

# WHALETEQ

## CTS/CSE Database Compliance Analyzer (CDCA)

### User Manual



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# Contents

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<b>1</b>	<b>Overview .....</b>	<b>4</b>
1.1	Reference & Scope .....	4
1.2	Installation and Environment Setup .....	4
<b>2</b>	<b>Software Interface Introduction .....</b>	<b>6</b>
2.1	Main Function .....	6
2.2	Compare and Get Testing Result .....	7
<b>3</b>	<b>Import/Export Data Format .....</b>	<b>7</b>
3.1	Required File Format for CSE Database Analysis .....	8
3.2	Required File Format for CSE Noise Database Analysis .....	8
3.3	Required File Format for CTS_Analog_LineX Database Analysis .....	10
3.4	Required File Format for CTS Digital Database Analysis .....	11
<b>4</b>	<b>Contact WhaleTeq .....</b>	<b>13</b>

# 1 Overview

CTS/CSE Database Compliance Analyzer (CDCA) helps customers to know their algorithm status in IEC60601-2-25: 2011 or YY0782-2010. It compares standard data with customer data, and calculates Pass/Fail result.

## 1.1 Reference & Scope

CTS/CSE Database Analysis is implements follow below standards:

### IEC60601-2-25: 2011

- **Standard Name:**  
Particular requirements for the basic safety and essential performance of electrocardiographs
- **Scope for this SW:**  
3 requirements in Subclause 201.12.1.101 (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)

- **Standard Name:**  
Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs
- **Scope for this SW:**  
4 requirements in Clause 50.101 (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 Installation and Environment Setup

The latest version of CDCA software can be downloaded on WhaleTeq's website. Please follow the below instructions to complete the installation.

- Click [Download] link to download the file to your computer
- Select to the download location
- Extract to the target folder

- Open the selected folder and ensure all the documents are extracted to the same folder
- Click and run the software

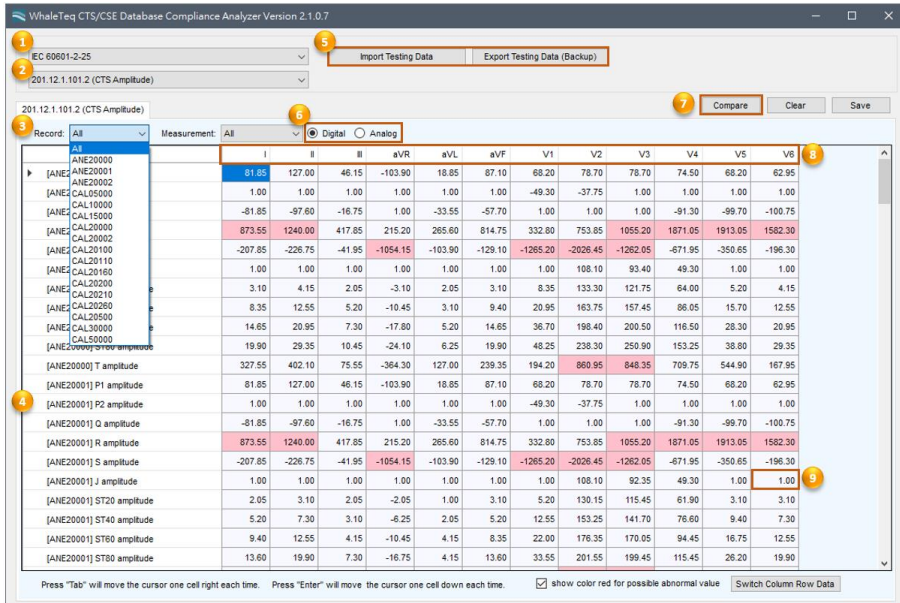
#### PC System Minimum Requirement

Items	Requirement
OS	Windows 7 or above
Disk Space	128 MB for Executable Installation; 1G for full RAF Database
Processor	Intel Core i3 or above
Memory	2G or above
Display	1366 X 768 or above

