

# WHALETEQ

## CTS/CSE Database Compliance Analyzer 医疗数据库比对软件

### User Manual



(Revision 2020-09-08)

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# 1 总览

CTS/CSE Database Compliance Analyzer (简称 CDCA) 帮助客户了解待测物算法在 IEC60601-2-25:2011 或 YY0782-2010 标准数据库测试下的性能；同时 CDCA 可对比客户待测物的测试数据，并确认是否有通过医疗数据库测试的标准。

## 1.1 相关标准及测试范围

CTS/CSE 数据库比对分析相关标准如下：

### **IEC60601-2-25: 2011**

- **标准内容简述：**  
Particular requirements for the basic safety and essential performance of electrocardiographs
- **测试范围：**  
在子条文 201.12.1.101 下共有三项测试需求-  
Essential Performance and accuracy of ME Equipment
  - ✓ 201.12.1.101.2 Requirements for amplitude measurements
  - ✓ 201.12.1.101.3.1 Requirements for absolute interval and wave duration Measurements
  - ✓ 201.12.1.101.3.2 Requirements for interval measurements on biological ECGS

### **YY 0782-2010 (IEC60601-2-51: 2003)**

- **标准内容简述：**  
特定安规测试需求，包含心电图机性能、单信道与多信道心电图机数据分析比对
- **测试范围：**  
在测试条文 50.101 下共有四项测试需求  
Automated measurements on ECGS (for Analyzing Electrocardiographs)
  - ✓ 50.101.2 Requirements for amplitude measurements
  - ✓ 50.101.3.1 Requirements for interval measurements
  - ✓ 50.101.3.2 Requirements for interval measurements on biological ECGS
  - ✓ 50.101.4 Disclosure requirements for stability of measurements against Noise

## 1.2 安装与环境设定

本軟體可以直接從網站上取得最新版本，安裝步驟如下：

- 点击“下载”链接，并下载文件至你的计算机
- 浏览到下载位置
- 解压缩到目标文件夹
- 打开目标文件夹，并确保所有文件都被解压锁在同一文件夹下
- 点击后执行的软件

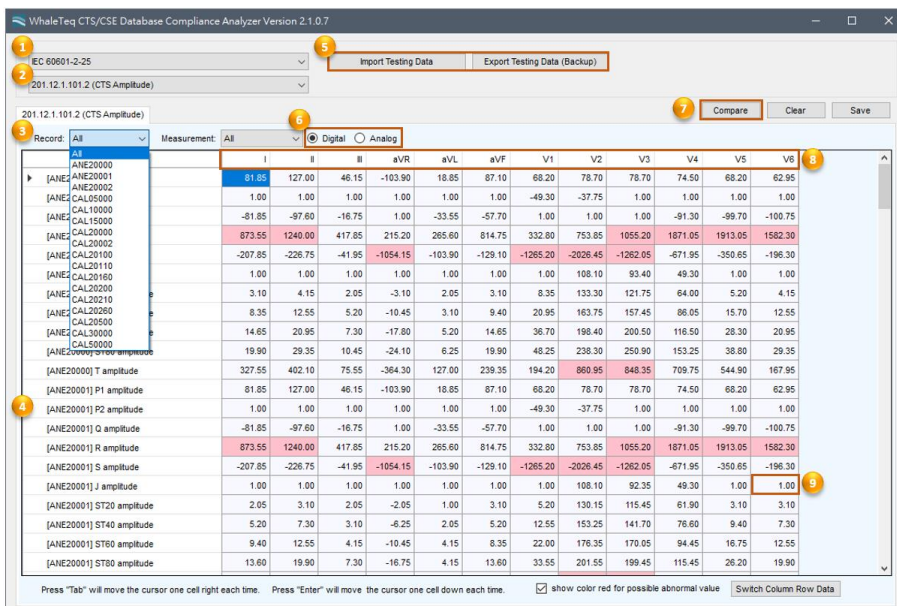
计算机最低硬件要求

| 项目   | 要求                           |
|------|------------------------------|
| 操作系统 | Windows 7 或更高                |
| 硬盘空间 | 128 MB 安装程序; 1GB TAF 档案的存放空间 |
| 处理器  | Intel Core i3 或更高            |
| 内存   | 2G 或更高                       |
| 屏幕   | 1366 X 768 或更高               |

