

Medical Power Supply GTDP61200-*24 series

Tested under

ANSI/AAMI ES60601-1:2005 + AMD1 1:2012 + AMD 2:2021, Medical electrical equipment— Part 1:
General requirements for basic safety and essential performance
UL 2089, Third Edition, Rev. May 7, 2018, Vehicle battery adapters

MET Report: 130644

Approved: Jan. 25, 2024

Applicant:

GlobTek, Inc.
186 Veterans Dr. Northvale, NJ 07647 USA

Prepared By:

Eurofins Electrical Testing Service (Shanghai) Co., Ltd.
Building 18, No. 2168 Chenhang Highway, Minhang District, Shanghai
China

Eurofins Electrical and Electronic Testing North America, Inc.

914 West Patapsco Avenue
Baltimore, Maryland 21230-3432
(410) 949-1802

This report shall not be reproduced except in full, without the express written consent of Eurofins Electrical and Electronic Testing North America, Inc.

Table of Contents

CHANGE RECORD	3
DESCRIPTION	4
MARKINGS.....	9
MANUAL/SERVICE INSTRUCTIONS	11
ALTERNATE LISTEE INFORMATION	12
APPLICANT'S RESPONSIBILITIES	13
PRODUCT MODIFICATIONS:	13
MANUFACTURING AND PRODUCTION-LINE TESTS AND DOCUMENTATION.....	15
CRITICAL COMPONENTS.....	16
CRITICAL DRAWINGS.....	18
FIGURES	19
ILLUSTRATIONS	23
CONCLUSION	31

Change Record

Change Number	Description	Approval Date	Project Number	Amendment Engineer	Engineer Initials
--	--	--	--	--	--

Description

Product Covered:

- Medical power supply, GTDP61200-*24 series
* denotes the rated output wattage designation, which can be “0” to “120”, with interval of 1W.

Product Description:

- The EUT is a DC-DC medical power supply with vehicle adapter that is intended to be supplied from a vehicle cigarette lighter receptacle.

Model Differences:

- All models in the series are identical except for different output power controlled by firmware.

Electrical Rating:

- Input: 12-32V DC, 15.0 A Min
- Output: 24V DC, 5.0 A Max, 120 W MAX

Engineering Considerations (Not For Field Representative's Use):

- The Power Supplies, GTDP61200-*24 series, have been investigated in accordance with ANSI/AAMI ES60601-1:2005 + AMD1 1:2012 + AMD 2:2021, Medical electrical equipment— Part 1: General requirements for basic safety and essential performance; UL 2089, Third Edition, Rev. May 7, 2018, Vehicle battery adapters, with the following considerations:

1 Exceptions:

The following clauses are not evaluated in this report:

- Clause 11.7 Biocompatibility, referencing ISO 10993
- Clause 12.2 Usability of ME equipment
- Clause 17 EMC, referencing IEC 60601-1-2

2 Scope of power supply evaluation defers the following clauses to be determined as part of the end-product evaluation:

- Clause 7.5 Safety signs,
- Clause 7.9 Accompany Documents,
- Clause 9 ME hazard, except 9.1 and 9.3 are evaluated,
- Risk management was excluded from this evaluation.

3. Rated operating altitude ≤ 3000 m. The equipment is powered by a safety extra-low voltage.

Description (Continued)

4 Risk control/Engineering considerations for component power supply:

For power supplies with no Risk Management installed in an end-product, consideration must be given to the following:

- a) End-product Risk Management Process to include consideration the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1, F2).
- b) End-product Risk Management Process to include consideration the need for simultaneous fault condition testing.
- c) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- d) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the movement of components or conductors as part of the power supply.
- e) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- f) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- g) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- h) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- i) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.
- j) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the selection of components as it pertains to the intend use, essential performance, transport, storage conditions as part of the power supply.

- This product must be installed in accordance with all codes applicable to the location of the installation and in accordance with its instructions for use.

Description (Continued)

Note to Field Representative:

- A sample of each component listed below and a purchase order for the work described below at the current hourly rate shall be submitted to:*

Eurofins E&E NA, Inc.
 914 West Patapsco Avenue
 Baltimore, Maryland 21230-3432

for reassessment processed under job # 130644 for verification of construction against the associated drawings also listed below. The component(s) shall be subjected to an annual audit by MET for continued compliance. The annual re-verification is a client incurred expense to be assessed at the current hourly rate at the time of the test. The estimated time for re-verification is also listed below.

Figure/ Item #	Component	Controlled Document Number	Re-Verification Type	Estimated Time
N/A	--	--	--	--

*Alternatively: If the evaluation is performed by the MET representative's lab other than the location above or by the MET representative during the Follow-up inspection, all data shall be returned to the Baltimore office listed above for surveillance tracking under the assigned job number mentioned above.

- The above inspections are a client incurred cost and will be billed at the hourly rate in place at the time of the inspection.

General Requirements

Scope of Requirements: The requirements contained within this section apply to all products contained within this Follow-Up Service Report File where applicable.

Definitions: *(as defined or used in the context of the standard)*

Term	Definitions
SELV:	Safety Extra Low Voltage
PCB:	Printed Circuit Board
Listed/Recognized Component:	A component evaluated to the applicable U.S. standards by a Nationally Recognized Testing Laboratory (NRTL).
Certified Component:	A component evaluated to the applicable Canadian standards by a Certification Organization (CO).
Listee:	Applicant

Measurements: All dimensions indicated in the body of this report are approximations unless otherwise indicated.

