






Test Report issued under the responsibility of:



<b>TEST REPORT</b> <b>IEC 60601-1</b> <b>Medical Electrical Equipment</b> <b>Part 1: General requirements for basic safety and essential performance</b>	
Report Number..... : 220201764SHA-001	
Date of issue..... : 2022-10-13	
Modification 1: 2023-08-30	
Total number of pages ..... : 32	
Name of Testing Laboratory preparing the Report .....	Intertek Testing Services Shanghai Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China
Applicant's name .....	GlobTek, Inc.
Address.....	186 Veterans Dr. Northvale, NJ 07647 USA
<b>Test specification:</b>	
Standard .....	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure .....	CB Scheme
Non-standard test method .....	N/A
TRF template used.....	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. ....	IEC60601_1U
Test Report Form(s) Originator ....	UL(US)
Master TRF .....	2022-05-13
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<b>Test item description..... :</b>	Medical Power Supply	
<b>Trade Mark(s) ..... :</b>	 <b>GlobTek, Inc.</b>	
<b>Manufacturer ..... :</b>	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA	
<b>Model/Type reference ..... :</b>	GT*96605-G2**** (Refer to the model list of P7and P8)	
<b>Ratings..... :</b>	Input: 1.5A, 100-240V~, 50-60Hz; Output: 3.6-20.0VDC, Max.4.6A, Max. 60W Refer to P8 model list for detail.	
<b>Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):</b>		
<input checked="" type="checkbox"/>	<b>CB Testing Laboratory:</b>	Intertek Testing Services Shanghai
<b>Testing location/ address..... :</b>		Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China
<b>Tested by (name, function, signature)..... :</b>		Vivian Xu(Engineer) 
<b>Approved by (name, function, signature).... :</b>		Larry Zhong (Mandated reviewer) 
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 1:</b>	
<b>Testing location/ address..... :</b>		
<b>Tested by (name, function, signature)..... :</b>		
<b>Approved by (name, function, signature).... :</b>		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 2:</b>	
<b>Testing location/ address..... :</b>		
<b>Tested by (name, function, signature)..... :</b>		
<b>Witnessed by (name, function, signature) . :</b>		
<b>Approved by (name, function, signature).... :</b>		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 3:</b>	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 4:</b>	
<b>Testing location/ address..... :</b>		
<b>Tested by (name, function, signature)..... :</b>		
<b>Witnessed by (name, function, signature) . :</b>		
<b>Approved by (name, function, signature).... :</b>		
<b>Supervised by (name, function, signature) :</b>		

**List of Attachments (including a total number of pages in each attachment):**

Attachment 1, Photo of EUT, total 15 pages

### Summary of testing:

**Tests performed (name of test and test clause):**

- 4.11 Power input
- 5.7 Humidity preconditioning treatment
- 5.9.2 Determination of applied part and accessible parts
- 7.1.2 Legibility of marking
- 7.1.3 Durability of marking test
- 8.4.2 ACCESSIBLE PARTS including APPLIED PARTS
- 8.4.3 Plug discharge test
- 8.5.4 Working voltage measurement
- 8.6.4 Impedance and current-carrying capability
- 8.7 Leakage current test
- 8.8.3 Dielectric strength test
- 8.8.4.1 Ball pressure test
- 8.9.4 Creepage and clearance measurements
- 11.1 Excessive temperatures in ME EQUIPMENT
- 13.2 Single fault conditions
- 15.5.1.2 Transformer short-circuit test
- 15.5.1.3 Transformer overload test

### Modification 1:

8.5.4 Work voltage

8.8.3 Dielectric strength test

8.9.4 Creepage and clearance measurements

**Testing location:**

Intertek Testing Services Shanghai  
Building No. 86, 1198 Qinzhou Road (North)  
200233 Shanghai China

Modification 1:

Intertek Testing Services Shanghai  
Building No. 86, 1198 Qinzhou Road (North)  
200233 Shanghai China

**Summary of compliance with National Differences (List of countries addressed):**

None.

☒ **The product fulfils the requirements of IEC 60601-1:2005/AMD2:2020 & EN 60601-1:2006+A2:2021&CAN/CSA-C22.2 No. 60601-1:14&AAMI 60601-1:2005 + AMD 1:2012& SN EN 60601-1:2006& JIS T 0601-1:2017**

**Statement concerning the uncertainty of the measurement systems used for the tests**

☒ Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:

**Procedure number, issue date and title:**

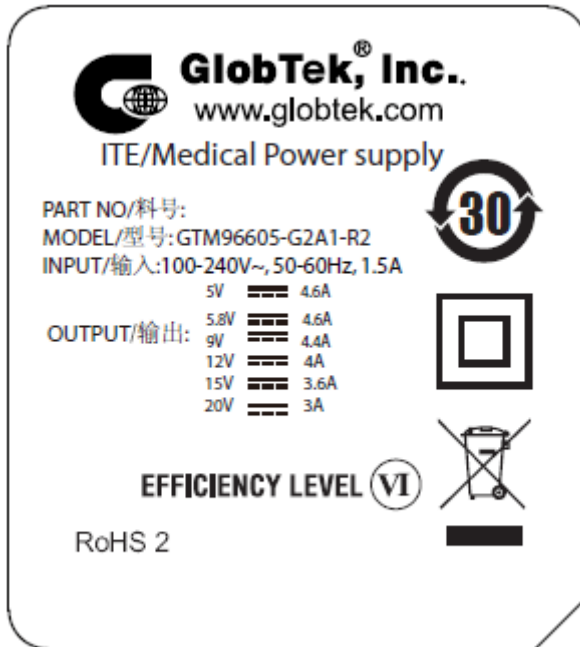
**GMS-QC-12 Estimation of Measurement Uncertainty, 1-July-2012 Initial Release, 19-April-2018 revision date.**

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☐ Statement not required by the standard used for type testing

**Copy of marking plate:**

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Note: The above markings are the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.

Other models are with similar label as corresponding above models except different model name and output ratings.