## 2 软件使用接口介绍

此章节会介绍软件接口的基本操作及功能

### 2.1 主要功能



|                            | I       | II      | III    | aVR      | aVL     | aVF     | V1       | V2       | V3       | V4      | V5      | V6      |
|----------------------------|---------|---------|--------|----------|---------|---------|----------|----------|----------|---------|---------|---------|
| [ANEZ20000] T amplitude    | 327.55  | 402.10  | 75.55  | -384.30  | 127.00  | 239.35  | 194.20   | 860.95   | 848.35   | 709.75  | 544.90  | 167.95  |
| [ANEZ20000] P1 amplitude   | 81.85   | 127.00  | 46.15  | -103.90  | 18.85   | 87.10   | 68.20    | 78.70    | 74.50    | 68.20   | 62.95   |         |
| [ANEZ20000] P2 amplitude   | 1.00    | 1.00    | 1.00   | 1.00     | 1.00    | 1.00    | -49.30   | -37.75   | 1.00     | 1.00    | 1.00    | 1.00    |
| [ANEZ20000] Q amplitude    | -81.85  | -97.60  | -16.75 | 1.00     | -33.55  | -57.70  | 1.00     | 1.00     | 1.00     | -91.30  | -99.70  | -100.75 |
| [ANEZ20000] R amplitude    | 873.55  | 1240.00 | 417.85 | 215.20   | 265.60  | 814.75  | 332.80   | 753.85   | 1055.20  | 1871.05 | 1913.05 | 1582.30 |
| [ANEZ20000] S amplitude    | -207.85 | -226.75 | -41.95 | -1054.15 | -103.90 | -129.10 | -1265.20 | -2026.45 | -1262.05 | -671.95 | -350.65 | -196.30 |
| [ANEZ20000] J amplitude    | 1.00    | 1.00    | 1.00   | 1.00     | 1.00    | 1.00    | 1.00     | 108.10   | 92.35    | 49.30   | 1.00    | 1.00    |
| [ANEZ20000] ST20 amplitude | 2.05    | 3.10    | 2.05   | -2.05    | 1.00    | 3.10    | 5.20     | 130.15   | 115.45   | 61.90   | 3.10    | 3.10    |
| [ANEZ20000] ST40 amplitude | 5.20    | 7.30    | 3.10   | -6.25    | 2.05    | 5.20    | 12.55    | 153.25   | 141.70   | 76.60   | 9.40    | 7.30    |
| [ANEZ20000] ST60 amplitude | 9.40    | 12.55   | 4.15   | -10.45   | 4.15    | 8.35    | 22.00    | 176.35   | 170.05   | 94.45   | 16.75   | 12.55   |
| [ANEZ20000] ST80 amplitude | 13.60   | 19.90   | 7.30   | -16.75   | 4.15    | 13.60   | 33.55    | 201.55   | 199.45   | 115.45  | 26.20   | 19.90   |

