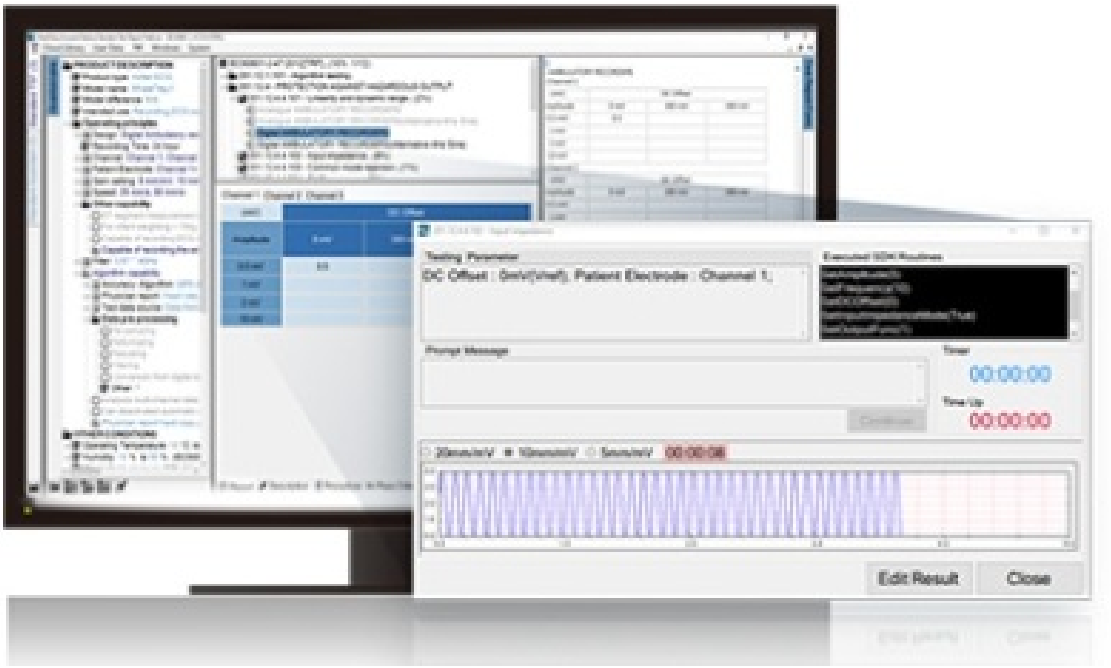
WHALETEQ TRF Generator Software User Guide

Contents

WHALETEQ TRF Generator Software



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Introduction

Basics
WhaleTeq Universal Medical Standard TRF Generator (“TRF Generator”) is designed to improve the efficiency of performance tests for medical devices. Both DUT testing and report generation can be done in TRF Generator with control over test equipment, medical standards assistant, and IEC Test Report Form unified.
Note: For now, the TRF Generator cannot receive data returned from the DUT. Therefore, the test operator will need to observe the results and fill them in the report record of TRF Generator manually.

System Requirements
A PC with CPU frequency at 1.5GHz or higher and 4G RAM or higher. Recommended OS is Windows 10, with Microsoft Word 2016 or higher installed.