<b>Test item particulars.....:</b>	
<b>Classification of installation and use.....:</b>	transportable / portable / stationary / mobile / fixed / permanently installed / hand-held, body-worn for power adapter model. Final evaluation in end product.
<b>Supply Connection .....</b>	appliance coupler / non-detachable cord for power adapter model.
<b>Device type (component/sub-assembly/ equipment/ system).....:</b>	Component
<b>Intended use (Including type of patient, application location).....:</b>	PSU (external power adapter or internal power supply board)
<b>Mode of operation.....:</b>	Continuous
<b>Accessories and detachable parts included.....:</b>	None
<b>Other options include.....:</b>	None
<b>Possible test case verdicts:</b>	
- test case does not apply to the test object.....: N/A	
- test object does meet the requirement.....: P (Pass)	
- test object was not evaluated for the requirement.....: N/E (collateral standards only)	
- test object does not meet the requirement.....: F (Fail)	
<b>Abbreviations used in the report</b>	
- normal condition.....: N.C.	- single fault condition .....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection ....: MOPP
<b>Testing.....:</b>	
<b>Date of receipt of test item .....</b>	2023-07-28
<b>Date (s) of performance of tests .....</b>	2023-07-28 to 2023-08-15
<b>General remarks:</b>	

"(See Enclosure #)" refers to additional information appended to the report.  
 "(See appended table)" refers to a table appended to the report.

**Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**

This report is for the exclusive use of Intertek's Client and is provided pursuant to the agreement between Intertek and its Client. Intertek's responsibility and liability are limited to the terms and conditions of the agreement. Intertek assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this report. Only the Client is authorized to permit copying or distribution of this report and then only in its entirety. Any use of the Intertek name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by Intertek. The observations and test results in this report are relevant only to the sample tested. This report by itself does not imply that the material, product, or service is or has ever been under an Intertek certification program.

**Manufacturer's Declaration per sub-clause 4.2.5 of IECCE 02:**

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided .....

☒ **Yes**  
☐ **Not applicable**

**When differences exist; they shall be identified in the General product information section.**

**Name and address of factory (ies) .....** : Factory 1  
 GlobTek, Inc.  
 186 Veterans Dr. Northvale, NJ 07647 USA  
 Factory 2  
 GlobTek (Suzhou) Co., Ltd  
 Building 4, No. 76, Jin Ling East Rd., Suzhou  
 Industrial Park, Suzhou, JiangSu 215021, China

**General product information and other remarks:**

Product covered by this report is medical power supply module.

All models have the same circuit diagram, PCB layout and transformer.

All models can be output Max. 60W power, all electronic components are mounted on minimum V-1 PWB and housed sealed inside the plastic enclosure. The top and bottom parts of the enclosure are ultrasonic welded.

The products were tested to be suitable for connection to  $\leq 16$  A (IEC) and  $\leq 20$  A (USA) branch circuit in series. The unit is approved for TN mains star connections. The unit provides internally two fuses.

The power supplies are rated class I or class II or class II units may have an optional functional earth connection.

All the types are designed for continuous operation.

Model list:

GT\*96605-G2\*\*\*\*\*

The 1st "\*" part can be 'M' or '-' or 'H' for market identification and not related to safety.

The 2nd "\*" can be A1, A2, A3 or any words for market use.

The 3rd "\*" can be "01" to "60" with interval of 0.1W, or blank, denotes the rated output wattage designation.

The 4th "\*" can be "-T2", "-T2A", "-T3", "-T3A", "-T3F", "-T3AF", "-R2", "-R3A", "-R3AF", "-T2" means desktop class II with C8 AC inlet.

“-T2A” means desktop class II with C18 AC inlet.

“-T3” means desktop class I or class II with functional earth with C14 AC inlet.

“-T3A” means desktop class I or class II with functional earth with C6 AC inlet.

“-T3F” means desktop class I or class II with functional earth with C14 AC inlet with FLOATING OUTPUT.

“-T3AF” means desktop class I or class II with functional earth with C6 AC inlet with FLOATING OUTPUT.

“-R2” means hybrid desktop housing class II with C8 AC inlet.

“-R3A” means hybrid desktop housing class I or class II with functional earth with C6 AC inlet.

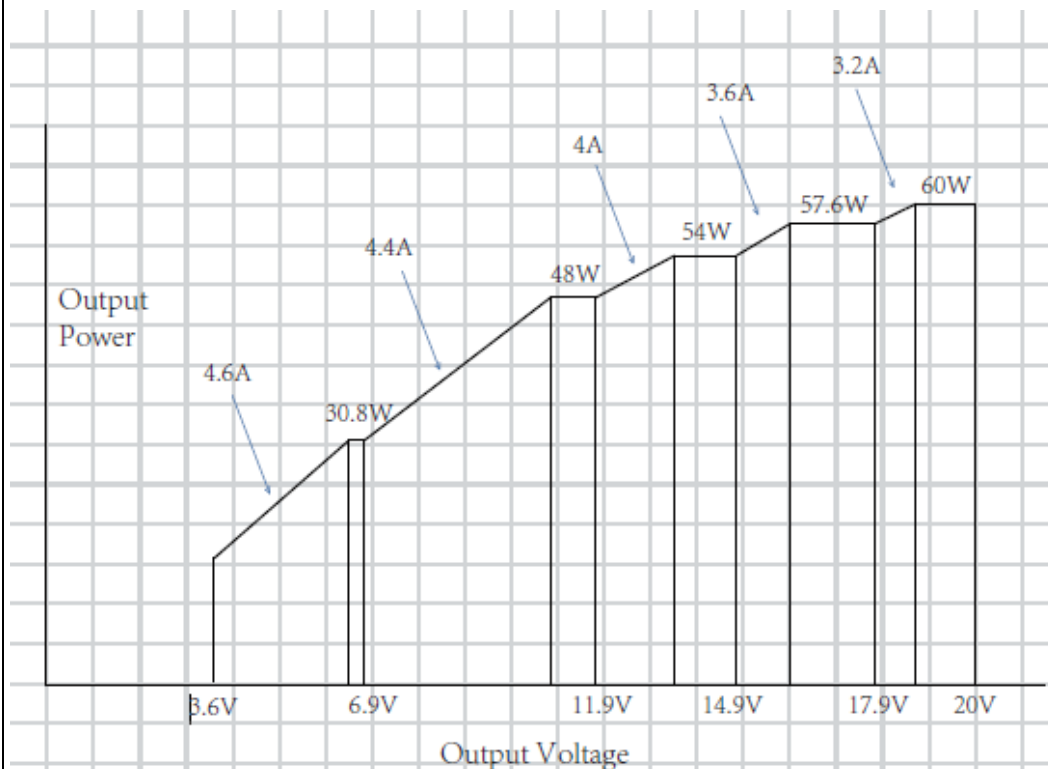
“-R3AF” means hybrid desktop housing class I or class II with functional earth with C6 AC inlet with FLOATING OUTPUT.

