



MECG 2.0

ECG Database Player

The ECG database player designed for system validation and software algorithm evaluation.

Suitable for R&D and compliance testing.

- Load and replay multichannel 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

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)	IEC 60601-2-25	Amplitude, global interval and duration
CSE	Common Standards for Quantitative Electrocardiography	Biological ECGs	INSERM	100	IEC 60601-2-25	Global interval
AHA	American Heart Association	Evaluation of Ventricular Arrhythmia Detectors	ECRI	80 (35 min. each)	IEC 60601-2-47	QRS, HR, VEB, VF
MIT-BIH	Massachusetts Institute of Technology-Beth Israel Hospital	Arrhythmia Database	MIT-BIH	48 (30 min. each)	IEC 60601-2-47	QRS, HR, VEB, VF, SVEB, AF
CU	Creighton University	Sustained Ventricular Arrhythmia Database	MIT-BIH	35 (8 min. each)	IEC 60601-2-47	VF
NST	Noise Stress Test	Noise database (only supplied with the MIT-BIH database)	MIT-BIH	12 ECG (30 min. each) +3 noise	IEC 60601-2-47	QRS, HR, VEB, SVEB, AF
ESC	European Society of Cardiology	ST-T Database	CNR, MIT-BIH	90 (2 hour each)	IEC 60601-2-47	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 $1\% \pm 5\mu V$ is derived from the device under test specification in IEC 60601-2-51 of $5\% \pm 25\mu V$.	For MECG 2.0, $\pm 1\%$ for values greater or equal to $500\mu V$ and $\pm 5\mu V$ for values under $500\mu V$. For MECG 2.0 (2020), $\pm 1\%$ for values greater or equal to $100\mu V$ and $\pm 5\mu V$ for values under $100\mu V$.
Output voltage resolution	MECG 2.0 uses 12 bit DAC and MECG 2.0 (2020) uses 16 bit DAC.	$2.4\mu V$ for MECG 2.0 and $0.15\mu V$ for MECG 2.0 (2020)
Output voltage	The output voltage on most of the database / ECG is $+5mV - -5mV$.	$\pm 5mV$
Output noise level 0 – 150Hz	Output noise should not influence the test. A value as $5\mu V$ is suitable for this requirement. Can be verified by monitoring the signal in the device under test using a “diagnostic” filter setting.	$< 5\mu V$
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
Environment	Intended for normal laboratory environment. The selection of critical components such as reference voltages, DAC, precision resistors are known to be stable in the range shown.	$15 - 30^{\circ}C$ $10 - 95\% RH$



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