Corrosion Protection: All corrosive metals shall be provided with a means to protect from corrosion. Acceptable methods include painting, plating and galvanizing. Dissimilar metals shall not be employed where reliable continuity is required.

Soldered Connections: All soldered connections shall be made mechanically secure before soldering. Tack soldering is not acceptable. Acceptable forms of mechanical securement include:

- A) Lead is inserted through an eyelet or opening of a terminal block prior to soldering.
- B) Lead is inserted into a U or V shaped slot in the terminal prior to soldering.
- C) Lead is wrapped around a terminal post prior to soldering.
- D) Lead is tied to adjacent lead with wire tie-wrap near termination point.

Electrical Connections: All electrical connections other than soldering shall be provided with positive detent, crimp type insulated Recognized Component connectors suitable for the voltage and temperatures involved. They shall be sized for the wire and mounting terminations. Where hazardous voltage or energy is involved, all wire connections to connectors shall employ a recognized method of double securement. Where fork-type lugs are used, they shall be snap-on or up-turned lug type.

Mechanical Assembly: All parts shall be secured by welding, bolts/nuts with lock or star washers, or thread forming screws.

Creepage and Clearances: Shall be in accordance with the evaluated product standards.

General Requirements (Continued)

Where present, the following items are required.

Internal Plastics: Shall be a Recognized/Certified Component, Plastic, rated minimum HB/5VA.

PCB: Shall be a Recognized Component, rated minimum 94V-2 and 130°C.

Tubing and Sleeving: Shall be a Listed/Recognized/Certified Component, rated minimum 300V, 75°C minimum, VW-1, unless otherwise noted.

Wire Connectors: (Various crimp-type) Shall be Listed/Recognized/Certified Components sized for the wire and mounting terminations. Both the wire insulation and the conductor shall be crimped.

Fuseholder: Operator accessible fuseholders, when provided, are connected to the ungrounded conductor(s) of the primary circuit.

Internal Wiring: All internal wiring and connections are properly jacketed or enclosed within the equipment. Wiring is routed and secured to reduce the possibility of stress being transmitted to electrical connections, as necessary. All internal conductors in the secondary circuits are routed away from primary circuit conductors and from uninsulated live parts. There is no internal wiring subject to contact by the user when the product is employed as intended. The internal wiring is acceptable for conditions of service to which it will be subjected. Internal conductors consist of Recognized Component AWM insulated individual conductors; sized in accordance with the National Electric code and Canadian Electrical code, as may be applicable for the current expected in the conductor, rated 300V, 80°C, 24-18AWG.

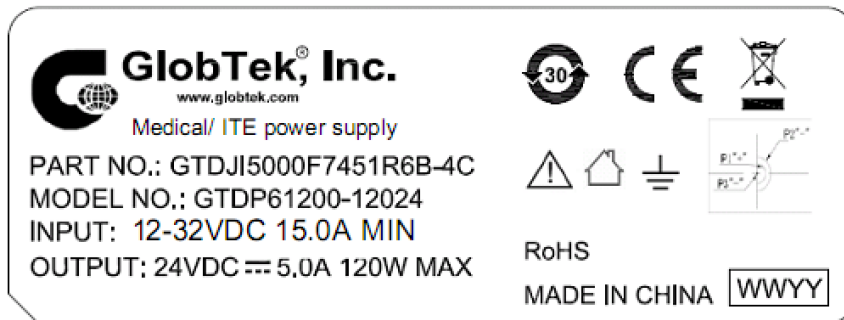
Interconnecting Cords and Cables: Flexible telecommunication cord and cable assemblies employed for interconnection between components are to be rated for and comply with temperatures, exposure to oil or grease and other conditions of service within the environment the product is to be utilized.

Markings

Etching, molding, die-stamping, silk-screening, stamped-, or etched-metal labels secured by rivets or screws are considered permanent. Recognized/Certified Component, Marking and Labeling Systems, and/or labels tested and deemed suitable for the surface to which it is applied is also considered permanent. Each product is to be permanently marked with the following information:

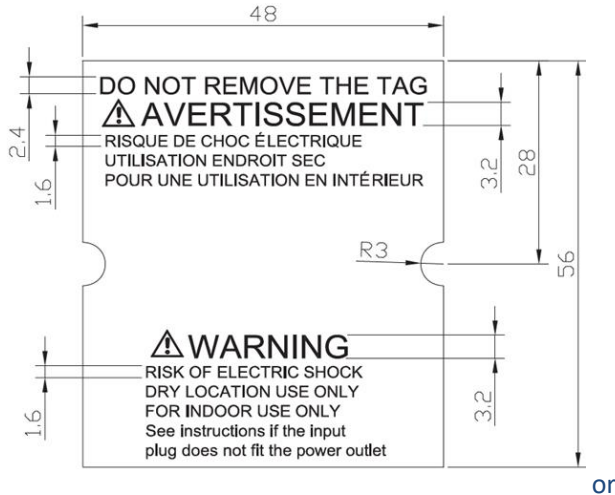
- The MET Mark (refer to MET Applicant Contract), with the applicant/listee name or alternate listee name as identified within this report, trade name or trade mark, product model number, and a date of manufacture or serial number. If the date of manufacture is in a code, it shall not repeat in less than 10 years and it shall not require reference to the manufacturer's records to determine when the product was manufactured.
- For Mains Connected Equipment, a rating label adjacent to the inlet connector identifying the voltage, current or power, frequency for the equipment.