The 5th “\*” can be blank or -RA. -RA denotes the product with RIGHT ANGLE daughter board (no output cord); blank denotes the product with output cord.

The last \* denote any six character = 0-9 or A-Z or ( ) [ ] or – or blank for marketing purposes.

The whole series output will be any one voltage/current combinations (Power Profiles), between 3.6V and 20V.

Model	Input	Output voltage (Vdc)	Max. output current (A)	Max. output power (W)
GT*96605-G2*****	100-240VAC, 50-60Hz, 1.5A	3.6V - 6.9V	4.6A	30.8W
		7.0V - 11.9V	4.4A	48.0W
		12.0V - 14.9V	4.0A	54.0W
		15.0V - 17.9V	3.6A	57.6W
		18.0V - 20.0V	3.2A	60.0W





**Technical Considerations:**

Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 11.7 (Biocompatibility),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)
- Clause 17 (EMC)
- Usability was excluded from this investigation.

Note: This report is not valid unless used in conjunction with the original report.  
Determination of the test conclusion is based on IEC Guide 115 in consideration of measurement uncertainty.

**Modification 1:**

The original test report ref. No. 220201764HA-001, dated 2022-10-13; issued by Intertek Testing Services Shanghai, was amendment on 2023-08-30, include the following changes and/or additions:

1. Retested the 8.8.3 Dielectric strength on the prototype GTM96605-G2A1-T3.

After review, clause 8.5.4, 8.8.3, 8.9.4 were performed on the prototype GTM96605-G2A1-T3.  
In this report, only those clauses which effected by the modification were mentioned.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

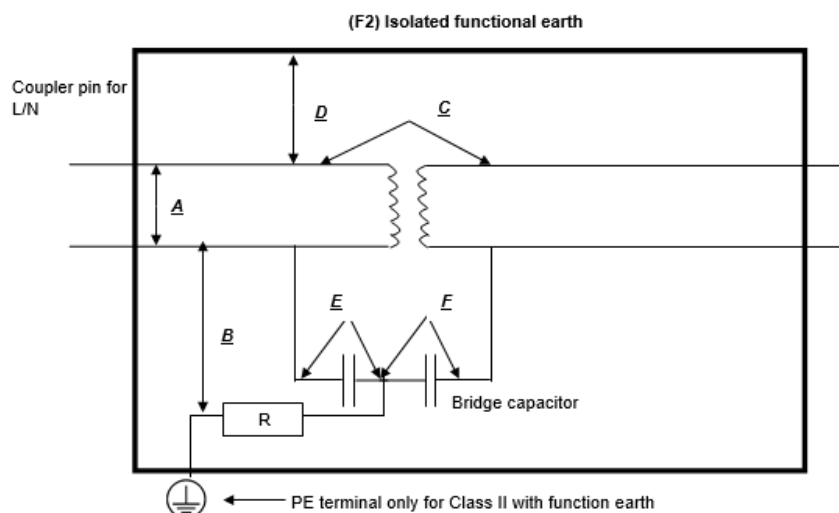
**INSULATION DIAGRAM**

TABLE: INSULATION DIAGRAM (GT*96605-G2****series)									P
Pollution degree .....: 2									—
Overvoltage category .....: II									—
Altitude .....: 5000m									—
Additional details on parts considered as applied parts .....: <input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ (See Clause 4.6 for details)									—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V <sub>rms</sub>	V <sub>pk</sub>					
A	1MOOP	IIIb	240	340	2.96	2.96	3.00	3.00	Opposite polarity of mains part
B	1MOPP	IIIb	240	340	4.0	3.22	6.15	6.15	Line/Neutral to PE terminal trace (for Class I) (floating for class II, shall be evaluated in end product) <sup>8</sup>
C	2MOPP	IIIb	240	352	8.0	6.5	8.05	8.05	Mains part to secondary circuits

IEC 60601-1									
Clause	Requirement + Test					Result - Remark			Verdict
									(Optocoupler)
C	2MOPP	IIIb	240	352	8.0	6.50	8.2	7.4	Mains part to secondary circuits (Transformer)
C	2MOPP	IIIb	240	340	7.9	6.45	8.05	8.05	Mains part to secondary circuits (Along PCB trace)
D	2MOOP	IIIb	240	340	5.92	5.92	8.26	8.26	Internal mains part to accessible outer enclosure
E	2MOPP	IIIb	240	340	7.9	6.45	10.26	10.26	Mains part to secondary circuits (Y capacitor)
<b>Supplementary Information:</b> 1) Multiplication factor for MOOP: 1.48; Multiplication factor for MOPP: 1.29. 2) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage. 3) The minimum creepage and clearance is selected from all the types of optocouplers. 4) The transformer core regarded as primary conductor is wrapped with 2 layers of insulating tape and the secondary pin-out adopts the jump lead wire soldering. 5) There is a slot min. 1 mm wide between two sides of pads of components. 6) A CREEPAGE DISTANCE cannot be less than the required air clearance. 7) For Encapsulated type, there is not earthing terminal for earthing wire in primary circuit, earthing wire is located on secondary circuit only, so no insulation J exist.									

