized as User-Replaceable with a capacity of 1300 mAh.

To provide the manufacturer with the intended authorization to use the UL Mark, the addressee must send a copy of this Notice and all attached material to each manufacturing location.

This authorization is effective for 90 days only from the date of this Notice. Records covering the product are now being prepared and will be sent to you in the near future.

Products produced which bear the UL Mark shall be identical to those which were evaluated by UL and found to comply with UL's requirements. If changes in construction are discovered, authorization to use the UL Mark may be withdrawn and products that bear the UL Mark may have to be revised (in the field or at the manufacturer's facility) to bring them into compliance with UL's requirements.

Very truly yours,
Andrea Bote

Reviewed by:
[Signature]

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MS. JIYOUNG KWANG
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Date: 05/25/2000
Subscriber: 128389009
File No: M09896
Project No: 003E04198
ID No: 00012653
Type: R
PO Number:

Subject: Procedure and/or Report Material

The following material resulting from the investigation under the above numbers is enclosed.

Issue Date	Vol.	Sec.	Page(s)	Revised Date
3/15/99	1	1	Initial Description Material 1, 5, 6A	5/15/00
3/15/99	1	1	See Illustrations 7 and 8	5/15/00
3/15/99	1	1	See Test Record 7	5/15/00

Please file revised pages and illustrations in place of material of like identity. New material should be filed in its proper numerical order.

NOTE: Follow-Up Service Procedure revisions DO NOT include Cover Pages, Test Records and Conclusion Pages. Report revisions DO NOT include Authorization Pages, Indices, Section General Pages and Appendices.

Please review this material and report any inaccuracies to SRIKANT PPM/PA (EXT. 31334), referring to the above Project and/or PO Numbers.

c:SC file:

A not-for-profit organization
dedicated to public safety and
committed to quality service.

Test Record Summary:

The results of this investigation indicate that the sample(s) evaluated comply with the applicable requirements, and therefore, such products are judged eligible to bear UL's Mark as described on the Conclusion Page of this Report.

Test Record by:

Srikant Mantha
Engineer
Conformity Assessment Services

Reviewed by:

Peter Devesco
Associate Project Engineer
Conformity Assessment Services

Andres Cote
Staff Engineer
Conformity Assessment Services

DESCRIPTION

PRODUCT COVERED:

Lithium ion rechargeable cells, Models ICR18650-W1, ICP103448, and ICP863448, ICP633048, and ICP633065.

GENERAL DESCRIPTION:

Model ICR18650-W1 is a cylindrical cell having a core consisting of a graphite carbon anode, a polyethylene sheet separator, a lithium cobalt oxide cathode, and an electrolyte containing lithium hexafluorophosphate. The components are contained in a nickel-plated steel casing with a safety vent in the cap. No Current-Interruptible Protector (CIP) provided.

Models ICP103448 and ICP863448 are prismatic cells having a core consisting of a graphite carbon anode, a polyethylene sheet separator, a lithium cobalt oxide cathode, and an electrolyte containing lithium hexafluorophosphate. The components are contained in an aluminum alloy casing with a safety vent in the cap. These batteries also contain an external PTC, Raychem Type VTP2103.

Models ICP863448, ICP633048, and ICP633065 are identical to ICP103448, except for capacity and cell casing thickness.

ENGINEERING CONSIDERATIONS (NOT FOR FIELD REPRESENTATIVE'S USE):

Use - For use only in products where the acceptability of the combination is determined by Underwriters Laboratories, Inc.

Conditions of Acceptability - The use of these cells may be considered generally acceptable under the conditions given below:

1. The cells are identified in accordance with "Marking" as described below.
2. Unless the conditions of Par. 2A are met, these batteries are to be used only in devices where servicing of the battery circuit and replacement of the lithium battery will be done by a trained technician.
- 2A. The cell Models ICR18650-W1, ICP633048, ICP633065, ICP103448, and ICP863448, are acceptable for use in user-replaceable applications when used in accordance with the following:
 - 2A.1 The end product must be designed to prevent reverse polarity installation of the cell, or if the cell is reversed, the short- or open-circuiting of any protective component, one component at a time, shall not result in forced-discharge of the cell.

- 2A.2 The end-product shall contain a permanent marking adjacent to the cell stating the following:

"Replace Cell With (Cell Manufacturer's Name or End-Product Manufacturer's Name), Part No. () Only. Use Of Another Cell May Present A Risk Of Fire Or Explosion. See Owner's Manual For Safety Instructions."

If it is not feasible to include the above marking on the device, the marking may be included in the operating (or safety) instructions providing the cell compartment is marked with the following: "See operating (or safety) instructions for type of cell to be used."

- 2A.3 The instruction manual supplied with the end product shall also contain the above warning notice along with instructions to the user as to where replacement cell can be obtained. The instruction manual shall also contain the following additional warning notice and information:

- A. CAUTION. The cells used in this device may present fire or chemical burn hazard if misreated. Do not disassemble, heat above 100°C (212°F) or incinerate.
- B. Complete instructions as to how to replace the cell ending with the statement:

"Dispose of used cell promptly. Keep away from children."

3. The cells are intended for use at ordinary temperatures where anticipated high temperature excursions are not expected to exceed 100°C (212°F).

4. The cells are rechargeable. The circuits for these cells shall be designed such that the shorting or opening of any protective component, one component at a time, shall not result in a charging current in excess of the value shown below:

Cells Model	Maximum Charging Current, mA
ICR18650-W1	1800
ICP103448	1350
ICP383448	1000
ICP633048	700
ICP633065	1000

5. The storage, handling and disposal of these cells should be in accordance with the "Warning Notice" described below.

TEST RECORD NO. 7

In order to evaluate new user Rechargeable, Rechargeable Lithium Ion Battery Models ICP633048 and ICP633065, the following tests were conducted. Unless otherwise stated, the as received samples were fully charged.

