

WHALETEQ

CTS/CSE Database Compliance Analyzer (CDCA)

User Manual

Revision Date: 2025-02-11 Software Version 2.1.2.2



Copyright (c) 2013-2025, All Rights Reserved. WhaleTeq Co. LTD

No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system, or translated into any language or computer language, in any form, or by any means, electronic, mechanical, magnetic, optical, chemical, manual or otherwise, without the prior written permission of WhaleTeq Co. LTD.

Disclaimer

WhaleTeq Co. LTD. provides this document and the programs "as is" without warranty of any kind, either expressed or implied, including, but not limited to, the implied warranties of merchantability or fitness for a particular purpose.

This document could contain technical inaccuracies or typographical errors. Changes are periodically made to the information herein; these changes will be incorporated in future revisions of this document. WhaleTeq Co. LTD. is under no obligation to notify any person of the changes.

The following trademarks are used in this document:

WHALETER is a registered trademark of WhaleTeq Co. LTD

All other trademarks or trade names are property of their respective holders.

Contents

1	Ove	erview	6
	1.1	Reference & Scope	6
	1.2	Product Specification	7
	1.3	Installation and Environment Setup	8
	1.4	Initiate the CDCA Software	9
2	Soft	tware Interface Introduction	.11
	2.1	Main Function	. 11
	2.2	Compare and Get Testing Results	. 12
3	Imp	oort/Export Data Format	.13
	3.1	Required File Format for CSE Database Analysis	. 14
	3.2	Required File Format for CSE Noise Database Analysis	. 15
	3.3	Required File Format for CTS_Analog_LineX Database Analysis	. 16
	3.4	Required File Format for CTS Digital Database Analysis	. 19
4	Ord	lering Information	.21
5	Rev	ision History	.22
6	Con	itact WhaleTeq	.22



List of Table

Table 1: Product Specification7
Table 2: PC System Minimum Requirement for CDCA Installation 8
Table 3: Definition of CSE File Format14
Table 4: Definition of CSE Noise File Format 15
Table 5: The Reference Codes of "Line Type"
Table 6: The Reference Codes of "Noise Type"
Table 7: Definition of CTS_Analog_LineX File Format 16
Table 8: Parameter Format of CTS Analog Test Files 17
Table 9: Global Interval Parameter of CTS Analog Test Files 18
Table 10: Number and Lead Cross Reference Table of CTS Analog
Table 10: Number and Lead Cross Reference Table of CTS AnalogTest Files
Table 10: Number and Lead Cross Reference Table of CTS AnalogTest Files
Table 10: Number and Lead Cross Reference Table of CTS AnalogTest Files
Table 10: Number and Lead Cross Reference Table of CTS AnalogTest Files
Table 10: Number and Lead Cross Reference Table of CTS Analog Test Files
Table 10: Number and Lead Cross Reference Table of CTS Analog Test Files
Table 10: Number and Lead Cross Reference Table of CTS Analog Test Files



List of Figure

9
10
10
11
12
13
13
14
16
19
21



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	RTF file (Compatible with MS Word)
Format	

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

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

Table 2: PC System Minimum Requirement for CDCA Installation



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.



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.



Software Account Login Information - CDCA
W Whaleteq 收件者
Hello!
Thank you for purchasing WhaleTeq software - CDCA
Your account is now created successfully.
The below account name and password can be used to login the software.
Account:
You can also visit <u>here</u> to download user manual, software and related documents.
Please feel free to contact WhaleTeq <u>Sales</u> if you have any questions. Thank you!
WHALETEQ Co., LTD E <u>service@whaleteg.com</u> T +886-2-2596-0701 <u>www.whaleteg.com</u>
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 <u>service@whaleteq.com</u>.

Authentication	_	
Email address:		
Password:		
	Save password	
Login	Cancel Run D	emo