### **INSULATION DIAGRAM CONVENTIONS and GUIDANCE:**

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

**Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:**

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure but are not terminated with an arrow.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
<b>8</b>	<b>PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT</b>		<b>P</b>
<b>8.5</b>	<b>Separation of parts</b>		<b>P</b>
<b>8.5.4</b>	<b>WORKING VOLTAGE</b>		<b>P</b>
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V).....:	240Vac	<b>P</b>
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V).....:	See Insulation Diagram and Insulation Table	<b>P</b>
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V).....:	See Insulation Diagram and Insulation Table	<b>P</b>
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	No patient connection.	<b>N/A</b>
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V).....:	No applied part.	<b>N/A</b>
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No defibrillation-proof applied parts.	<b>N/A</b>
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V).....:	No motor.	<b>N/A</b>
<b>8.8</b>	<b>Insulation</b>		<b>P</b>
<b>8.8.1</b>	<b>Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing</b>		<b>P</b>
	Insulation exempted from test (complies with clause 4.8)		<b>P</b>
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	No such part.	<b>N/A</b>
<b>8.8.2</b>	<b>Distance through solid insulation or use of thin sheet material</b>		<b>P</b>

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		<b>P</b>
	a) 0.4 mm, min, distance through insulation, or	Enclosure is 2.0mm thick	<b>P</b>
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		<b>P</b>
	– <i>at least two layers of material, each passed the appropriate dielectric strength test.....</i>	See appended Table 8.8.3	<b>P</b>
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test .....		<b>N/A</b>
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		<b>N/A</b>
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	See appended Table 8.8.3	<b>P</b>
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		<b>N/A</b>
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		<b>N/A</b>
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		<b>N/A</b>
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	Certified triple insulated wire is used.	<b>P</b>
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		<b>N/A</b>
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		<b>N/A</b>
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		<b>P</b>
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		<b>N/A</b>

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension.....:	Additional protection by insulating tape.	<b>P</b>
	Finished component complied with routine dielectric strength tests of 8.8.3.....:	See appended Table 8.8.3	<b>N/A</b>
	Tests of Annex L not repeated since material data sheets confirm compliance.....:		<b>N/A</b>
<b>8.8.3</b>	<b>Dielectric Strength</b>		<b>P</b>
	Solid insulating materials with a safety function withstood dielectric strength test voltages .....	See appended Table 8.8.3	<b>P</b>
<b>8.9.3</b>	<b>Spaces filled by insulating compound</b>		<b>P</b>
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound	Certified optocoupler.	<b>P</b>
	Thermal cycling, humidity preconditioning, and dielectric strength tests	Certified optocoupler has conformed to these tests.	<b>P</b>
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage).....:	Certified optocoupler.	<b>P</b>
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	Certified optocoupler has conformed to these tests.	<b>P</b>
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	No such construction.	<b>N/A</b>
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		<b>N/A</b>
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage .....		<b>N/A</b>
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		<b>N/A</b>

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.4	Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree .....:	Pollution degree: II	<b>P</b>
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	Refer to Insulation Diagram supplemental information for location and force used	<b>P</b>

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

**TABLE 8.5.4: Working Voltage Measurement**

Location From/ To (Insulation Diagram Designation)	Measured Voltage (Vrms)	Measured Voltage (Vpk)	Measured Peak-to- peak ripple (V)	Required Clearance (mm)	Required Creepage (mm)	Measured Clearance (mm)	Measured Creepage (mm)	Remarks
<b>Tested on model GTM96605-G2A1-T3</b>								
T1 Pin 12 to Pin A	171	298	--	--	--	--	--	--
T1 Pin 12 to Pin B	202	346	--	--	--	--	--	--
T1 Pin 10 to Pin A	186	312	--	--	--	--	--	--
T1 Pin 10 to Pin B	204	352	--	--	--	--	--	Max Vpk
T1 Pin 1 to Pin A	190	323	--	--	--	--	--	--
T1 Pin 1 to Pin B	192	329	--	--	--	--	--	--
T1 Pin 2 to Pin A	196	331	--	--	--	--	--	--
T1 Pin 2 to Pin B	202	349	--	--	--	--	--	--
U4 Pin 1 to 3	197	328	--	--	--	--	--	--
U4 Pin 1 to 4	220	332	--	--	--	--	--	--
U4 Pin 2 to 3	194	318	--	--	--	--	--	--
U4 Pin 2 to 4	195	322	--	--	--	--	--	--
CY1 primary pin– CY2 secondary pin	167	296	--	--	--	--	--	--

Supplementary Information:

Note:

Vrms measurements for non-DC voltages

Peak to Peak ripple measurement was conducted only on DC voltage

Energy measurement made when Power exceeded 240 VA for longer than 60 s



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.8.3	<b>TABLE: Dielectric strength test of solid insulating materials with safety function – means of operator protection (MOOP) / means of patient protection (MOPP)</b>				<b>P</b>
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s <sup>1)</sup>	Dielectric breakdown after 1 minute Yes/No <sup>2)</sup>
		PEAK WORKING VOLTAGE (U) V <sub>peak</sub>	PEAK WORKING VOLTAGE (U) V d.c.		
B	1MOPP	340	--	1500	No breakdown
C	2MOPP	352	--	4000	No breakdown
C	2MOPP	352	--	4000	No breakdown
C	2MOPP	340	--	4000	No breakdown
D	2MOOP	340	--	3000	No breakdown
E	1MOPP	340	--	1500	No breakdown
F	1MOPP	340	--	1500	No breakdown
<b>Supplementary information:</b> <sup>1</sup> Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used. <sup>2</sup> A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).					