For the purpose of testing, existing Recognition of lithium ion battery Model ICP863749 was considered representative of the Short Circuit, Abnormal Charge, Crush, Impact, Shock, Vibration and Heating tests for Model ICP633065 and of the Shock and Vibration Tests for Model ICP633048.

Test results relate only to the items tested.

TEST METHODS:

Unless otherwise stated the following tests were conducted in accordance with the standard for Lithium Batteries, UL 1642, Third Edition, Model ICP633048.

Test	Test Condition	Number of Samples Tested
Short Circuit (at Room Temp)	As Received, Fully Charged	5
Short Circuit (at 60°C)	As Received, Fully Charged	5
Abnormal Charging	As Received, Fully Charged	5
Crush	As Received, Fully Charged	5
Impact	As Received, Fully Charged	5
Heating	As Received, Fully Charged	5
Flaming Particles	As Received, Fully Charged	5
Projectile	As Received, Fully Charged	5

Model ICP633065

Test	Test Condition	Number of Samples Tested
Flaming Particles	As Received, Fully Charged	5
Projectile	As Received, Fully Charged	5

SHORT CIRCUIT TESTS:**SAMPLES**

Lithium Ion Battery Model ICP633048

METHOD

The samples were short-circuited by connecting the positive and negative terminals of the battery with a short length of copper wire. The temperature on the exterior surface of the metal cell casing was monitored during the test by means of a thermocouple.

Short Circuit Tests were conducted on cells at room temperature and on cells at 60°C (140°F). The tests at 60°C (140°F) were conducted in an air convection oven. The cells were allowed to come to equilibrium at this temperature before they were shorted. After the tests, the cells were examined for any signs of change.

RESULTS

Room Temperature				
Sample	Condition	Voltage (V)	Max Temp. (°C)	Comments
1	A	3.73	42	1
2	A	3.71	37	1
3	A	3.73	43	1
4	A	3.73	42	1
5	A	3.73	40	1

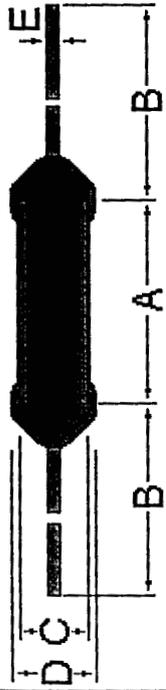
60°C				
Sample	Condition	Voltage (V)	Max Temp. (°C)	Comments
1	A	3.73	73	1
2	A	3.73	66	1
3	A	3.71	74	1
4	A	3.73	75	1
5	A	3.73	74	1

- 1 -Condition: (A) Fresh,
(B) At room temperature, one half discharge,
(C) At room temperature, completely discharged,
(D) Charge-discharge cycled at room temperature.

- 2 -Comments: (1) Sample remained intact,
(2) Sample bulged,
(3) Sample vented,
(4) Sample opened and leaked electrolyte,
(5) Sample exploded,
(6) Sample caught on fire.

SC015

Dimensions (mm)	(A)	(B)	(C)	(D)	(E)
Regular	11.5 ± 0.5	37 ± 3	3.3 ± 0.2	3.6 or Below	1.0 ± 0.05
Long	11.5 ± 0.5	67 ± 3	3.3 ± 0.2	3.6 or Below	1.0 ± 0.05

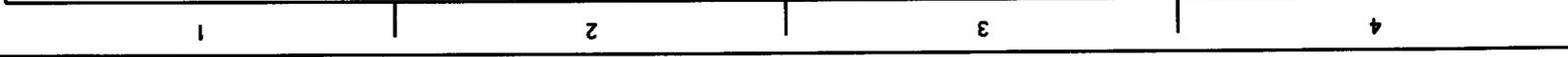
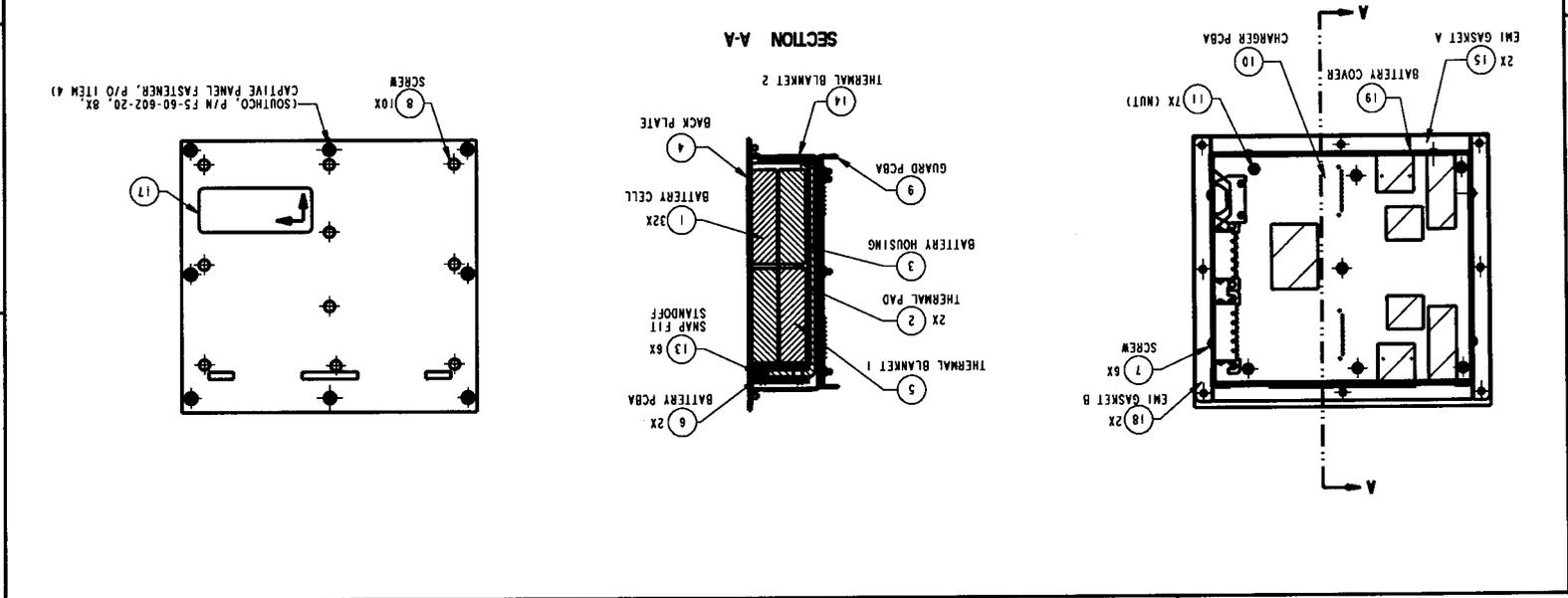