(Engraving or Silkscreen or Laser printing)



Markings (Continued)

Separate warning label or Warnings in the marking plate:



WARNING/Avertissement:
RISK OF ELECTRIC SHOCK
DRY LOCATION USE ONLY
FOR INDOOR USE ONLY
Risque de choc électrique
Utilisation endroit sec
Pour une utilisation en intérieur

Manual/Service Instructions

- Operations and Service instructions are provided with the equipment.
- See illustration 1 to 5.

Alternate Listee Information

Alternate listees and product names or model numbers: None

Applicant's Responsibilities

Product Modifications:

Minor product modifications by the manufacturer may be allowed using the following guidelines:

1. Components identified in this report as "Listed, Recognized, or Certified" and **NOT** identified with a manufacturer name or part number may be exchanged with an alternate "Listed, Recognized, or Certified" component of equivalent value.

Example: Appliance Inlet Connector - Listed/Certified Component, IEC 320 style male connector, rated 250 volts and 20 amperes. Mechanically secured to the front panel with screws and locking washers.

- This inlet connector may be replaced with any Listed/Certified inlet connector with the same ratings as stated and where mechanical securement is maintained.

2. Components identified by a manufacturer name, part number, or with specific comments, (such as AC only, indoor use only, approved for use in this product only), may **NOT** be replaced or modified without prior approval from MET Laboratories.

Example: Circuit Breaker - Recognized/Certified Component, ABCD Co. P/N XYZ123, rated 250 volts maximum, 50/60 Hz, 25 full-load amperes, 31.3 trip amperes. Toggle handle marked with IEC on/off symbols. Mechanically secured to the front panel with screws and locking washers.

- This circuit breaker can **NOT** be modified or changed without prior approval by MET Laboratories, Inc.

Applicant's Responsibilities (Continued)

Project Amendments:

For any changes related to product construction, manufacturing locations, if the product is intended to be marketed/sold under an alternate name or model number than that originally listed, or any issues which would require notification or change in the status of this file, please complete the form and return to Eurofins E&E NA following the instructions provided on the form.

For your convenience a Project Amendment Request (PAR) form is available for download at <http://corp.metlabs.com/safetyreq/> Alternatively, please provide it to your local Eurofins office or Eurofins Partner Representative.

If you are terminating or temporarily suspending production of this product for an extended period, please send a letter on company letterhead to:

Eurofins E&E NA, Inc.
Attn: Follow Up Services Department
914 West Patapsco Avenue
Baltimore, Maryland 21230
USA
Fax: (410) 354-3313

Applicant's Responsibilities (Continued)

Manufacturing and Production-Line Tests and Documentation

- This product is exempt from production line testing.

Critical Components

Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
1,2,6/1	Plastic enclosure	SABIC INNOVATIVE PLASTICS US L L C	CH6410(G G)	PC/ABS, V-0, min. 2.0 mm thickness, 100°C	UL 94	UL recognized E121562	Fixed by screws and ultrasonic welding
	(Alternative)	SABIC INNOVATIVE PLASTICS B V	CH6410(G G)	PC/ABS, V-0, min. 2.0 mm thickness, 100°C	UL 94	UL recognized E45329	
	(Alternative)	SABIC INNOVATIVE PLASTICS B V	945(GG)	PC, V-0, min. 2.0 mm thickness, 120°C	UL 94	UL recognized E45329	
	(Alternative)	SABIC INNOVATIVE PLASTICS US L L C	945(GG)	PC, V-0, min. 2.0 mm thickness, 120°C	UL 94	UL recognized E121562	
	(Alternative)	SABIC JAPAN L L C	945(GG)	PC, V-0, min. 2.0 mm thickness, 120°C	UL 94	UL recognized E207780	
	(Alternative)	Sabic Innovative Plastics	940(f1)(gg *)	PC, V-0, min. 2.0 mm thickness, 120°C	UL 94	UL recognized E121562	
	(Alternative)	Nan Ya Plastics (Hui Zhou) Corp Ltd	6410G5	PA66, V-0, min. 2.0 mm thickness, 115°C	UL 94	UL recognized E235269	
	(Alternative)	Nan Ya Plastics Corp Plastics 3RD DIV	6410G5	PA66, V-0, min. 2.0 mm thickness, 115°C	UL 94	UL recognized E130155	
4,5/2	PCB material	Interchangeable	Interchangeable	Min.V-0 Min.105°C	UL796	UL recognized	Fixed by enclosure
5/3	Fuse	XC ELECTRONICS (SHENZHEN) CORP LTD	6G	15AL 250Vac	UL 1412	UL recognized E249609	Fixed by enclosure
	(Alternative)	ZHONG SHAN LANBAO ELECTRICAL APPLIANCES CO LTD	RFI-30	15AL 250Vac	UL 1412	UL recognized E213695	

Critical Components (Continued)

Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	(Alternative)	DONGGUAN BETTER ELECTRONICS TECHNOLOGY CO LTD	614	15AL 250Vac	UL 1412	UL recognized E300003	
5/4	Winding of inductor	Interchangeable	Interchangeable	Min 130°C	UL 1446	UL recognized	Fixed on core
1,2,6/5	Input wire	Interchangeable	SPT-2, SPE-2, SP-2, SP-3, SV, SVE, SVT, S, SE, SO, ST, STO, SJ, SJE, SJO, SJT, SJTO	Min.105°C, Min 14 AWG	ANSI/UL 62 CSA-C22.2 No. 49	UL listed	Fixed by enclosure
1,2/6	Output wire	Interchangeable	Interchangeable	VW-1, min. 300V, min. 80°C, min. 16AWG	UL758	UL recognized	Fixed by enclosure
5/7	Heat-shrinkable tube	Interchangeable	Interchangeable	VW-1, min. 125°C, min. 300V	UL 224	UL recognized	Fixed on component
1/8	Marking plate	GlobTek	--	Permanently secured Engraving or Silkscreen or Laser printing	UL 60601-1	Tested with equipment	Permanently secured on enclosure
1/9	Label	ZHONGSHAN FUZHOU ADHESIVE PRODUCT CO LTD	TL-SM25, TL-A25	Rated min 80 °C	UL 969	UL/CSA Recognized MH30090	Sticked on wire or stucked on enclosure
	(Alternative)	Various	Various	Rated min 80 °C	UL 969	UL/CSA Recognized	

Critical Drawings

Title:	Drawing No.:	Rev. Level:	Date:
Circuit diagram	Illustration 6	A2	2012-11-22
PCB layout	Illustration 7	A5	2013-11-01

Figures

Figure 1.

Overview



Figure 2.

Overview



Figures (Continued)

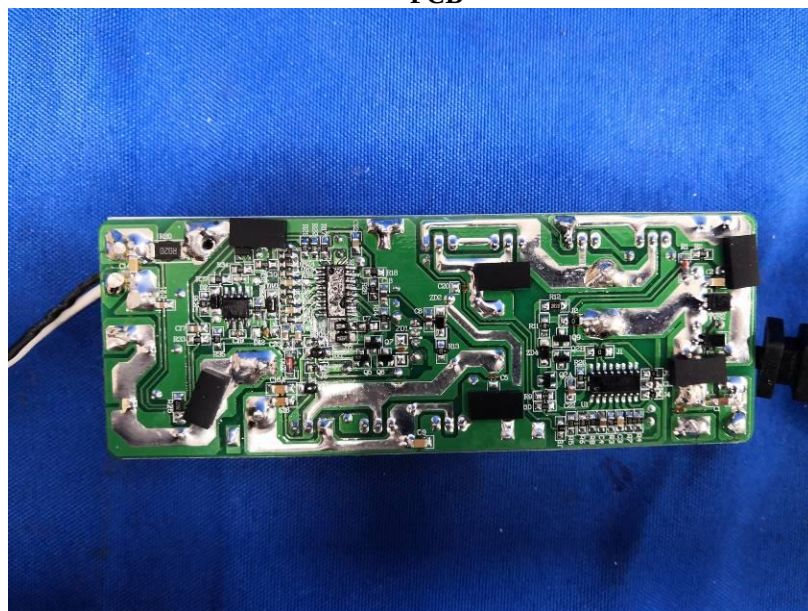
Figure 3.

Internal view



Figure 4.

PCB



Figures (Continued)

Figure 5.

PCB

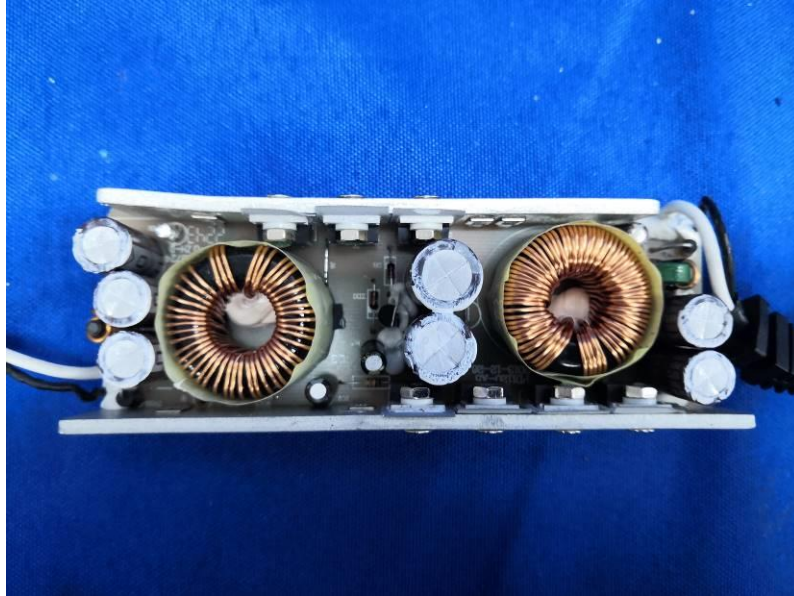


Figure 6.

