Test report

Test report Nr.:	**CR-2023-028**	Order Nr.:	**CL-2023-003**
Manufacturer:	**QX WORLD Ltd.** HUNGARY, 1095, Budapest, Tinodi street 1-3, A. building, IV floor, door 93.		
Applicant:	**QX WORLD Ltd.** HUNGARY, 1095, Budapest, Tinodi street 1-3, A. building, IV floor, door 93.		
Test item:	Universal Electrophysiological Biofeedback Device	Type:	QUEX ED
Receipt No.:	CL-2023-003/1	Date and location of receipt:	2023.09.08 1043 Budapest, Dugonics utca 11
Test			
Condition of test item:	complete, undamaged	Duration of test:	2023.09.08 ... 2023.12.05
Name of the testing laboratory:	**ConformiTICs Lab Kft.** H-1134 Budapest, Váci út 49., Hungary		
Test location:	**ConformiTICs Lab Kft.** H-1043 Budapest, Dugonics utca 11., Hungary		
Test specifications:	IEC 80601-2-26:2019		
Test result:			
The test item passed the test specifications.			
Note:	—		

Tested by:		**Erik Reichert (test engineer)**	**Approved by:**		**Péter Martin (aproover)**
Date:	2023-12-07	Signature:	Date:	2023-12-07	Signature:

This test report relates to the a. m. test sample. Without permission of the testing laboratory is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Elektronikusan aláírta:
Reichert Erik

Elektronikusan aláírta:
Martin Péter

Test Report issued under the responsibility of:

TEST REPORT

IEC 80601-2-26

Particular requirements for the basic safety and essential performance of electroencephalographs

Report Number..... :	CR-2023-028
Date of issue ..... :	**2023-12-07**
Total number of pages ..... :	29
Name of Testing Laboratory preparing the Report ..... :	**ConformiTICs Lab Kft.** **H-1134 Budapest, Váci út 49., Hungary**
Applicant's name ..... :	**QX WORLD Ltd.**
Address..... :	HUNGARY, 1095, Budapest, Tinodi street 1-3, A. building, IV floor, door 93.
Test specification:	
Standard ..... :	IEC 80601-2-26:2019
Test procedure..... :	Type test
Non-standard test method..... :	N/A
Test Report Form No. ..... :	IEC80601_2_26A
Test Report Form(s) Originator.... :	UL(US)
Master TRF ..... :	Dated 2020-02-14

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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 CB Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description ..... :	Universal Electrophysiological Biofeedback Device
Trade Mark(s) ..... :	QUEX | ED
Manufacturer ..... :	**QX WORLD Ltd.** HUNGARY, 1095, Budapest, Tinodi street 1-3, A. building, IV floor, door 93.
Model/Type reference ..... :	QUEX ED
Ratings ..... :	5V DC; Max 1.2A; Type BF applied part

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**Testing Laboratory:**	**ConformiTICs Lab Kft.**	
Testing location/ address ..... :		**H-1043 Budapest, Dugonics utca 11., Hungary**	
Tested by (name, function, signature) ..... :		Erik Reichert (test engineer)	See first page of test report as "tested by".
Approved by (name, function, signature) .. :		Péter Martin (reviewer)	See first page of test report as "approved by".
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :		N/A	
Tested by (name, function, signature) ..... :		N/A	N/A
Approved by (name, function, signature) .. :		N/A	N/A
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :		N/A	
Tested by (name + signature) ..... :		N/A	N/A
Witnessed by (name, function, signature) . :		N/A	N/A
Approved by (name, function, signature) .. :		N/A	N/A
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :		N/A	
Tested by (name, function, signature) ..... :		N/A	N/A
Witnessed by (name, function, signature) . :		N/A	N/A
Approved by (name, function, signature) .. :		N/A	N/A
Supervised by (name, function, signature) :		N/A	N/A

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

- Test equipment list (page 26)
- Photos of the tested equipment (pages 27 ... 29)

The following documents are not attached to this test report, but kept in file:

Referred in this test report as	Description	Pages
User Manual	QUEX ED User Manual issue 2_US.docx, Edition: 2, dated: 2023-02-23	23
Essential Performance Document	Essential performance QUEX ED_rev0_22-11-2023.pdf, Version: 1.0, dated: 2023-11-22	2

Summary of testing:

This test report does not cover parameters that are influenced by the installation of optional equipment and accessory that might affect safety in the meaning of this standard. The equipment were tested only with the submitted accessories in the provided configuration.

Tests performed (name of test and test clause):

201.8.5.2.3 PATIENT leads or PATIENT cables
201.12.1.102 Accuracy of signal reproduction
201.12.1.103 Input dynamic range and differential offset voltage
201.12.1.104 Input noise
201.12.1.105 Frequency response
201.12.1.106 Common mode rejection

Testing location:

ConformiTICs Lab Kft.
H-1043 Budapest, Dugonics utca 11., Hungary

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

☒ **The product fulfils the requirements of IEC 80601-2-26:2019**

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

(may be required by the product standard or client)

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

Procedure number, issue date and title:

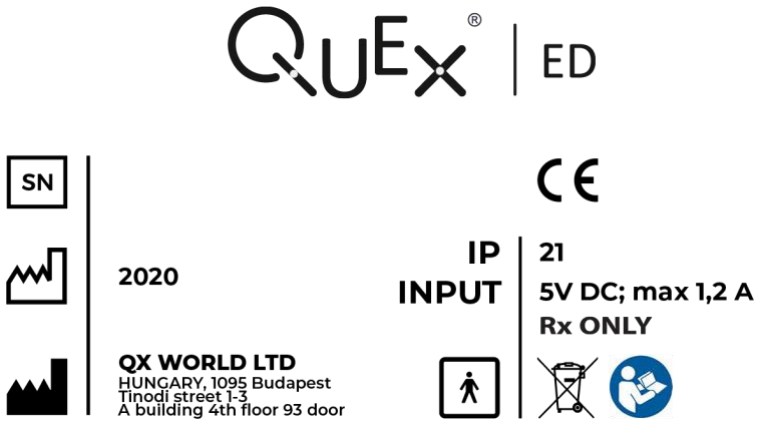
Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☒ **Statement not required by the standard used for type testing**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

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.



Test item particulars .....:	portable
Classification of installation and use .....:	equipment
Supply Connection.....:	No direct connection to the Mains. Powered via USB.
.....:	
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object does not meet the requirement .....:	F (Fail)
Testing .....:	
Date of receipt of test item .....:	2023.09.08
Date (s) of performance of tests .....:	2023.09.08 ... 2023.12.05

General remarks:

"(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.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 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).....:	Hungary, 1043 Budapest, Lórántffy Zsuzsanna utca 15/B

General product information and other remarks:

The QUEX ED device is indicated for use as a Universal Electrophysiological Biofeedback System. The Universal Electrophysiological Biofeedback System is made up of the following Seven Universal Items which are functions of the QUEX ED device:
1. Stress Reduction and Lifestyle Stressors Questionnaire;
2. Simple EEG [electroencephalography measuring volts] biofeedback brain wave stress reduction;
3. GSR [galvanic skin response measuring resistance] biofeedback and TVEP [transcutaneous voltammetric evoked potential] biofeedback (electrophysiological reactivity).

