Test Report issued under the responsibility of:

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	E357129-D1002-1/A0/C0-UL
Date of issue.....:	2017-7-31
Total number of pages.....:	146
Testing Laboratory.....:	Underwriters Laboratories Taiwan Co., Ltd.
Address.....:	260 Da-Yeh Road, 112 Peitou Taipei City, Taiwan
Applicant's name .....:	CYBERNET MANUFACTURING ING
Address.....:	4F 25 LN 140 XING-AI RD, NEIHU DISTRICT, TAIPEI, 114 TAIWAN
Test specification:	
Standard .....:	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	UL Certification
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1K

General disclaimer:

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing UL testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting UL.

Test item description:	All in One PC
Trade Mark:	N/A
Manufacturer:	Same as Applicant
Model/Type reference:	CyberMed NB24, iOne NB24, CyberMed S24, iOne S24
Ratings:	Specified power adaptor: Mfr.: EDAC POWER ELECTRONICS CO., LTD Model: EM11011M Input rating: 100-240Vac, 50-60Hz, 2.0-1.0A Output rating: 19-24Vdc, 6.31A, 120W max. Panel PC Input rating: 19Vdc, 6.31A

Testing procedure and testing location:		
[X] UL/DAP Testing Laboratory:		
Testing location/ address:	Underwriters Laboratories Taiwan Co., Ltd. 260 Da-Yeh Road, 112 Peitou Taipei City, Taiwan	
Tested by (name, function, signature):	Chenchen Lee, Handler	
Approved by (name, function, signature):	Conga Chen, Reviewer	
[ ] Testing procedure: WMT:		
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		

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

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing

Tests performed (name of test and test clause): Testing location:

Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

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 owners of these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of Installation and Use:	Fixed or Portable
Device type (component/sub-assembly/ equipment/ system):	Equipment
Intended use (Including type of patient, application location):	The equipment is intended to use for general pc application for health care environment and for diagnosis. It maybe use for Radiology, PACS (Picture Archiving Communication Systems),LIS (Lab Information Systems) and Electronic Medical Record purpose. It shall not be used for life-supporting system.
Mode of Operation:	Continuous
Supply Connection:	Appliance Coupler
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s) .....:	2016-12-08, 2017-04-25
Dates tests performed .....:	2016-12-08 to 2017-07-31
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement ..... :	N/E
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition: N.C.	- single fault condition: S.F.C.
- means of Operator protection: MOOP	- means of Patient protection: MOPP

General remarks:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version “J” of TRF for IEC for 60601-1 3rd edition with Amendment 1.
"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a point is used as the decimal separator.

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Refer to the Report Modifications page for any modifications made to this report.

Product Description

This Panel PC consists of 24 inch LCD with LED backlight display, CPU, main board, Touch Screen, Hard Disk Drive or Solid-State Drive, Web Cam, Speakers, 3 hot swappable battery pack (not provide for CyberMed S24, iOne S24) which are enclosed in a plastic & metal enclosure, supplied by external power adaptor. This equipment is intended for general pc application for health care environment and for

diagnosis. It maybe be used for Radiology, PACS (Picture Archiving Communication Systems),LIS (Lab Information Systems) and Electronic Medical Record purpose. It shall not be used for life-supporting system.

The insulation system of the equipment has been evaluated in compliance with means of patient protection (MOPP).

The operation environment of this Panel PC specified by the manufacturer is 0 to 30 degree C, 10 to 90% RH (Non-condensing) and 0 to 3000m.

Model Differences

For models CyberMed NB24, iOne NB24, CyberMed S24, iOne S24 are similar except for following difference:

1) CyberMed: enclosure color is white

2) iOne: enclosure color is black

3) NB: product with battery.

4) S: product without battery.

Additional Information

The risk management requirements were evaluated as part of external power adaptors by themselves.

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  From Country Differences:

  - USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
  - Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14

  Additional Standards:

  None

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Biocompatibility (ISO 10993-1), Electromagnetic Compatibility (IEC 60601-1-2), Usability (IEC 60601-1-6), Clause 11.7 Biocompatibility, Clause 17 EMC and Clauses 7.9.1 & 12.2 Usability
- The following accessories were investigated for use with the product: None
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

None

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Clause	Requirement + Test	Result - Remark	Verdict