**Attachment 1: Photo of EUT**

External view for GTM96605-G2A1-R3AF



External view for GTM96605-G2A1-R3AF



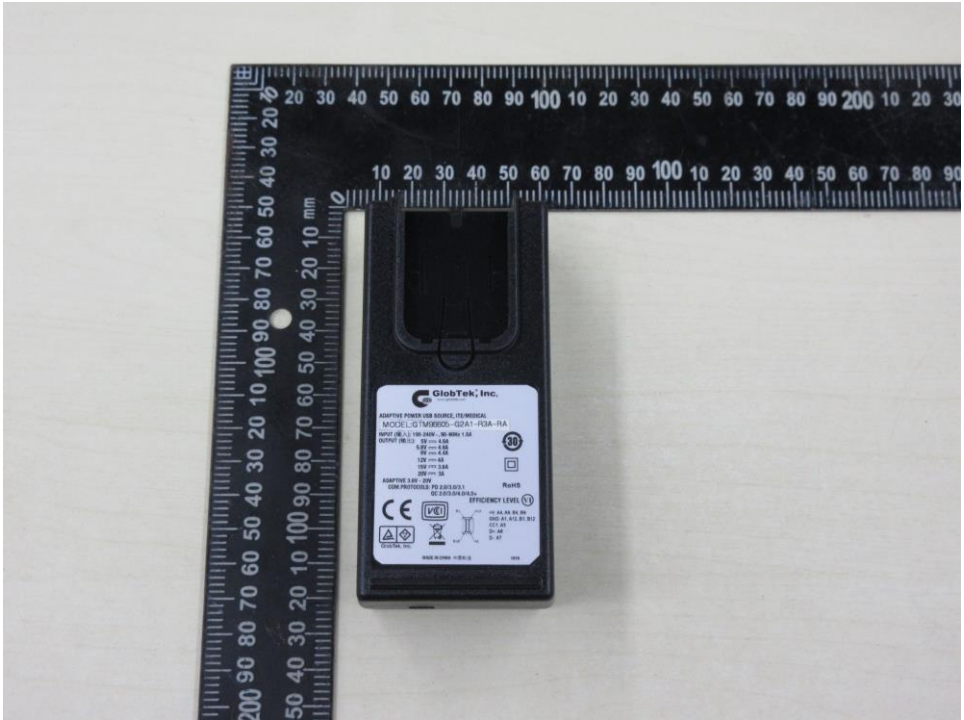
External view for GTM96605-G2A1-T3



External view for GTM96605-G2A1-T3



External view for GTM96605-G2A1-R3A-RA