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
201.4	**GENERAL REQUIREMENTS**		Pass
201.4.3	**Essential Performance**		Pass
	Distributed essential performance requirements specified in this standard are met ..... :	See Essential performance document.	Pass
201.5	**GENERAL REQUIREMENTS FOR TESTING OF ME EQUIPMENT**		Pass
201.5.4	If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE may be replaced by an external battery or DC power supply to provide the necessary test voltage.	Tested with the provided accessories.	Pass
201.5.8	Sequence of tests was observed		Pass
201.6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		Pass
201.6.6	**Mode of operation**		Pass
	ME EQUIPMENT is for CONTINUOUS OPERATION	Equipment classified for continous operation.	Pass
201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		Pass
201.7.2.1	**Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts**		Pass
	Parts of ME EQUIPMENT specified as being protected against the effects of defibrillation are marked with symbol 26 or 27 of Table D.1 in Appendix D of the general standard according to the classification as TYPE BF APPLIED PART or TYPE CF APPLIED PART. ..... :	Applied part is not classified as defibrillation-proof applied part.	N/A
201.7.9.2	**Instructions for use include:**		Pass
	a) The INTENDED USE/INTENDED PURPOSE including environment of use with likely misuse identified by risk analysis and disclosed if necessary	See section 4 and 7 in the User manual.	Pass
	b) The procedures necessary for safe operation	See section 4 in the User manual.	Pass

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
	c) That conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth	See section 2 in the User manual. "WARNING: Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth."	Pass
	d) Information whether the ELECTROENCEPHALOGRAPH incorporates means to protect the PATIENT against burns when used with HF SURGICAL EQUIPMENT and advice regarding the location of ELECTRODES and LEAD WIRES etc., to reduce the HAZARD of burns in the event of a defect in the NEUTRAL ELECTRODE connection of the HF SURGICAL EQUIPMENT.	See section 2 in the User manual. "WARNING: The device should not be used while the patient is connected to high-frequency surgical equipment. It may cause burn injuries on the skin under the electrodes."	Pass
	e) The need for regular testing of the ME EQUIPMENT and its ACCESSORIES	See section 9 in the User manual. "WARNING: Some decontamination methods can lead to increased wear of the QUEX S Electrophysiological System. Check the device / harness and electrodes before use for signs of wear."	Pass
	f) Precautions to take when using a defibrillator on a patient; if APPLIED PARTS not protected against the effects of defibrillation are being used; a description of how the discharge of a defibrillator affects the ELECTROENCEPHALOGRAPH.	See section 2 in the User manual. "WARNING: The device is not defibrillation proof; defibrillator shall not be used until the electrodes are on the patient."	Pass
	g) The subsequent operation of the ELECTROENCEPHALOGRAPH after interruption of supply mains exceeding 30 s (see 201.11.8).	See section 5 in the User manual. "Use this device with a computer on battery mode free from wall current or with a medically safe surge protector. Use this device with a computer with internal battery in good conditions. The computer shall work at least 30 minutes without external power supply."	Pass

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
	h) Any HAZARD due to simultaneous use of other PATIENT-connected ME EQUIPMENT	See section 5 in the User manual. "Do not use this device with a pacemaker."	Pass
	i) Technical specifications for the ELECTROENCEPHALOGRAPH of sufficient detail to allow the operator to understand what is being measured and any limitations. This included: – accuracy of signal reproduction; – input dynamic range and maximum offset voltage; – noise; – frequency range and bandwidth; – common mode rejection – a description of all functions; – a description of waveform displays (if applicable).	See section 12 in the User manual.	Pass
	j) Any known susceptibilities to electromagnetic phenomena	See section 2 in the User manual.	Pass
	k) If applicable, limitations of multipurpose CHANNELS and to which clauses of applicable standards (e.g. IEC 80601-2-xx) they were tested, if any.	Not applicable.	N/A

201.8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		Pass
201.8.1.101	**Multipurpose channel(s)**		Pass
	Electroencephalographs allowing channels to be used for signals other than EEG was tested to applicable clauses of relevant standards as specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS:	Other channels used for Skin resistance measurement there is no additional requirement.	N/A
201.8.5.2.3	**PATIENT leads or PATIENT cables**		Pass
	Any detachable ELECTRODE connector of a LEAD WIRE, when separated from the ELECTRODE, had an air clearance between connector pins and a flat surface of at least 0,5 mm..... :	The air clearance is bigger than 0.5mm.	Pass
201.8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**		N/A
201.8.5.5.1	**Defibrillation protection**	Applied part is not classified as defibrillation-proof applied part.	N/A
	For defibrillator testing the ME EQUIPMENT is operated using the PATIENT CABLES as specified by the MANUFACTURER		N/A
	Common mode test		N/A

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
	Compliance checked according to Fig. 201.101		N/A
	The ME EQUIPMENT resumed normal operation in the previous operating mode, without loss of OPERATOR settings or stored data within 30 s and continued to perform its intended function		N/A
	ME EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE rechargeable from the SUPPLY MAINS tested with and without the SUPPLY MAINS connection when the ME EQUIPMENT is capable of operating while connected to the SUPPLY MAINS		N/A
	Differential mode test		N/A
	Compliance checked according to Fig. 201.102		N/A
	Within 30 s after exposure to the defibrillation voltage, the ME EQUIPMENT resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and continued to perform its intended function		N/A
201.8.5.5.2	**Energy reduction test**	Applied part is not classified as defibrillation-proof applied part.	N/A
	Compliance checked according to Fig.201.103		N/A
201.8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		Pass
	Test conducted with any input or montage selectors set so as to produce the worst case conditions..... :	Considered.	Pass
	The worst case was determined by inspection of the circuit diagram and/or the ELECTROENCEPHALOGRAPH and its associated ACCESSORIES		Pass

201.11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**	Pass
201.11.8	**Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT**	Pass

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
	When the supply mains to the ELECTROENCEPHALOGRAPH was interrupted for less than 30 s, no change of operator settings occurred, including the mode of operation, or loss of all stored patient data	The EUT powered from laptop, no direct connection to the Supply mains. See section 5 in the User manual: “Use this device with a computer on battery mode free from wall current or with a medically safe surge protector. Use this device with a computer with internal battery in good conditions. The computer shall work at least 30 minutes without external power supply.”	Pass
	When the SUPPLY MAINS was interrupted for more than 30 s, the subsequent operation was one of the following:		N/A
	– reversion to the MANUFACTURER’S default settings,	See below.	N/A
	– reversion to previous RESPONSIBLE ORGANIZATION’S default settings or;		N/A
	– reversion to the last settings used.		N/A
	When the supply mains for the ELECTROENCEPHALOGRAPH containing an internal electrical power source, was interrupted, the me equipment continued normal operation by switching automatically to operating from its internal electrical power source, and the mode of operation, all operator settings and stored data were not changed.	The EUT powered from laptop, no direct connection to the Supply mains. See section 5 in the User manual: “Use this device with a computer on battery mode free from wall current or with a medically safe surge protector. Use this device with a computer with internal battery in good conditions. The computer shall work at least 30 minutes without external power supply.”	Pass
	When power-saving measures were taken, the ELECTROENCEPHALOGRAPH continued to conform to this standard		Pass
	ELECTROENCEPHALOGRAPH visually indicated that it is operating from its internal electrical power source and the ‘on-off’ switch remained in the ‘on’ position		Pass

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
201.11.8.101	**Protection against depletion of the INTERNAL ELECTRICAL POWER SOURCE**		N/A
	ELECTROENCEPHALOGRAPHS powered from an INTERNAL ELECTRICAL POWER SOURCE do not cause a HAZARDOUS SITUATION to the PATIENT when the state of discharge can no longer maintain the NORMAL USE of the ELECTROENCEPHALOGRAPHS.	No internal electrical power source, powered from computer via USB.	N/A
	ELECTROENCEPHALOGRAPHS powered down in a manner which causes no HAZARDOUS SITUATION to the PATIENT other than loss of function		N/A
201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		Pass
201.12.1.101	**Scale and calibration signal**		Pass
	The ELECTROENCEPHALOGRAM was displayed with a scale or calibration signal labelled in µV or mV. :	Labelled in uV.	Pass
201.12.1.102	**Accuracy of signal reproduction**		Pass
	Input voltages in the ranges and varying at rates selected from "Scalp" and/or "Cerebral cortex or subdural locations" according to Table 201.102 ware reproduced on the output with an error of ≤ ±20 % of the nominal value of the output or ±10 µV, whichever is greater..... :	Not intended for use on Cerebral cortex or subdural location. See Table 201.12.1.102 and figures 1 … 8 attached to the end of this test report.	Pass
	Compliance checked according to Fig.201.104		Pass
201.12.1.103	**Input dynamic range and differential offset voltage**		Pass
	With a d.c. offset voltage in the range of ±150 mV and differential input signal voltages of ±0,5 mV that vary at rates up to 12 mV/s, when applied to any LEAD WIRE, the time-varying output signal amplitude did not change by more than ±10 % over the specified range of d.c. offset ..... :	See Table 201.12.1.103 and figures 9 … 14 attached to the end of this test report.	Pass
201.12.1.104	**Input noise**		Pass
	The signal noise caused by the EEG amplifier and PATIENT CABLE did not exceed 6 µV peak-to-valley referred to the input (RTI)..... :	Not exceed 6uV.	Pass
	Compliance checked according to Fig.201.105		Pass