## 2 Software Interface Introduction

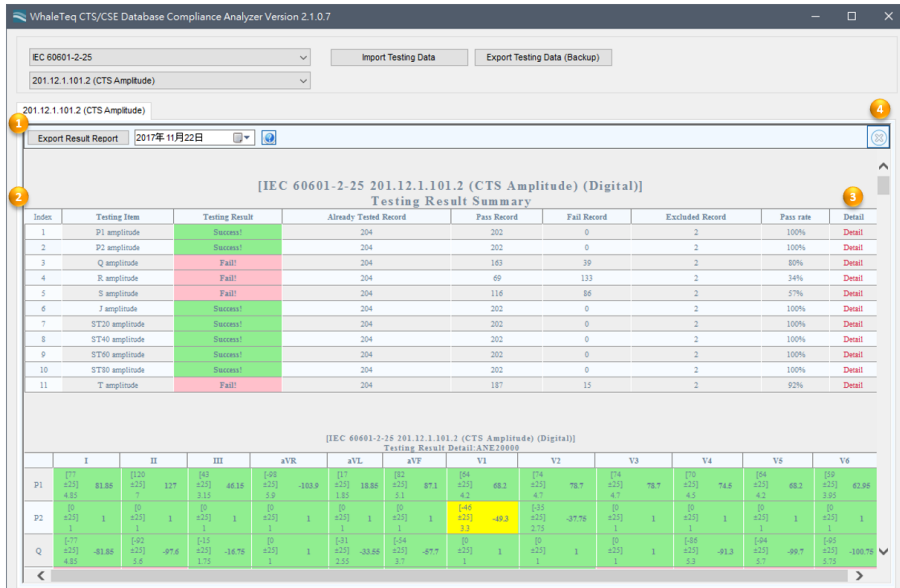
This section introduces the basic functions of software interface.

### 2.1 Main Function



- 01 – Select Standard Name: YY0782 or IEC60601-2-25
- 02 – Select Test Clause
- 03 – Select Database Waveform
- 04 – Column Data: Test Waveform and Parameter
- 05 – Export or Import Data from the ECG
- 06 – Select Testing Method: Digital or Analog
- 07 – Compare and Get Comparison Result
- 08 – Row Data: Test Lead
- 09 – Data Example: V6, ANE20002, S duration

## 2.2 Compare and Get Testing Result



WhaleTeq CTS/CSE Database Compliance Analyzer Version 2.1.0.7

IEC 60601-2-25    Import Testing Data    Export Testing Data (Backup)

201.12.1.101.2 (CTS Amplitude)

201.12.1.101.2 (CTS Amplitude)

Export Result Report    2017年11月22日

[IEC 60601-2-25 201.12.1.101.2 (CTS Amplitude) (Digital)]  
Testing Result Summary

Index	Testing Item	Testing Result	Already Tested Record	Pass Record	Fail Record	Excluded Record	Pass rate	Detail
1	P1 amplitude	Success!	204	202	0	2	100%	Detail
2	P2 amplitude	Success!	204	202	0	2	100%	Detail
3	Q amplitude	Fail!	204	163	39	2	80%	Detail
4	R amplitude	Fail!	204	69	133	2	34%	Detail
5	S amplitude	Fail!	204	116	88	2	57%	Detail
6	J amplitude	Success!	204	202	0	2	100%	Detail
7	ST20 amplitude	Success!	204	202	0	2	100%	Detail
8	ST40 amplitude	Success!	204	202	0	2	100%	Detail
9	ST80 amplitude	Success!	204	202	0	2	100%	Detail
10	ST160 amplitude	Success!	204	202	0	2	100%	Detail
11	T amplitude	Fail!	204	187	15	2	92%	Detail

[IEC 60601-2-25 201.12.1.101.2 (CTS Amplitude) (Digital)]  
Testing Result Detail:ANE20000

	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
P1	[77 83] 81.88	[130 133] 117	[94 115] 68.18	[49 59] -33.9	[17 18] 18.88	[82 81] 87.1	[84 82] 88.2	[74 67] 78.7	[74 67] 78.7	[70 65] 74.6	[84 82] 88.2	[18 18] 82.88
P2	[0 0] 1	[0 0] 1	[0 0] 1	[0 0] 1	[0 0] 1	[0 0] 1	[46 43] -49.3	[13 12] -87.78	[0 0] 1	[0 0] 1	[0 0] 1	[0 0] 1
Q	[77 83] -81.88	[130 133] -97.6	[94 115] -16.78	[49 59] 1	[17 18] -33.88	[82 81] -87.7	[84 82] 1	[74 67] 1	[74 67] 1	[70 65] -91.3	[84 82] -87.7	[18 18] -186.78

- 01 – Result Area
- 02 – Export Result Report
- 03 – Detail Link
- 04 – Exit Button

## 3 Import/Export Data Format

This section introduces the format for importing and exporting data.

The Testing Data in CTS/CSE DB Analysis will be imported or exported into 8 separated files. And the format for those files will be introduced in Section 3.1 to 3.4.