Attachment

2

ITEM	QTY	DESCRIPTION	ITEM	QTY	DESCRIPTION
1	1	480-0029-01	19	1	480-0020-01
2	2	420-0017-01	2	2	401-0023-01
3	1	480-0021-01	3	1	401-0024-01
4	1	480-0019-01	4	1	401-0025-01
5	1	401-0025-01	5	2	401-0024-01
6	2	750-0218-01	6	1	401-0026-01
7	6	420-0016-01	7	1	431-1001-01
8	10	420-0017-01	8	1	400-0007-01
9	1	480-0029-01	9	1	452-0008-01
10	1	480-0029-01	10	1	750-0220-01
11	32	370-0015-02	11	1	480-0020-01
12	2	401-0021-01	12	1	480-0020-01
13	3	480-0021-01	13	1	480-0020-01
14	1	480-0019-01	14	1	480-0020-01
15	1	401-0025-01	15	1	480-0020-01
16	2	750-0218-01	16	1	480-0020-01
17	6	420-0016-01	17	1	480-0020-01
18	10	420-0017-01	18	1	480-0020-01
19	1	480-0029-01	19	1	480-0020-01

THIS DOCUMENT CONTAINS INFORMATION THAT IS UNCLASSIFIED EXCEPT WHERE SHOWN OTHERWISE. IT IS THE POLICY OF THE DEPARTMENT OF DEFENSE TO RELEASE THIS INFORMATION TO THE PUBLIC AS SOON AS IS REASONABLY PRACTICABLE.