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
201.12.1.105	**Frequency response**		Pass
	ME EQUIPMENT meets the requirement for a frequency response (bandwidth) of at least 0,5 Hz to 50 Hz when tested with sinusoidal input signals.		Pass
	The output at 0,5 Hz and 50 Hz was within 71 % to 110 % of the output obtained with a 5 Hz sine wave input signal.		Pass
	Compliance checked according to Fig.201.104		Pass
201.12.1.106	**Common mode rejection**		Pass
	A 1 V r.m.s. signal at mains frequency (50 Hz/60 Hz) with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together did not produce an output signal greater than 100 uV peak-to-valley over a 10 s period.....:		Pass
	In series with each ELECTRODE was a 10 kΩ resistor in parallel with a 47 nF capacitor and PATIENT CABLE specified by the MANUFACTURER were used.		Pass
	Compliance checked using Fig.201.105 with any mains frequency notch filter (if provided) turned off.		Pass
	The measured output amplitude was not be greater than 100 uV peak-to-valley .....:		Pass
201.15	**CONSTRUCTION OF ME EQUIPMENT**		N/A
201.15.4.4.101	**Indicator of operation from the INTERNAL ELECTRICAL POWER SOURCE and the status of the INTERNAL ELECTRICAL POWER SOURCE**		N/A
	ELECTROENCEPHALOGRAPH visually indicates when it is operating from its INTERNAL ELECTRICAL POWER SOURCE, unless it is only INTERNALLY POWERED.	Not an internally powered ME equipment.	N/A
	ELECTROENCEPHALOGRAPH visually indicated its remaining battery capacity when operating from its INTERNAL ELECTRICAL POWER SOURCE		N/A

202	**ELECTROMAGNETIC COMPATIBILITY – REQUIREMENTS AND TESTS**		N/E
	IEC 60601-1-2:2014 was applied with the following modifications	EMC test according to the relevant EN 60601-1-2 standards was not part of this test. Separately evaluated.	N/E

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
202.4.3.1	**Configurations**		N/E
	ELECTROENCEPHALOGRAPHS was tested with the PATIENT CABLES and LEAD WIRES as specified by the MANUFACTURER	See RMF Reference Document:	N/E
	If the MANUFACTURER specifies different PATIENT CABLES and LEAD WIRES, only one representative sample of each length has to be tested.	See RMF Reference Document:	N/E
	The lead wires were connected to a PATIENT signal simulator instead of the common node to verify IMMUNITY pass/fail criteria determined by the MANUFACTURER	See RMF Reference Document:	N/E
	Tests conducted according to Fig. Figure 202.101		N/E
202.8	**Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS**		N/E
202.8.1	**GENERAL**		N/E
	During and after non-transient electromagnetic phenomena, the ELECTROENCEPHALOGRAPH meat the IMMUNITY pass/fail criteria as determined by the MANUFACTURER for BASIC SAFETY and ESSENTIAL PERFORMANCE and did not change operating modes, OPERATOR settings and any stored data.		N/E
	During transient electromagnetic phenomena the ELECTROENCEPHALOGRAPH meat IMMUNITY pass/fail criteria for BASIC SAFETY as determined by the MANUFACTURER		N/E
	Within 30 s after exposure to transient electromagnetic phenomena the ELECTROENCEPHALOGRAPH resumed normal operation without loss of any OPERATOR settings or stored data and meat the input noise requirement in 201.12.1.104 and the IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE as determined by the MANUFACTURER.	See RMF Reference Document: Test report of IEC60601-1-2:2014:	N/E
202.8.9	**IMMUNITY TEST LEVELS**		N/E
	PATIENT CABLES and LEAD WIRES are exempt from testing for conducted disturbances induced by RF fields.		N/E
202.8.101	**Disturbances from HF SURGICAL EQUIPMENT**		N/E

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict
	If the intended environments of use as specified by the MANUFACTURER include environments where HF SURGICAL EQUIPMENT is used, the ELECTROENCEPHALOGRAPH returned to its previous operating mode within 30 s after exposure to disturbances produced by HF SURGICAL EQUIPMENT, without any change in operating mode and OPERATOR settings and without loss of any stored data		N/E
	Tests conducted according to Fig. Figure 202.102 and 202.103		N/E

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.102	**TABLE: Accuracy Of Amplitude And Rate Of Variation**							**Pass**
	U [uV]				**Deviation [%]**			
P1	**1000**	**500**	**200**	**100**	**1000**	**500**	**200**	**100**
Measurements for Scalp								
CH1	1102	586	236	108	10.2	17.2	18	8
CH2	1122	546	208	109	12.2	9.2	4	9
Measurements for Cerebral cortex or subdural locations								
—	—	—	—	—	—	—	—	—

NOTES:
1. Using test circuit of Fig. 201.104 and test procedure in Sub clause 201.12.1.102,
2. The scale of the ELECTROENCEPHALOGRAPH such that the input signal according to Table 201.102. Output of signal generator increased by factors of 2, 5 and 10.
3. The Displayed output shall be linear within ± 20 % of the nominal value of the output or ±10uV.

Supplementary information:
Not intended for use on Cerebral cortex or subdural location.

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.103	**TABLE: Input Dynamic Range And Differential Offset Voltage**					**Pass**
Offset Voltage	0	+150mV	-150mV	0	+150mV	-150mV
P1 Lead under test	U [uV]			Deviation [%]		
CH1	1103	1083	1123	10.3	8.3	12.3
CH2	1112	1134	1125	11.2	13.4	12.5

NOTES:

1. Using test circuit of Fig. 201.104 and test procedure in Clause 201.12.1.103, signal generator adjusted to produce a 6 Hz triangular signal of 1 mV P-to-V to any lead wire and all other lead wires connected to P2.
2. Set the scale of the ELECTROENCEPHALOGRAPH such that a 1 mV peak-to-valley signal can be displayed without clipping
3. Time-varying output signal amplitude did not change by more than ±10% over the specified d.c. offset voltage range ±150 mV

Supplementary information:

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.104	**TABLE: Input Noise**			**Pass**
Lead Setting	Filter	Noise (μV)	Verdict	*Remarks*
CH1	50 Hz notch filter	3	Pass	—
CH2	50 Hz notch filter	4	Pass	—

Notes:

1. Using test circuit of Fig. 201.105 and test procedure in Sub clause 201.12.1.104, Insert in series with each LEAD WIRE of the PATIENT CABLE a 10 kΩ resistor in parallel with a 47 nF capacitor as shown in Fig.
2. Verify that the noise is no greater than 6 μV peak to valley referred to inputs.

Supplementary information:

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.105	**TABLE: Frequency response**							**Pass**
		U [uV]			Deviation [%]			
Chanel	Name	5Hz	0.5Hz	50Hz	5Hz	0.5Hz	50Hz	
CH1	CH1	60.6	62.6	54.6	0	3.3	-9.8	

NOTES:

1. Using test circuit of Fig. 201.104 and test procedure in Clause 201.12.1.105, signal generator adjusted to produce a 50uV sine wave P-to-V to any lead wire and all other lead wires connected to P2.
2. Set the scale of the ELECTROENCEPHALOGRAPH such that a 100 µV peak-to-valley signal can be displayed without clipping
3. Time-varying output signal amplitude should be within 70% to 110of the output obtained with a 5 Hz sine wave input signal.