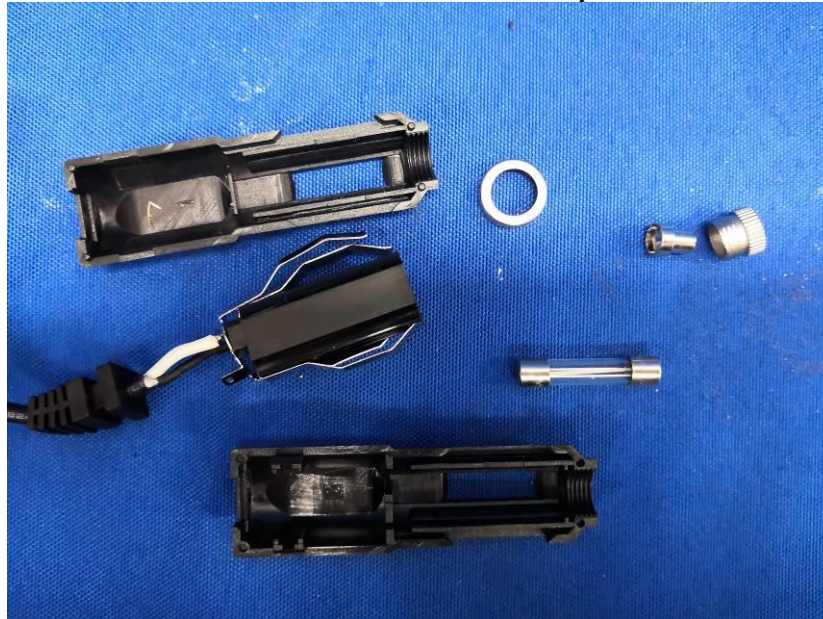
Vehicle adapter



Figures (Continued)

Figure 7.

Internal view of vehicle adapter



Illustrations

Illustration 1.

GlobTek, Inc. www.globtek.com 186 Veterans Drive, Northvale, NJ 07647 Tel. (201) 784-1000 Fax (201) 784-0111	Drawing Title: GTDP61200-12024, ICT/ITE Power Supply, Efficiency Level: USA DOE Level VI / Eco-design Directive 2009/125/EC, (EU) 2019/1782, Case Color/Style: GlobTek Black, Desktop/External, DC-DC, Input Rating: 12-32 VDC, Male Cigarette Lighter Plug , Output Rating: 120W, 24.0V@5.0A, Output Configuration: 1530 mm, 16/1C + Shield Cond, UL 1185, 4 Pin Kycon Locking Plug no substitute, Ferrite: Core Size:14.2*28.5*6.35, GlobTek Black, GT Cord # C55855, Pin Out: PINS 1, 2: +V, PINS 3, 4: COM/GROUND, Blades/Input Cord: (Order Separately), Approvals: EAC; CB 60601-1; CE; VCCI; WEEE; China RoHS; RoHS; Model No. GTDP61200-12024 Part No./Ordering No. GTDJI5000YL4R6B-4C Rev D
--	---

POWER SUPPLY INFORMATION

TYPE:	Desktop/External
TECHNOLOGY:	DC-DC
CASE COLOR:	GlobTek Black
NAMEPLATE RATED INPUT:	12-32 VDC, 0 - 15A
INPUT CONFIG:	Male Cigarette Lighter Plug
WATTS:	120.0
VOLTS OUT:	24.0
CURRENT OUT (Amps):	5.0
BLADE/CORD INCLUDED:	None (Order Separately)
BLADE/CORD INSTALLED:	None :(Order Separately)
INGRESS PROTECTION:	
GROUNDING CONFIGURATION:	(X1) Not a power supply (Not applicable)
EFFICIENCY LEVEL:	USA DOE Level VI / Eco-design Directive 2009/125/EC, (EU) 2019/1782
OUTPUT CONFIGURATION:	1530 mm, 16/1C + Shield Cond, UL 1185, 4 Pin Kycon Locking Plug no substitute, Ferrite: Core Size:14.2*28.5*6.35, GlobTek Black, GT Cord # C55855
OVERMOLDED:	Yes
OUTPUT CONNECTOR GENDER:	Male
CONNECTOR PIN OUT:	PINS 1, 2: +V, PINS 3, 4: COM/GROUND
LABEL SPECS:	GTDJI5000YL4R6B-4C,L-1627
SPECIAL BARCODE LABEL	
MATERIAL:	No
PACK SPEC:	Standard DT, Individually Box
USER MANUAL:	

Illustrations (Continued)

Illustration 2.

IMPORTANT SAFETY INSTRUCTIONS

1. **SAVE THESE INSTRUCTIONS-** This manual contains important instructions for model GTDP61200-*24 series.
2. Before using this product, read all instructions and cautionary markings on power supply.
3. To reduce risk of damage to cigarette lighter connector and cord, pull by cigarette lighter connector rather than cord when disconnecting charger.
4. Make sure cord is located so that it will not be stepped on, tripped over, or otherwise subjected to damage or stress.
5. Do not operate power supply with damaged cord or cigarette lighter connector- replace it immediately.
6. Do not operate power supply if it has received a sharp blow, been dropped, or otherwise damaged in any way; take it to a qualified serviceperson.
7. Do not disassemble power supply; take it to a qualified serviceperson when service or repair is required. Incorrect reassembly may result in a risk of electric shock or fire.
8. To reduce risk of electric shock, unplug adapter before attempting any maintenance or cleaning. Turning off controls will not reduce this risk.
9. Use of an attachment not recommended or sold by the power supply manufacturer may result in a risk of fire, electric shock, or injury to persons.

Illustrations (Continued)

Illustration 3.