01 – 选择测试标准：YY0782 或 IEC60601-2-25

02 – 选择测试条文

03 – 选择数据库波形

04 – 字段数据：测试波形及参数

05 – 汇入或转存 ECG 测试数据

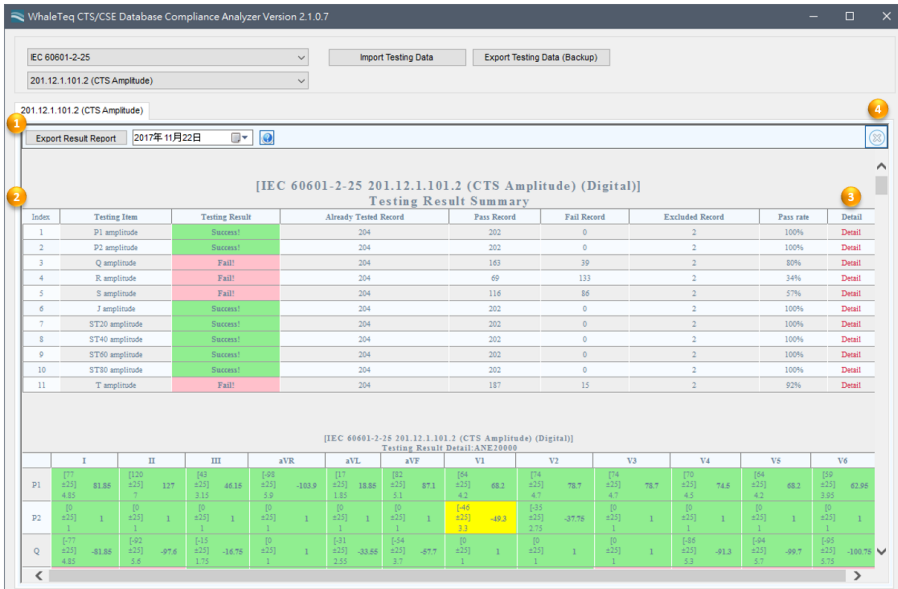
06 – 选择测试方法：数字或模拟

07 – 执行数据库数据比对

08 – 测试导联区分

09 – 测试数据范例说明: 导联、波形、区间振幅

## 2.2 比对并取得比对结果



- 01 – 输出比对结果报表
- 02 – 显示比对结果
- 03 – 显示详尽比对结果
- 04 – 退出比对结果窗口

## 3 汇入及导出测试数据

此章节介绍如何汇入及导出测试数据。

CDCA 数据库比对软件的导出或汇入的测试数据是 8 个独立的档案。

- CSE
- CSE\_Noise
- CTS\_Analog\_Line1
- CTS\_Analog\_Line2
- CTS\_Analog\_Line3
- CTS\_Analog\_Line4
- CTS\_Analog\_Line5
- CTS\_Digital

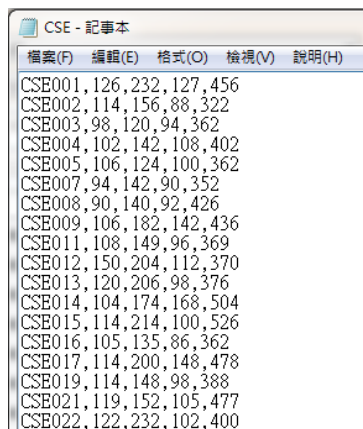
档案的格式将于章节 3.1~3.4 做进一步介绍。

### 3.1 CSE 数据库比对需求文件格式

下列表格为 CSE 数据库比对需求文件格式的定义 -

| CSE Format (5 x 100) |               |            |             |              |             |
|----------------------|---------------|------------|-------------|--------------|-------------|
| Column Number        | 1             | 2          | 3           | 4            | 5           |
| Row Number           | Waveform Name | P Duration | PR Interval | QRS Duration | QT Interval |
| 1                    | CSE001        |            |             |              |             |
| 2                    | CSE002        |            |             |              |             |
| 3                    | CSE003        |            |             |              |             |
| 4                    | CSE004        |            |             |              |             |
| 5                    | CSE005        |            |             |              |             |
| ...                  | ...           |            |             |              |             |
| 99                   | CSE124        |            |             |              |             |
| 100                  | CSE125        |            |             |              |             |