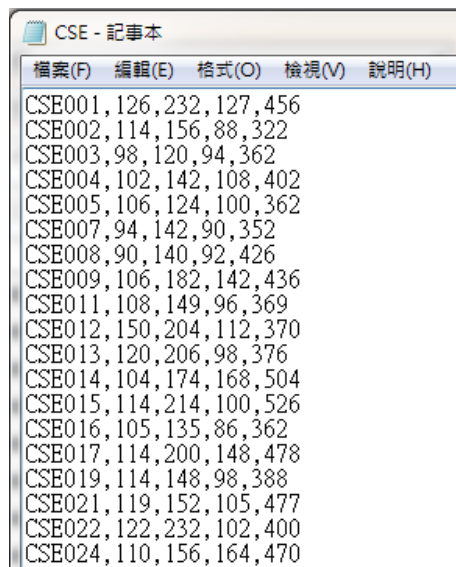
- CSE
- CSE\_Noise
- CTS\_Analog\_Line1
- CTS\_Analog\_Line2
- CTS\_Analog\_Line3
- CTS\_Analog\_Line4
- CTS\_Analog\_Line5
- CTS\_Digital

### 3.1 Required File Format for CSE Database Analysis

Below table shows the definition of CSE file format -

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				

The example of CSE file format is as below -



### 3.2 Required File Format for CSE Noise Database Analysis

CSE\_Noise is only required to test in YY0782-2010 (IEC 60601-2-51).

Below table shows the definition of CSE\_Noise file format-



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			

The reference codes of the “Line Type” and “Noise Type” are as below:

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

The example of CSE\_Noise file format is as below –

```

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
  
```

### 3.3 Required File Format for CTS\_Analog\_LineX Database Analysis

For CTS analog test files, there are 5 files with the same format, and the naming rule for those files are “CTS\_Analog\_Line” + “test number” (X). The range for “test number”(X) is 1 to 5, and it represents which test is recorded.

Below table shows the definition of CTS\_Analog\_LineX file format-

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)	

In the file format, there is a big structure with 172 parameters and below is the format for the 172 parameters:

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

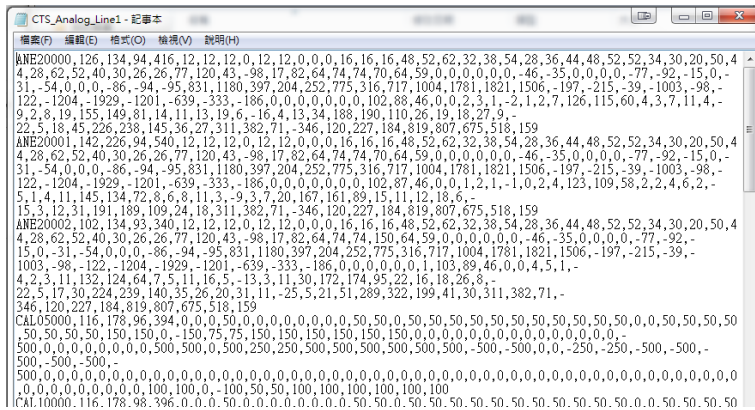
Within the 172 parameters, the first 4 parameters are global intervals with the sequences of P Duration, PR Interval, QRS Duration, and QT interval.

S:[Global_Interval]			
1	2	3	4
P Duration	PR Interval	QRS Duration	QT Interval

The rest 168 parameters are separated into 14 groups and each group represent 1 measurement (amplitude or duration). In each group, there are 12 numbers which represents 12 leads.

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

The example of CTS\_Analog\_LineX file format is as below –



### 3.4 Required File Format for CTS Digital Database Analysis

The format for CTS Digital is the same with 3.3 (CTS\_Analog\_LineX) and below table shows the definition of CTS\_Digital file format-

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)		

In the file format, there is a big structure with 172 parameters. Below is the format for the 172 parameters:

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

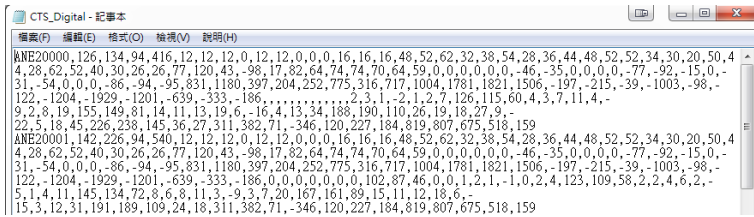
Within the 172 parameters, the first 4 parameters are global intervals with the sequences of P Duration, PR Interval, QRS Duration, and QT interval.

S:[Global_Interval]			
1	2	3	4
P Duration	PR Interval	QRS Duration	QT Interval

The rest 168 parameters are separated into 14 groups, each group represent 1 measurement (amplitude or duration). And there are 12 numbers in each group, which represents 12 leads.

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

The example of CTS\_Digital file format is as below –



## 4 Contact WhaleTeq

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