

WHALETEQ

Rhythm Database Compliance Analyzer Database Comparison Software

USER MANUAL

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1 Introduction

This product is designed for analyzing and comparing the differences between the outcome of ECG algorithms and databases required by IEC 60601-2-47, EC57 and YY0885. In other words, this is the software that analyzes and compares Test Annotation File (TAF) of a diagnostic ECG with standard-required databases.

In addition to analysis and comparison functions, RDCA software also serves as a useful tool for algorithm engineers to adjust and fix errors in analog tests.

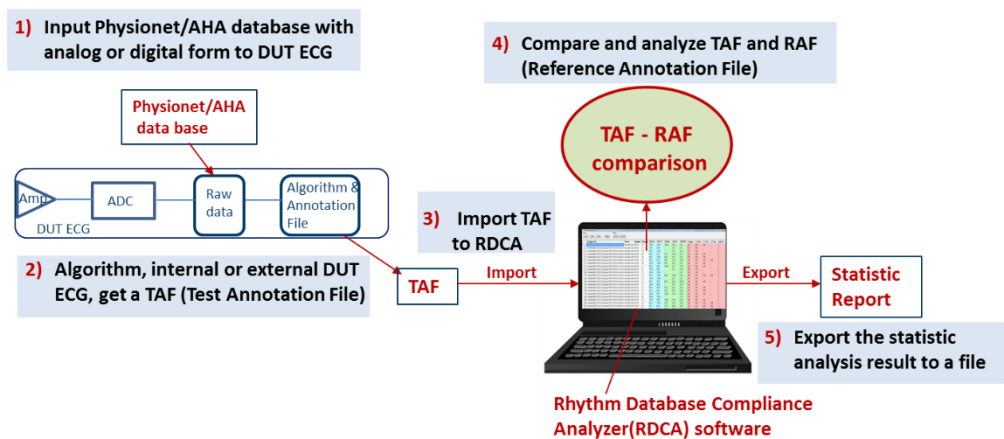


Figure 1: RDCA Comparison Process

1.1 Who Needs RDCA Database Comparison Software

- 1. Single-lead ECG manufacturer:** RDCA software is the database analysis software for database tests of IEC 60601-2-47, EC57 and YY0885. These medical standards are specifically written for verifying single-lead ECGs.
- 2. Diagnostic ECG manufacturer:** IEC 60601-2-47 and EC57 are ECG standards with requirements of disease diagnosis function for heart rhythm disorders. If ECG is declared to have disease diagnosis function, it would need RDCA software or equivalent tool to verify the compliance.

3. **Heart Rhythm Disorder Algorithm provider:** RDCA software can manage to analyze the gross and average rate between diagnostic ECG algorithm and standard requirements.
4. **Certification Laboratory:** RDCA software can generate required test reports of IEC 60601-2-47, EC57 and YY0885.
5. **Engineers who want to improve diagnostic algorithm:** After analyzing the gross and average rate between algorithms and databases, RDCA software further displays sections that are different from the databases, so that algorithm engineers can easily modify and improve algorithms.

1.2 Product Specification

Table 1: RDCA Specification

Category	Detail
Supported Standards	IEC 60601-2-47, ANSI/AAMI EC57, YY 0885
Supported Databases	MIT-BIH, AHA, NST, CU, ESC
Supported Test Options – 17 Required Capabilities	<ul style="list-style-type: none"> • QRS Se, QRS +P • VEB Se, VEB +P, VEB FPR • VEB COU Se, VEB COU +P, VEB S_Run Se, VEB S_Run +P, VEB L_Run Se, VEB L_Run +P • RMS heart rate error • % beats missed, % N and S missed, % V missed, % F missed, Total SHUTDOWN time
Supported Test Options – 25 Optional Capabilities	<ul style="list-style-type: none"> • SVEB Se, SVEB +P, SVEB FPR • SVEB COU Se, SVEB COU +P, SVEB S_Run Se, SVEB S_Run +P, SVEB L_Run Se, SVEB L_Run +P • VF EP Se, VF EP +P, VF DU Se, VF DU +P, VF FPR, VF Time • AF EP Se, AF EP +P, AF DU Se, AF DU +P, AF FPR, AF Time • ST EP Se, ST EP +P, ST DU Se, ST DU +P
TAF Format	<ul style="list-style-type: none"> • Binary-MIT annotation (*.atr) • Text-MIT Label (*.txt)

Category	Detail
	<ul style="list-style-type: none"> • Text-AHA Label (*.txt) • Text-AAMI Label (*.txt) • Text -AHA 2 fields (*.txt) • Text -AAMI 2 fields (*.txt)
Supported Time Unit	<ul style="list-style-type: none"> • Sample Index (100Hz ~ 1500Hz) • Absolute Time
Supported Report Export Format	TXT, CSV, Excel, Word

Note:

- (1) For details of Test Annotation File (TAF) format, please refer to section 4.
- (2) The RDCA calculates the RR interval heart rate of the reference annotation file (RAF) and TAF based on the heart rate program provided in PhysioNet's WFDB, and then performs a comparison. If users wish to use a custom heart rate calculation method, please refer to [item 8 in section 2.2](#).

1.2.1 Database Description

Below table is based on IEC 60601-2-47:2012 and databases of AHA, MIT-BIH, NST and CU, it also indicates waveforms which are needed to test or waveforms which can be excluded.

Table 2: Database Description

Database	Record ID	Description	Number of records
AHA database (included)	1201–1210	No VEBs	10
	2201, 2203–2210	Isolated uniform VEBs	9
	3201–3210	Isolated multiform VEBs	10
	4201–4210	Bigeminy	10
	5201–5210	R-on-T VEBs	10
	6201–6210	Ventricular couplets	10
	7201–7210	Ventricular tachycardia	10
	8201–8204, 8206–8210	Ventricular fibrillation	9
	AHA records in complete test		78
(excluded)	2202, 8205	Paced beats	2
MIT-BIH database	100, 101, 103, 105, 106, 108, 109, 111–119, 121–124	Records include no or common arrhythmias	20
	200–203, 205, 207–210, 212–215, 219–223, 226, 230–234	Records include less common but clinically important arrhythmias	<u>24</u>
		MIT-BIH records in complete test	44
(excluded)	102, 104, 107, 217	Paced beats	4
NST database	118e00, 119e00, 118e06, 119e06, 118e12, 119e12, 118e18, 119e18, 118e24, 119e24, 118e_6, 119e_6,	Noise Stress Test Database	12
CU database	cu01-cu35	Ventricular Tachyarrhythmia Database	35
NOTE The AHA record ID numbers given refer to the 35 min version of the AHA database. The second digit from left in the ID numbers is "0" (rather than "2") for the corresponding 3 h records. Only the last 35 min of the 3 h records (equivalent to the 35 min records) may be presented to the algorithm as part of a complete test if the 3 h records are used.			

For ECG declares to have diagnostic function of “ST-segment”, it is a must to test ESC database in accordance with ANSI/AAMI EC57:2007. For details about ESC database, please refer to:

<https://physionet.org/physiobank/database/edb/>

1.3 Installation and Environment Setup

The latest version of RDCA 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 3: Minimum System Requirements

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

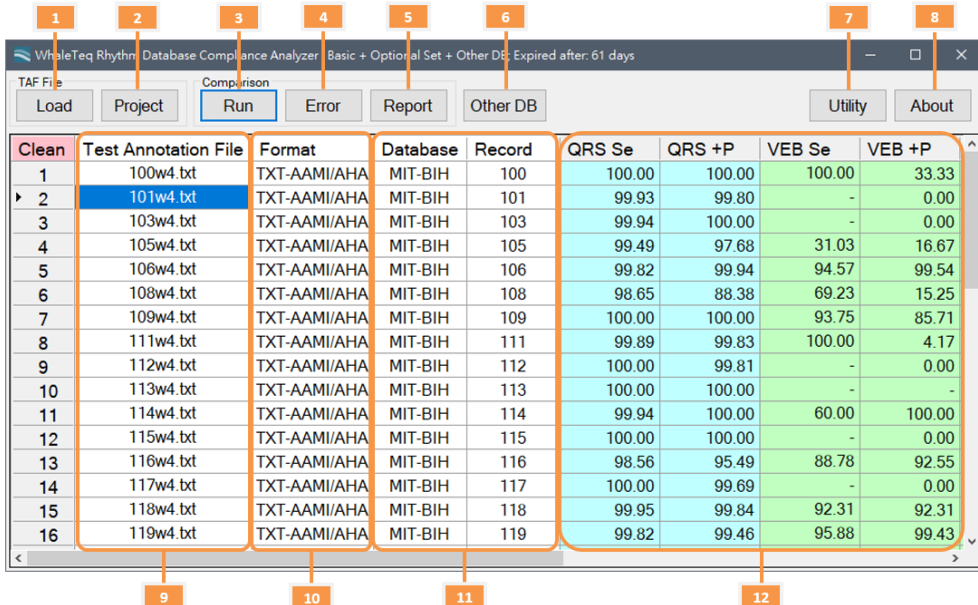
1.4 Cautions

- After the purchase of RDCA software, WhaleTeq server will send out a notification email to the assigned email address with the account name and activation link. After clicking the link and successfully activating the account, you will receive another email with the password. For more information, please refer to [section 3.1](#).
- The software availability period counts from the time you click on the “activation link”.
- Make sure to secure the account information and password carefully. If they are lost, please contact service@whaleteq.com.