External view for GTM96605-G2A1-R3A-RA





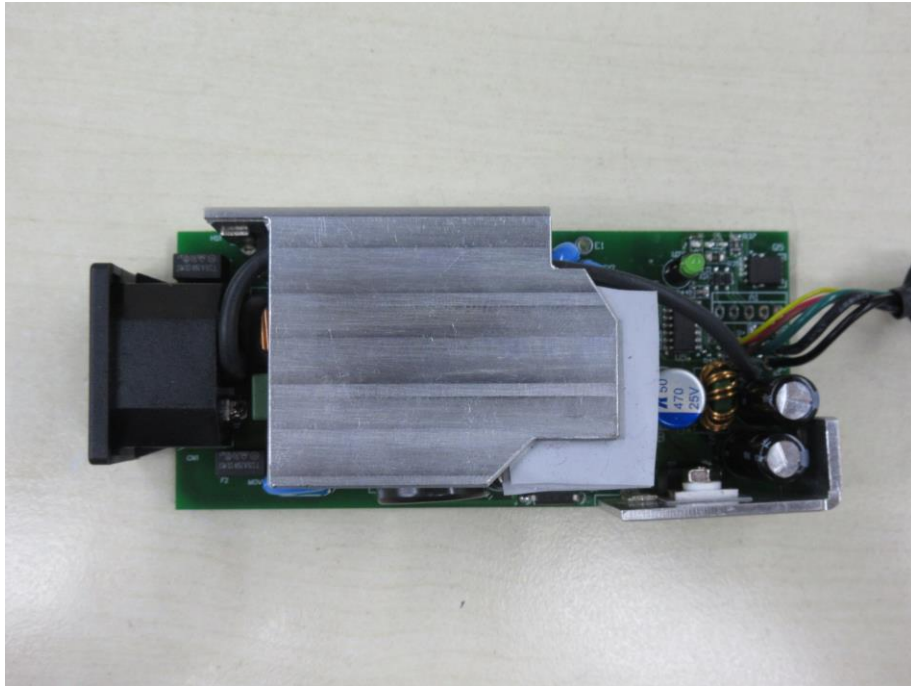
Internal view



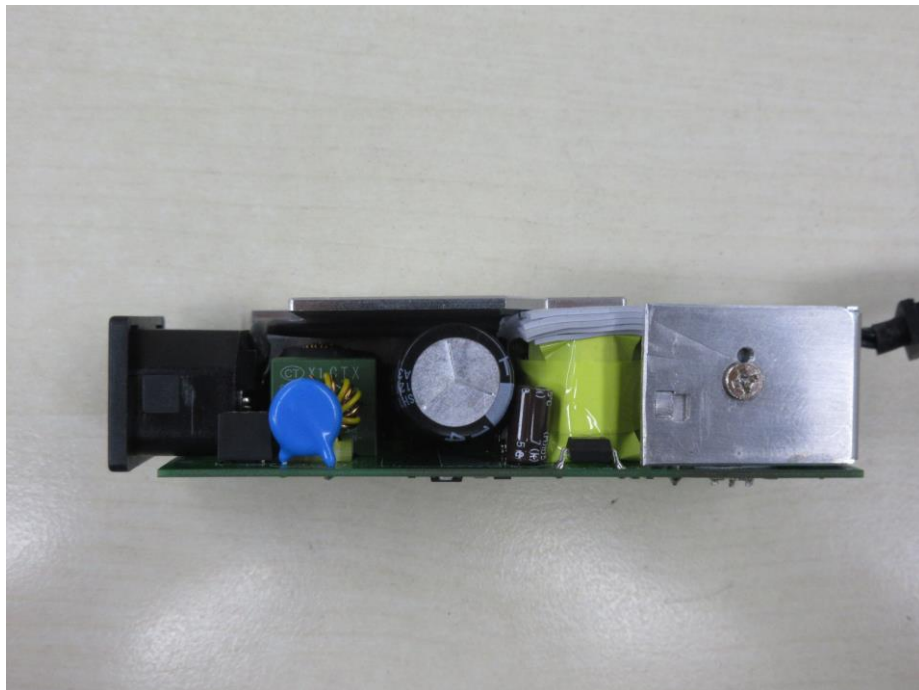
Internal view



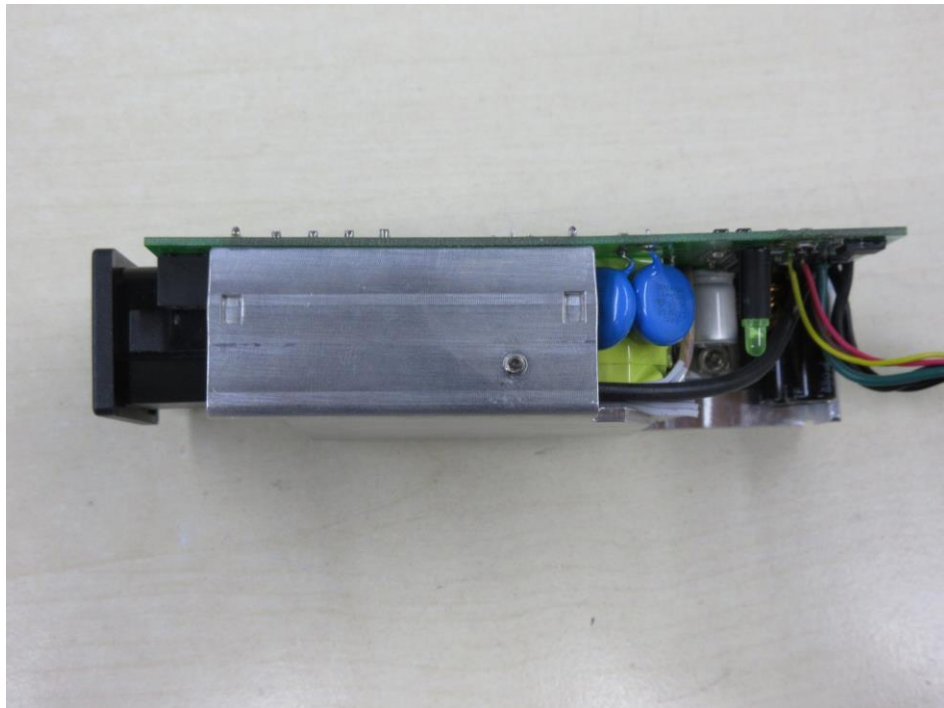
PCB view



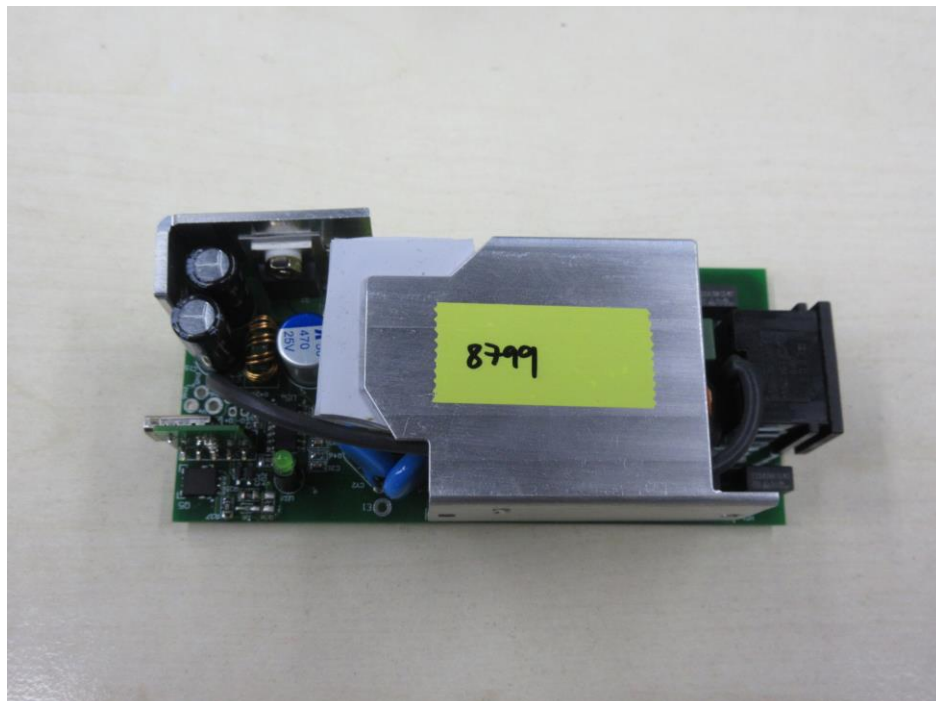
PCB view



PCB view



PCB view



PCB view