CSE 数据库比对需求档案范例内容如下 -



```

CSE - 記事本
檔案(F) 編輯(E) 格式(O) 檢視(V) 說明(H)
CSE001,126,232,127,456
CSE002,114,156,88,322
CSE003,98,120,94,362
CSE004,102,142,108,402
CSE005,106,124,100,362
CSE007,94,142,90,352
CSE008,90,140,92,426
CSE009,106,182,142,436
CSE011,108,149,96,369
CSE012,150,204,112,370
CSE013,120,206,98,376
CSE014,104,174,168,504
CSE015,114,214,100,526
CSE016,105,135,86,362
CSE017,114,200,148,478
CSE019,114,148,98,388
CSE021,119,152,105,477
CSE022,122,232,102,400
    
```

### 3.2 CSE\_Noise 数据库比对需求文件格式

CSE\_Noise 仅需要在 YY0782-2010 (IEC 60601-2-51) 测试。

下列表格为 CSE\_Noise 数据库比对需求文件格式的定义 -

| CSE_Noise Format (6 x 240) |               |            |           |            |              |             |
|----------------------------|---------------|------------|-----------|------------|--------------|-------------|
| Column Number              | 1             | 2          | 3         | 4          | 5            | 6           |
| Row Number                 | Waveform Name | Noise Type | Line Type | P Duration | QRS Duration | QT Interval |
| 1                          | CSE008        | N1         | 0         |            |              |             |



|     |        |    |   |  |  |  |
|-----|--------|----|---|--|--|--|
| 2   | CSE008 | N1 | 1 |  |  |  |
| 3   | CSE008 | N1 | 2 |  |  |  |
| 4   | CSE008 | N1 | 3 |  |  |  |
| 5   | CSE008 | N1 | 4 |  |  |  |
| 6   | CSE008 | N1 | 5 |  |  |  |
| 7   | CSE008 | N2 | 0 |  |  |  |
| 8   | CSE008 | N2 | 1 |  |  |  |
| ... | ...    |    |   |  |  |  |
| 234 | CSE061 | N3 | 5 |  |  |  |
| 235 | CSE061 | N4 | 0 |  |  |  |
| 236 | CSE061 | N4 | 1 |  |  |  |
| 237 | CSE061 | N4 | 2 |  |  |  |
| 238 | CSE061 | N4 | 3 |  |  |  |
| 239 | CSE061 | N4 | 4 |  |  |  |
| 240 | CSE061 | N4 | 5 |  |  |  |

“Line Type” 及 “Noise Type” 可使用的代码列表如下 -

| Line Type | Description |
|-----------|-------------|
| 0         | Digital     |
| 1         | Analog 1    |
| 2         | Analog 2    |
| 3         | Analog 3    |
| 4         | Analog 4    |
| 5         | Analog 5    |

| Noise Type | Description                     |
|------------|---------------------------------|
| N1         | 50Hz noise 25uV peak            |
| N2         | 60Hz noise 25uV peak            |
| N3         | HF noise 15u Vrms               |
| N4         | Baseline noise 0.3Hz 0.5mV peak |

CSE\_Noise 数据库比对需求档案范例内容如下 -

```

CSE_Noise - 記事本
檔案(F) 編輯(E) 格式(O) 檢視
CSE008,N1,0,1,8,4
CSE008,N1,1,33,33,33
CSE008,N1,2,,,
CSE008,N1,3,55,55,55
CSE008,N1,4,,,
CSE008,N1,5,,,
CSE008,N2,0,99,107,435
CSE008,N2,1,,,
CSE008,N2,2,,,
CSE008,N2,3,,,
CSE008,N2,4,,,
CSE008,N2,5,,,
CSE008,N3,0,99,107,435
CSE008,N3,1,,,
CSE008,N3,2,,,
CSE008,N3,3,,,
CSE008,N3,4,,,
    
```

### 3.3 CTS\_Analog\_LineX 数据库比对需求文件格式

在 CTS 模拟测试档案中共有 5 个一样格式的档案，档案的命名规则是“CTS\_Analog\_Line” + “test number” (X). test number(X) 中 (X) 的范围是 1 到 5，代表的是不同的测试纪录。

