WHALETEQ

CTS/CSE Database Compliance Analyzer (CDCA)

User Manual

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Software Version 2.1.2.2

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Contents

List of Table

List of Figure

1 Overview

CTS/CSE Database Compliance Analyzer (CDCA) helps customers to know their algorithm status in IEC 60601-2-25:2011 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:

IEC 60601-2-25:2011

- **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 (IEC 60601-2-51:2003)

- **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 Product Specification

Table 1: Product Specification

Category	Detail
Supported Standards	IEC 60601-2-25:2011, YY 0782-2010
Supported Databases	CTS, CSE
Supported Test Options – CTS Amplitude	• P1 amplitude • P2 amplitude • Q amplitude • R amplitude • S amplitude • J amplitude • ST20 amplitude • ST40 amplitude • ST60 amplitude • ST80 amplitude • T amplitude
Supported Test Options – CTS Interval & Duration Absolute	• P Duration • PR Interval • QRS Duration • QT Interval • Q Duration • R Duration • S Duration
Supported Test Options – CSE Global Intervals	• P Duration • PR Interval • QRS Duration • QT Interval
Supported Test Options – CSE Against NOISE (YY0782)	• P Duration • QRS Duration • QT Interval • 50 Hz noise • 60 Hz noise • High frequency noise • Baseline noise
Supported Report	• CTS Amplitude Analog Testing Report • CTS Amplitude Digital Testing Report • CTS Absolute Interval and Duration Analog Testing Report

Category	Detail
	• CTS Absolute Interval and Duration Digital Testing Report • CSE Global Intervals Testing Report • CSE Against NOISE Analog Testing Report • CSE Against NOISE Digital Testing Report
Supported Report Export Format	RTF file (Compatible with MS Word)

1.3 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

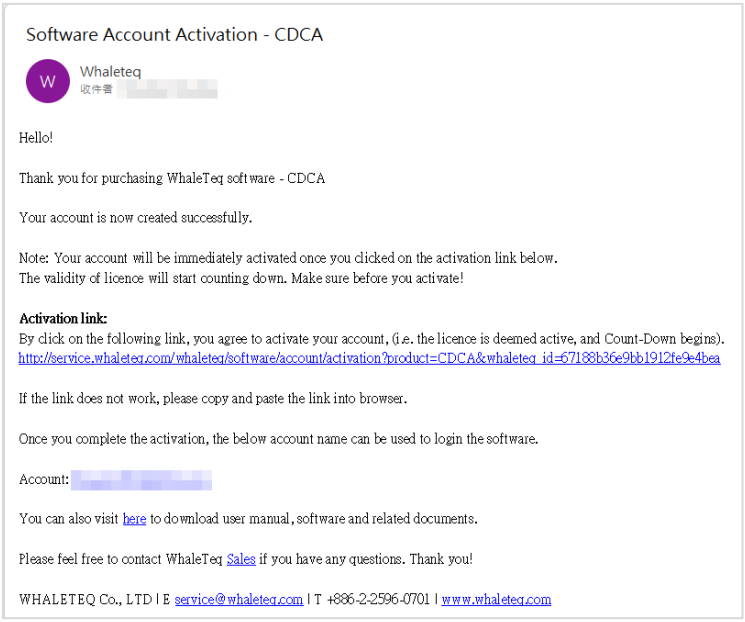
Table 2: PC System Minimum Requirement for CDCA Installation

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

1.4 Initiate the CDCA Software

Step 1: Get the notification email with the activation link and account

After purchasing the CDCA software, you will receive a notification email on the assigned email address with the account name and activation link for activating the CDCA software.



Software Account Activation - CDCA

Whaleteq
收件者 [redacted]

Hello!

Thank you for purchasing WhaleTeq software - CDCA

Your account is now created successfully.

Note: Your account will be immediately activated once you clicked on the activation link below.
The validity of licence will start counting down. Make sure before you activate!

Activation link:
By click on the following link, you agree to activate your account, (i.e. the licence is deemed active, and Count-Down begins).
http://service.whaleteq.com/whaleteq/software/account/activation?product=CDCA&whaleteq_id=67188b36e9bb1912fe9e4bea

If the link does not work, please copy and paste the link into browser.