Supplementary information:

—

IEC 80601-2-26			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.106	**TABLE: Table: Common mode rejection**	**Pass**

Lead under test [1]	Output amplitude over a 10 s period at 1 V rms, 50/60 Hz connected between Lead under test & all leads connected together[2] & Sdc in position B, (mm)	Output amplitude at 1Vrms 50/60 Hz with a + 150 mV dc offset voltage in series with the imbalance impedance & Sdc in position A; (mm)	Output amplitude at 1Vrms 50/60 Hz with a - 150 mV dc offset voltage in series with the imbalance & Sdc in position A; (mm)
CH1	9.1	9.2	7.6
CH2	9.2	9.2	7.8

NOTES:
Circuit of Fig. 201.105 was used for these tests.
Acceptance criteria: measured output amplitude was not greater than 100 uV peak-to-valley.
[1] Tests repeated on all available LEADS
[2] With 100 pF source capacitance. In series with each ELECTRODE was a 10 kΩ resistor in parallel with a 47 nF capacitor. The PATIENT CABLE specified by the manufacturer used

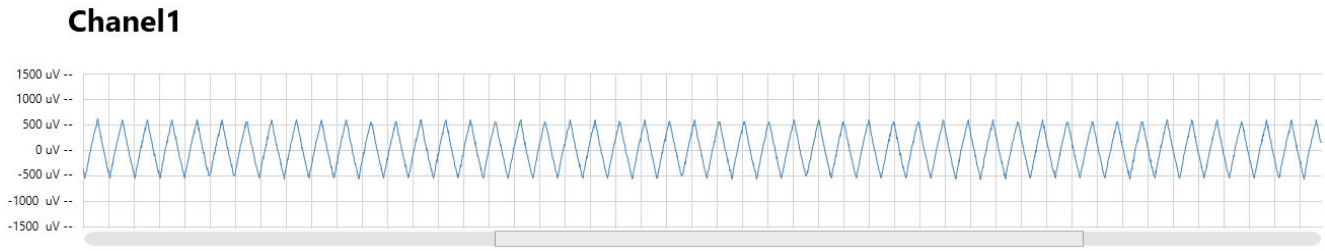


Figure 1 – 201.12.1.102, CH1, 1000uV

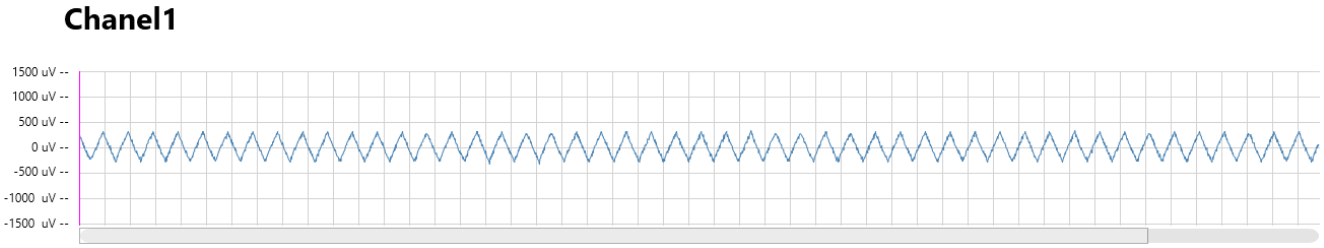


Figure 2 – 201.12.1.102, CH1, 500uV

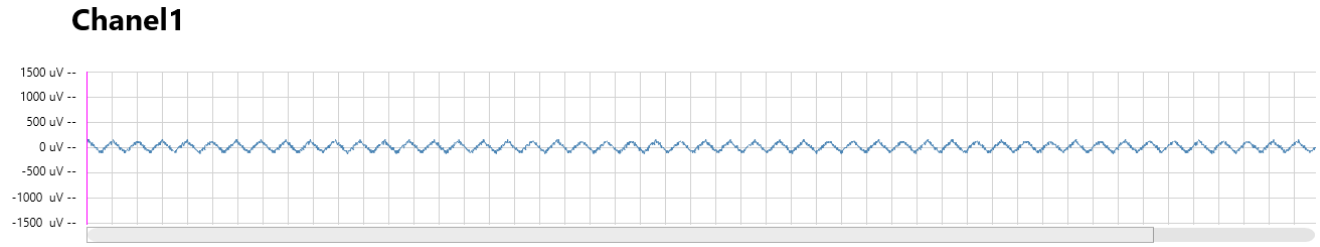


Figure 3 – 201.12.1.102, CH1, 200uV

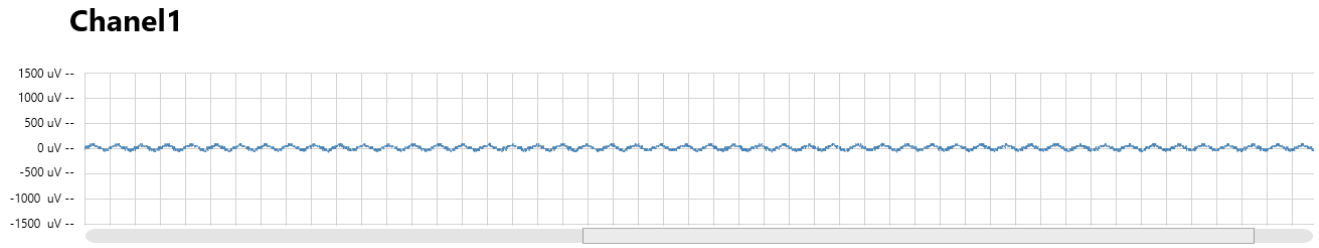


Figure 4 – 201.12.1.102, CH1, 100uV

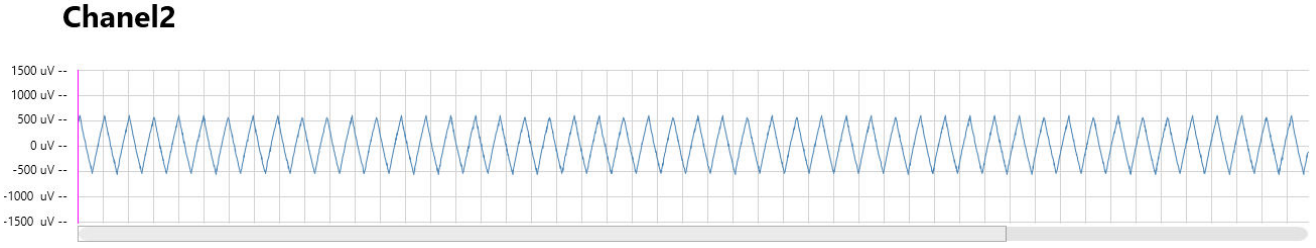


Figure 5 – 201.12.1.102, CH2, 1000uV

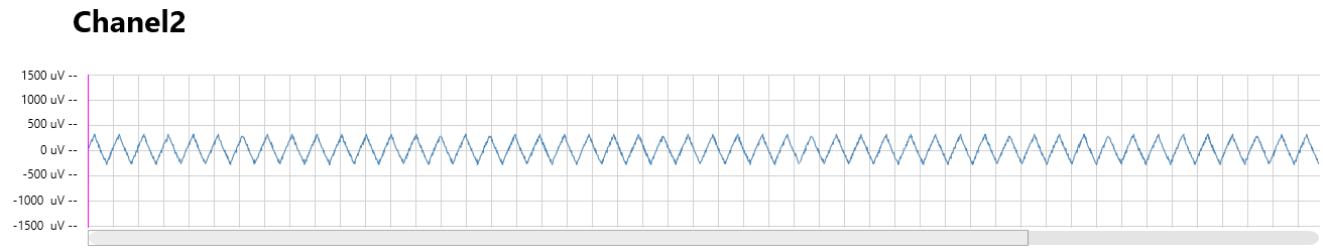


Figure 6 – 201.12.1.102, CH2, 500uV

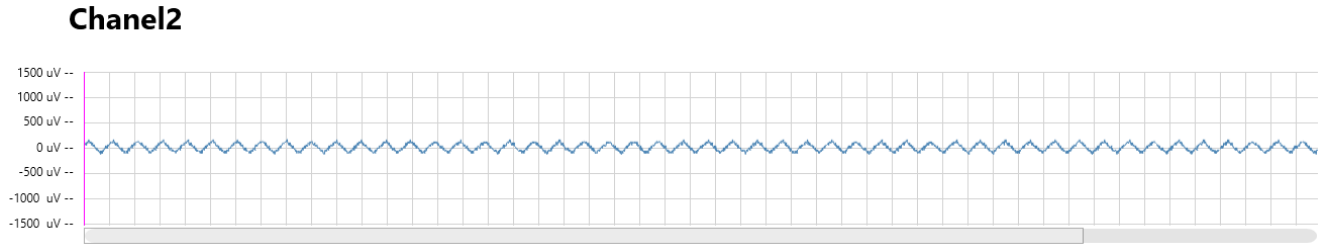


Figure 7 – 201.12.1.102, CH2, 200uV

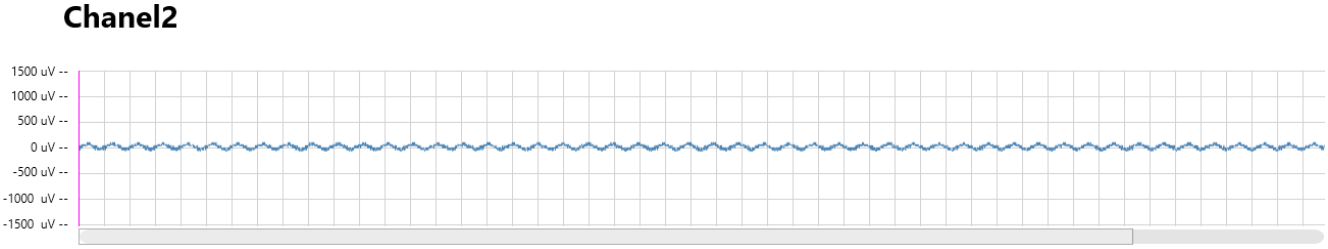


Figure 8 – 201.12.1.102, CH2, 100uV

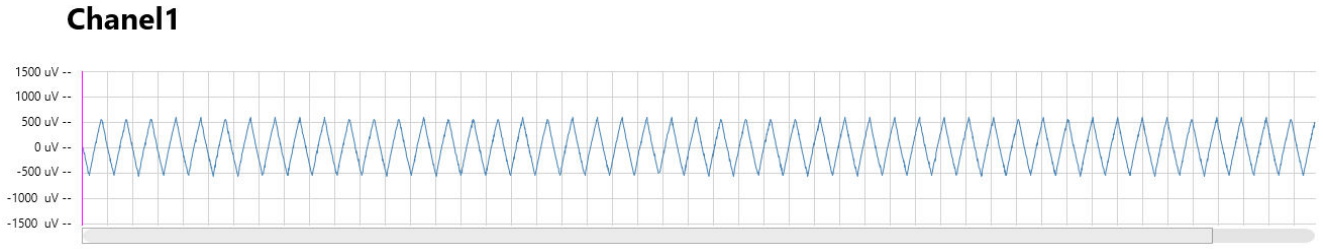


Figure 9 – 201.12.1.103, CH1, 1000uV

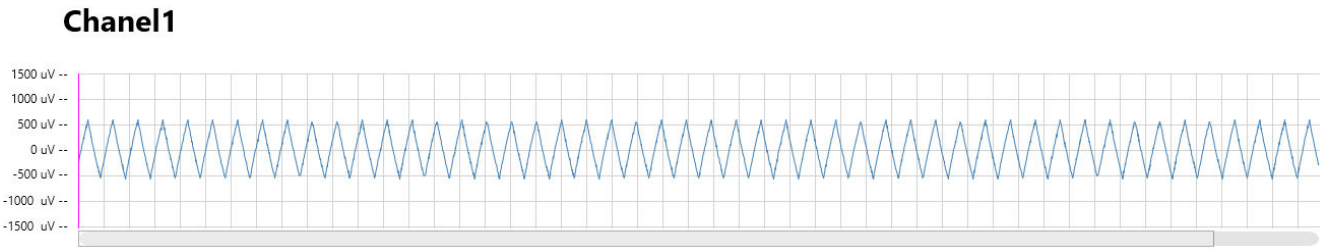


Figure 10 – 201.12.1.103, CH1, 1000uV, +150mV DC offset