2 Software Interface Instruction

This section describes software interface of major functions.

2.1 Home Screen



Clean	Test Annotation File	Format	Database	Record	QRS Se	QRS +P	VEB Se	VEB +P
1	100w4.txt	TXT-AAMI/AHA	MIT-BIH	100	100.00	100.00	100.00	33.33
2	101w4.txt	TXT-AAMI/AHA	MIT-BIH	101	99.93	99.80	-	0.00
3	103w4.txt	TXT-AAMI/AHA	MIT-BIH	103	99.94	100.00	-	0.00
4	105w4.txt	TXT-AAMI/AHA	MIT-BIH	105	99.49	97.68	31.03	16.67
5	106w4.txt	TXT-AAMI/AHA	MIT-BIH	106	99.82	99.94	94.57	99.54
6	108w4.txt	TXT-AAMI/AHA	MIT-BIH	108	98.65	88.38	69.23	15.25
7	109w4.txt	TXT-AAMI/AHA	MIT-BIH	109	100.00	100.00	93.75	85.71
8	111w4.txt	TXT-AAMI/AHA	MIT-BIH	111	99.89	99.83	100.00	4.17
9	112w4.txt	TXT-AAMI/AHA	MIT-BIH	112	100.00	99.81	-	0.00
10	113w4.txt	TXT-AAMI/AHA	MIT-BIH	113	100.00	100.00	-	-
11	114w4.txt	TXT-AAMI/AHA	MIT-BIH	114	99.94	100.00	60.00	100.00
12	115w4.txt	TXT-AAMI/AHA	MIT-BIH	115	100.00	100.00	-	0.00
13	116w4.txt	TXT-AAMI/AHA	MIT-BIH	116	98.56	95.49	88.78	92.55
14	117w4.txt	TXT-AAMI/AHA	MIT-BIH	117	100.00	99.69	-	0.00
15	118w4.txt	TXT-AAMI/AHA	MIT-BIH	118	99.95	99.84	92.31	92.31
16	119w4.txt	TXT-AAMI/AHA	MIT-BIH	119	99.82	99.46	95.88	99.43

Figure 2: RDCA Software Home Screen

- 01 – Load:** Used for loading test annotation file (TAF). Available options are [Select Files] and [Whole Folder].
- 02 – Project:** Available options are [Load], [Save] and [New].
- 03 – Run:** Starts comparison and provides options for timing and test clause setup before comparison.
- 04 – Error:** Lists all the timing and waveform incorrectly determined by the algorithm in the compared record. This is designed for debugging algorithm.
- 05 – Report:** Get example reports in medical standards
- 06 – Other DB:** Imports other databases into RDCA and calculates for results using standard algorithm.

Note:

- (1) This function requires the purchase of the Enterprise version of RDCA.

- (2) The database to be imported must include waveform files (.dat) and reference annotation files (.atr).
- (3) The capabilities and formats of the database to be imported need to align with those of the RDCA to perform the comparison. For details on supported capabilities, please refer to item 3 and item 4 in "[Specification](#)".

- 07 – Utility:** Provides utilities such as “TAF Factory”, “Error Browser”, “DB Downloader”, etc.
- 08 – About:** Provides RDCA product information, including purchased features, expires days, etc.
- 09 – Test Annotation File:** List all TAFs to be calculated and those have been calculated.
- 10 – Format:** Displays format of imported TAF. Once TAF is imported, RDCA software will automatically analyze and determines its format. However, it is recommended to check whether the result is correct.
- 11 – Settings of compared record:** Configures database type and record number of Reference Annotation File (RAF).
- 12 – Results:** After clicking “Run”, this area displays the result for selected compared items. If there is no corresponding disorder in the compared TAF, it shows “-”.

2.2 Analyze Configuration Window

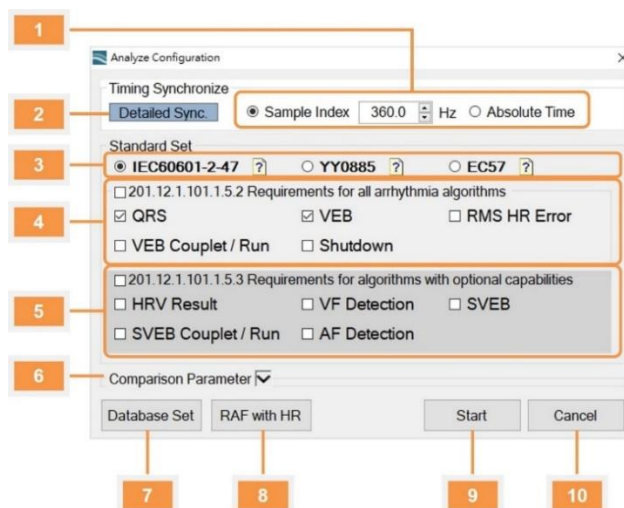


Figure 3: “Analyze Configuration” Window

- 01 – TAF time unit:** Choose whether the comparison standard of TAF uses [Sample Index] or [Absolute Time]. Select [Sample Index] requires to input sample rate of TAF file.
- 02 – Detailed Sync.:** This button connects to a utility for synchronizing timing. Please see 2.3 for the detailed interface and 3.3 for the user guide.
- 03 – Standard Set:** Choose which standard to be based on. “Test clause selection” differs when changing to different standards set.
- 04 – Essential Test clause selection:** Choose test clauses which are needed to test to meet the standard.
- 05 – Optional Test clause selection:** Choose test clauses that are required when declared to support specific disease disorder. Note: This function requires the purchase of the Pro or Enterprise version of RDCA. For details on the provided capabilities, please refer to item 4 in "[Specification](#)".
- 06 – Comparison Parameter:** Time period that is actually counted into comparison. Typically, this is to set the learning period time.¹
- 07 – Database Set:** After clicking the set of a database, RDCA software assists to select test clauses based on whether the standard requires that database to be tested.
- 08 – RAF with HR:** The RDCA calculates the heart rate of RAF and TAF based on the heart rate program provided in PhysioNet's WFDB. To use a custom heart rate calculation method for comparison, please click this button and load the RAF with heart rate values calculated using that method into the window below.

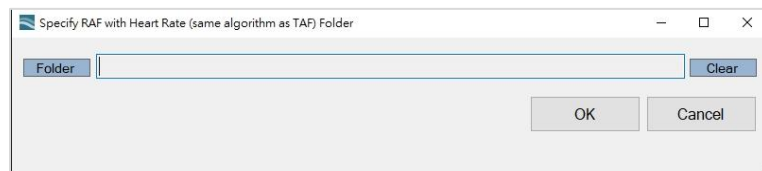


Figure 4: Load the RAF with Heart Rate Values Calculated using a Custom Heart Rate Calculation Method

- 09 – Start:** Starts comparing TAF with RAF using the calculation method documented in the standard.
- 10 – Cancel:** Cancels comparison and go back to main interface.

¹ IEC 60601-2-47: “The first 5 min of each record are designated as a learning period. The remainder of each record is the test period. Device performance is measured only during the test period of each record.” Therefore, learning period should not be count into the actual comparison record.

2.3 Detailed Timing Synchronize before Analyze Window

Please see section 3.3 for detailed operation of this function.

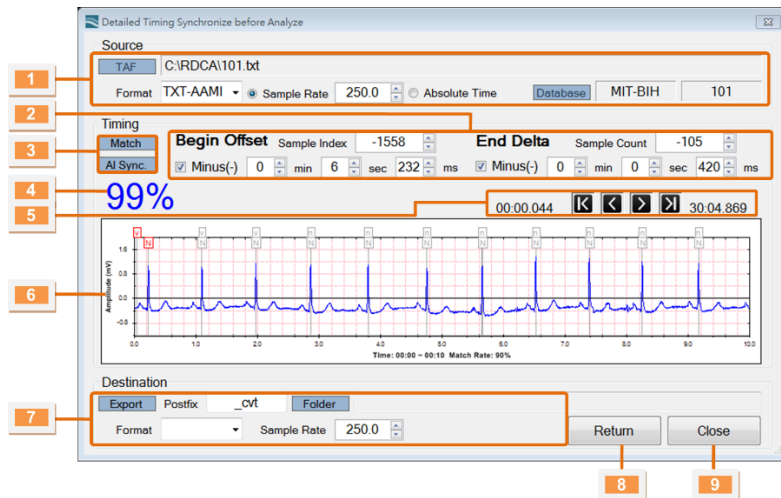


Figure 5: "Detailed Timing Synchronize before Analyze" Window

- 01 – TAF:** This area displays the file path of test annotation file (TAF), file format, time unit, database to be compared and database number.
- 02 – Syncing parameters:** This area includes parameters such as [Begin Offset] and [End Delta]. [Begin Offset] is used to sync the beginning of TAF and RAF; [End Delta] is used to eliminate accumulative errors caused by different hardware clock.
- 03 – Syncing matches:** To take action to synchronize matches. Options include manual [Match] and [AI Sync.] AI sync allows RDCA software to automatically looks for [Begin Offset] and [End Delta] parameters that are most suitable.
- 04 – Matching ratio:** After performing synchronizing operation, RDCA displays the matching ratio of the TAF.
- 05 – Time Period Selector:** Use for switching to the different time period. Buttons from left to right are: resume to the beginning time period, previous time period, next time period and final time period.
- 06 – Waveform Viewer:** Displays detailed matching status and waveform of test annotation file (TAF) and reference

annotation file (RAF). Capital letter indicates the label of RAF while lower-case letter indicates the label of TAF. Label in grey color indicates the matching is within $\pm 150\text{ms}$ while label in red color indicates the matching is not within $\pm 150\text{ms}$.