Insulation Diagram - (01) (5-04) Insulation diagram

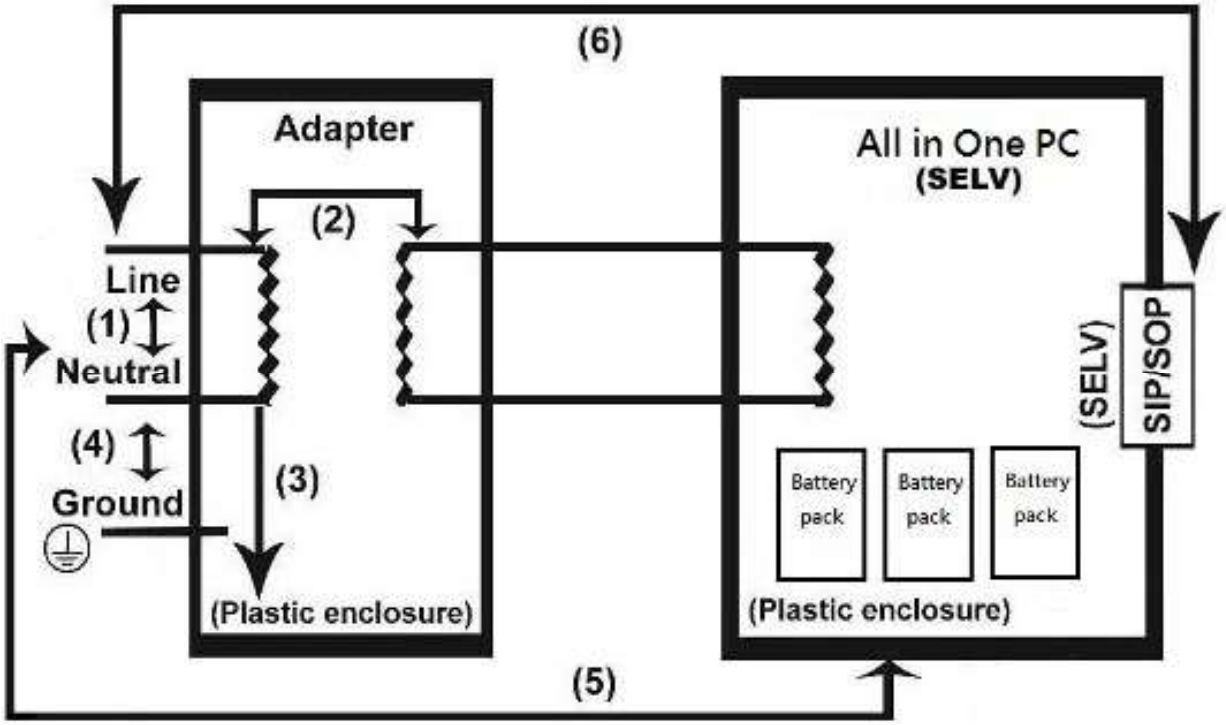

TABLE: INSULATION DIAGRAM									Pass
Pollution Degree:				**2**					-
Overvoltage category:				**II**					-
Altitude:				**3000 (m)**					-
Additional details on parts considered as applied parts:				**[X] None [ ] Areas: ___ (See Clause 4.6 for details)**					-
Area	**Number and type of Means of Protection: MOOP, MOPP**	**CTI**	**Working Voltage V_{rms}**	**Working Voltage V_{pk}**	**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**
1	MOOP (1)	IIIb	250	354	2.5	2.3	--	--	Evaluated in UL/cUL 60601-1 recognized power adaptors. (Mfr: ADAPTER, type ATM120-P240; Mfr: EDAC, type EM11011M)
2	MOPP (2)	IIIb	270	504	8.6	7	--	--	Evaluated in UL/cUL 60601-1 recognized power adaptors. (Mfr: ADAPTER, type ATM120-P240; Mfr: EDAC, type EM11011M)

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Clause	Requirement + Test					Result - Remark			Verdict
2	MOPP (2)	IIIb	264	448	8.4	7	--	--	Evaluated in UL/cUL 60601-1 recognized power adaptors. (Mfr: ADAPTER, type ATM120-P240; Mfr: EDAC, type EM11011M)
3	MOPP (2)	IIIb	250	354	8	5	--	--	Evaluated in UL/cUL 60601-1 recognized power adaptors. (Mfr: ADAPTER, type ATM120-P240; Mfr: EDAC, type EM11011M)
4	MOPP (1)	IIIb	250	354	4	2.5	--	--	Evaluated in UL/cUL 60601-1 recognized power adaptors. (Mfr: ADAPTER, type ATM120-P240; Mfr: EDAC, type EM11011M)
5	MOPP (2)	IIIb	270	504	8.6	7	10	10	Primary of power adaptor (Mfr: EDAC, type EM11011M) to Panel PC metal/plastic enclosure
6	MOPP (2)	IIIb	270	504	8.6	7	10	10	Primary of power adaptor (Mfr: EDAC, type EM11011M) to Panel PC SIP/SOP
6	MOPP (2)	IIIb	264	448	8.4	7	10	10	Primary of power adaptor (Mfr: ADAPTER, type EM11011M) to Panel PC SIP/SOP

Supplementary Information:

Functional Insulation: Insulation that is necessary only for the correct functioning of the equipment and does not protect against electric shock.

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.

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Clause	Requirement + Test	Result - Remark	Verdict

Area 1 ~ 4: Evaluated in UL/cUL 60601-1 recognized power adaptors used. (Mfr: Adapter Technology Co Ltd / Model: ATM120-P120) (Mfr: EDAC POWER ELECTRONICS CO LTD. / Model: EM1101H)
Area 2, 5, 6, 8: Test reference voltage based on Transformer working voltage of external power adapter per client's declaration.

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

4	GENERAL REQUIREMENTS		Pass
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		Pass
4.2	RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS		Pass
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007):	See Appended RM Results Table 4.2.2.	Pass
4.2.3	Evaluating RISK		Pass
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		Pass
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN:	RISK MANAGEMENT Document: Document Ref. (Project Number: 161201402_3057, Version: 1.00, Creation Date: 2017-06-16).	Pass
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		Pass
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		Pass
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		N/A
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	No Essential Performance Declared.	N/A
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		N/A
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		N/A
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE:		N/A
	- RISK CONTROL measures implemented		N/A
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE:	30,000 hours	Pass
4.5	Alternative RISK CONTROL methods utilized:	No such conditions	N/A