ELECTRICAL SPECIFICATIONS

A) ELECTRICAL SPECIFICATIONS:

01. Input Voltage: 12~32Vdc
02. Input current: Maximum 15A
03. Output Current(Max.): 5.0A
04. Output Power(Max.): 120W
05. Output Ripple & Noise : 240mV max
06. Efficiency: ≥85%

B) PROTECTION

01. Over voltage protection: autorecovery
02. Limit current protection: Optional
03. Short-circuit protection: autorecovery

C) SAFETY & EMC

01. CE, LVD

D) OTHER:

01. MTBF: 200,000 Hours @ 25°C ambient temperature
02. Operating Temperature: 0°C to 40°C ambient temperature
03. Humidity: 0% to 90% relative humidity
04. Storage Temperature: -20°C to 85°C
05. Cooling: Convection
06. RoHS 2: Complies with EU 2011/65/EU China SJ/T 11363-2006

E) ENCLOSURE

01. Housing: High impact plastic, 94V0 polycarbonate, non-vented
02. Size: 134*54*30.5 mm +/-1.0 mm
03. Markings: Label and/or Pad Printed and/or Molded in the case

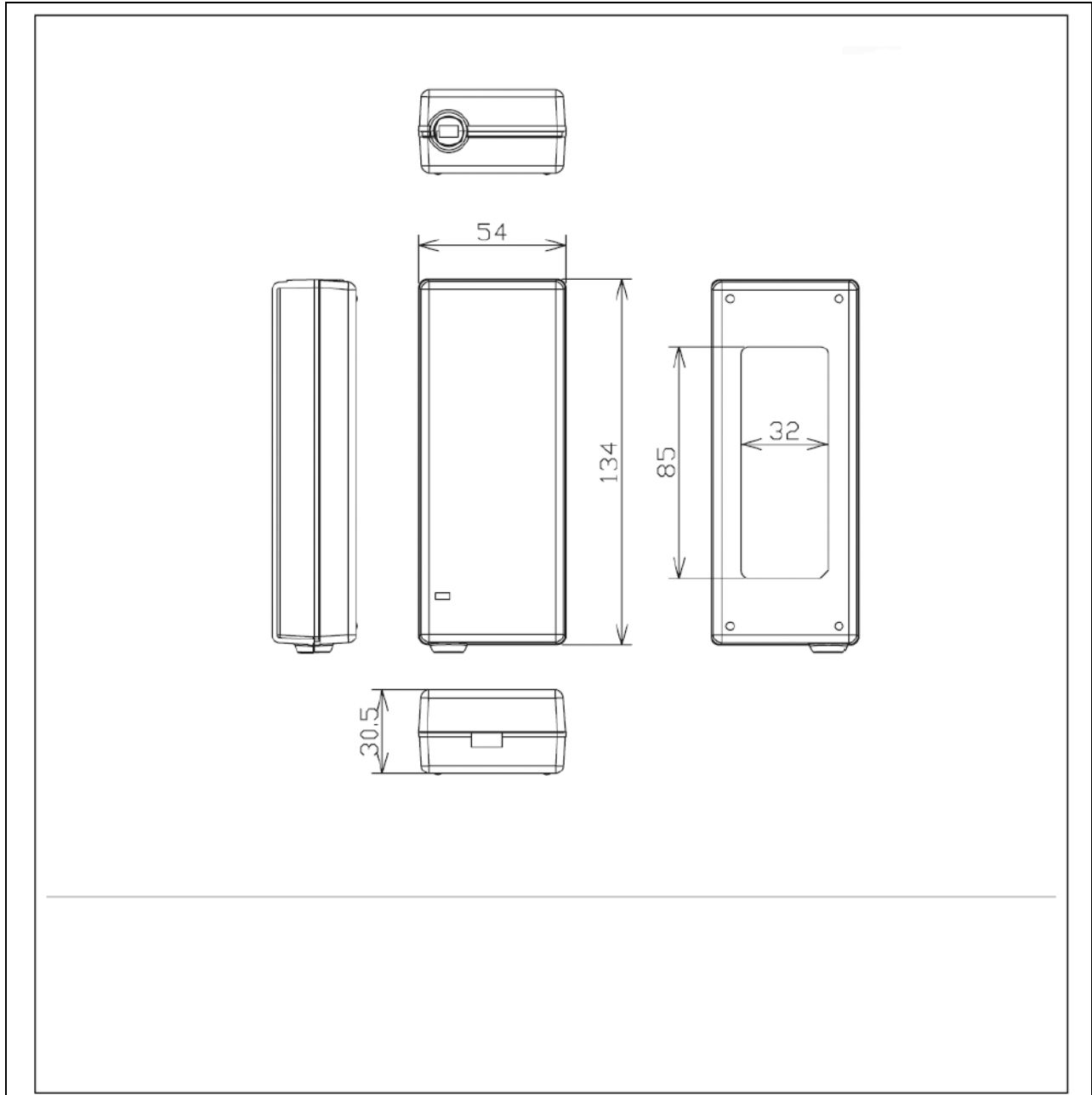
TO ADDRESS SYSTEM-LEVEL EMI CONCERNS, FERRITE CHOKES/BEADS MAY BE ADDED/REVISED UPON REQUEST. A SAMPLE KIT OF GLOBTEK'S STANDARD FERRITES IS AVAILABLE UNDER GLOBTEK P/N: EMI-MITIGATION-KIT1

FOR ADDITIONAL INFORMATION, PLEASE READ OUR WHITE PAPER AT:

<https://en.globtek.com/technical-articles/ferrite-kit-radiated-emi-suppression-kit-for-globtek-power-supplies-cable-assemblies>

Illustrations (Continued)

Illustration 4.