DO NOT SCALE DRAWING
DIMENSIONS ARE IN INCHES
UNLESS OTHERWISE SPECIFIED

THE POWER ELECTRIC, INC.
Ann Arbor, Michigan, USA

ITEM NO. 78422
P/N PLEXUS
958951

TITLE: BATTERY PACK ASSEMBLY II, CONSOLE A

PART NO. 802736
REV. C

802736
2 OF 2

DWG. SCALE: 0.5X SHEET
THIRD ANGLE PROJECTION

Attachment

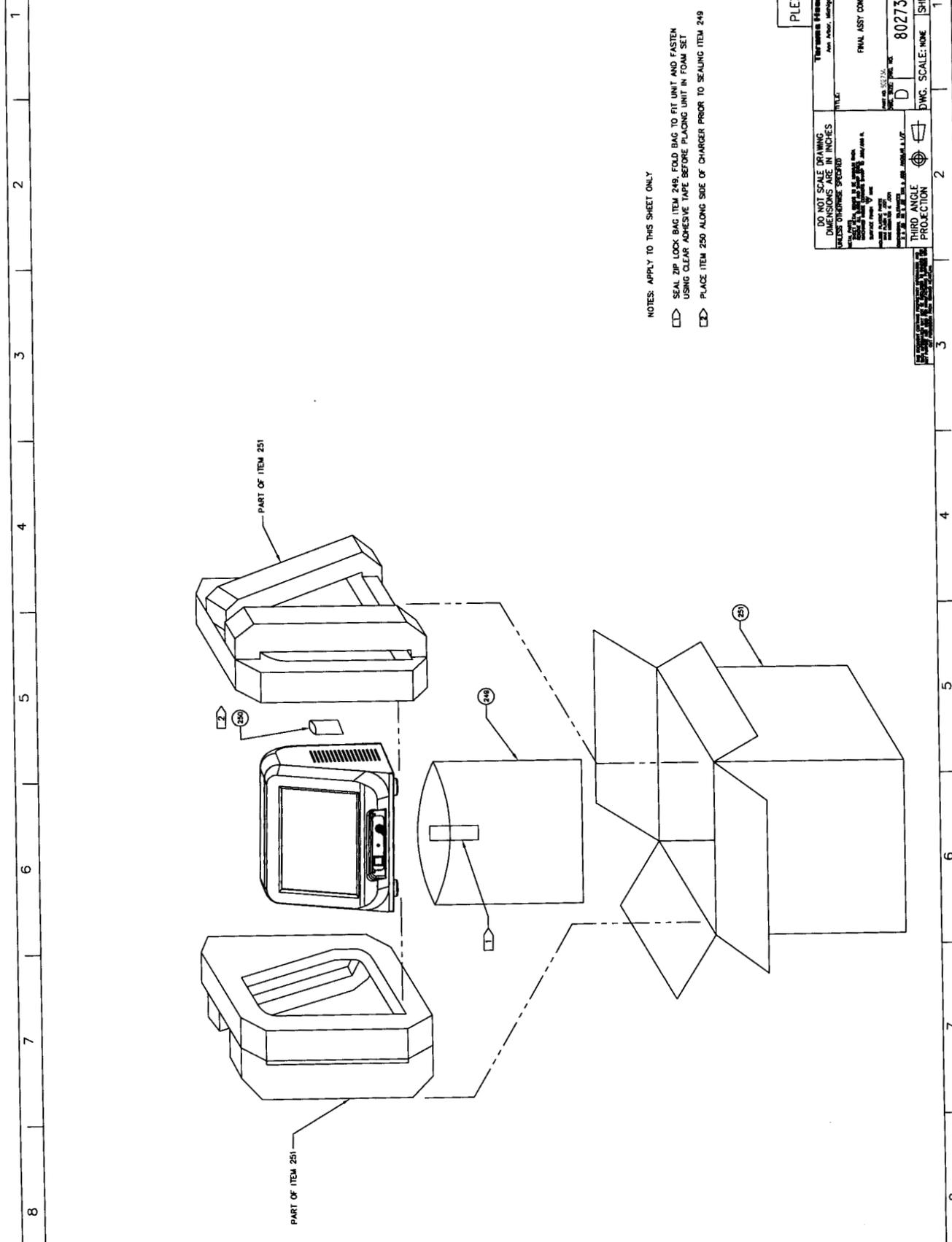
3

Attachment

4

Attachment

5



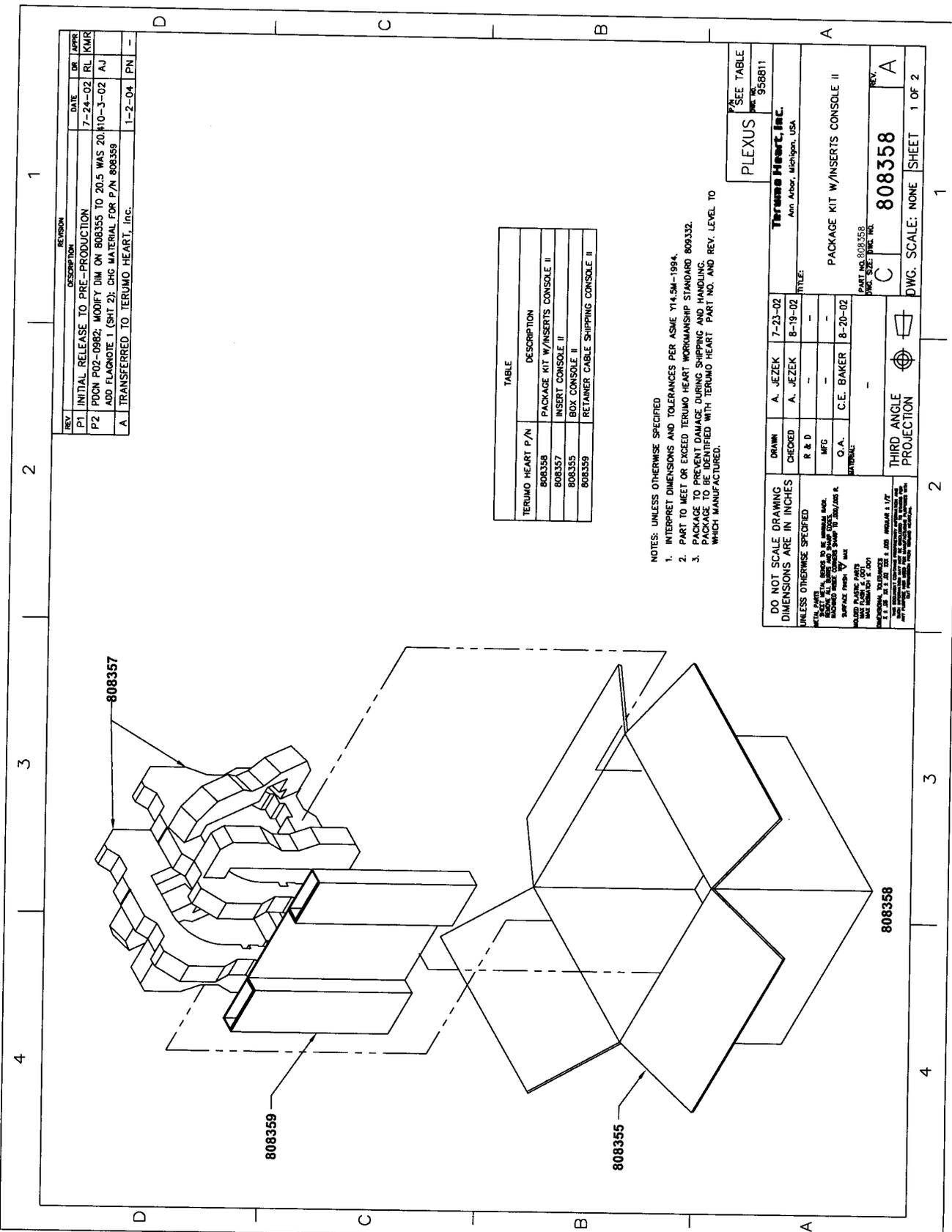
NOTES: APPLY TO THIS SHEET ONLY

- SEAL ZIP LOCK BAG ITEM 249. FOLD BAG TO FIT UNIT AND FASTEN USING CLEAR ADHESIVE TAPE BEFORE PLACING UNIT IN FOAM SET
- PLACE ITEM 250 ALONG SIDE OF CHARGER PRIOR TO SEALING ITEM 249

PLEXUS <small>THE PLEXUS ELECTRONIC, INC. 1000 N. W. 10TH AVE., MIAMI, FLORIDA 33136, U.S.A.</small>	
<small>DO NOT SCALE DRAWING DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED</small>	<small>DATE: 11/11/81 DRAWN BY: [illegible] CHECKED BY: [illegible] APPROVED BY: [illegible]</small>
<small>THIRD ANGLE PROJECTION</small>	<small>DRG. SCALE: NONE</small>
<small>ITEM NO. 802734</small>	<small>SHEET 3 OF 6</small>