- 07 – Export TAF:** Exports test annotation file that has been debugged based on Begin Offset and End Delta (TAF), and sets location and postfix of TAF.
- 08 – Return:** If you entered this interface via [Run] window, clicking this button returns parameters back. Then, you can continue the comparison.
- 09 – Close:** Closes this window.

2.4 Error Browser Window

Error Browser function is designed to browse all the error information after the comparison, including beat-by-beat (bxb), run-by-run (rxr), VF, AF (epic), and shut-down periods. Error information can be saved as a single file as well.

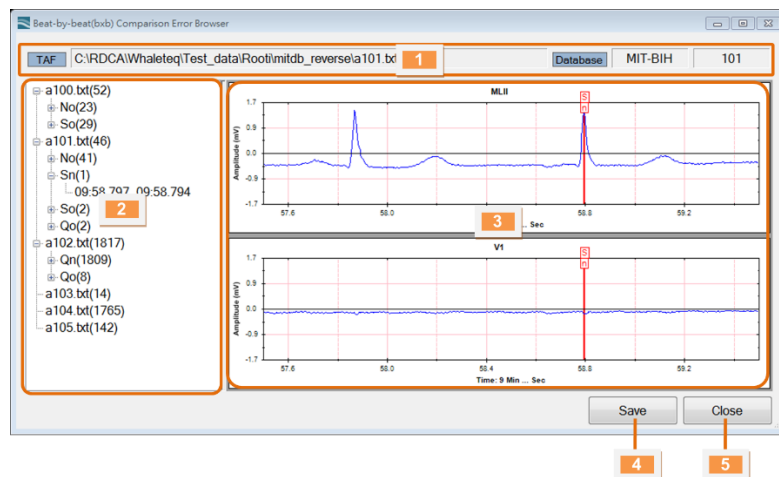


Figure 6: “Error Browser” Window

- 01 – TAF information:** Describes the corresponding TAF information for “Waveform display”.
- 02 – Error list:** Lists name and time frame of all TAFs with errors
- 03 – Waveform display:** Displays waveform intervals with errors and marks annotation labels.

- 04 – Save/Load:** Saves the current list or loads a list that is previously saved.
- 05 – Close:** Closes [Error Browser] window.

2.5 Database Downloader Window

Click the “Utility” button and select “DB Downloader” to bring up the “Database Downloader” window, where users can download the required databases.

Note: Users must purchase a separate license for the AHA database before importing it into the RDCA for comparison.

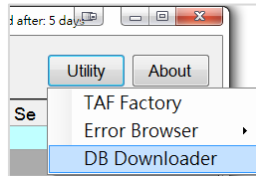


Figure 7: “DB Downloader” Option

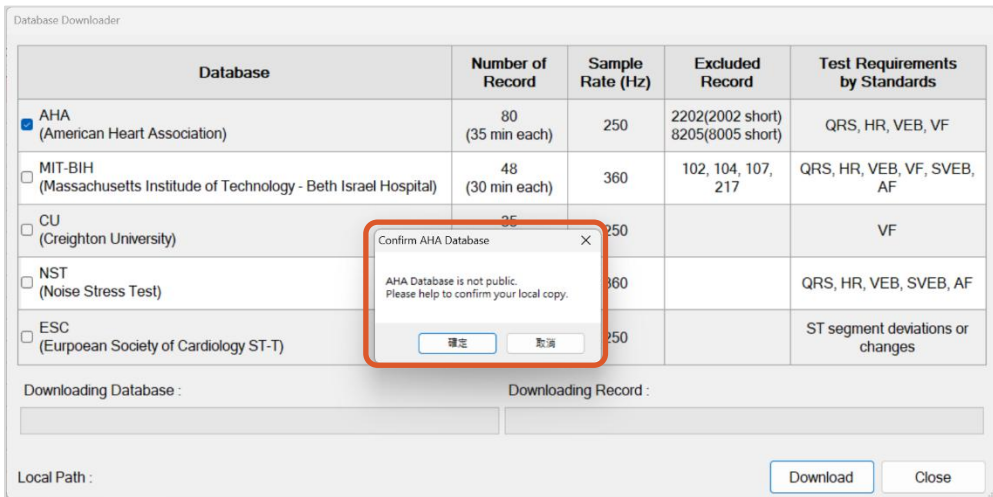


Figure 8: “Confirm AHA Database” Window

3 Using RDCA Software

This section walks you through the operation of RDCA software.

3.1 Initiate the RDCA Software

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

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

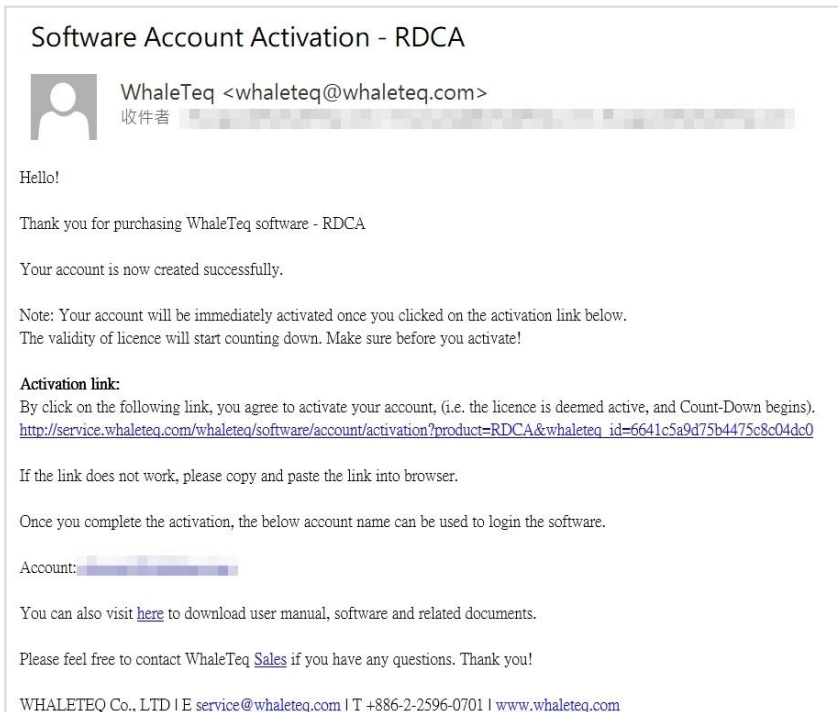


Figure 9: Initiate the RDCA Software (Step 1)

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 RDCA software will fail if you launch the software without clicking the activation link.
- (2) **The availability period of RDCA software counts from the time you click on the activation link.**

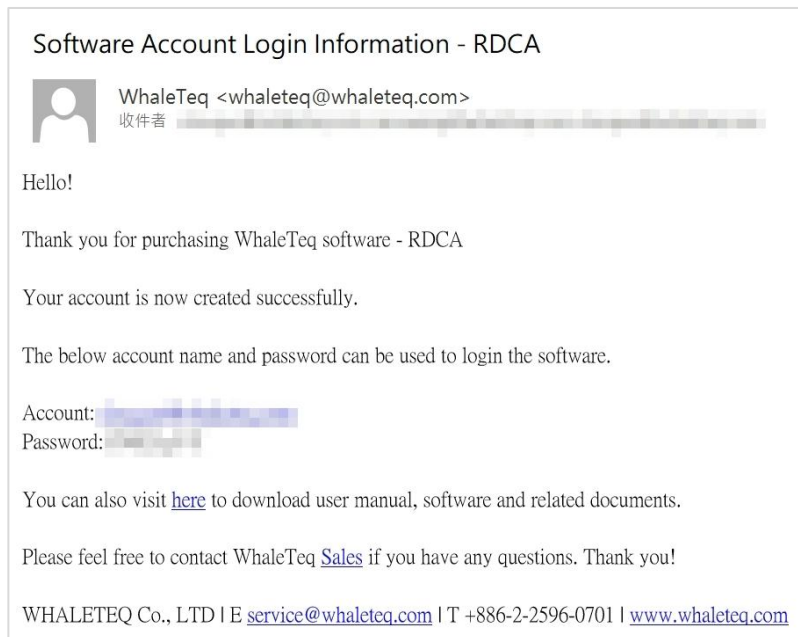


Figure 10: Initiate the RDCA Software (Step 2)

Step 3: Launch and log in to the RDCA

After launching the RDCA, click "About" in the upper-right corner of the screen, then click "Account Reset" in the "About" window to bring up the login window. Please use the account and password provided in the notification email to log in.