Illustrations (Continued)

Illustration 5.

INPUT CONFIGURATION

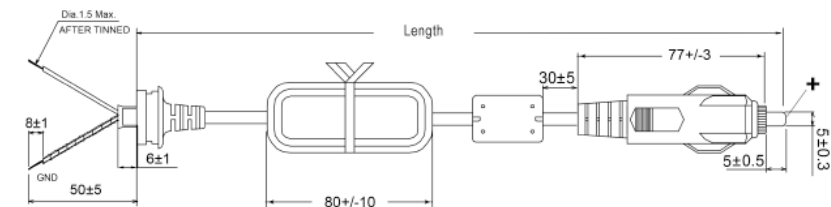
(X1) Not a power supply (Not applicable)

[Alternate grounding configurations](#) available upon request.

Blades/Cord Included:None:(Order Separately)

Blades/Cord Installed:None:(Order Separately)

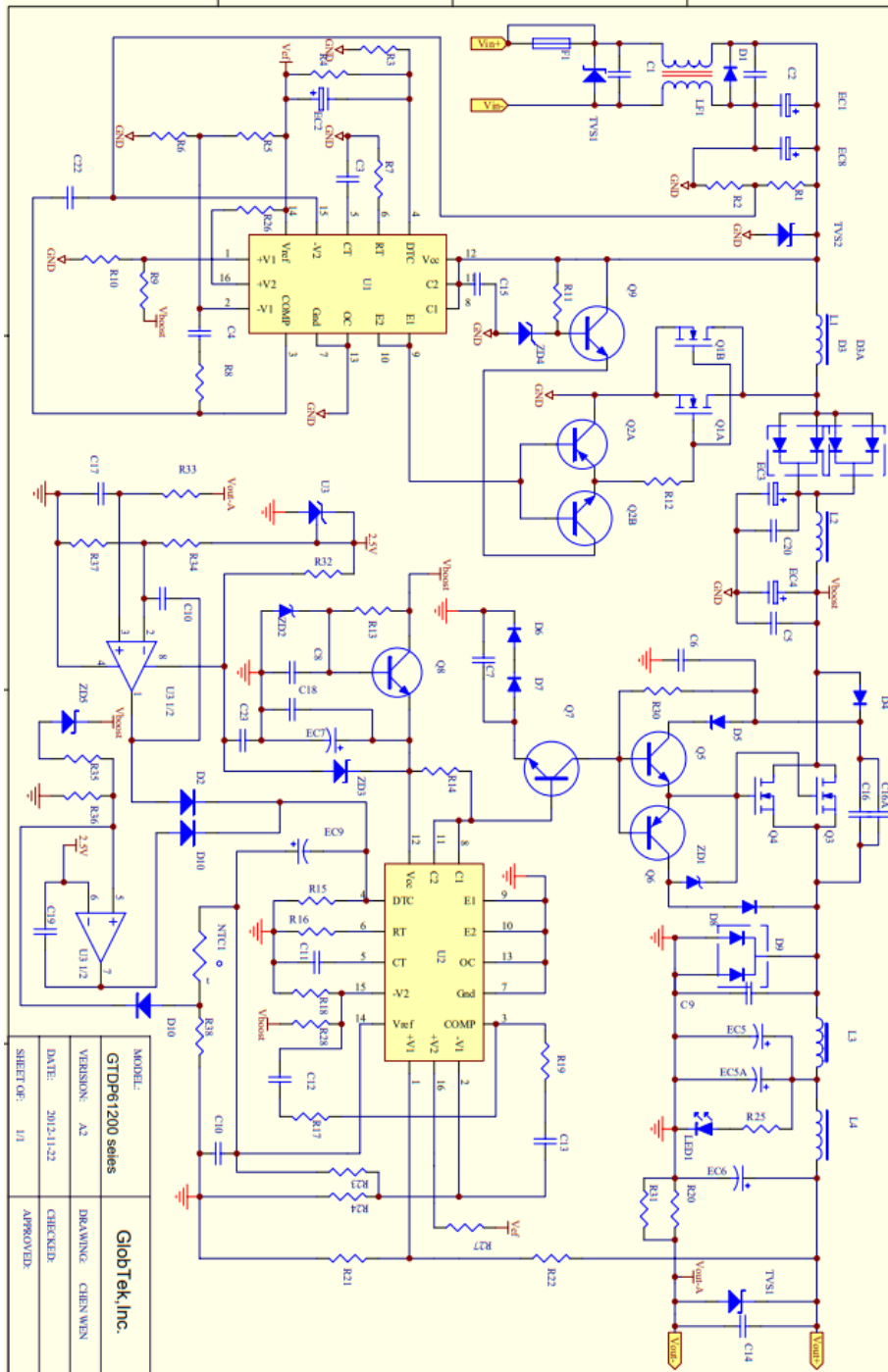
Male Cigarette Lighter Plug for GTDP61200-120VV



Illustrations (Continued)

Illustration 6.