Attachment

6

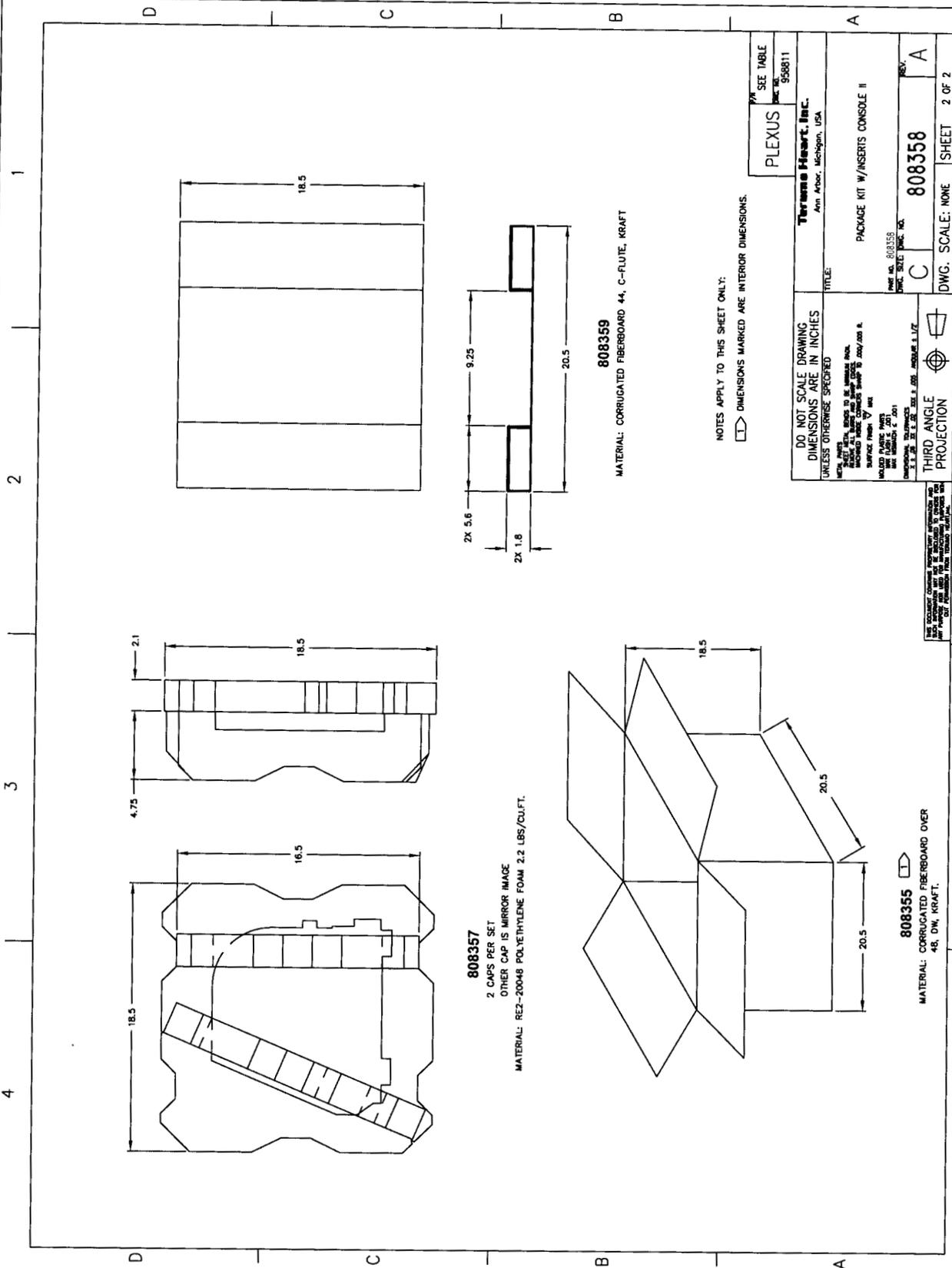


REV.	DESCRIPTION	DATE	DR.	APPR.
P1	INITIAL RELEASE TO PRE-PRODUCTION	7-24-02	RL	KMR
P2	POCN P02-0982; MODIFY DIM ON 808355 TO 20.5 WAS 20.110-3-02 A1 ADD FLAGNOTE 1 (SHT 2); CHG MATERIAL FOR P/N 808359	10-3-02	A1	
A	TRANSFERRED TO TERUMO HEART, INC.	1-2-04	PN	-

TERUMO HEART P/N	DESCRIPTION
808358	PACKAGE KIT W/INSERTS CONSOLE II
808357	INSERT CONSOLE II
808355	BOX CONSOLE II
808359	RETAINER CABLE SHIPPING CONSOLE II

- NOTES: UNLESS OTHERWISE SPECIFIED
1. INTERPRET DIMENSIONS AND TOLERANCES PER ASME Y14.5M-1994.
 2. PART TO MEET OR EXCEED TERUMO HEART WORKMANSHIP STANDARD 809332.
 3. PACKAGE TO PREVENT DAMAGE DURING SHIPPING AND HANDLING.
- PACKAGE TO BE IDENTIFIED WITH TERUMO HEART PART NO. AND REV. LEVEL TO WHICH MANUFACTURED.