Transformer view





Transformer view



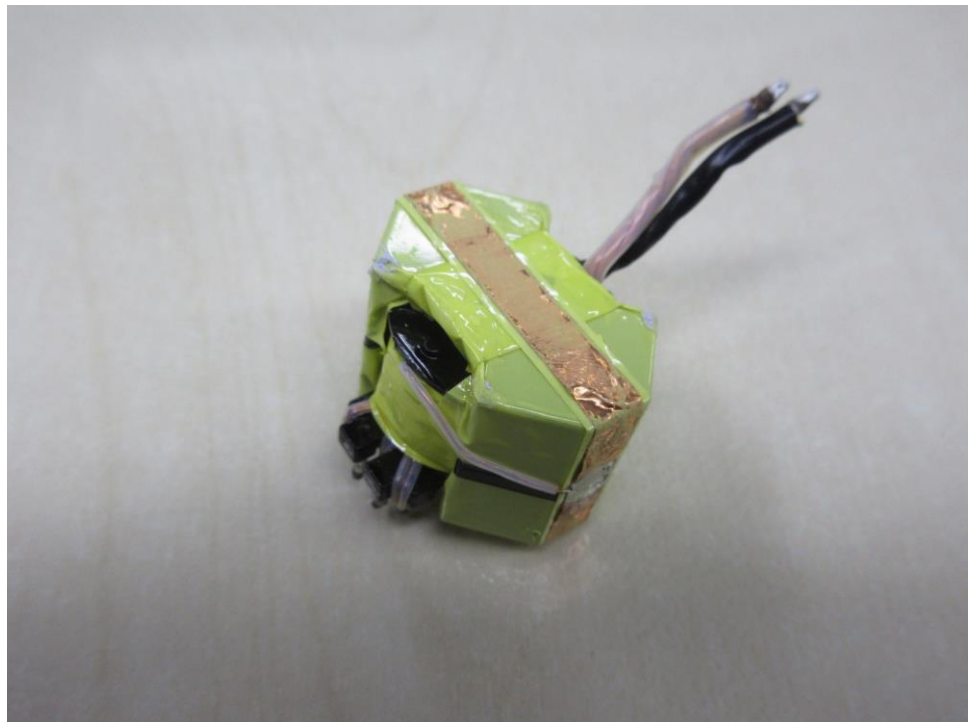
Transformer view



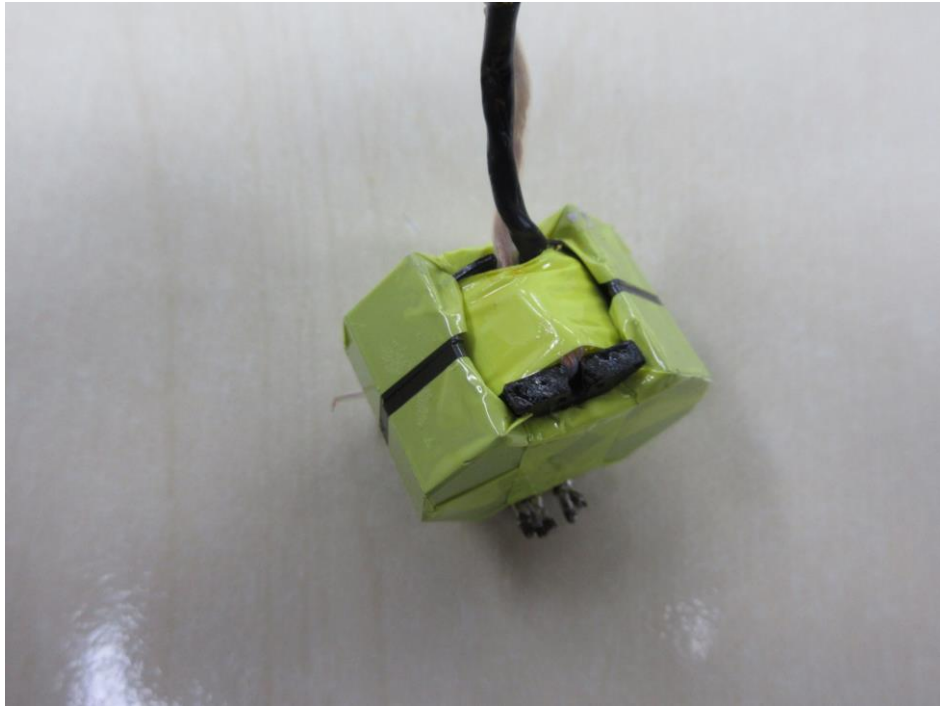
Transformer view



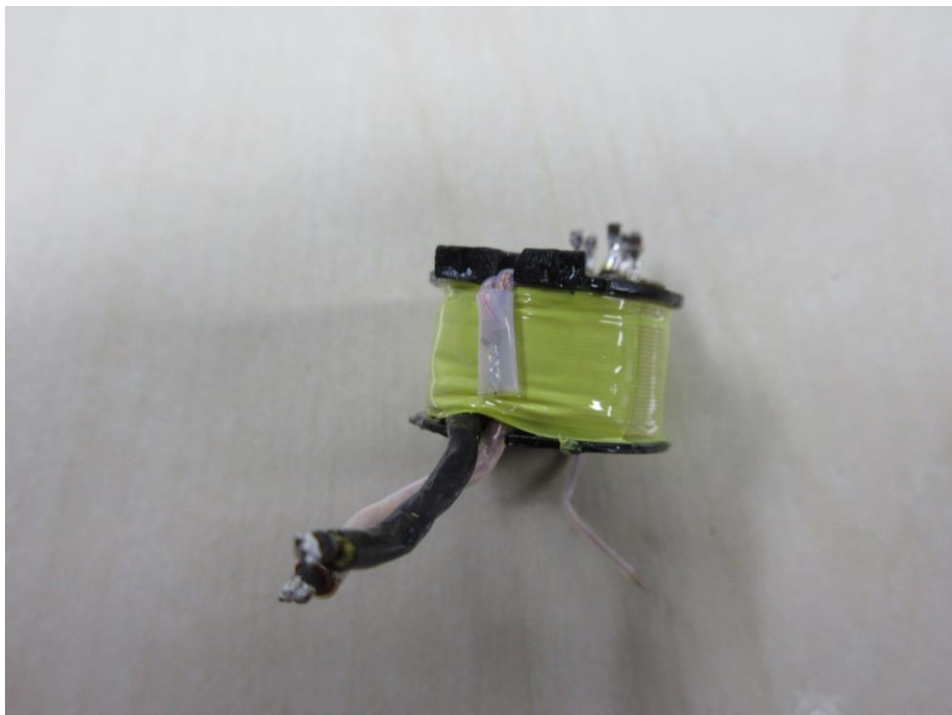
Transformer view



Transformer view



Transformer view