下列表格为 CTS\_Analog\_LineX 数据库比对需求文件格式的定义 -

| CTS_Analog_LineX Format (173 x 17, "with" J amplitude) |               |                     |     |     |
|--|---------------|---------------------|-----|-----|
| Column Number  | 1             | 2                   | ... | 173 |
| Row Number   | Waveform Name | CTS Structure       |     |     |
| 1  | ANE20000      | CTS Structure (172) |     |     |
| 2  | ANE20001      | CTS Structure (172) |     |     |
| 3  | ANE20002      | CTS Structure (172) |     |     |
| 4  | CAL05000      | CTS Structure (172) |     |     |
| 5  | CAL10000      | CTS Structure (172) |     |     |
| 6  | CAL15000      | CTS Structure (172) |     |     |
| 7  | CAL20000      | CTS Structure (172) |     |     |
| 8  | CAL20002      | CTS Structure (172) |     |     |
| 9  | CAL20100      | CTS Structure (172) |     |     |
| 10   | CAL20110      | CTS Structure (172) |     |     |
| 11   | CAL20160      | CTS Structure (172) |     |     |
| 12   | CAL20200      | CTS Structure (172) |     |     |
| 13   | CAL20210      | CTS Structure (172) |     |     |
| 14   | CAL20260      | CTS Structure (172) |     |     |
| 15   | CAL20500      | CTS Structure (172) |     |     |
| 16   | CAL30000      | CTS Structure (172) |     |     |
| 17   | CAL50000      | CTS Structure (172) |     |     |

测试文件格式内包含 172 个参数，以下为 172 个参数的格式说明:

| CTS Structure |  |   |   |   |   |   |   |   |   |    |    |    |     |    |
|---------------|--|---|---|---|---|---|---|---|---|----|----|----|-----|----|
| Start         | 1  | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | End |    |
| 1             | CTS Interval & Duration - Absolute, S:[Global Intervals]           |   |   |   |   |   |   |   |   |    |    |    | 4   |    |
| 5             | CTS Interval & Duration - Absolute, Q duration S:[Durations in MS] |   |   |   |   |   |   |   |   |    |    |    |     | 16 |
| 17            | CTS Interval & Duration - Absolute, R duration S:[Durations in MS] |   |   |   |   |   |   |   |   |    |    |    |     | 28 |
| 29            | CTS Interval & Duration - Absolute, S duration S:[Durations in MS] |   |   |   |   |   |   |   |   |    |    |    |     | 40 |
| 41            | CTS Amplitude, P1 amplitude S:[Durations in MS]                    |   |   |   |   |   |   |   |   |    |    |    |     | 52 |
| 53            | CTS Amplitude, P2 amplitude S:[Durations in MS]                    |   |   |   |   |   |   |   |   |    |    |    |     | 64 |



### 3.4 CTS\_Digital 数据库比对需求文件格式

CTS\_Digital 数据库比对需求文件格式与章节 3.3 CTS\_Analog\_LineX 数据库比对需求文件格式一致，下列表格为 CTS\_Analog\_LineX 数据库比对需求文件格式的定义-

| CTS_Digital Format (173 x 17) |               |                     |     |     |
|-------------------------------|---------------|---------------------|-----|-----|
| Column Number                 | 1             | 2                   | ... | 173 |
| Row Number                    | Waveform Name | CTS Structure       |     |     |
| 1                             | ANE20000      | CTS Structure (172) |     |     |
| 2                             | ANE20001      | CTS Structure (172) |     |     |
| 3                             | ANE20002      | CTS Structure (172) |     |     |
| 4                             | CAL05000      | CTS Structure (172) |     |     |
| 5                             | CAL10000      | CTS Structure (172) |     |     |
| 6                             | CAL15000      | CTS Structure (172) |     |     |
| 7                             | CAL20000      | CTS Structure (172) |     |     |
| 8                             | CAL20002      | CTS Structure (172) |     |     |
| 9                             | CAL20100      | CTS Structure (172) |     |     |
| 10                            | CAL20110      | CTS Structure (172) |     |     |
| 11                            | CAL20160      | CTS Structure (172) |     |     |
| 12                            | CAL20200      | CTS Structure (172) |     |     |
| 13                            | CAL20210      | CTS Structure (172) |     |     |
| 14                            | CAL20260      | CTS Structure (172) |     |     |
| 15                            | CAL20500      | CTS Structure (172) |     |     |
| 16                            | CAL30000      | CTS Structure (172) |     |     |
| 17                            | CAL50000      | CTS Structure (172) |     |     |