DO NOT SCALE DRAWING DIMENSIONS ARE IN INCHES		DRAWN A. JEZEK	7-23-02
UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS TO BE SHOWN UNLESS OTHERWISE SPECIFIED SURFACE FINISH TO BE AS SHOWN UNLESS OTHERWISE SPECIFIED MATERIAL TO BE AS SHOWN UNLESS OTHERWISE SPECIFIED DIMENSIONS TO BE SHOWN UNLESS OTHERWISE SPECIFIED DIMENSIONS TO BE SHOWN UNLESS OTHERWISE SPECIFIED DIMENSIONS TO BE SHOWN UNLESS OTHERWISE SPECIFIED		CHECKED R & D	8-19-02
		MFG	
		G.A.	8-20-02
		MATERIAL	
		THIRD ANGLE PROJECTION	
		DWG. SCALE: NONE	
		SHEET 1 OF 2	
		PART NO. 808358	
		PART SIZE: P/NK: N/A	
		KEY: A	
		TITLE: PACKAGE KIT W/INSERTS CONSOLE II	
		TERUMO HEART, INC. Ann Arbor, Michigan, USA	
		P/N SEE TABLE 958811	



808357

2 CAPS PER SET
 OTHER CAP IS MIRROR IMAGE
 MATERIAL: REZ-20048 POLYETHYLENE FOAM 2.2 LBS/CU.FT.

808355

MATERIAL: CORRUGATED FIBERBOARD OVER
 48, DW, KRAFT.

808359

MATERIAL: CORRUGATED FIBERBOARD 44, C-FLUTE, KRAFT

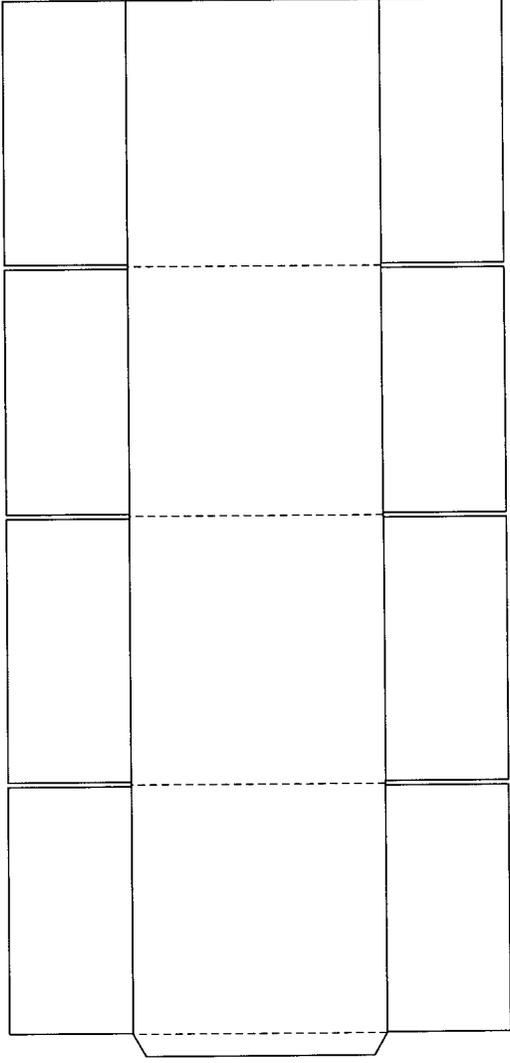
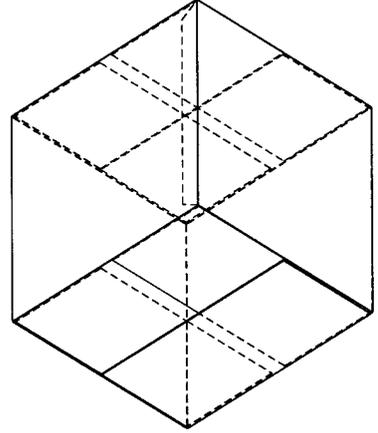
NOTES APPLY TO THIS SHEET ONLY:
 DIMENSIONS MARKED ARE INTERIOR DIMENSIONS.

PLEXUS <small>SEE TABLE FOR PLEXUS NO. 958811</small>	
Typhoon Harsco, Inc. <small>Ann Arbor, Michigan, USA</small>	
TITLE: DO NOT SCALE DRAWING DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED <small>METAL PARTS ALL DIMENSIONS TO UNLESS NOTED UNLESS OTHERWISE SPECIFIED TO DIMENSIONS SURFACE FINISH: V. 100 MATERIAL: 304 STAINLESS STEEL DIMENSIONS: 1.001</small>	PACKAGE KIT W/INSERTS CONSOLE II PLEXUS NO. 808358 PLEXUS NO. 958811
THIRD ANGLE PROJECTION	DWG. SCALE: NONE SHEET 2 OF 2