Once you complete the activation, the below account name can be used to login the software.

Account: [redacted]

You can also visit here to download user manual, software and related documents.

Please feel free to contact WhaleTeq Sales if you have any questions. Thank you!

WHALETEQ Co., LTD | E service@whaleteq.com | T +886-2-2596-0701 | www.whaleteq.com

Figure 1: Initiate the CDCA Software (Step 1)

Step 2: Click the "Activation Link"

After clicking the activation link in the notification email, you will be directed to a web browser where a success message confirming activation will appear. Additionally, you will receive a "Software Account Login Information" notification email with your login account and password.

Note:
(1) Login to the CDCA software will fail if you launch the software without clicking the activation link.
(2) The availability period of CDCA software counts from the time you click on the activation link.

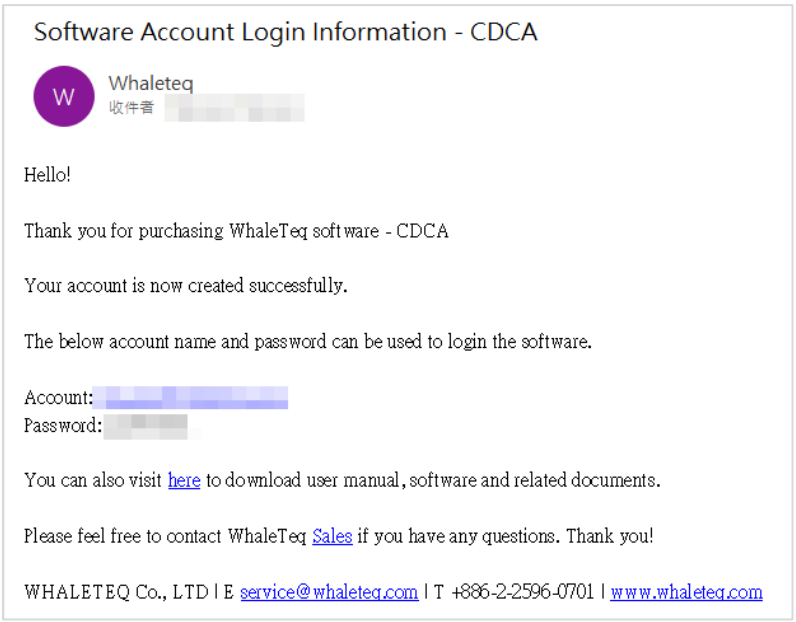


Figure 2: Initiate the CDCA Software (Step 2)

Step 3: Launch and log in to the CDCA

After launching the CDCA, the login window will appear. Please use the account and password provided in the notification email to log in.

Note: Please secure the account information and password carefully. If they are lost, please contact service@whaleteq.com.

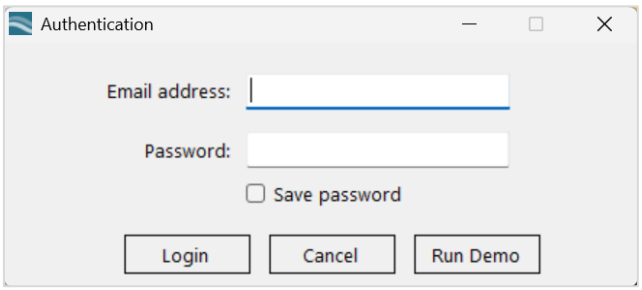


Figure 3: Initiate the CDCA Software (Step 3)

2 Software Interface Introduction

This section introduces the basic functions of software interface.