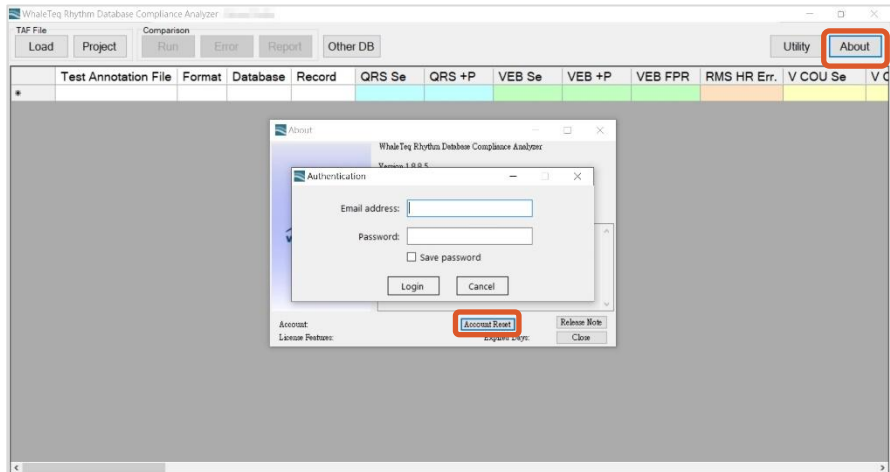


Figure 11: Initiate the RDCA Software (Step 3)

3.2 Start Comparison and Generate Reports

Step 1: Load Test Annotation File (TAF)

Click “Load” button and choose the file or folder to be tested.

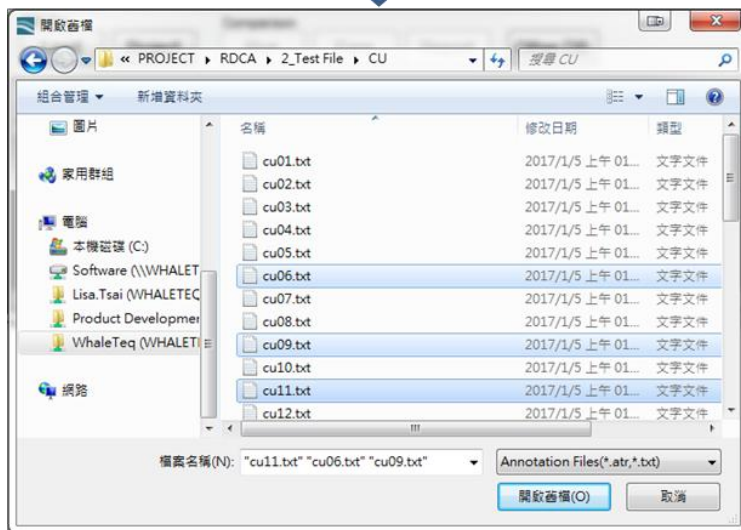
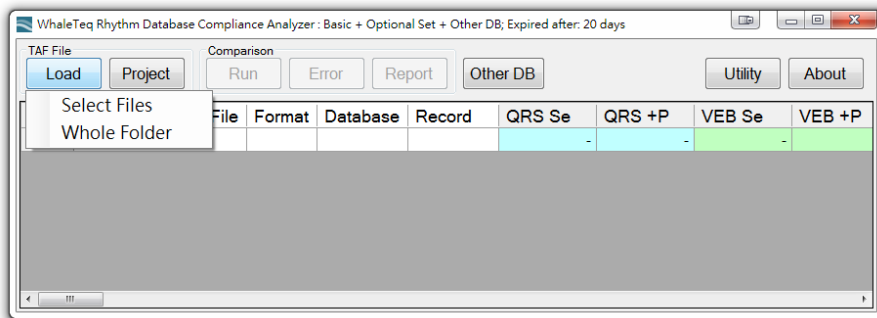


Figure 12: Start Comparison and Generate Reports (Step 1)

- **Select Files:** Load one or more TAF(s). You can choose multiple files by pressing “ctrl” or “shift” key.
- **Whole Folder:** Load all TAFs in a folder.

Step 2: Check and select [Format], [Database] and [Record]

RDCA software automatically determines possible File Format, Database and Record by identifying the file name of TAF. You can also click on the column to modify the configuration manually. For description of each Format, please click “?” and “Help” at the bottom.

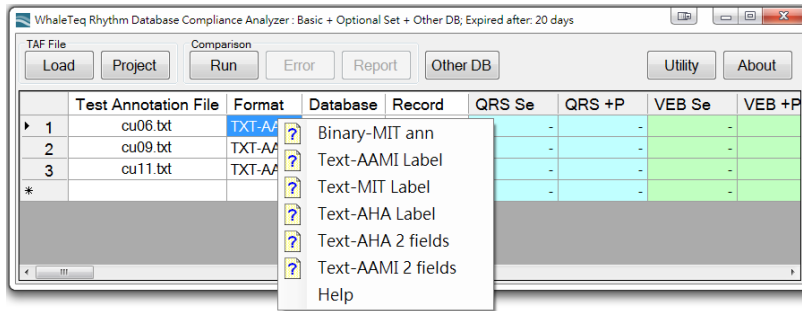


Figure 13: Start Comparison and Generate Reports (Step 2)

Step 3: Adjust begin offset and sample rate

A window appears once you click [Run] button.

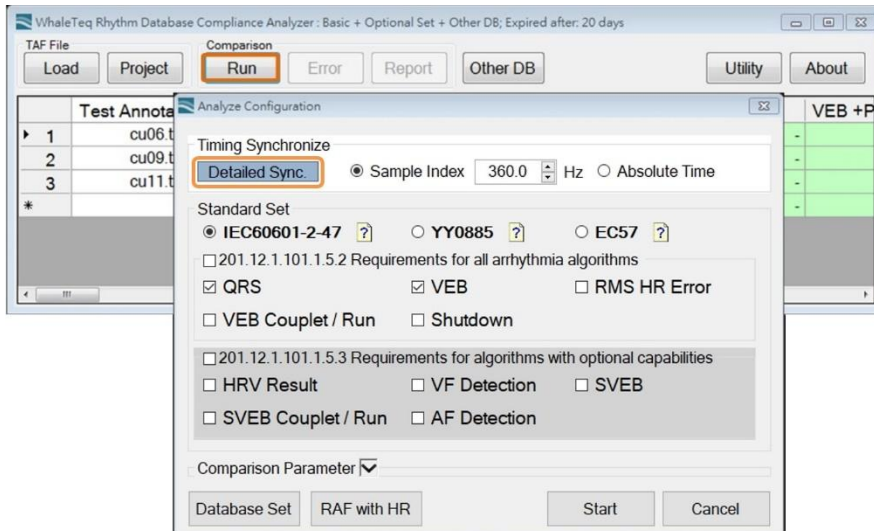


Figure 14: Start Comparison and Generate Reports (Step 3)

- TAF and RAF initialize at the same time position: Choose between sample index and absolute time as the time unit.
- TAF does not initiate at the same location as RAF: Click [Detailed Sync.] for further adjustment.
Please refer to 3.3 for details of [Detailed Sync].

Step 4: Choose test standards and clauses

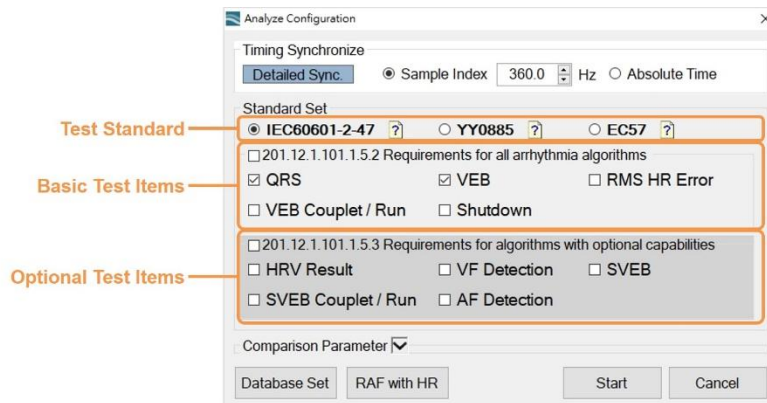


Figure 15: Start Comparison and Generate Reports (Step 4)

- **Test Standard:** RDCA software supports three standards. Test clauses and database to be tested differ among standards. Click “?” next to the standard for information of clauses and database required by the standard.
- **Basic Test Items:** Required to test for complying with the standard.
- **Optional Test Items:** For DUT that is declared to have diagnostic function for specific disease disorders. This function requires the purchase of the Pro or Enterprise version of RDCA. For details on the provided capabilities, please refer to item 4 in "[Specification](#)".

Step 5: Start testing

The test starts once you click [start]. Test results will directly show on the page.