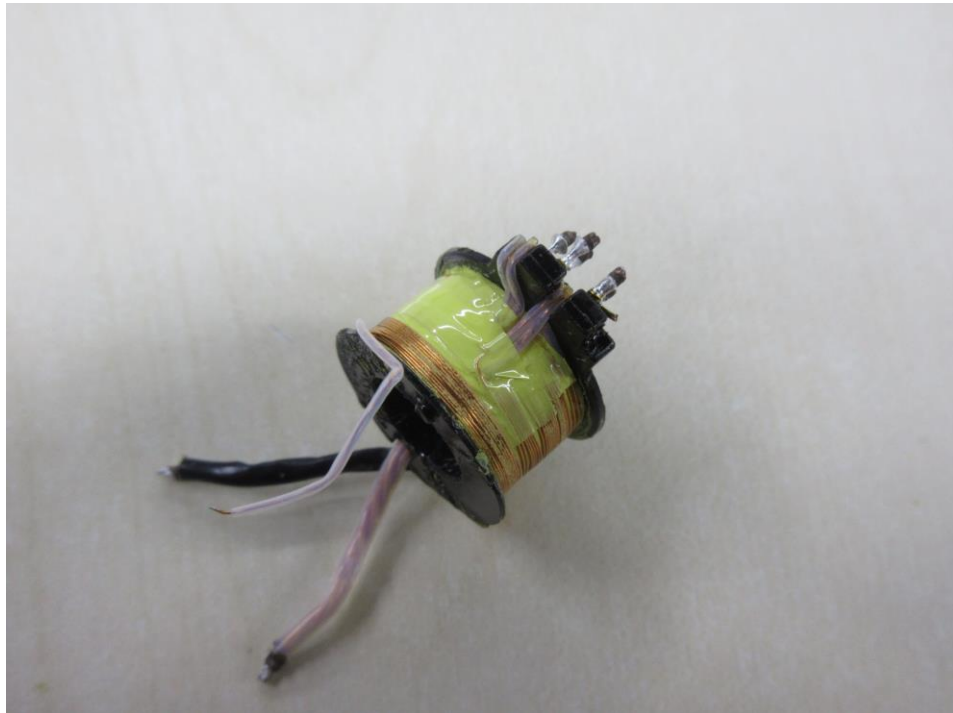
Transformer view



Transformer view



Transformer view

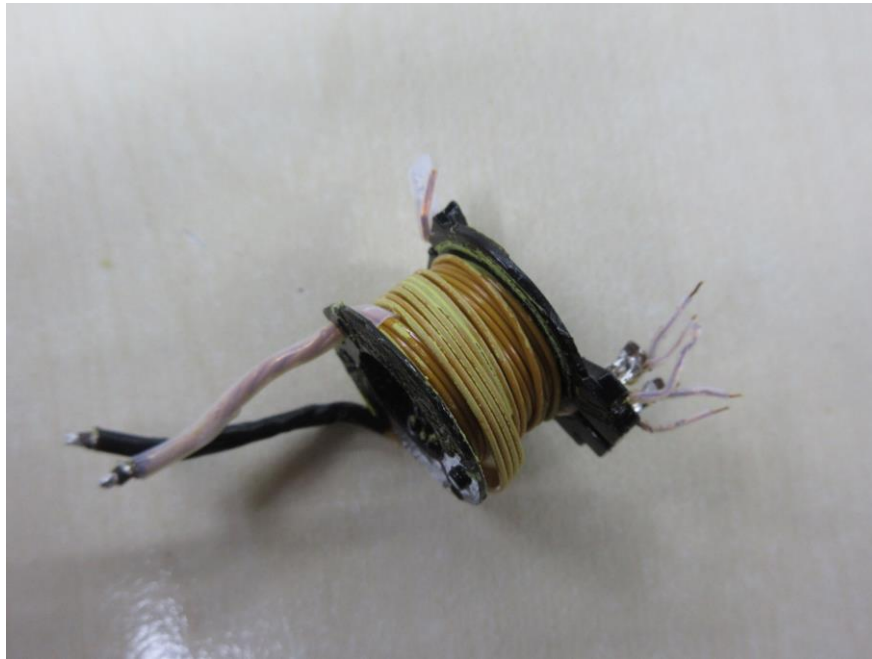


Transformer view



Transformer view

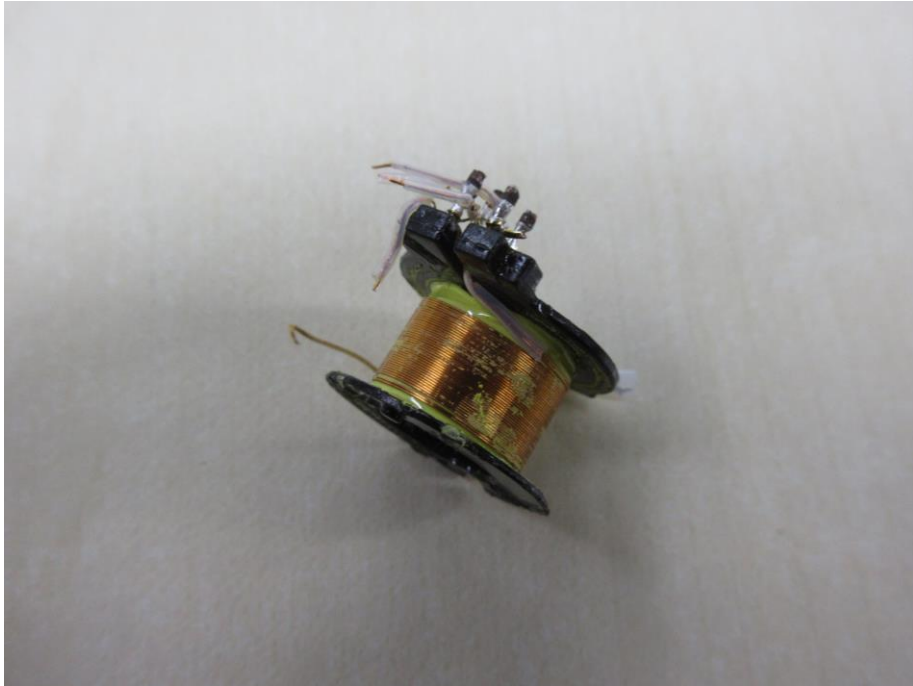




Transformer view



Transformer view



Transformer view



Transformer view