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

InaleTeq CTS/CSE Databa	se Compliance	Analyzer Ve	ersion 2.1.0											_	
C 60601-2-25			~	i in	port Testing	Data	Export	Testing Data	(Backup)						
01.12.1.101.2 (CTS Amplitude)			~												
12.1.404.2 (CTC Amelitude)			-									Compare	Clea	ar	Save
.12.1.101.2 (CTS Amplitude)			- 6		_						-				
Record: All 🗸	Measurement:	All	~ •	Digital 🔘	Analog										
AI ANE20000		1	1		aVR	aVL	aVF	V1	V2	V3	V4	V5	V6	8	
[ANE2 ANE20001		81.85	127.00	46.15	-103.90	18.85	87.10	68.20	78.70	78.70	74.50	68.20	62.95	-	
[ANE2 CAL05000		1.00	1.00	1.00	1.00	1.00	1.00	-49.30	-37.75	1.00	1.00	1.00	1.00		
[ANE2 CAL15000		-81.85	-97.60	-16.75	1.00	-33.55	-57.70	1.00	1.00	1.00	-91.30	-99.70	-100.75		
ANE2 CAL20000		873.55	1240.00	417.85	215.20	265.60	814.75	332.80	753.85	1055.20	1871.05	1913.05	1582.30		
CAL20002 [ANE2 CAL20100		-207.85	-226.75	-41.95	-1054.15	-103.90	-129.10	-1265.20	-2026.45	-1262.05	-671.95	-350.65	-196.30		
CAL20110		1.00	1.00	1.00	1.00	1.00	1.00	1.00	108.10	93.40	49.30	1.00	1.00		
CAL20200		3.10	4.15	2.05	-3.10	2.05	3.10	8.35	133.30	121.75	64.00	5.20	4.15		
CAL20210		8.35	12.55	5.20	-10.45	3.10	9.40	20.95	163.75	157.45	86.05	15.70	12.55		
CAL20500		14.65	20.95	7 30	-17.80	5 20	14.65	36.70	198.40	200.50	116 50	28.30	20.95		
CALS0000		19.00	20.00	10.45	24.10	6.25	10.00	48.25	238.30	250.00	153.25	38.80	20.00		
[ANE20000] Stop amplitude		207.66	402.40	76.66	204.00	407.00	220.25	404.20	200.00	2.30.30	700.76	50.00	467.05		
[ANE20000] T amplitude		327.55	402.10	10.00	-304.30	127.00	239.35	184.20	70.70	040.35	709.75	044.90	107.95		
[ANE20001] P1 amplitude		81.85	127.00	46.15	-103.90	18.85	87.10	68.20	78.70	78.70	74.50	68.20	62.95		
[ANE20001] 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		
[ANE20001] 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		
[ANE20001] 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		
[ANE20001] 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		
[ANE20001] 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	ె	
[ANE20001] 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		
[ANE20001] 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		
[ANE20001] 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		
[ANE20001] 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		
								-							

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

	601-2-25						\sim		Import	Testing	Data		Export T	esting Da	ta (Backup)							
01.13	2.1.101.2 (CT	S Amplitude	:)				~																
12.1	101 2 (CTS 4	molitude)																					
			-00.00			1 (2)																	_
Expo	rt Result Rep	ort 201	7年11月	22日																			
						[IE C	6060]	L-2-2	520 Te	1.12 stin	.1.101 g Res	1.2 (0 ult S	CTS An	mplitu ry	ıde) (I	ligita]]					1	3
ndex	Tes	ting Item		Test	ting Result			Already	Already Tested Record				Pass Record		Fail Rec	ord	E	xcluded F	Record		Pass rate	1	Detail
1	Pl	emplitude		S	Success!				204				202 0				2				100%		Detail
2	P2	emplitude		S	Success!			204					202 0			2					1	Detail	
3	Qa	mplitude			Fail!			204			163		39	9		2			8096		Detail		
4	Ra	mplitude			Fail!			204			69			133	3		2			3496		Detail	
5	Sa	mplitude			Fail!			204				116 86			2				5796		Detail		
6	Ja	mplitude		S	Success!			204			202		0	2				100%		Detail			
7	ST20	amplitude		S	Success!			204			202			0			2		100%			Detail	
S	ST40	amplitude		S	Success!			204					202		0			2			100%		Detail
9	ST60	amplitude		S	Success?			204					202		0			2			100%6		Detail
10	ST80	amplitude		S	Success!			204					202		0			2			100%		Detail
11	Та	mplitude			Fail!			204				187 15			5 2					9296		Detai1	
10	ST80 T a	amplitude mplitude		S	Success! Fail!			[IEC 60	204 204	25 201.	.12.1.10	.2 (CT	202 187 S Amplitu	ide) (Dig	0 15 ital)]			2			92%		Detail Detail
	I	1	п	r	п	al	/R	aV	L	a l	VF	Detail	VI	1	12		V3	1	74	V	5	V	6
21	[77 ±25] \$1.5	[120 5 ±25]	127	[43 ±25]	46.15	[-98 ±25]	-103.9	[17 ±25]	18.85	[82 ±25]	\$7.1	[64 ±25]	68.2	[74 ±25]	78.7	[74 ±25]	78.7	[70 ±25]	74.5	[64 ±25]	68.2	[59 ±25]	62.9
_	4.85					3.9		1.85				4.2		4.7		4.7		4.5		4.2		3.95	
22	[0 ±25] 1 1	[0 ±25] 1	1	[0 ±25] 1	1		1	[0 ±25] 1	1		1	[-46 ±25] 3.3	-49,3		-37.75		1	[0 ±25] 1	1		1	[0 ±25] 1	1
																		1.96					