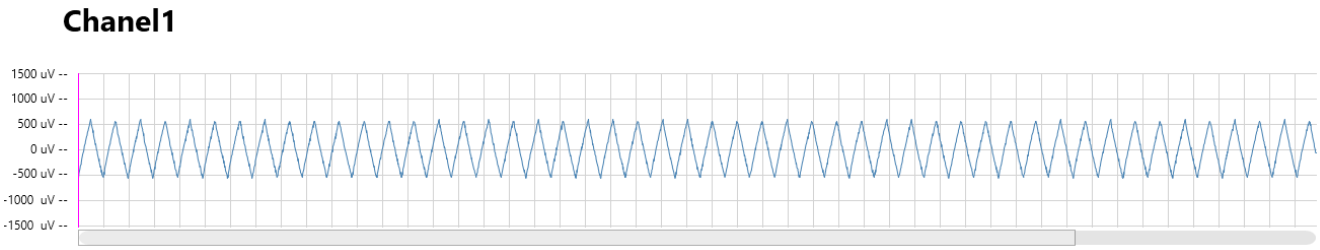


Figure 11 – 201.12.1.103, CH1, 1000uV, -150mV DC offset

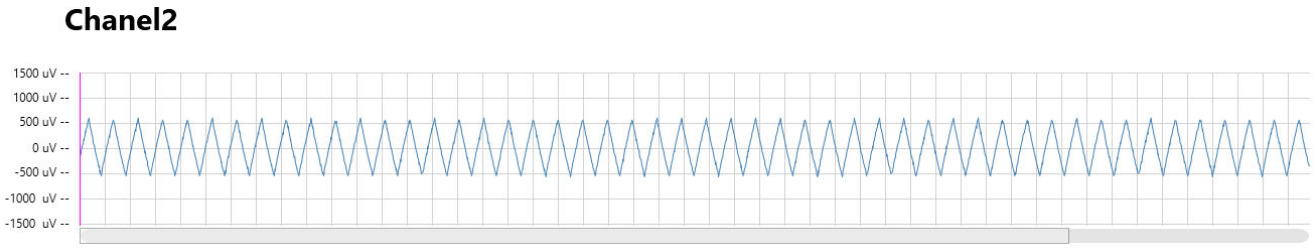


Figure 12 – 201.12.1.103, CH2, 1000uV

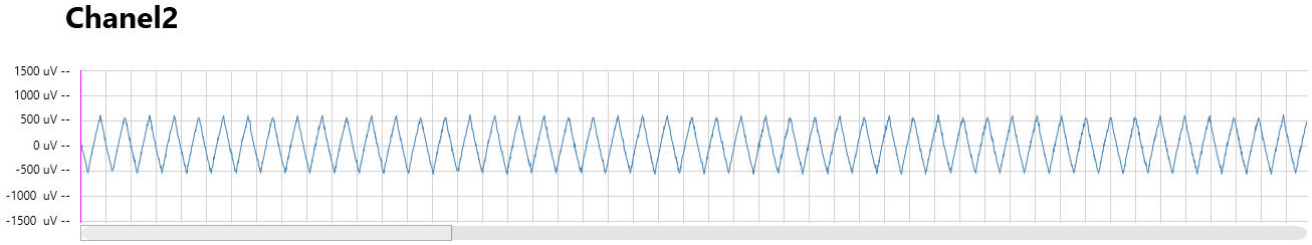


Figure 13 – 201.12.1.103, CH2, 1000uV, +150mV DC offset

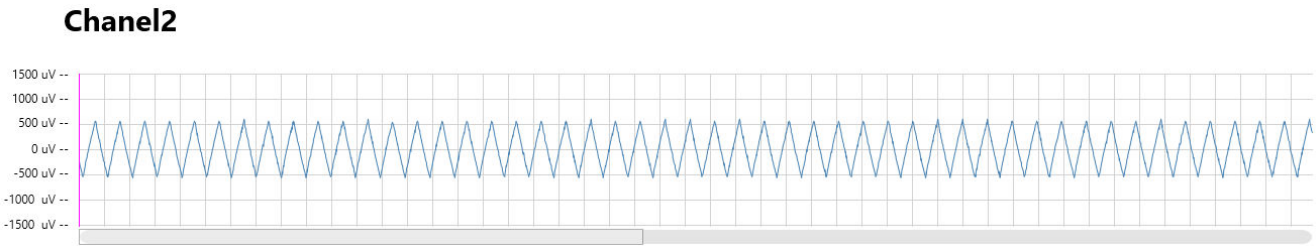


Figure 14 – 201.12.1.103, CH2, 1000uV, -150mV DC offset

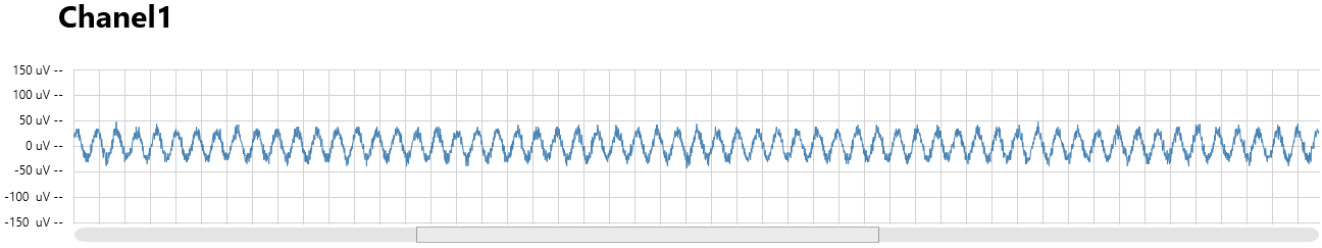


Figure 15 – 201.12.1.105, CH1, 100uV, 5Hz

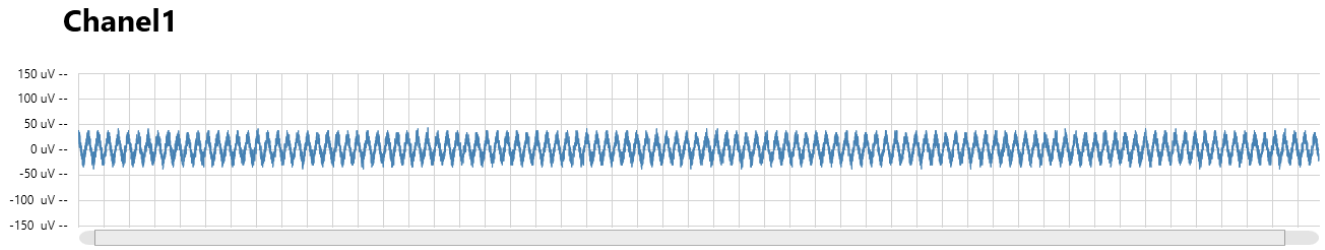


Figure 16 – 201.12.1.105, CH1, 100uV, 0.5Hz

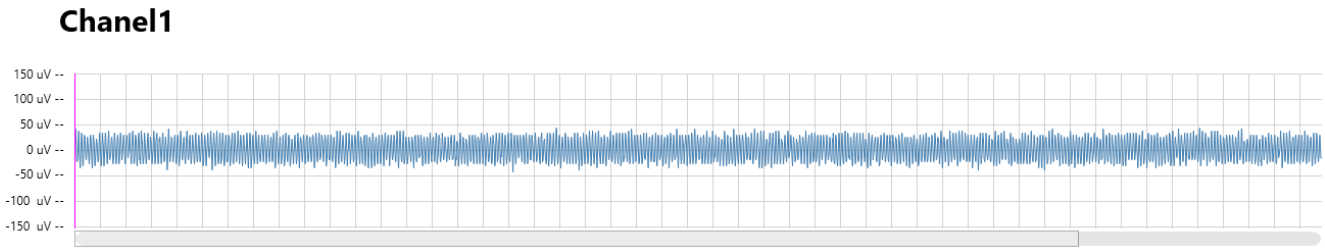


Figure 17 – 201.12.1.105, CH1, 100uV, 50Hz

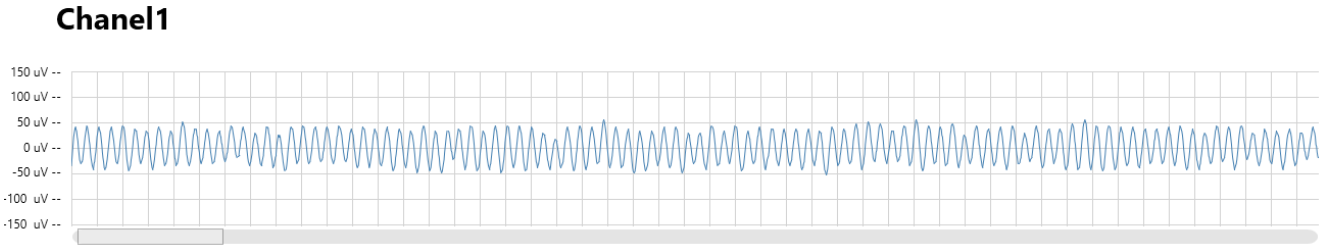


Figure 18 – 201.12.1.106, CH1, CMRR

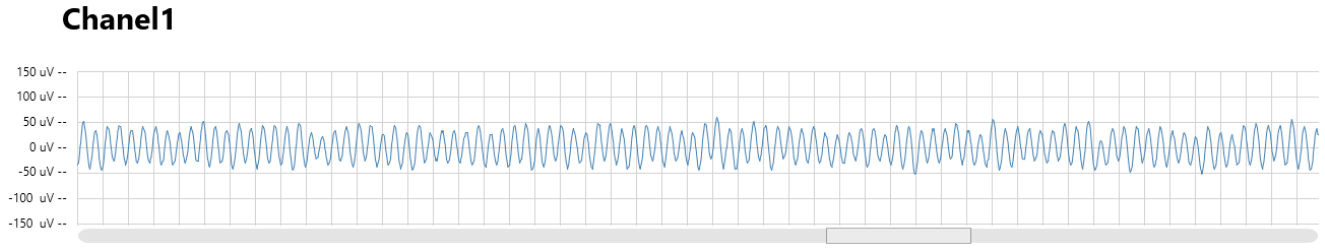


Figure 19 – 201.12.1.106, CH1, CMRR, +150mV DC offset

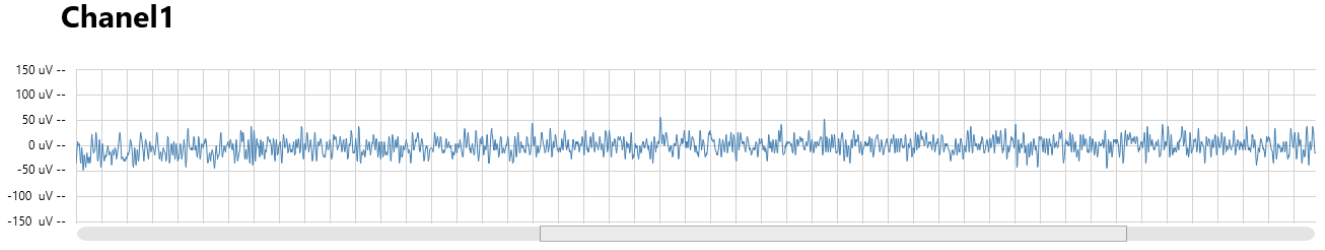


