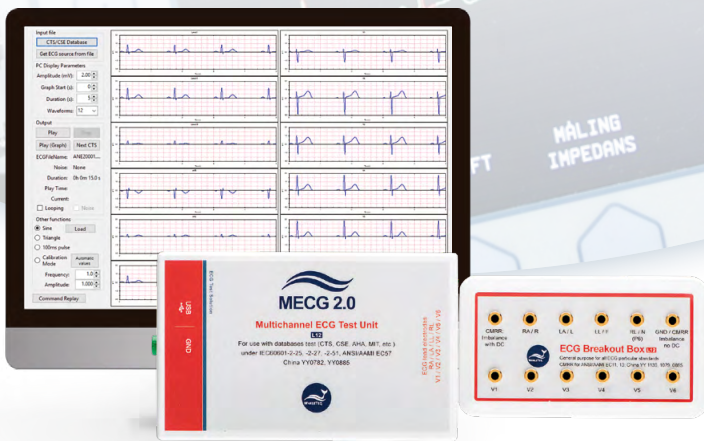


MECG 2.0



R&D



Compliance

ECG Database Player

The ECG database player designed for system alidation and software algorithm evaluation.
Suitable for R&D and compliance testing.

- Load and replay multi channel ECG waveforms for diagnostic and ambulatory ECG.
- Output analog signals simultaneously up to 8 channels and support 12 lead ECG.
- Embedded CAL, ANE, NST and biological waveforms.
- Directly support AHA, MIT, CU, NST, ESC and PhysioNet format databases
- Support digital file playback function for user to repeatedly play clinical-recorded or programmed waveforms.
- Extreme output voltage resolution - 0.15 μ V for MECG 2.0 (2020)
- Command replay function enables to program test sequences with commands.
- Software Development Kit (SDK) allows to develop customized or automated test software with less efforts.



IEC 60601-2-25, IEC 60601-2-47, AAMI EC57,
YY0782 and YY0885



R&D



Compliance



MECG 2.0 Supported Medical Databases

DB	Full Name of Database	Purpose	Source	# of Records	Standards	Test Requirements by standards
CTS	Clinical Trial Subject	Calibration and Analytical ECGs	Corscience	19 (3 ANA waveforms and 16 CAL waveforms)	IEC60601-2-25	Amplitude ,global interval and duration
CSE	Common Standards for Quantitative Electrocardiography	Biological ECGs	INSERM	100	IEC60601-2-25	Global interval
AHA	American Heart Association	Evaluation of Ventricular Arrhythmia Detectors	ECRI	80 (35 min each)	IEC60601-2-47	QRS, HR, VEB, VF
MIT-BIH	Massachusetts Institute of Technology – Beth Israel Hospital	Arrhythmia Database	MIT-BIH	48 (30 min each)	IEC60601-2-47	QRS, HR, VEB, VF,SVEB, AF
CU	Creighton University	Sustained Ventricular Arrhythmia Database	MIT-BIH	35 (8 mins each)	IEC60601-2-47	VF
NST	Noise Stress Test	Noise database (only supplied with the MIT-BIH database)	MIT-BIH	12 ECG (30 min each) + 3 noise	IEC60601-2-47	QRS, HR, VEB, SVEB, AF
ESC	European Society of Cardiology	ST-T Database	CNR, MIT-BIH	90 (2 hour each)	IEC60601-2-47	ST segment deviations or changes

MECG 2.0 Specifications

Item	Details / Reference	Value
Output channels	The 8 output channels are provided through a network as specified in IEC 60601-2-51 to provide signals to 10 lead electrodes; in the device under test, this will be displayed as 12 leads.	8 outputs/10 lead electrodes/12 leads
Voltage accuracy	IEC 60601-2-51 specifies a limit of $\pm 1\%$, but does not provide a lower limit (all systems must have a lower limit). An inferred specification of $1\% \pm 5\mu\text{V}$ is derived from the device under test specification in IEC 60601-2-51 of $5\% \pm 25\mu\text{V}$.	For MECG 2.0, $\pm 1\%$ for values greater or equal to $500\mu\text{V}$ and $\pm 5\mu\text{V}$ for values under $500\mu\text{V}$. For MECG 2.0 (2020), $\pm 1\%$ for values greater or equal to $100\mu\text{V}$ and $\pm 5\mu\text{V}$ for values under $100\mu\text{V}$.
Output voltage resolution	MECG 2.0 uses 12 bit DAC and MECG 2.0 (2020) uses 16 bit DAC.	$2.4\mu\text{V}$ for MECG 2.0 and $0.15\mu\text{V}$ for MECG 2.0 (2020)
Output voltage	The output voltage on most of the database/ECG is $+5\text{mV} \sim -5\text{mV}$.	$\pm 5\text{mV}$
Output noise level 0-150Hz	Output noise should not influence the test. A value a $5\mu\text{V}$ is suitable for this requirement. Can be verified by monitoring the signal in the device under test using a "diagnostic" filter setting.	$< 5\mu\text{V}$
Time accuracy	IEC 60601-2-51 does not provide any limits. An inferred limit from the device under test. An inferred limit of $\pm 1\%$ is used. The system' s design accuracy exceeds 0.1% as a 100ppm crystal reference is used.	$\pm 1\%$
Sampling rate	A maximum sampling rate of 1kHz matches the sampling rates of ECG files.	1kHz (8 channels)
Power supply	Powered from the USB supply (5V 0.2A)	N/A