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:

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

Table 3: Definition of CSE File Format

The example of CSE file format is as below:

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
CSE005,100,124,100,502
CSE008,90,140,92,426
CSE009,106,182,142,436
CSE011,108,149,96,369
CSE012, 150, 204, 112, 370
CSE013,120,200,98,370
CSE014,104,174,100,504
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 CSE024 110 156 164 470
MC02027,110,100,104,470

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:

CSE_Noise Format (6 x 240)								
Column Number	1	2	3	4	5	6		
Row	Waveform	Noise	Line Type	Р	QRS	QT		
Number	Name	Туре	сте туре	Duration	Duration	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					

Table 4: Definition of CSE Noise File Format

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



Noise TypeDescriptionN150Hz noise 25 uVpeakN260Hz noise 25 uVpeakN3HF noise 25 uVrmsN4Baseline noise 0.3Hz 0.5 mVpeak

Table 6: The Reference Codes of "Noise Type"

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				
2SE008	,N1,O,1	,8,4					
CSE008	, <u>N1,1</u> ,3	3,33,33					
CSE008	,N1,2,,	·					
CSE008	,MI,S,D MI 4	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
ICSE008	N1 5	,					
CSE008	,N2,0,9	9,107,4	35				
CSE008	,N2,1,,	,					
CSE008	, <u>N</u> 2,2,,	,					
CSE008	,N2,3,,	,					
CSE008	,MZ,4,, MD 5	,					
CSE008	.N3.0.9	9.107.4	35				

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:

CTS_Analog_LineX Format (173 x 17, "with" J amplitude)								
Column Number 1 2 173								
Row Number	Waveform Name	СТ	S Structu	ıre				
1	1 ANE20000 CTS Structure (172)							

Table 7: Definition of CTS_Analog_LineX File Format



CTS_Analog_Lir	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

					СТЅ	Stru	ctur	e					
Start	1	2	3	4	5	6	7	8	9	10	11	12	End
CTS Interval & Duration - Absolute, S:[Global_Intervals]									4				
5 CTS Interval & Duration - Absolute, Q duration S:[Durations in MS]									16				
17	7 CTS Interval & Duration - Absolute, R duration S:[Durations in MS]								28				
29	9 CTS Interval & Duration - Absolute, S duration S:[Durations in MS]									40			
41	CTS Amplitude, P1 amplitude S:[Durations in MS]								52				
53	C	rs An	nplitu	de, P2	2 am	plitu	ide S	5:[Du	ratic	ons ir	n MS	5]	64