Figure 20 – 201.12.1.106, CH1, CMRR, -150mV DC offset

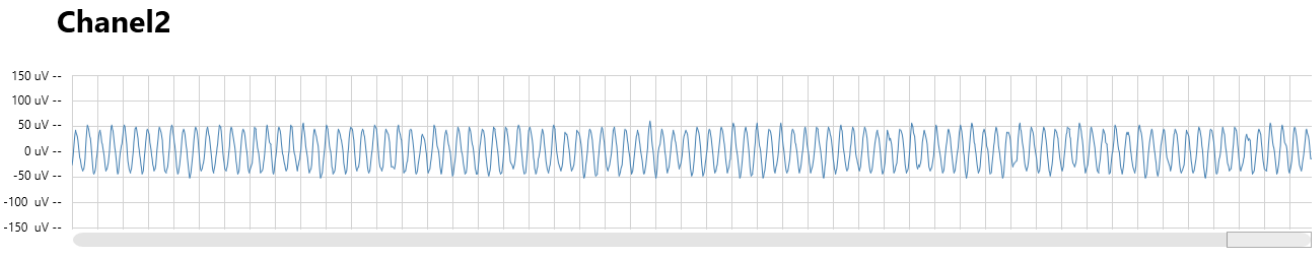


Figure 21 – 201.12.1.106, CH2, CMRR

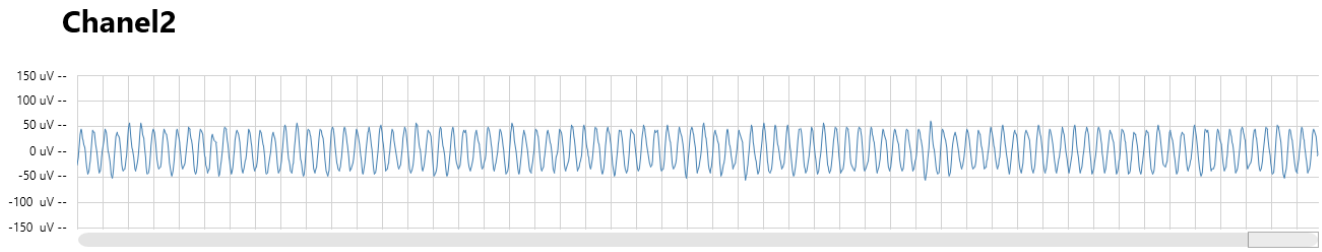


Figure 22 – 201.12.1.106, CH2, CMRR, +150mV DC offset

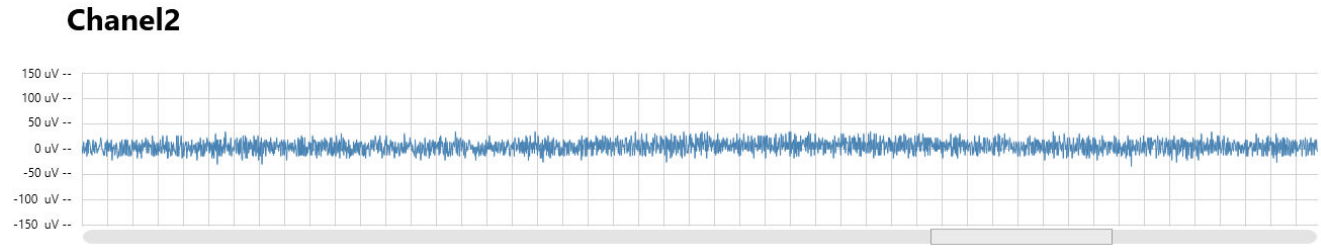


Figure 23 – 201.12.1.106, CH2, CMRR, -150mV DC offset

Test equipment list

Measuring equipment		Manufacturer	Type	Inventory or Serial No.	Last calibration	Next calibration
1	Single channel EEG tester	Whaleteq Co LTD	SEEG	LAB0065	12/15/2022	12/14/2024
2	CMRR tester	Whaleteq Co LTD	CMRR 3.0	LAB0041	1/25/2023	1/24/2025
3	EEG CMRR Circuit	ConformiTICs Lab	EEG CMRR	LAB0070	5/24/2023	5/23/2025
4	Caliper	RS Pro	LIN9531195	LAB0053	7/31/2023	7/30/2025
5	Stop watch	BASETech	WT-034	LAB0014	7/27/2023	7/26/2025
6	Temperature and Humidity logger	TFA	KLIMA LOGG...PRO R08B	LAB0022	6/22/2023	6/21/2025
Supplementary information: —						