2.1 Main Function

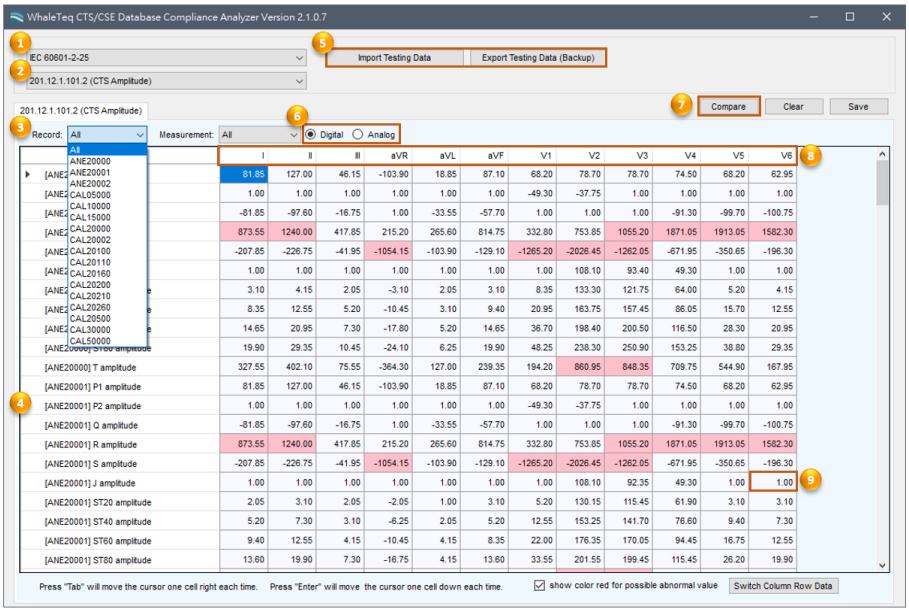


Figure 4: CDCA Home Screen

01 – Select Standard Name: YY0782 or IEC 60601-2-25
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 Results

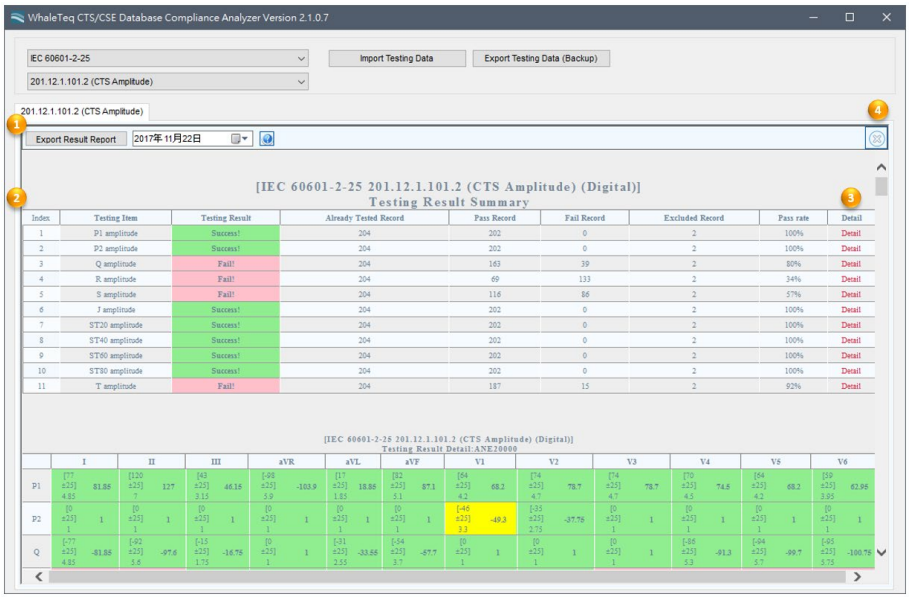


Figure 5: Comparison Result

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

Note:
Before performing IEC 60601-2-25 and CSE database comparisons, a confirmation window will appear, prompting users to verify whether they have purchased licenses for IEC 60601-2-25 and the CSE database.
Please ensure that the required licenses have been purchased, check "Yes", then click the "Submit" button and the "Import CSE Original File Name" button.

Figure 6: ''Check IEC 60601-2-25:2011 Standard'' Window

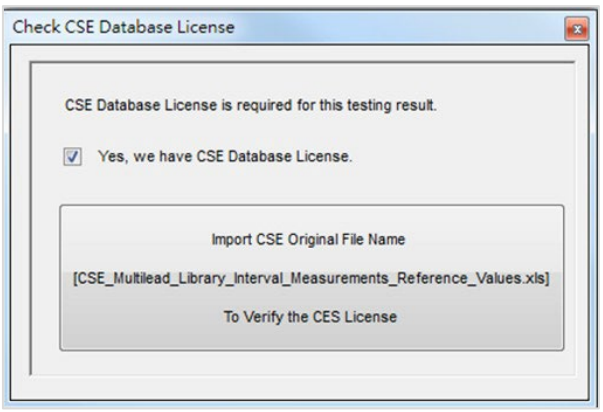


Figure 7: ''Check CSE Database License'' Window

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:

Table 3: 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:

Figure 8: Example of CSE File Format

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:

Table 4: 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:

Table 5: The Reference Codes of “Line Type”

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

Table 6: The Reference Codes of "Noise Type"

Noise Type	Description
N1	50Hz noise 25 uVpeak
N2	60Hz noise 25 uVpeak
N3	HF noise 25 uVrms
N4	Baseline noise 0.3Hz 0.5 mVpeak

The example of CSE Noise file format is as below:

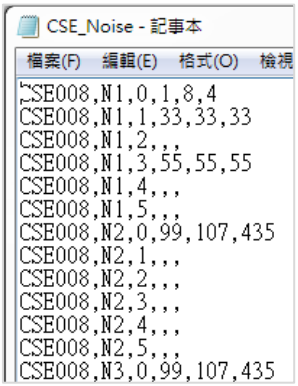


Figure 9: Example of CSE Noise File Format

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:

Table 7: 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)		

CTS_Analog_LineX Format (173 x 17, "with" J amplitude)				
Column Number	**1**	**2**	**...**	**173**
Row Number	Waveform Name	CTS Structure		
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:

Table 8: Parameter Format of CTS Analog Test Files

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

CTS Structure													
Start	1	2	3	4	5	6	7	8	9	10	11	12	End
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.

Table 9: Global Interval Parameter of CTS Analog Test Files

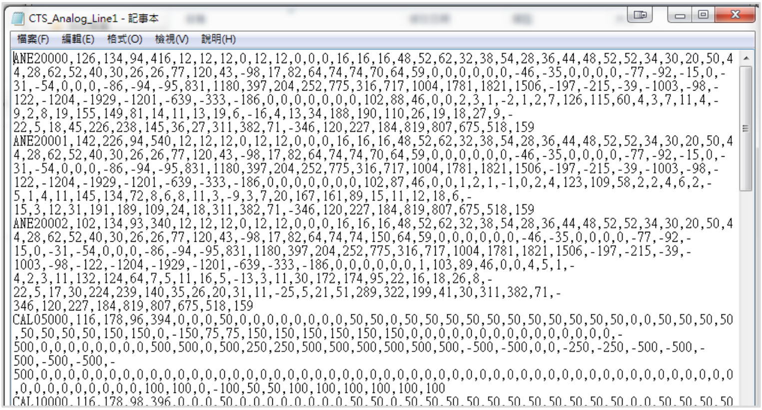
S:[Global_Interval]			
1	2	3	4
P Duration	PR Interval	QRS Duration	QT Interval

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.