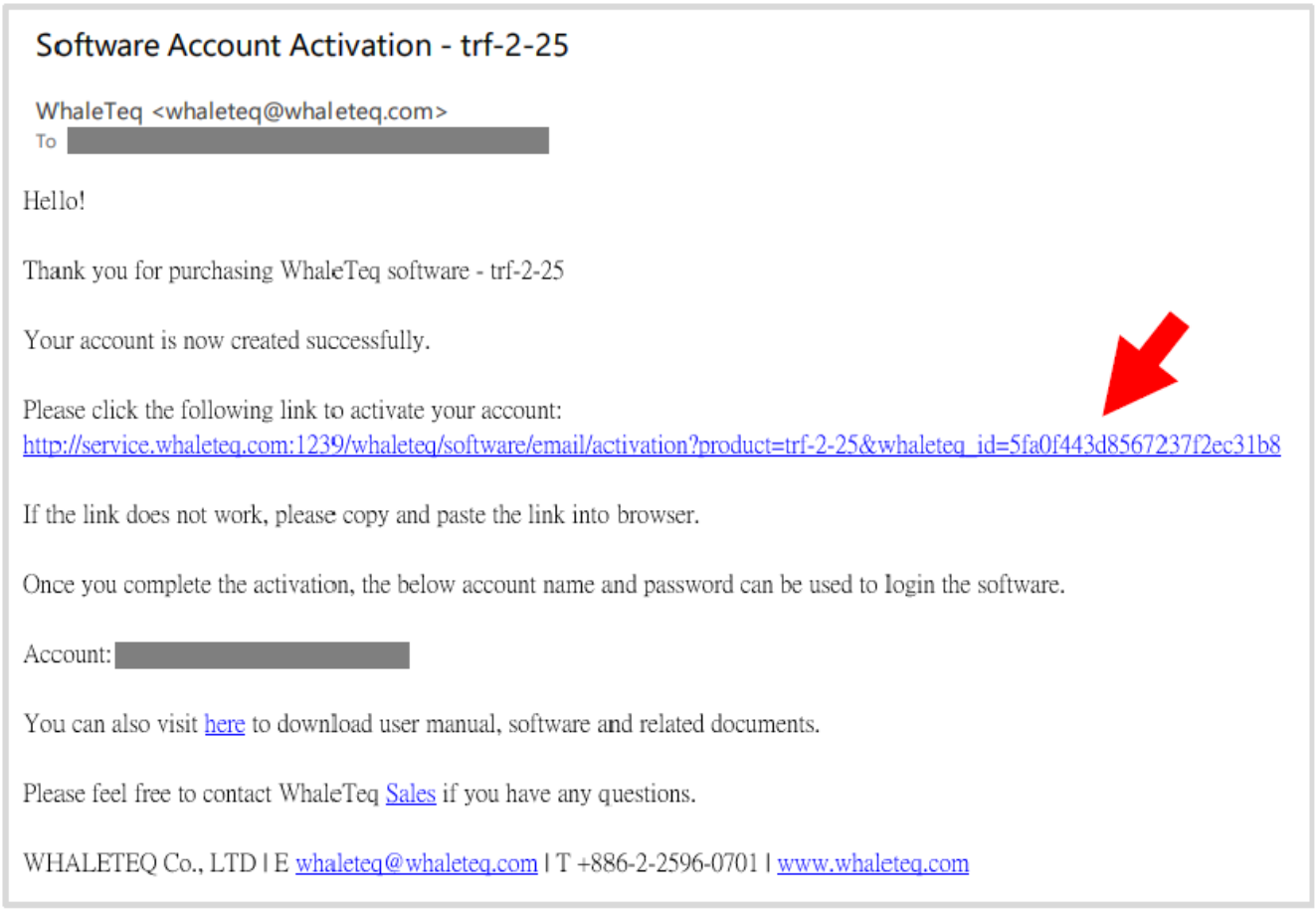
Software Setup
Visit WhaleTeq’s website to download and install TRF Generator on PC.

Software Auto Updates
When TRF Generator launches, it automatically checks whether there’re any updates for TRF generator software or medical standard project files via internet access. Update if needed.

Operation Mode

Login

After purchasing TRF Generator, you will receive an activation mail with a link from WhaleTeq. Click the link to activate the account.



Software Account Activation - trf-2-25

WhaleTeq <whaleteq@whaleteq.com>
To [redacted]

Hello!

Thank you for purchasing WhaleTeq software - trf-2-25

Your account is now created successfully.

Please click the following link to activate your account:
http://service.whaleteq.com:1239/whaleteq/software/email/activation?product=trf-2-25&whaleteq_id=5fa0f443d8567237f2ec31b8

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

Once you complete the activation, the below account name and password 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.

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

Figure 1: TRF Generator Account Activation Mail

Once activation is done, you will receive another email with login details.

Software Account Login Information - trf-2-25

WhaleTeq <whaleteq@whaleteq.com>
To [redacted]

Hello!