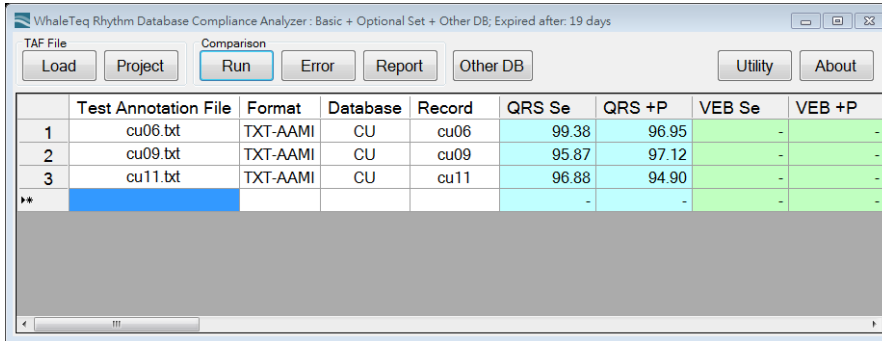
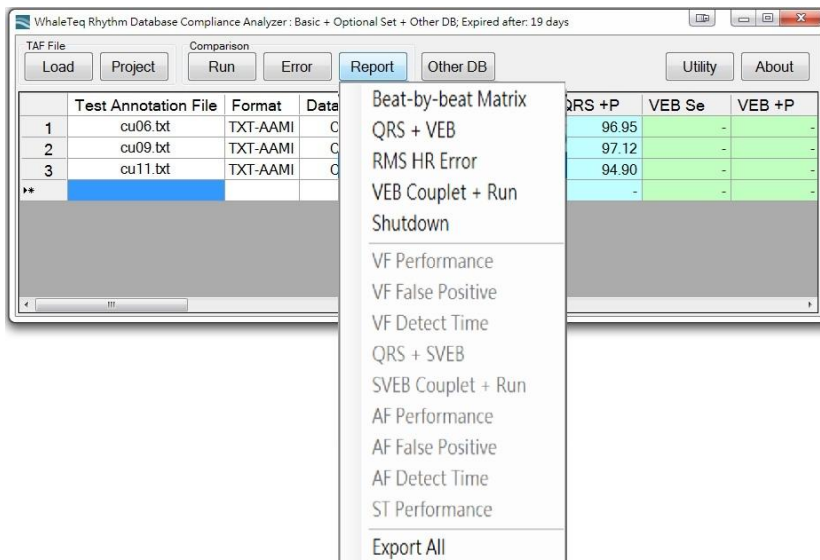
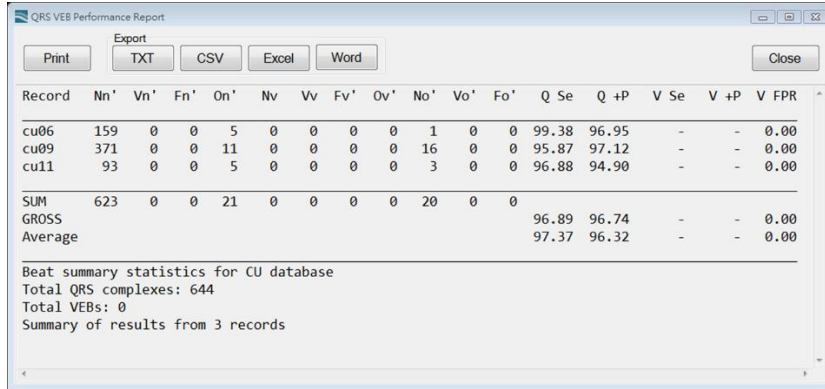


Figure 16: Start Comparison and Generate Reports (Step 5)

Step 6: Reporting

Click [Report] button to select the report type to view on main screen. Click [Export All] option indicates exporting a report for all selected test clauses to a text file.





Record	Nn'	Vn'	Fn'	On'	Nv	Vv	Fv'	Ov'	No'	Vo'	Fo'	Q Se	Q +P	V Se	V +P	V FPR
cu06	159	0	0	5	0	0	0	0	1	0	0	99.38	96.95	-	-	0.00
cu09	371	0	0	11	0	0	0	0	16	0	0	95.87	97.12	-	-	0.00
cu11	93	0	0	5	0	0	0	0	3	0	0	96.88	94.90	-	-	0.00
SUM	623	0	0	21	0	0	0	0	20	0	0	96.89	96.74	-	-	0.00
GROSS												97.37	96.32	-	-	0.00
Average																

Beat summary statistics for CU database
 Total QRS complexes: 644
 Total VEBs: 0
 Summary of results from 3 records

Figure 17: Start Comparison and Generate Reports (Step 6)

3.3 Adjust TAF Timing (TAF Factory / Detailed Sync.)

Step 1: Enter [TAF Factory / Detailed Sync.]

There are two ways to use [TAF Factory / Detailed Sync.] function:

1. Choose [TAF Factory] under [Utility]
2. Click [Run] button, then choose [Detailed Sync.]

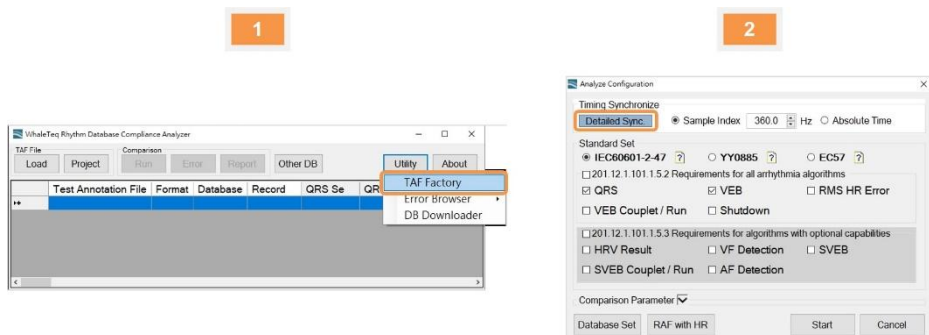


Figure 18: Adjust TAF Timing (Step 1)

Step 2: Import TAF and check compared data

Click [TAF] button to import the designated TAF file. Check and adjust data including TAF format, time unit, database and record.



Figure 19: Adjust TAF Timing (Step 2)

Step 3: Click [Match] to see the comparison status

Click [Match] to allow RDCA software to show status and matching ratio of TAF-to-RAF label.

Step 4: Click [AI Sync.] to proceed automatic configuration

If the result of TAF-to-RAF label did not come out as expected, you can use [AI Sync.] to let RDCA software find the appropriate “Begin Offset” and “End Delta” value automatically.

Step 5: Adjust Begin Offset value manually

If the result still did not go as expected after “AI Sync.,” you can manually adjust “Begin Offset” value using the pane for label status to sync the beginning label of TAF and RAF.

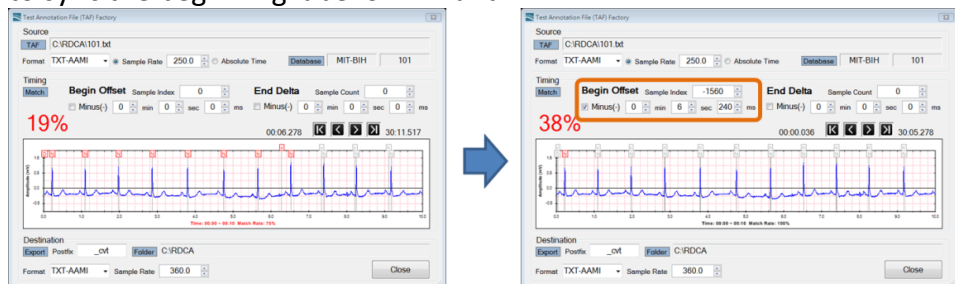


Figure 20: Adjust TAF Timing (Step 5)

Step 6: Adjust End Delta value manually

Click button to go to the end of status pane. Then, adjust “End Delta” value manually to sync the ending label of TAF and RAF².

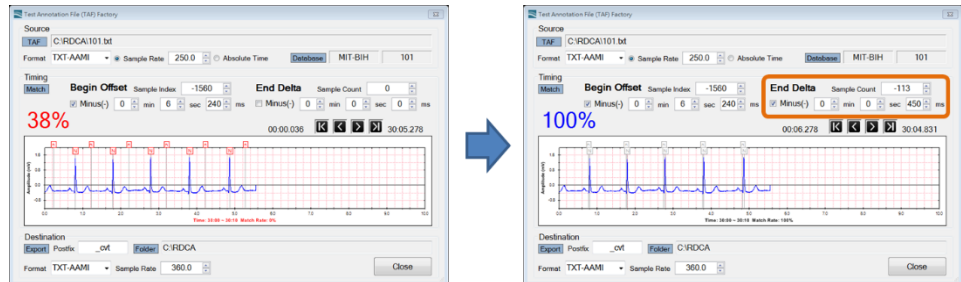


Figure 21: Adjust TAF Timing (Step 6)

Step 7: Export file

Finally, click [Export] button to export the adjusted file (TAF). The name of exported file consists of “original file name” and “content of [Postfix] field”. Exported file can be found under the path in [Folder] field.