CTS Structure													
Start	1	2	3	4	5	6	7	8	9	10	11	12	End
65	C	TS Ar	nplitu	de, C) am	plitu	de S	:[Du	ratio	ns in	MS]	76
77	C	TS Ar	nplitu	ide, F	R am	olitu	de S	:[Du	ratio	ns in	MS		88
89	C	CTS Ar	nplitu	ide, S	amp	olitu	de Sa	:[Dui	ratio	ns in	MS]		100
101	(CTS A	mplitu	ide, J	amp	olitu	de S:	[Dur	atio	ns in	MS]		112
113	CT	S Am	olitud	e, ST	20 ar	nplit	tude	S:[D	urat	ions	in M	IS]	124
125	CT	S Am	olitud	e, ST	40 ar	nplit	tude	S:[D	urat	ions	in M	IS]	136
137	CTS Amplitude, ST60 amplitude S:[Durations in MS] 14									148			
149	CTS Amplitude, ST80 amplitude S:[Durations in MS] 1								160				
161	C	TS Ar	nplitu	ıde, T	amp	olitu	de S	:[Du	ratio	ns 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	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
Ι	П		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	41.18	10	
檔案(F) 編輯(E) 桔式(O) 檢視(V) 說明(H)			
$ \begin{array}{l} kHE20000, 126, 134, 94, 416, 12, 12, 12, 0, 12, 12, 0, 0, 0, 16, 16, 16, 16, 13, 14, 28, 62, 52, 40, 30, 26, 26, 77, 120, 43, -98, 17, 82, 64, 74, 74, 70, 64, 13, 54, 10, 0, 86, 94, 95, 831, 1160, 397, 204, 252, 775, 316, 71, 122, -1204, -1929, -1201, -639, -333, -186, 0, 0, 0, 0, 0, 0, 0, 0, 102, 69, 28, 81, 55, 149, 81, 141, 11, 31, 96, -16, 4, 13, 34, 188, 190, 11, 22, 51, 84, 55, 149, 81, 144, 11, 13, 19, 6, -16, 41, 13, 34, 188, 190, 11, 22, 51, 84, 55, 149, 81, 144, 11, 21, 96, -16, 12, 12, 12, 0, 0, 0, 16, 16, 16, 42, 862, 52, 40, 30, 26, 26, 77, 120, 43, -98, 17, 82, 64, 74, 74, 70, 63, 31, -160, 34, 00, -86, -94, -95, 331, 1180, 337, 204, 252, 775, 10, 16, 16, 16, 422, 862, 52, 40, 30, 26, 26, 77, 120, 43, -98, 17, 82, 64, 74, 74, 70, 63, 31, -54, 0, 0, 0, -86, -94, -95, 331, 1180, 337, 204, 252, 775, 10, 1122, -1204, -1929, -1201, -639, -333, -186, 0, 0, 0, 0, 0, 0, 102, 82, 122, -1204, -1929, -1201, -639, -333, -186, 0, 0, 0, 0, 0, 0, 0, 102, 82, 122, 120, 0, 0, 0, 0, 0, 0, 0, 1122, 122, $	48,52,62,32,38 4,59,0,0,0,0,0 7,1004,1781,18 8,46,0,0,2,3,1 0,26,19,18,27, ,819,807,675,5 48,52,62,32,38 4,59,0,0,0,0,0 7,1004,1781,18 7,46,0,0,1,2,1	,54,28,36,44,48, ,0,-46,-35,0,0,0 21,1506,-197,-21, ,-2,1,2,7,126,11 9,- 18,159, ,54,28,36,44,48, ,0,-46,-35,0,0,0 21,1506,-197,-21, ,-1,0,2,4,123,10	52,52,34,30,20,50,4 0,-77,-92,-15,0,- 5,-39,-1003,-98,- 5,60,4,3,7,11,4,- 52,52,34,30,20,50,4 0,-77,-92,-15,0,- 5,-39,-1003,-98,- 9,58,2,2,4,6,2,-
5,1,4,11,145,134,72,8,6,8,11,3,-9,3,7,20,167,161,89,151, 15,31,2,31,19,189,109,241,8,31,832,71,-346,120,227,184 ANE20002,102,134,93,340,12,12,12,0,12,12,0,0,0,16,16,16, 4,28,62,52,40,30,62,67,71,20,43,-98,17,83,64,74,74,150, 15,0,-31,-54,0,0,0,-86,-94,-95,831,1180,397,204,222,775, 1003,-98,-122,-1204,-1929,-1201,-639,-333,-186,0,0,0,0,0, 4,2,3,11,3,12,124,647,75,11,16,5,-13,3,11,30,172,174,95,2 22,5,17,30,224,239,140,35,26,20,31,11,-25,5,21,51,289,32	1,12,18,6,- ,819,807,675,5 48,52,62,32,38 64,59,0,0,0,0, 316,717,1004,1 ,0,1,103,89,46 2,16,18,26,8,- 2,199,41,30,31	18,159 ,54,28,36,44,48, 0,0,-46,-35,0,0, 781,1821,1506,-1 ,0,0,4,5,1,- 1,382,71,-	52,52,34,30,20,50,4 0,0,-77,-92,- 97,-215,-39,-
$ \begin{array}{c} 340, 120, 227, 109, 8019, 807, 872, 186, 129\\ 24L05000, 116, 178, 96, 334, 0, 0, 0, 50, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0$,50,50,50,50,5 0,0,0,0,0,0,0,0,0,0,0,0,0	0,50,50,50,50,50,50 0,0,0,0,0,0,0,0,0, ,-500,0,0,-250,- 0,0,0,0,0,0,0,0,0,0,	,50,0,0,50,50,50,50 0,- 250,-500,-500,- 0,0,0,0,0,0,0,0,0,0,0
164,100000-116-178 98 396 0 0 50 0 0 0 0 0 0 0 0 0 0 0 50 0 Figure 10: Example of CTS 4	50 50 50 50 5	o so so so so so neX File For	.50.0.0.50.50.50.50