Thank you for purchasing WhaleTeq software - trf-2-25

Your account is now created successfully.

The below account name and password can be used to login the software.

Account: [redacted]
Password: [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.

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Figure 2: TRF Generator Account Login Information

Launch TRF and click any test item. When [Activate TRF License] window shows, enter the Account email from the login information email and click [Login].

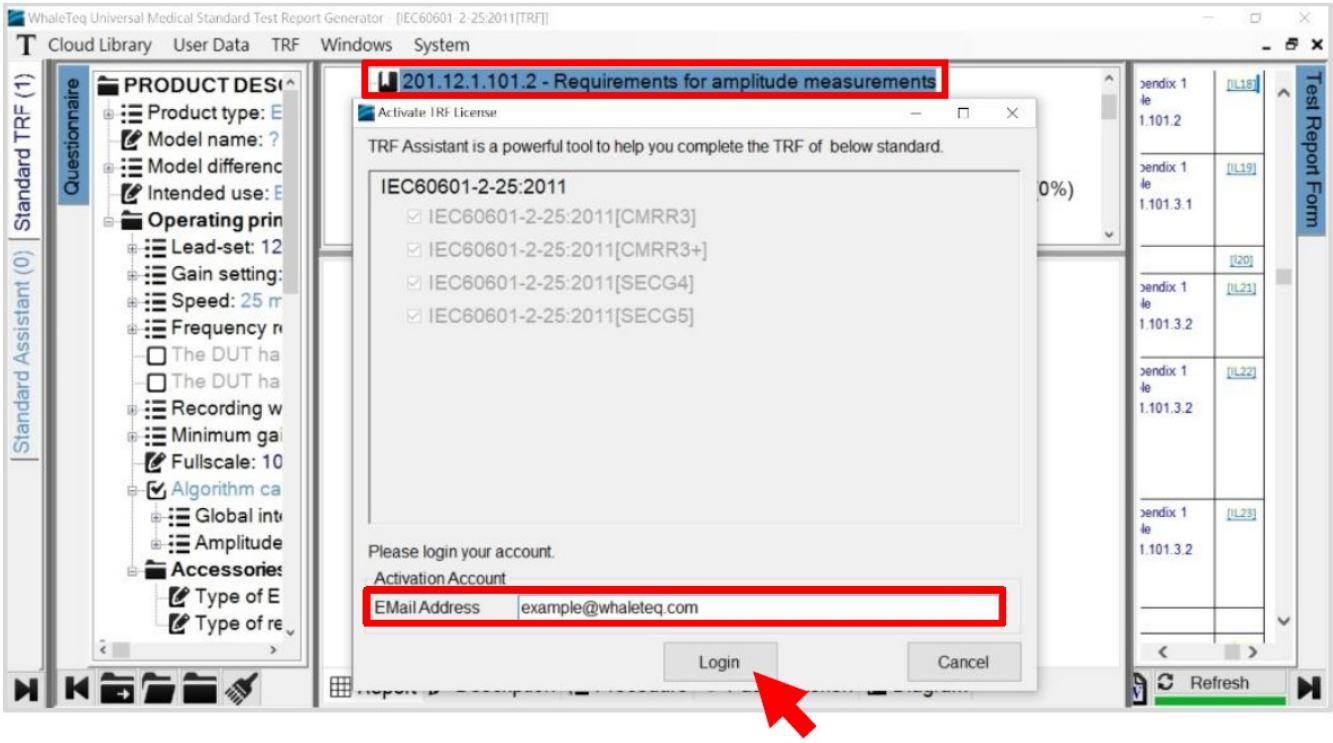


Figure 3: Activate TRF License Window

Then [Authentication] window shows. Enter the Password from the login information email and you will be able to access the full functionality of TRF Generator.
If you have any questions or need help with account activation, feel free to contact WhaleTeq for assistance.