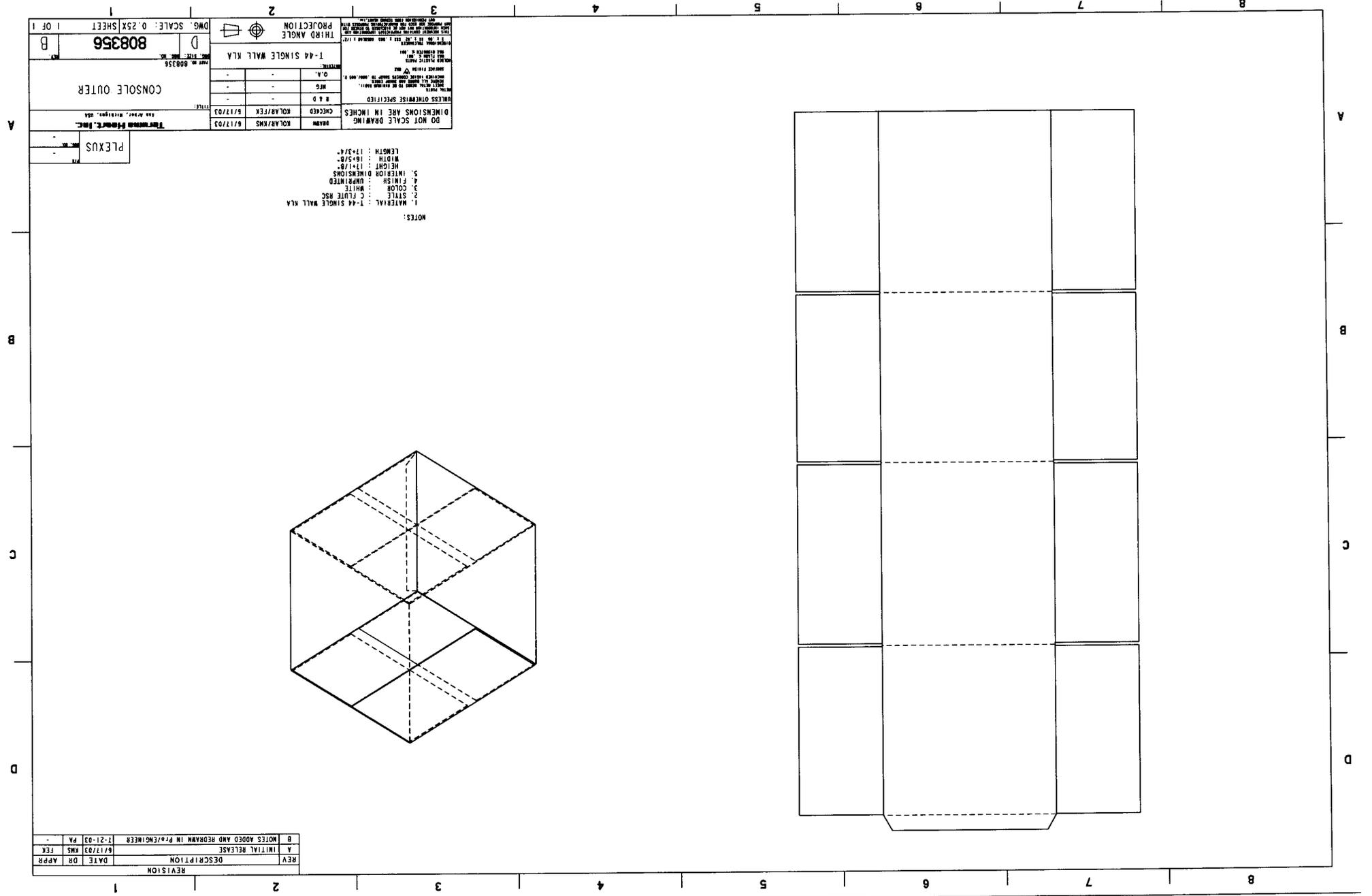
Attachment

7

1 OF 1		DWG. SCALE: 0.25X SHEET	
808356		THIRD ANGLE PROJECTION	
CONSOLE OUTER		1-44 SINGLE WALL KLA	
PLEXUS		DO NOT SCALE DRAWING	
THORNTON ENGINEERING, INC.		DIMENSIONS ARE IN INCHES	
8/17/03		UNLESS OTHERWISE SPECIFIED	
8/17/03		MATERIAL: 1-44 SINGLE WALL KLA	
8/17/03		1. FINISH: UNPAINTED	
8/17/03		2. COLOR: WHITE	
8/17/03		3. STYLE: C FLUTE RSC	
8/17/03		4. INTERIOR DIMENSIONS	
8/17/03		5. HEIGHT: 171/8"	
8/17/03		6. WIDTH: 161/8"	
8/17/03		7. LENGTH: 173/4"	



REV	DESCRIPTION	DATE	DR	APP
A	INITIAL RELEASE	8/17/03	MMS	FEK
B	NOTES ADDED AND REDRAWN IN P&E/ENGINEER	1-21-03	PA	-



Attachment

8

Terumo Heart, Inc.

TERUMO HEART, INC.

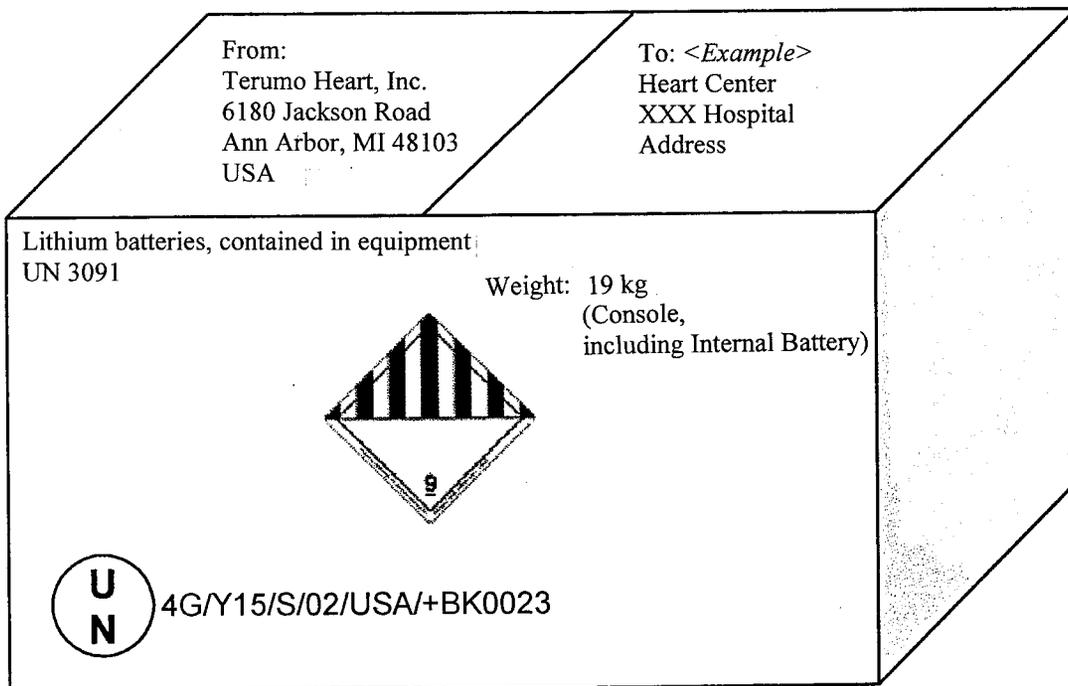
6180 JACKSON ROAD, ANN ARBOR, MI 48103-9300, U.S.A.