Photos of the tested equipment

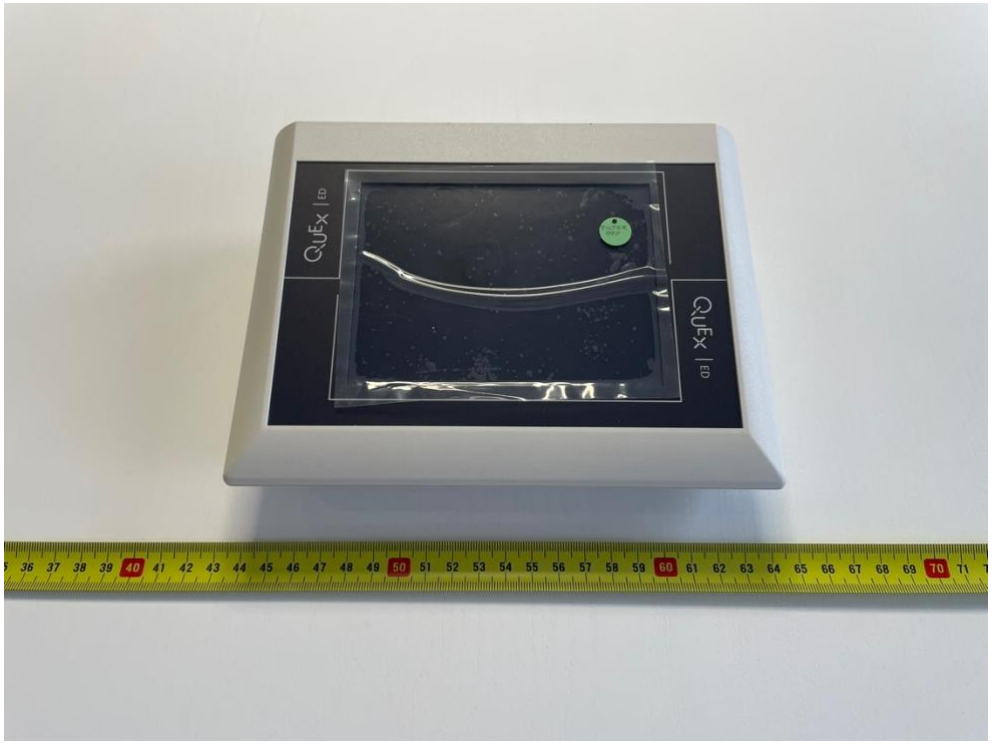


Photo 1

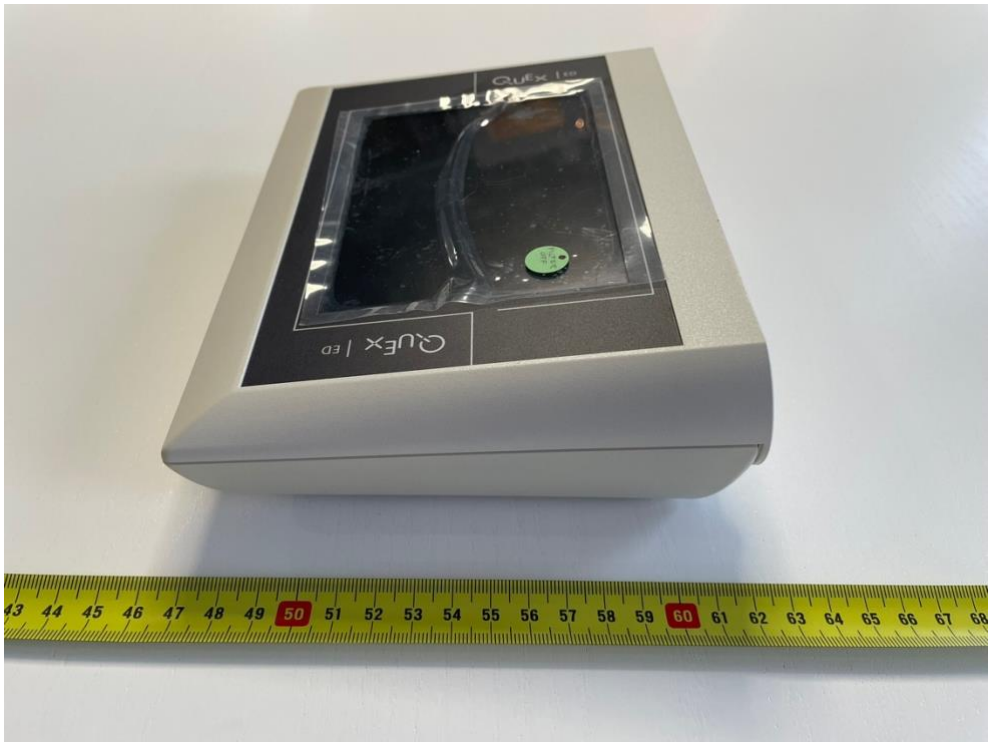


Photo 2

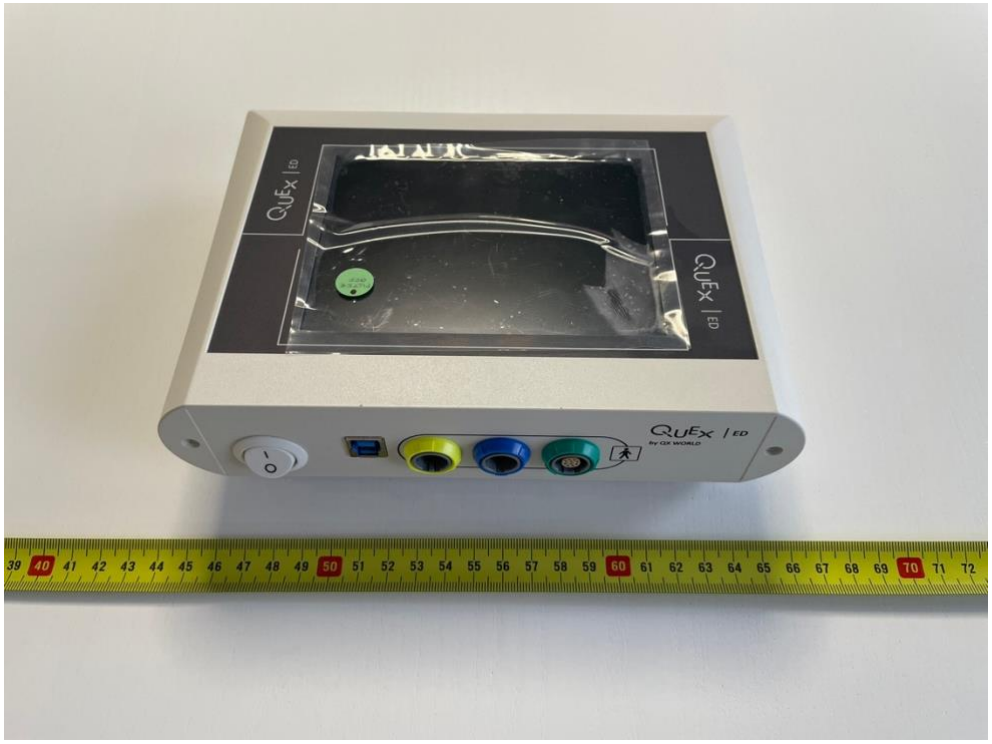


Photo 3

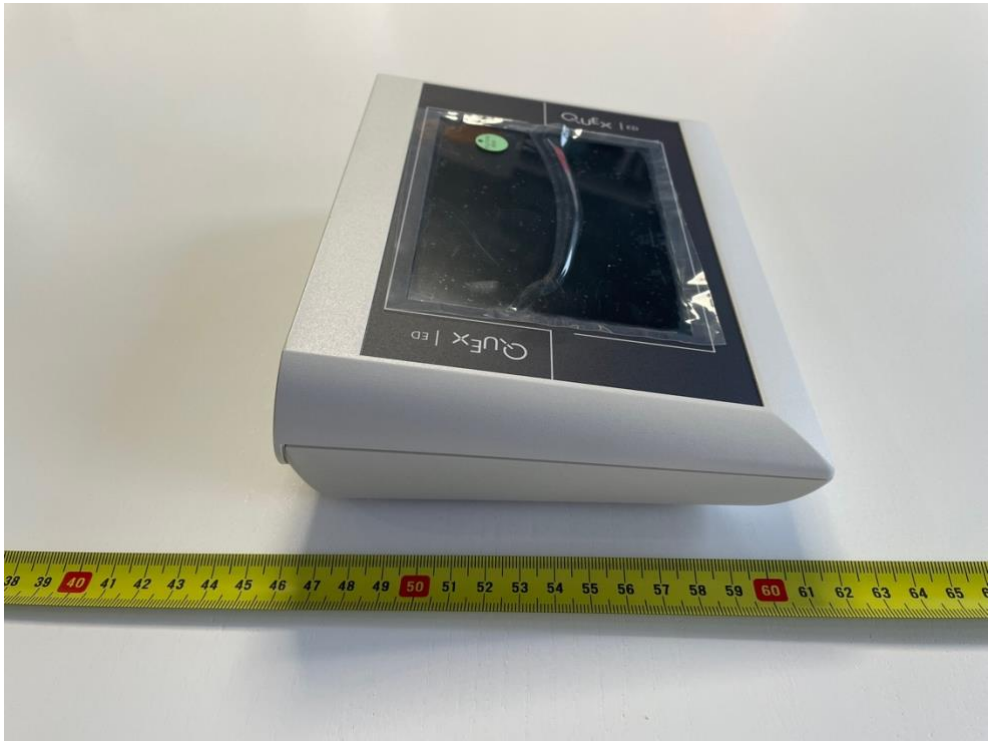


Photo 4

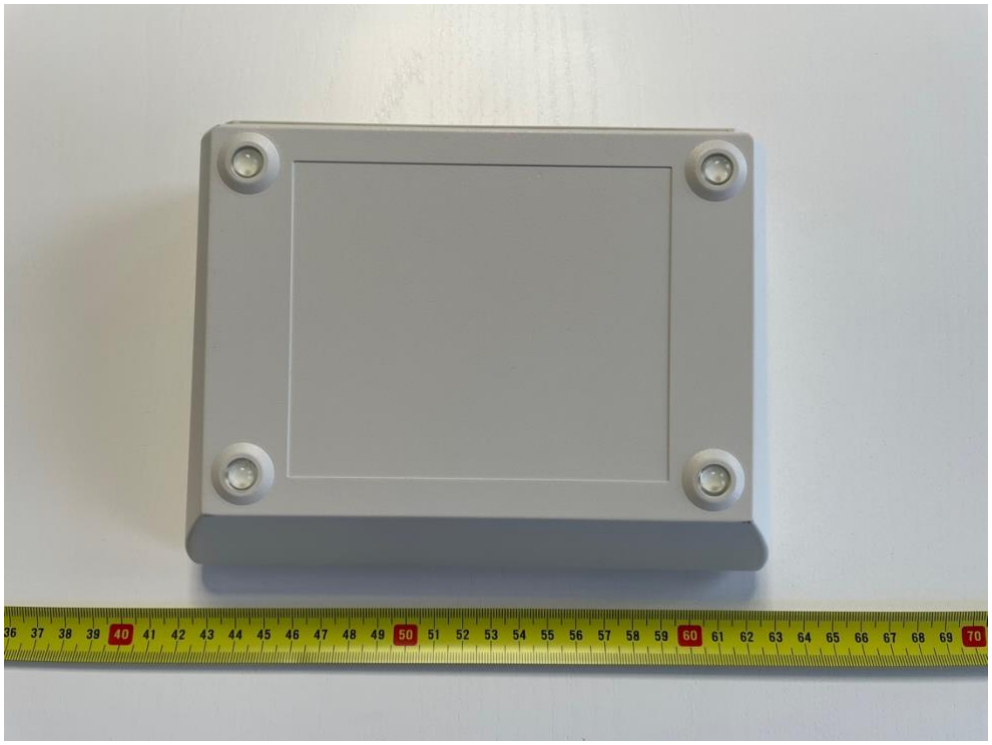


Photo 5

End of the Test report