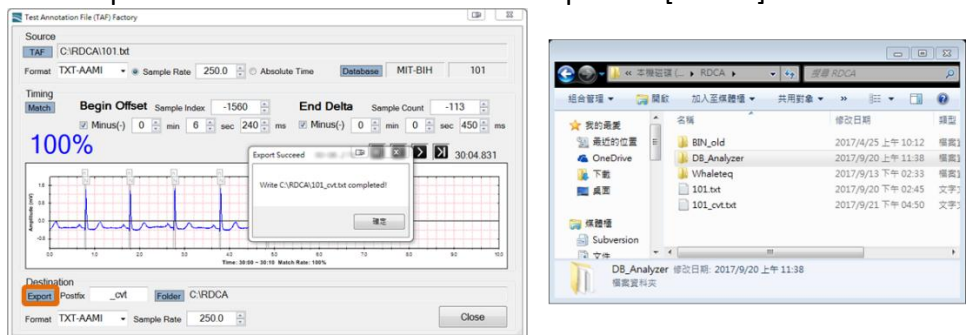


Figure 22: Adjusting TAF Timing (Step 7)

²As specified in standards, if labels of TAF and RAF have a difference over 150ms, they cannot be treated as the same label set. But in analog tests, there is time difference between ECG and simulator because they use different clocks as operation base. The difference can exceed 150ms as accumulated over time and affect the comparison result. The parameter "End Delta" is used to distribute the difference between TAF and RAF to TAF' evenly.

4 Test Annotation File (TAF) Format

RDCA currently supports six import formats:

1. Binary-MIT annotation (*.atr)
2. Text-AAMI Label (*.txt)
3. Text-MIT Label (*.txt)
4. Text-AHA Label (*.txt)
5. Text-AHA 2 fields (*.txt)
6. Text-AAMI 2 fields (*.txt)

If not familiar with these formats, it's recommended to use "Text-AAMI Label (*.txt)" and "Text-AAMI 2 fields (*.txt)", whose heart beat labels are the least and same as the standards.

For more details about formats, click [Format] field in RDCA software, then select "?" or "Help".

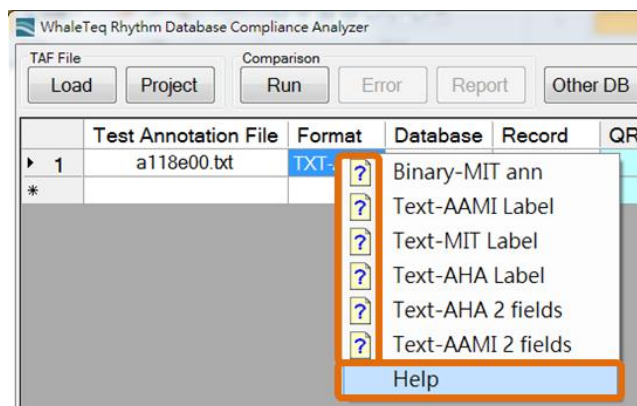


Figure 23: Test Annotation File (TAF) Format from the RDCA Software

4.1 Binary-MIT annotation (*.atr)

File Format Characteristics:

- ✓ A binary document
- ✓ Used by reference annotation file (RAF)
- ✓ Similar with Text-MIT Label. Both of them have fields "Annotation", "Num", "Sub", "Chan", "Aux", etc.

Details:

Each annotation occupies even bytes. The leading byte in each pair is the least significant bit.

The six most significant bits of each byte (A) are the code of annotation type, and the other ten bits (I) specify time period of annotation and sample interval of previous annotation (or the first annotation from the beginning of annotation).

If $0 < A = \text{ACMAX}$ [49.], it uses those from MIT annotation code.

Other possibilities are:

- ✓ A = SKIP [59.]
 - I = 0; the following four bytes are the interval of long integer format of PDP-11 (high 16 bits followed by low 16 bits, with least significant bytes first).
- ✓ A = NUM [60.]
 - I = Num character of current and following annotations; otherwise, assume the previous annotation num (initially 0).
- ✓ A = SUB [61.]
 - I = Annotation subtype character of current annotation only; otherwise, assume subtype = 0.
- ✓ A = CHN [62.]
 - I = Annotation chan character of current and following annotations; otherwise, assume the previous chan (initially 0).
- ✓ A = AUX [63.]
 - I = Number of bytes in auxiliary messages (included in the next I byte); if this is an odd, append an additional empty value that is not included in number of bytes.
- ✓ A = I = 0: End of document.

Table 4: MIT Annotation Code – Annotations for Beats

Code	AAMI	Name	Description
[1.]	N	[NORMAL]	Normal beat
[2.]	N	[LBBB]	Left bundle branch block beat
[3.]	N	[RBBB]	Right bundle branch block beat

Code	AAMI	Name	Description
[25.]	N	[BBB]	Bundle branch block beat (unspecified)
[8.]	S	[APC]	Atrial premature beat
[4.]	S	[ABERR]	Aberrated atrial premature beat
[7.]	S	[NPC]	Nodal (junctional) premature beat
[9.]	S	[SVPB]	Supraventricular premature or ectopic beat (atrial or nodal)
[5.]	V	[PVC]	Premature ventricular contraction
[41.]	V	[RONT]	R-on-T premature ventricular contraction
[6.]	F	[FUSION]	Fusion of ventricular and normal beat
[34.]	S	[AESC]	Atrial escape beat
[11]	S	[NESC]	Nodal (junctional) escape beat
[35]	S	[SVESC]	Supraventricular escape beat (atrial or nodal)
[10.]	V	[VESC]	Ventricular escape beat
[12.]	Q	[PACE]	Paced beat
[38]	Q	[PFUS]	Fusion of paced and normal beat
[13.]	Q	[UNKNOWN]	Unclassifiable beat
[30]	Q	[LEARN]	Beat not classified during learning

Table 5: MIT Annotation Code – Annotations without Beats

Code	Char	Name	Description
[32.]	[[VFON]	Start of ventricular flutter/fibrillation
[33.]]	[VFONF]	End of ventricular flutter/fibrillation
[14.]	SUB	[NOISE]	Change in signal quality
	&0x30		Start of unreadable (AAMI U label for Shutdown test) segment
	!=0x30		End of unreadable (AAMI U label for Shutdown test) segment
[28.]	AUX	[RHYTHM]	Rhythm change
	(AFIB		Atrial fibrillation

Code	Char	Name	Description
	(AFL		Atrial flutter
	(VFL		Ventricular flutter
[18]	AUX	[STCH]	ST segment change
	(ST		ST episode, either signal
	(ST0		ST episode, signal 0
	(ST1		ST episode, signal 1

4.2 Text-AAMI Label (*.txt)

File Format Characteristics:

- ✓ A text file with annotations that are the same as standards.
- ✓ Six rows in total. Major information is in the first three rows: 1st row is time, 2nd row is sample index and 3rd row is annotation.
- ✓ Similar with “Text-MIT Label” and “Text-AHA Label”. The major difference is in annotation and represented disorders.

Details:

This format has one annotation in each column. Each column includes the following characters (from left to right) separated with SPACE or TAB:

- # 1. Annotation time in hour, minute, second and ms.
- # 2. Annotation time that takes annotation-point-based index as unit.
- # 3. Annotation label of AAMI collection. Please see the following table for description of labels.
- # 4. SUB field: Annotation subtype field of current annotation only; otherwise, assume subtype = 0.
- # 5. CHN field: Chan field of current and following annotations; otherwise, assume the previous chan (initially 0).
- # 6. NUM field: Annotation number field of current and following annotations; otherwise, assume the previous annotation num (initially 0).

Table 6: AAMI Annotation Label – Labels for Beats

AAMI	Name	Description
N	A normal beat or a bundle branch block beat	Any beat that does not fall into the S, V, F, or Q categories described below
S	A supraventricular ectopic beat (SVEB)	An atrial or nodal (junctional) premature or escape beat, or an aberrated atrial premature beat.
V	A ventricular ectopic beat (VEB)	A ventricular premature beat, an R-on-T ventricular premature beat, or a ventricular escape beat.
F	A fusion of a ventricular and a normal beat	Fusion of a ventricular and a normal beat
Q	A paced beat	A fusion of a paced and a normal beat, or a beat that cannot be classified.
U	A label that marks a segment of unreadable data	Beats cannot be located because of excessive noise or signal loss in the signals.

Table 7: AAMI Annotation Label – Labels for Rhythm

AAMI	Description
[Beginning of ventricular flutter or fibrillation (VF) segment
]	End of ventricular flutter or fibrillation (VF) segment
{	Beginning of atrial flutter or fibrillation (AF) segment
}	End of atrial flutter or fibrillation (AF) segment

Examples:

0 : 02 : 29.678	19725	N	0	0	0
0 : 02 : 29.888	19800	N	0	0	0
0 : 02 : 30.398	19983	Q	0	0	0
0 : 02 : 30.976	20191	N	0	0	0

0 : 02 : 31.436	20356	Q	0	0	0
0 : 02 : 31.864	20510	N	0	0	0
0 : 02 : 32.076	20586	V	0	0	0
0 : 02 : 32.540	20753	Q	0	0	0
0 : 02 : 32.870	20871	N	0	0	0
0 : 02 : 33.064	20941	N	0	0	0

4.3 Text-MIT Label (*.txt)

File Format Characteristics:

- ✓ A text file
- ✓ Similar annotation as Binary-MIT annotation
- ✓ Seven rows in total. Major information is in the first three rows: 1st row is time, 2nd row is sample index, 3rd row is annotation and 7th row is auxiliary annotation
- ✓ Similar with “Text-MIT Label” and “Text-AHA Label”. The major difference is in annotation and represented disorders.