PHONE: (734) 741-6213 TOLL FREE: (800) 262-3304



DRAFT

Marking on the Console Outer Box



== DRAFT ==

Attachment

9

Terumo Heart, Inc.

TERUMO HEART, INC.

6180 JACKSON ROAD, ANN ARBOR, MI 48103-0300, U.S.A.

PHONE: (734) 741-6213 TOLL FREE: (800) 262-3304



DRAFT

SHIPPER'S CERTIFICATION

This is to certify that the Lithium Ion Batteries Contained in Equipment (Hospital Console of DuraHeart System) via this shipment are properly classified, described, packaged, marked, and labeled, and are in proper condition for transportation according to the applicable international and national governmental regulations, and also refer to the DOT granted exemption, No. _____.

Signature of Shipper: _____

Place / Date of Signing (if shipping by air): _____ / _____

== DRAFT ==

Attachment

10

MATERIAL SAFETY DATA SHEET**Model ICR18650S2 Lithium Ion Rechargeable Battery****LG CHEMICAL LTD****1. Chemical Product and Company Identification****Product Identification**

LG CHEM ICR18650S2 Lithium-Ion Battery

ManufacturerLG Chemical Ltd.
Twin Tower
Youido-Dong 120, Youngdeungpo-Ku
Seoul, Korea**Emergency Telephone Number**

82-2-3773-0837

2. Composition Information

Hazardous Ingredients	%	CAS Number
Aluminum Foil	2-10	7429-90-5
Metal Oxide (proprietary)	20-50	
Polyvinylidene Fluoride (PVDF)	<5	24937-79-9
Copper Foil	2-10	7440-50-8
Carbon (proprietary)	10-30	7440-44-0
Electrolyte (proprietary)	10-20	
Stainless steel, Nickel and inert materials	Remainder	N/A

* Equivalent Lithium content : 0.66g

3. Hazards Identification

Emergency Overview

May explode in a fire, which could release hydrogen fluoride gas.
Use extinguishing media suitable for materials burning in fire.

Primary routes of entry

Skin contact	:	NO
Skin absorption	:	NO
Eye contact	:	NO
Inhalation	:	NO
Ingestion	:	NO

Symptoms of exposure

Skin contact

No effect under routine handling and use.

Skin absorption

No effect under routine handling and use.

Eye contact

No effect under routine handling and use.

Inhalation

No effect under routine handling and use.

Reported as carcinogen

Not applicable

4. First Aid Measures

Inhalation

Not a health hazard.

Eye contact

Not a health hazard.

Skin contact

Not a health hazard.

Ingestion

If swallowed, obtain medical attention immediately.

IF EXPOSURE TO INTERNAL MATERIALS WITHIN CELL DUE TO DAMAGED OUTER CASING, THE FOLLOWING ACTIONS ARE RECOMMENDED ;

Inhalation

Leave area immediately and seek medical attention.

Eye contact

Rinse eyes with water for 15 minutes and seek medical attention.

Skin contact

Wash area thoroughly with soap and water and seek medical attention.

Ingestion

Drink milk/water and induce vomiting; seek medical attention.

5. Fire Fighting Measures

General Hazard

Cell is not flammable. Combustion products include, but are not limited to hydrogen fluoride, carbon monoxide and carbon dioxide.

Extinguishing Media

Use extinguishing media suitable for the materials that are burning.

Special Firefighting Instructions

If possible, remove cell(s) from fire fighting area. If heated above 160°C, cell(s) may explode/vent.

Firefighting Equipment

Use NIOSH/MSHA approved full-face self-contained breathing apparatus (SCBA) with full protective gear.

6. Accidental Release Measures

On Land

Place material into suitable containers and call local fire/police department.

In Water

If possible, remove from water and call local fire/police department.

7. Handling and Storage

Handling

No special protective clothing required for handling individual cells.

Storage

Store in a cool, dry place.

8. Exposure Controls / Personal Protection

Engineering controls

Keep away from heat and open flame. Store in a cool dry place.

Personal Protection

Respirator

Not required during normal operations. SCBA required in the event of a fire.

Eye/face protection

Not required beyond safety practices of employer.

Gloves

Not required for handling of cells.

Foot protection

Steel toed shoes recommended for large container handling.

9. Physical and Chemical Properties

State	Solid
Odor	N/A
PH	N/A
Vapor pressure	N/A
Vapor density	N/A
Boiling point	N/A
Solubility in water	Insoluble
Specific gravity	N/A
Density	N/A

10. Stability and Reactivity

Reactivity

None

Incompatibilities

None during normal operation. Avoid exposure to heat, open flame, and corrosives.

Hazardous Decomposition Products

None during normal operating conditions. If cells are opened, hydrogen fluoride and carbon monoxide may be released.

Conditions To Avoid

Avoid exposure to heat and open flame. Do not puncture, crush or incinerate.

11. Toxicological Information

This product does not elicit toxicological properties during routine handling and use.

Sensitization	Teratogenicity	Reproductive toxicity	Acute toxicity
NO	NO	NO	NO

If the cells are opened through misuse or damage, discard immediately. Internal components of cell are irritants and sensitizers.

12. Ecological Information

Some materials within the cell are bioaccumulative. Under normal conditions, these materials are contained and pose no risk to persons or the surrounding environment.

13. Disposal Considerations

California regulated debris

RCRA Waste Code : Nonregulated

Dispose of according to all federal, state, and local regulations.

14. Transport Information

DOT Hazard Class : Nonregulated

15. Regulatory Information

OSHA hazard communication standard (29 CFR 1910.1200)

Hazardous Non-hazardous