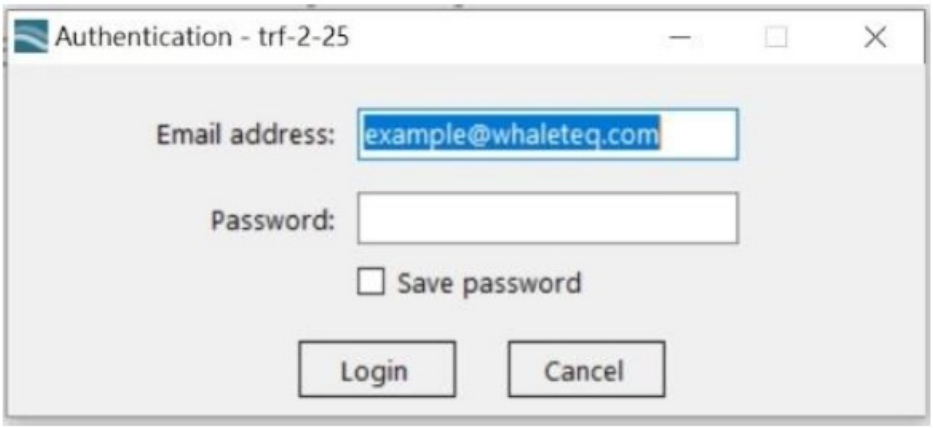


Figure 4: Authentication Window

Download Project File for Different Medical Standards

1. Click [Cloud Library] then [Management].

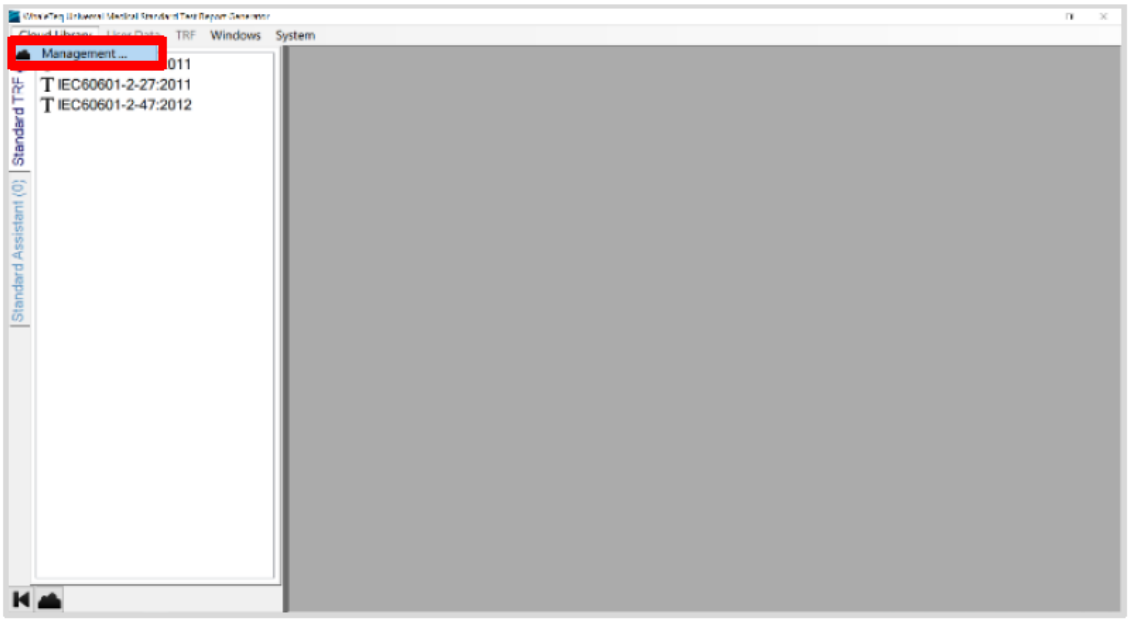


Figure 5: Download Project File for Different Medical Standards (Step 1)

2. In [Cloud TRF], select the Standard TRF profile or Standard Assistant profile to be used. Once selected, click [Download] to download it to the PC.

Standard TRF contains Questionnaire, IEC Test Report Form, and Standard Assistant. Standard Assistant contains test projects and the control capability for WhaleTeq test equipment.
We will update the profiles once there are any IEC Test Report Form updates available. If you have any questions, email us at **service@whaleteq.com**. We will get back to you as soon as possible.