Details:

This format has one annotation in each column. Each column includes the following characters (from left to right) separated with SPACE or TAB:

- # 1. Annotation time in hour, minute, second and ms.
- # 2. Annotation time that takes annotation-point-based index as unit.
- # 3. Annotation label of MIT collection. Please see the following table for description of labels.
- # 4. SUB field: Annotation subtype field of current annotation only; otherwise, assume subtype = 0.
- # 5. CHN field: Chan field of current and following annotations; otherwise, assume the previous chan (initially 0).

- # 6. NUM field: Annotation number field of current and following annotation; otherwise, assume the previous annotation num (initially 0).
- # 7. Auxiliary field: Auxiliary message string (if available) (assumed as an ASCII string with null terminator).

Table 8: MIT Annotation Code – Annotations for Beats

Label	AAMI	Name	Description
N	N	[NORMAL]	Normal beat
L	N	[LBBB]	Left bundle branch block beat
R	N	[RBBB]	Right bundle branch block beat
B	N	[BBB]	Bundle branch block beat (unspecified)
A	S	[APC]	Atrial premature beat
a	S	[ABERR]	Aberrated atrial premature beat
J	S	[NPC]	Nodal (junctional) premature beat
S	S	[SVPB]	Supraventricular premature or ectopic beat (atrial or nodal)
V	V	[PVC]	Premature ventricular contraction
r	V	[RONT]	R-on-T premature ventricular contraction
F	F	[FUSION]	Fusion of ventricular and normal beat
e	S	[AESC]	Atrial escape beat
j	S	[NESC]	Nodal (junctional) escape beat
n	S	[SVESC]	Supraventricular escape beat (atrial or nodal)
E	V	[VESC]	Ventricular escape beat
/	Q	[PACE]	Paced beat
f	Q	[PFUS]	Fusion of paced and normal beat
Q	Q	[UNKNOWN]	Unclassifiable beat
?	Q	[LEARN]	Beat not classified during learning

Table 9: MIT Annotation Code – Annotations without Beats

Label	Char	Name	Description
[[[VFON]	Start of ventricular flutter/fibrillation
]]	[VFONF]	End of ventricular flutter/fibrillation
~	SUB	[NOISE]	Change in signal quality
	&0x30		Start of unreadable (AAMI U label for Shutdown test) segment
	! =0x30		End of unreadable (AAMI U label for Shutdown test) segment
+	AUX	[RHYTHM]	Rhythm change
	(AFIB		Atrial fibrillation
	(AFL		Atrial flutter
	(VFL		Ventricular flutter
S	AUX	[STCH]	ST segment change
	(ST		ST episode, either signal
	(ST0		ST episode, signal 0
	(ST1		ST episode, signal 1

Examples:

```

7 : 51.642  169791      V    0    0    0
7 : 52.625  170145      N    0    0    0
7 : 53.833  170580      N    0    0    0
7 : 55.103  171037      N    0    0    0
7 : 56.389  171500      N    0    0    0
7 : 57.264  171815      +    0    0    0      (AFIB
7 : 57.453  171883      V    0    0    0
7 : 57.956  172064      a    0    0    0
7 : 58.431  172235      a    0    0    0
7 : 59.064  172463      N    0    0    0

```

7	: 59.536	172633	a	0	0	0
7	: 59.914	172769	a	0	0	0
8	: 00.575	173007	N	0	0	0

4.4 Text-AHA Label (*.txt)

File Format Characteristics:

- ✓ A text file
- ✓ Six rows in total. Major information is in the first three rows: 1st row is time, 2nd row is sample index and 3rd row is annotation.
- ✓ Similar with “Text-MIT Label” and “Text-AHA Label”. The major difference is in annotation and represented disorders.

Details:

This format has one annotation in each column. Each column includes the following characters (from left to right) separated with SPACE or TAB:

- # 1. Annotation time in hour, minute, second and ms.
- # 2. Annotation time that takes annotation-point-based index as unit.
- # 3. Annotation label of MIT collection. Please see the following table for description of labels.
- # 4. SUB field: Annotation subtype field of current annotation only; otherwise, assume subtype = 0.
- # 5. CHN field: Chan field of current and following annotations; otherwise, assume the previous chan (initially 0).
- # 6. NUM field: Annotation number field of current and following annotations; otherwise, assume the previous annotation num (initially 0).

Table 10: AHA Annotation Code – Annotations for Beats

Label	AAMI	Description
N	N	Beat of Non-Ventricular Origin
V	V	Premature Ventricular Complex (PVC)

Label	AAMI	Description
E	V	Ventricular Escape
F	F	Fusion Beat
R	V	R-on-T Beat
P	Q	Paced Beat
Q	Q	Questionable Beat - Indeterminate Origin
U	U	Unreadable

Table 11: AHA Annotation Code – Labels for Rhythm

Label	AAMI	Description
[[Beginning of Ventricular Fibrillation or Flutter
]]	End of Ventricular Fibrillation or Flutter

Examples:

0 : 02 : 29.678	19725 N	0	0	0
0 : 02 : 29.888	19800 N	0	0	0
0 : 02 : 30.398	19983 Q	0	0	0
0 : 02 : 30.976	20191 N	0	0	0
0 : 02 : 31.436	20356 Q	0	0	0
0 : 02 : 31.864	20510 N	0	0	0
0 : 02 : 32.076	20586 V	0	0	0
0 : 02 : 32.540	20753 Q	0	0	0
0 : 02 : 32.870	20871 N	0	0	0
0 : 02 : 33.064	20941 U	0	0	0

4.5 Text-AHA 2 fields (*.txt)

File Format Characteristics:

- ✓ A text file
- ✓ A simplified version of “Text-AHA Label”.
Two rows in total. 1st row is sample index and 2nd row is annotation.
- ✓ Similar with “Text-AAMI 2 fields”. The major difference is in annotation and represented disorders.

Details:

This format is a refined version of AHA annotation format. There are only 2 characters in each column, which are separated with SPACE or TAB:

- # 1. Annotation time that takes annotation-point-based index as unit.
- # 2. Annotation label of AHA collection. Please refer to the following table for description of labels.

Table 12: AHA Annotation Code – Annotations for Beats

Label	AAMI	Description
N	N	Beat of Non-Ventricular Origin
V	V	Premature Ventricular Complex (PVC)
E	V	Ventricular Escape
F	F	Fusion Beat
R	V	R-on-T Beat
P	Q	Paced Beat
Q	Q	Questionable Beat - Indeterminate Origin
U	U	Unreadable

Table 13: AHA Annotation Code – Labels for Rhythm

Label	AAMI	Description
[[Beginning of Ventricular Fibrillation or Flutter
]]	End of Ventricular Fibrillation or Flutter

Examples:

19725	N
19800	N
19983	Q
20191	N
20356	Q
20510	N
20586	V
20753	Q
20871	N
20941	U

4.6 Text-AAMI 2 fields (*.txt)

File Format Characteristics:

- ✓ A text file with annotations that are the same as standards
- ✓ A simplified version of “Text-AAMI Label”.
Two rows in total. 1st row is sample index and 2nd row is annotation.
- ✓ Similar with “Text-AHA 2 fields”. The major difference is in annotation and represented disorders.

Details:

This format is a refined version of AAMI annotation format. There are only 2 characters in each column, which are separated with SPACE or TAB:

- # 1. Annotation time that takes annotation-point-based index as unit.
- # 2. Annotation label of AAMI collection. Please refer to the following table for description of labels.

Table 14: AAMI Annotation Code – Annotations for Beats

AAMI	Name	Description
N	A normal beat or a bundle branch block beat	Any beat that does not fall into the S, V, F, or Q categories described below
S	A supraventricular ectopic beat (SVEB)	An atrial or nodal (junctional) premature or escape beat, or an aberrated atrial premature beat.
V	A ventricular ectopic beat (VEB)	A ventricular premature beat, an R-on-T ventricular premature beat, or a ventricular escape beat.
F	A fusion of a ventricular and a normal beat	Fusion of a ventricular and a normal beat
Q	A paced beat	A fusion of a paced and a normal beat, or a beat that cannot be classified.
U	A label that marks a segment of unreadable data	Beats cannot be located because of excessive noise or signal loss in the signals.

Table 15: AAMI Annotation Code – Labels for Rhythm

AAMI	Description
[Beginning of ventricular flutter or fibrillation (VF) segment
]	End of ventricular flutter or fibrillation (VF) segment
{	Beginning of atrial flutter or fibrillation (AF) segment
}	End of atrial flutter or fibrillation (AF) segment

Examples:

19725	N
19800	N
19983	Q
20191	N
20356	Q
20510	N



20586	V
20753	Q
20871	N
20941	N

5 FAQ

This section introduces frequently asked questions. If none of them describes your situation, please feel free to contact WhaleTeq.

5.1 Forgot the Password

When this happens, please send your login account to service@whaleteq.com via email and confirm that you need to reset the password. WhaleTeq will soon handle and send a new password to your email.