Table 10: Number and Lead Cross Reference Table of CTS Analog Test Files

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:



```
CTS_Analog_Line1 - 記事本
檔案(F) 編輯(E) 格式(O) 檢視(V) 說明(H)
ANE20000,126,134,94,416,12,12,12,0,12,12,0,0,0,16,16,16,48,52,62,32,38,54,28,36,44,48,52,52,34,30,20,50,4
4,28,62,52,40,30,26,26,77,120,43,-98,17,82,64,74,74,70,64,59,0,0,0,0,0,0,-46,-35,0,0,0,0,-77,-92,-15,0,-
31,-54,0,0,0,-86,-94,-95,831,1180,397,204,252,775,316,717,1004,1781,1821,1506,-197,-215,-39,-1003,-98,-
122,-1204,-1929,-1201,-639,-333,-186,0,0,0,0,0,0,0,102,88,46,0,0,2,3,1,-2,1,2,7,126,115,60,4,3,7,11,4,-
9,2,8,19,155,149,81,14,11,13,19,6,-16,4,13,34,188,190,110,26,19,18,27,9,-
22,5,18,45,226,238,145,36,27,311,382,71,-346,120,227,184,819,807,675,518,159
ANE20001,142,226,94,540,12,12,12,0,12,12,0,0,0,16,16,16,48,52,62,32,38,54,28,36,44,48,52,52,34,30,20,50,4
4,28,62,52,40,30,26,26,77,120,43,-98,17,82,64,74,74,70,64,59,0,0,0,0,0,0,-46,-35,0,0,0,0,-77,-92,-15,0,-
31,-54,0,0,0,-86,-94,-95,831,1180,397,204,252,775,316,717,1004,1781,1821,1506,-197,-215,-39,-1003,-98,-
122,-1204,-1929,-1201,-639,-333,-186,0,0,0,0,0,0,0,102,87,46,0,0,1,2,1,-1,0,2,4,123,109,58,2,2,4,6,2,-
5,1,4,11,145,134,72,8,6,8,11,3,-9,3,7,20,167,161,89,15,11,12,18,6,-
15,3,12,31,191,189,109,24,18,311,382,71,-346,120,227,184,819,807,675,518,159
ANE20002,102,134,93,340,12,12,12,0,12,12,0,0,0,16,16,16,48,52,62,32,38,54,28,36,44,48,52,52,34,30,20,50,4
4,28,62,52,40,30,26,26,77,120,43,-98,17,82,64,74,74,150,64,59,0,0,0,0,0,0,-46,-35,0,0,0,0,-77,-92,-
15,0,-31,-54,0,0,0,-86,-94,-95,831,1180,397,204,252,775,316,717,1004,1781,1821,1506,-197,-215,-39,-
1003,-98,-122,-1204,-1929,-1201,-639,-333,-186,0,0,0,0,0,0,1,103,89,46,0,0,4,5,1,-
4,2,3,11,132,124,64,7,5,11,16,5,-13,3,11,30,172,174,95,22,16,18,26,8,-
22,5,17,30,224,239,140,35,26,20,31,11,-25,5,21,51,289,322,199,41,30,311,382,71,-
346,120,227,184,819,807,675,518,159
CAL05000,116,178,96,394,0,0,0,50,0,0,0,0,0,0,0,0,50,50,0,50,50,50,50,50,50,50,50,50,50,0,0,50,50,50,50
,50,50,50,50,150,150,0,-150,75,75,150,150,150,150,150,150,0,0,0,0,0,0,0,0,0,0,0,0,0,0,-
500,0,0,0,0,0,0,0,0,500,500,0,500,250,250,500,500,500,500,500,500,-500,-500,0,0,-250,-250,-500,-500,-
500,-500,-500,-
500,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0
,0,0,0,0,0,0,0,0,0,0,100,100,0,-100,50,50,100,100,100,100,100,100
CAL10000,116,178,98,396,0,0,0,50,0,0,0,0,0,0,0,0,50,50,0,50,50,50,50,50,50,50,50,50,50,0,0,50,50,50,50
```

Figure 10: Example of CTS_Analog_LineX File Format

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:

Table 11: Definition of CTS_Digital_LineX 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)		

CTS_Digital Format (173 x 17)				
Column Number	**1**	**2**	**…**	**173**
Row Number	Waveform Name	CTS Structure		
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:

Table 12: Parameter Format of CTS Digital Test Files

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.

Table 13: Global Interval Parameter of CTS Digital Test Files

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.

Table 14: Number and Lead Cross Reference Table of CTS Digital Test Files

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:

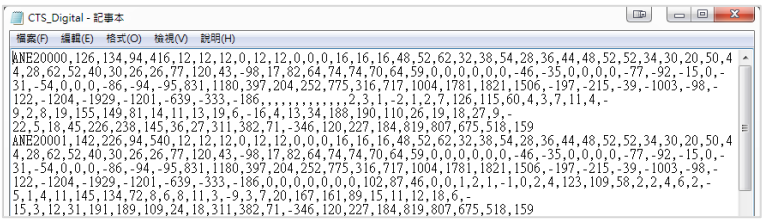


Figure 11: Example of CTS Digital File Format

4 Ordering Information

Table 15: Ordering Information

Part No.	Description
HB0-CD00099	**Model No.**: CDCA CTS / CSE medical database comparison software

5 Revision History

Table 16: Revision History

Version	Modified Contents	Issued Date
2025-02-12	• Add 1.2 Product Specification 1.4 Initiate the CDCA Software 4 Ordering Information 5 Revision History • Update 2.2 Compare and Get Testing Results	2025-03-12

6 Contact WhaleTeq

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