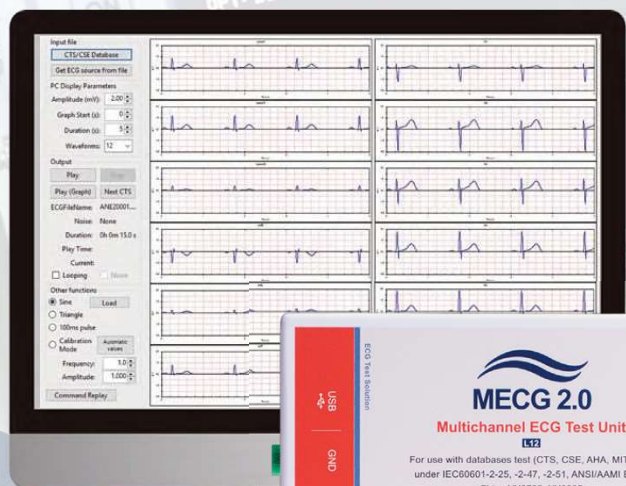


# MECG 2.0



## ECGデータベースプレイヤー

ECGデータベースプレイヤーは、システム検証とソフトウェアのアルゴリズムの評価の為に設計されています。R&Dとコンプライアンステストに適しています。

- 診断用および外来用のマルチチャンネルECG波形の読み込みおよび再生
- 最大8チャンネルのアナログ信号を同時出力、12リードのECGに対応
- CAL、ANE、NST、および生体波形が組み込まれています。
- AHA、MIT、CU、NST、ESC、Physionetフォーマットのデータベースを直接サポート
- デジタルファイル再生機能により、臨床記録波形やプログラム波形を繰り返し再生可能
- 最大出力電圧分解能 - MECG2.0(2020)の場合0.15μV
- コマンド・リプレイ機能により、テスト・シーケンスをコマンドでプログラム可能
- ソフトウェア開発キット (SDK) により、カスタマイズされたテストソフトウェアや自動テストソフトウェアを少ない労力で開発することができます。



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



Compliance

## MECG2.0対応 医療データベース

| DB      | Full Name of Database                                      | Purpose                                                  | Source       |                                | Standards     | Test Requirements by standards          |
|---------|------------------------------------------------------------|----------------------------------------------------------|--------------|--------------------------------|---------------|-----------------------------------------|
| CTS     | Clinical Trial Subject                                     | Calibration and Analytical ECGs                          | Corscience   |                                | 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        |

## MECG2.0対応 仕様

| 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 $+5mV \sim -5mV$ .                                                                                                                                                                                               | $\pm 5mV$                                                                                                                                                                                                                                |
| Output noise level 0-150Hz | Output noise should not influence the test. A value a $5\mu V$ 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.                                                                                     | $15-30^{\circ}C$<br>$10-95\% RH$                                                                                                                                                                                                         |