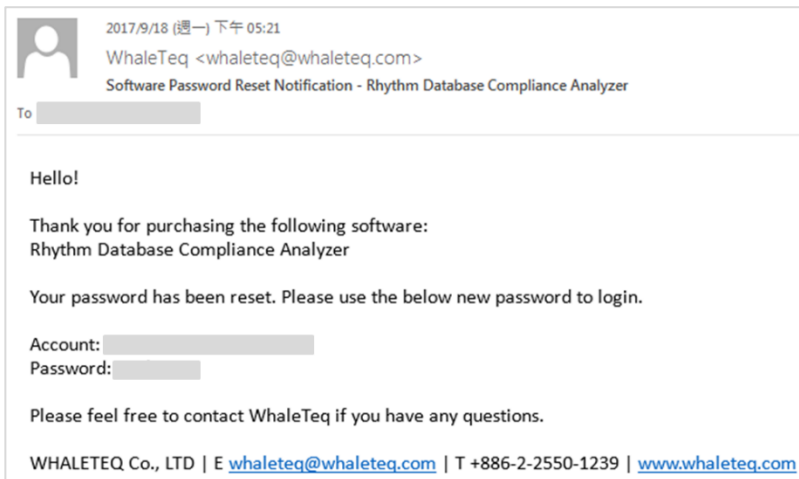


Figure 24: Software Password Reset Notification Email

5.2 Poor Comparison Results

Please use “TAF Factory/Detailed sync.” Function first to identify why the comparison result is not as expected. “TAF Factory” operation can be found in section 3.3. Check if TAF information is correctly input, then click [Match] or [AI Sync.] button to check the matching ratio.

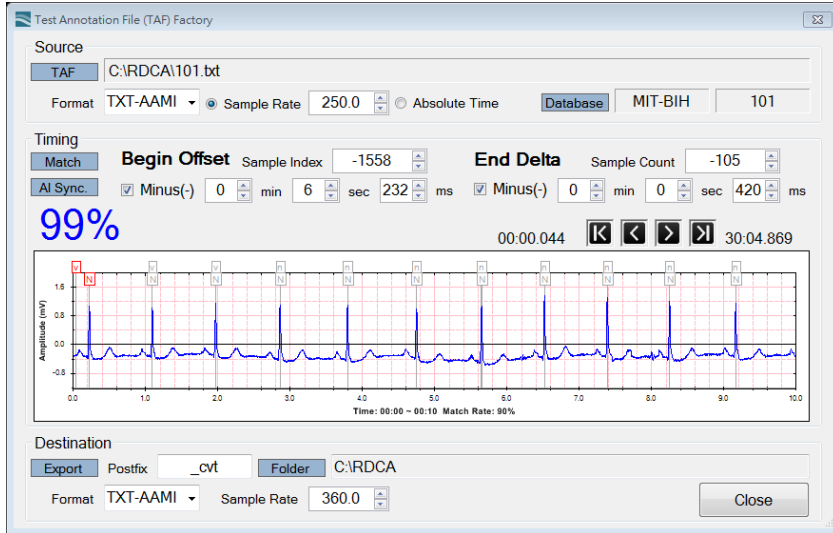


Figure 25: Troubleshoot Poor Comparison Results (Step 1)

If the result is still not as expected, you can look into the content of TAF-to-RAF pane to see if there are lots of exceeded beats in TAF. If so, it is possible that the test environment was not ideal and ECG DUT mistakenly identifies noises as heart beats. The other possible root cause is that the algorithms need to be improved.

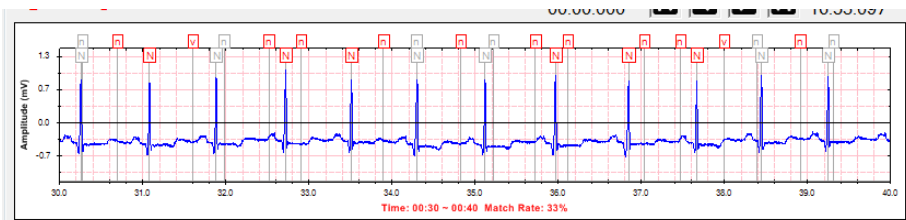


Figure 26: Troubleshoot Poor Comparison Results (Step 2)

If there is no anomaly in TAF-to-RAF pane, you can check out bxb matrix and other corresponding matrix, error browser, etc. Below shows an unexpected result of VEB Predictivity in which many N were determined as V.

VEB positive predictivity

MIT-BIH:100.atr vs 100_0913.txt

Beat Label Classifications		Reference Label						
		N	S	V	F	Q	O	X
Algorithm Label	v	175	3	1	-	-	0	0

$$\text{VEB+P} = \frac{\text{VTP}}{\text{VTP} + \text{VFP}} = \frac{1}{1 + 175} = 0.56\%$$

Figure 27: Troubleshoot Poor Comparison Results (Step 3)

5.3 No Waveforms Shown in the Waveform Browser

Waveforms can be incomplete if they are downloaded via poor network connectivity. Please go to `C:\RDCA\DB_Analyzer\DB\$(DatabaseName)\$(RecordID).dat` to delete the file and select to browse the waveform again.

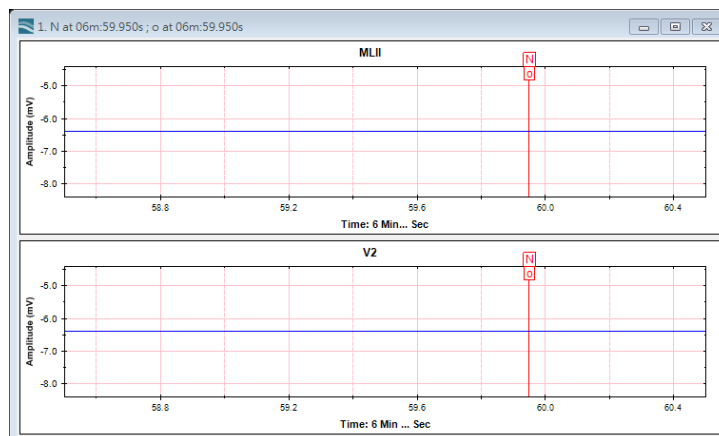


Figure 28: No Waveforms Shown in the Waveform Browser

In addition, a feature that “downloads all waveforms at once and detects any incomplete downloads at the same time” is available in [DB Downloader] under “Utility” button.

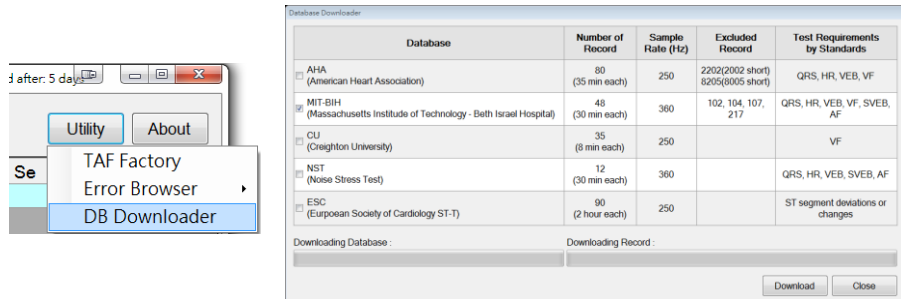


Figure 29: "Database Downloader" Function

6 Ordering Information

Table 16: Ordering Information

Part No.	Description
HBO-RDBA099	Model No.: RDCA Basic Rhythm database comparison software for 17 capabilities ⁽¹⁾ of all arrhythmia algorithm requirements.
HBO-RDPR099	Model No.: RDCA Pro Rhythm database comparison software for 17 capabilities of all arrhythmia algorithm requirements and optional 25 capabilities ⁽²⁾ .
HBO-RDEN099	Model No.: RDCA Enterprise Rhythm database comparison software for 17 capabilities of all arrhythmia algorithm requirements and optional 25 capabilities. Supports comparison with other databases ⁽³⁾ besides AHA, MIT-BIH, NST, CU, and ESC.

Note:

- (1) The 17 capabilities of all arrhythmia algorithm requirements include QRS, VEB, RMS, and Total SHUTDOWN time. Please refer to item 3 in "[Specification](#)" for details.
- (2) The optional 25 capabilities include SVEB, VF, AF, and ST and exclude HRV. Please refer to item 4 in "[Specification](#)" for details.

- (According to the standard, test operators should provide and publish HRV test results themselves.)
- (3) The capabilities and formats of other databases need to align with those of the RDCA to perform the comparison. For details of supported capabilities, please refer to item 3 and item 4 in "[Specification](#)".

7 Revision History

Table 17: Revision History

Version	Modified Contents	Issued Date
2017-12-08	First release	2017-12-08
2024-05-10	<ul style="list-style-type: none"> • Update <ul style="list-style-type: none"> 1.2 Product Specification 1.4 Cautions 2.1 Main Interface 2.2 Analyze Configuration 3.1 Initiate the RDCA Software 3.2 Start Comparison and Generate Report • Add <ul style="list-style-type: none"> 6 Ordering Information 7 Revision History 	2024-06-13
2025-02-17	<ul style="list-style-type: none"> • Update <ul style="list-style-type: none"> 2.1 Home Screen • Add <ul style="list-style-type: none"> 2.5 Database Downloader Window 	2025-03-12

8 Contact WhaleTeq

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