测试文件格式内包含 172 个参数，以下为 172 个参数的格式说明：

| CTS Structure |  |   |   |   |   |   |   |   |   |    |    |    |     |
|---------------|--|---|---|---|---|---|---|---|---|----|----|----|-----|
| Start         | 1  | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | End |
| 1             | CTS Interval & Duration - Absolute, S:[Global_Intervals]           |   |   |   |   |   |   |   |   |    |    |    | 4   |
| 5             | CTS Interval & Duration - Absolute, Q duration S:[Durations in MS] |   |   |   |   |   |   |   |   |    |    |    | 16  |
| 17            | CTS Interval & Duration - Absolute, R duration S:[Durations in MS] |   |   |   |   |   |   |   |   |    |    |    | 28  |
| 29            | CTS Interval & Duration - Absolute, S duration S:[Durations in MS] |   |   |   |   |   |   |   |   |    |    |    | 40  |
| 41            | CTS Amplitude, P1 amplitude S:[Durations in MS]                    |   |   |   |   |   |   |   |   |    |    |    | 52  |
| 53            | CTS Amplitude, P2 amplitude S:[Durations in MS]                    |   |   |   |   |   |   |   |   |    |    |    | 64  |
| 65            | CTS Amplitude, Q amplitude S:[Durations in MS]                     |   |   |   |   |   |   |   |   |    |    |    | 76  |

|     |   |     |
|-----|---|-----|
| 77  | CTS Amplitude, R amplitude S:[Durations in MS]    | 88  |
| 89  | CTS Amplitude, S amplitude S:[Durations in MS]    | 100 |
| 101 | CTS Amplitude, J amplitude S:[Durations in MS]    | 112 |
| 113 | CTS Amplitude, ST20 amplitude S:[Durations in MS] | 124 |
| 125 | CTS Amplitude, ST40 amplitude S:[Durations in MS] | 136 |
| 137 | CTS Amplitude, ST60 amplitude S:[Durations in MS] | 148 |
| 149 | CTS Amplitude, ST80 amplitude S:[Durations in MS] | 160 |
| 161 | CTS Amplitude, T amplitude S:[Durations in MS]    | 172 |

在 172 个参数内，头 4 个参数是 Global Interval，依序分别代表 P Duration、PR Interval、QRS Duration 及 QT interval。

| S:[Global Interval] |             |              |             |
|---------------------|-------------|--------------|-------------|
| 1                   | 2           | 3            | 4           |
| P Duration          | PR Interval | QRS Duration | QT Interval |

其余的 168 个参数分为 14 个群组，每个群组代表一组量测数值 (振幅或是间期)。每组量测数值中有 12 个数字，分别代表 12 个导联。

| S:[Duration in MS] |    |     |     |     |     |    |    |    |    |    |    |
|--------------------|----|-----|-----|-----|-----|----|----|----|----|----|----|
| 1                  | 2  | 3   | 4   | 5   | 6   | 7  | 8  | 9  | 10 | 11 | 12 |
| I                  | II | III | aVR | aVL | aVF | V1 | V2 | V3 | V4 | V5 | V6 |

CTS\_Digital 数据库分析需求档案范例内容如下 -

## 4 联系鲸扬科技

WHALETEQ Co., LTD 鲸扬科技股份有限公司

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