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	2 173								
Row Number	Waveform Name		CTS Structure								
1	ANE20000	СТ	S Structure (17	2)							
2	ANE20001	СТ	S Structure (17	2)							
3	ANE20002	CTS Structure (172)									
4	CAL05000	СТ	S Structure (17	2)							
5	CAL10000	СТ	S Structure (17	2)							
6	CAL15000	СТ	S Structure (17	2)							
7	CAL20000	СТ	S Structure (17	2)							
8	CAL20002	СТ	S Structure (17	2)							
9	CAL20100	СТ	S Structure (17	2)							
10	CAL20110	СТ	S Structure (17	2)							
11	CAL20160	CTS Structure (172)									
12	CAL20200	СТ	S Structure (17	2)							

Table 11: Definition of CTS_Digital_LineX File Format



CTS_Digital Format (173 x 17)									
Column Number	1	2 173							
Row	Waveform								
Number	Name								
13	CAL20210	CT	S Structure (17	2)					
14	CAL20260	CT	S Structure (17	2)					
15	CAL20500	CT	S Structure (17	2)					
16	CAL30000	CTS Structure (172)							
17	CAL50000	CT	S Structure (17	2)					

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

					CTS	Stru	cture	9					
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] 1					100							
101	CTS Amplitude, J amplitude S:[Durations in MS] 1					112							
113	CTS Amplitude, ST20 amplitude S:[Durations in MS] 1					124							
125	CTS Amplitude, ST40 amplitude S:[Durations in MS] 1					136							
137	CTS Amplitude, ST60 amplitude S:[Durations in MS] 1					148							
149	CTS Amplitude, ST80 amplitude S:[Durations in MS] 16						160						
161	CTS Amplitude, T amplitude S:[Durations in MS] 17						172						

Table 12: Parameter Format of CTS Digital Test Files



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		aVR	aVL	aVF	V1	V2	V3	V4	V5	V6

The example of CTS_Digital file format is as below:

「 📺 CTS_Digital - 記事本	
福案(F) 編輯(E) 格式(○) 檢視(V) 説明(H)	
BNE20000 , 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, 42, 428, 62, 52, 40, 30, 26, 26, 77, 120, 43, -98, 17, 82, 264, 74, 74, 70, 64, 59, 0, 0, 0, 0, -46, -35, 0, 0, 0, 1, -54, 0, 0, -86, -94, -95, 831, 1180, 397, 204, 252, 775, 316, 717, 104, 1781, 1621, 1506, -197, -215, -122, -1204, -1929, -1201, -639, -333, -186,,,,, 12, 3, 1, -2, 1, 2, 7, 126, 115, 600, 43, 7, 11, 4, -99, 24, 89, 155, 149, 81, 141, 11, 13, 19, 6, -164, -134, 11, 188, 190, 110, 26, 191, 192, 194, 133, 7, 11, 4, -99, 24, 89, 155, 149, 81, 141, 11, 13, 19, 6, -164, 13, 341, 188, 1190, 110, 26, 191, 182, 79, -1, -1, -1, -1, -1, -1, -1, -1, -1, -1	52,34,30,20,50,4 -77,-92,-15,0,- 39,-1003,-98,-
[22, 5, 18, 45, 226, 238, 145, 36, 27, 311, 382, 71, -346, 120, 227, 184, 819, 807, 675, 518, 159 ARE20001, 142, 226, 94, 540, 12, 12, 12, 00, 10, 12, 12, 0, 0, 0, 0, 16, 16, 16, 48, 55, 26, 32, 32, 85, 42, 83, 64, 44, 48, 52, 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, 55, 0, 0, 0, 0, 31, -54, 0, 0, -36, -94, -95, 831, 1180, 397, 204, 252, 775, 316, 717, 1004, 1781, 1821, 1506, -197, -215, - 122, -1204, -1929, -1201, -639, -333, -186, 0, 0, 0, 0, 0, 0, 0, 12, 87, 46, 0, 0, 1, 2, 1, -1, 0, 2, 4, 123, 109, 5 5, 1, 4, 114, 5134, 72, 86, 84, 113, 03, 70, 201, 623, 0161, 80, 85, 111, 12, 18, 66, 84, 113, 03, 70, 165, 101, 12, 18, 16, 111, 12, 18, 16, 14, 12, 14, 142, 160, 14, 123, 109, 5	52,34,30,20,50,4 -77,-92,-15,0,- 39,-1003,-98,- 58,2,2,4,6,2,-
(15,3,12,31,191,189,109,24,18,311,382,71,-346,120,227,184,819,807,675,518,159	

Figure 11: Example of CTS Digital File Format

4 Ordering Information

Table 15: Ordering Information

Part No.	Description					
	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

WHALETEQ Co., LTD
<u>service@whaleteq.com</u> (O)+886 2 2517 6255
8F., No. 125, Songjiang Rd., Zhongshan Dist., Taipei City 104474, Taiwan