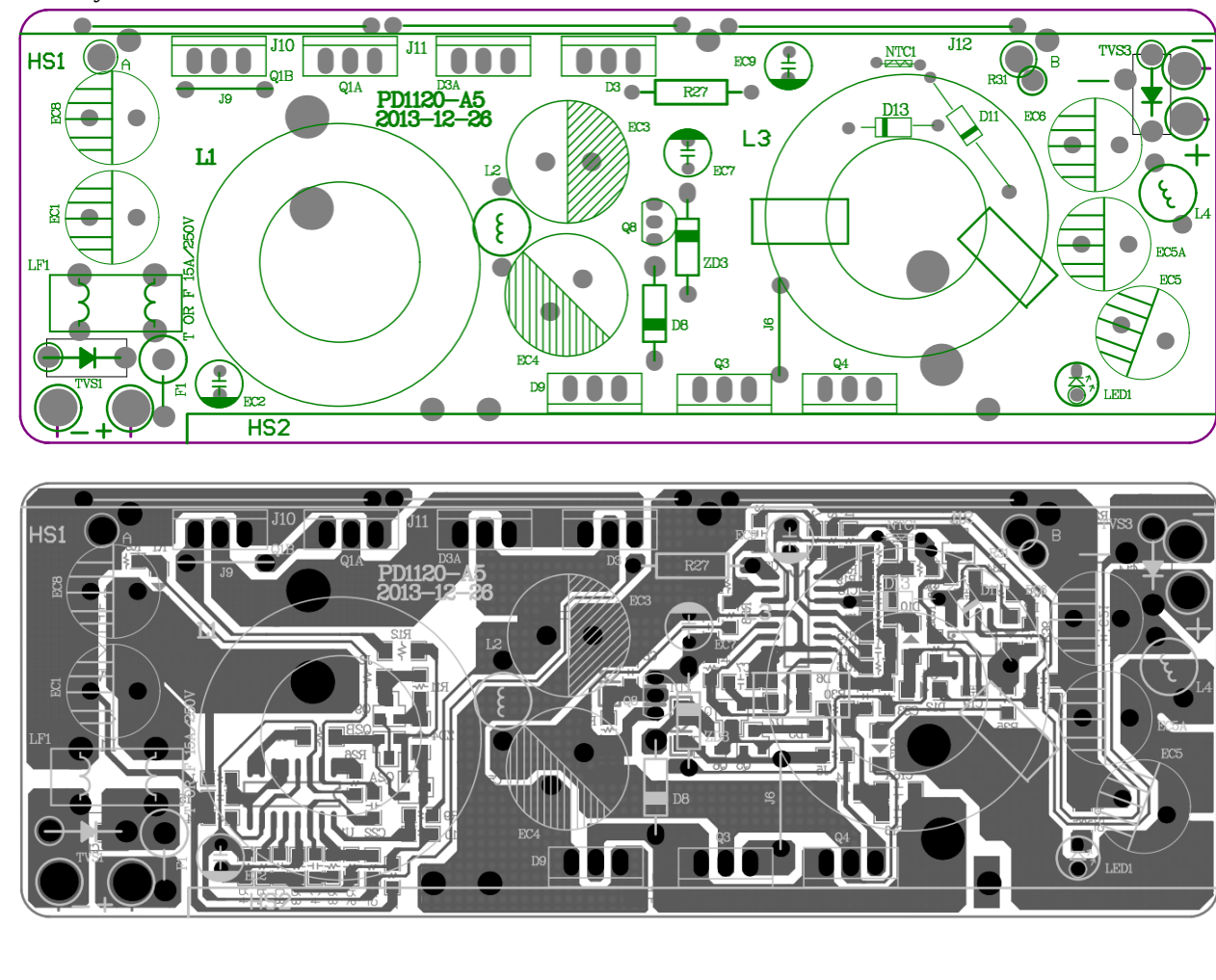
Circuit Diagram:



Illustrations (Continued)

Illustration 7.

PCB layout:



Testing Considerations

A sample of the power supply with model number GTDP61200-12024 was subjected to the following test program with satisfactory results. All tests were conducted in accordance with:
ANSI/AAMI ES60601-1:2005 + AMD1 1:2012 + AMD 2:2021, Medical electrical equipment— Part 1: General requirements for basic safety and essential performance; UL 2089, Third Edition, Rev. May 7, 2018, Vehicle battery adapters.

Only these tests were considered necessary due to engineering considerations. Detailed test results are on file at MET Laboratories under project number 130644.

TESTS CONDUCTED:

ANSI AAMI ES60601-1

Item	Clause	Test
1	4.11	Power input
2	7.1.2	Legibility of markings
3	7.1.3	Durability of markings
4	9.4.2.1	Instability in transport position
5	9.4.2.2	Instability excluding transport position
6	11.1.1	Maximum temperature during normal use
7	13.2	Single fault conditions in accordance with 13.2.2 to 13.2.13
8	15.3	Mechanical strength

ANSI UL 2089

Item	Clause	Test
1	23	Maximum output voltage test
2	24	Power input test
3	25	Temperature test
4	27	Abnormal tests
5	28	Resistance to crushing test
6	29	Strain relief test
7	30	Push-back relief test

Conclusion

The products covered by this report have been tested, examined, and found to comply with the applicable requirements of ANSI/AAMI ES60601-1:2005 + AMD1 1:2012 + AMD 2:2021, Medical electrical equipment— Part 1: General requirements for basic safety and essential performance; UL 2089, Third Edition, Rev. May 7, 2018, Vehicle battery adapters.

Prepared By:



Jack Gan
Project Engineer,
Eurofins Electrical Testing Service(Shanghai) Co.,Ltd.

Reviewed By:



Jackie Zhao
Reviewer,
Eurofins Electrical Testing Service(Shanghai) Co.,Ltd.