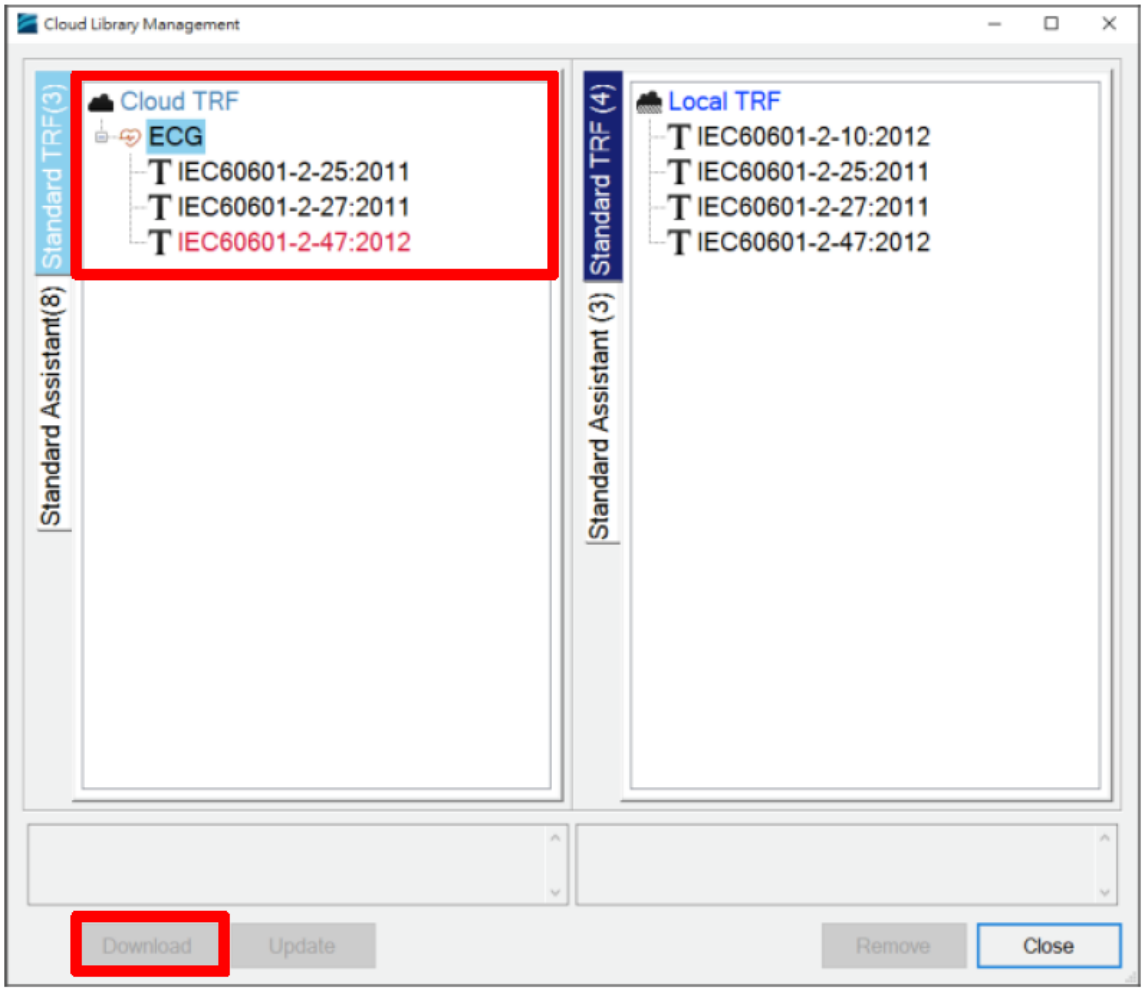


Figure 6: Download Project File for Different Medical Standards (Step 2)

3. When the download completes, the profiles will show in [Local TRF].
If an item in [Cloud TRF] is in RED, it indicates that the versions are not matching between Local TRF and Cloud RTF. Please update if needed.

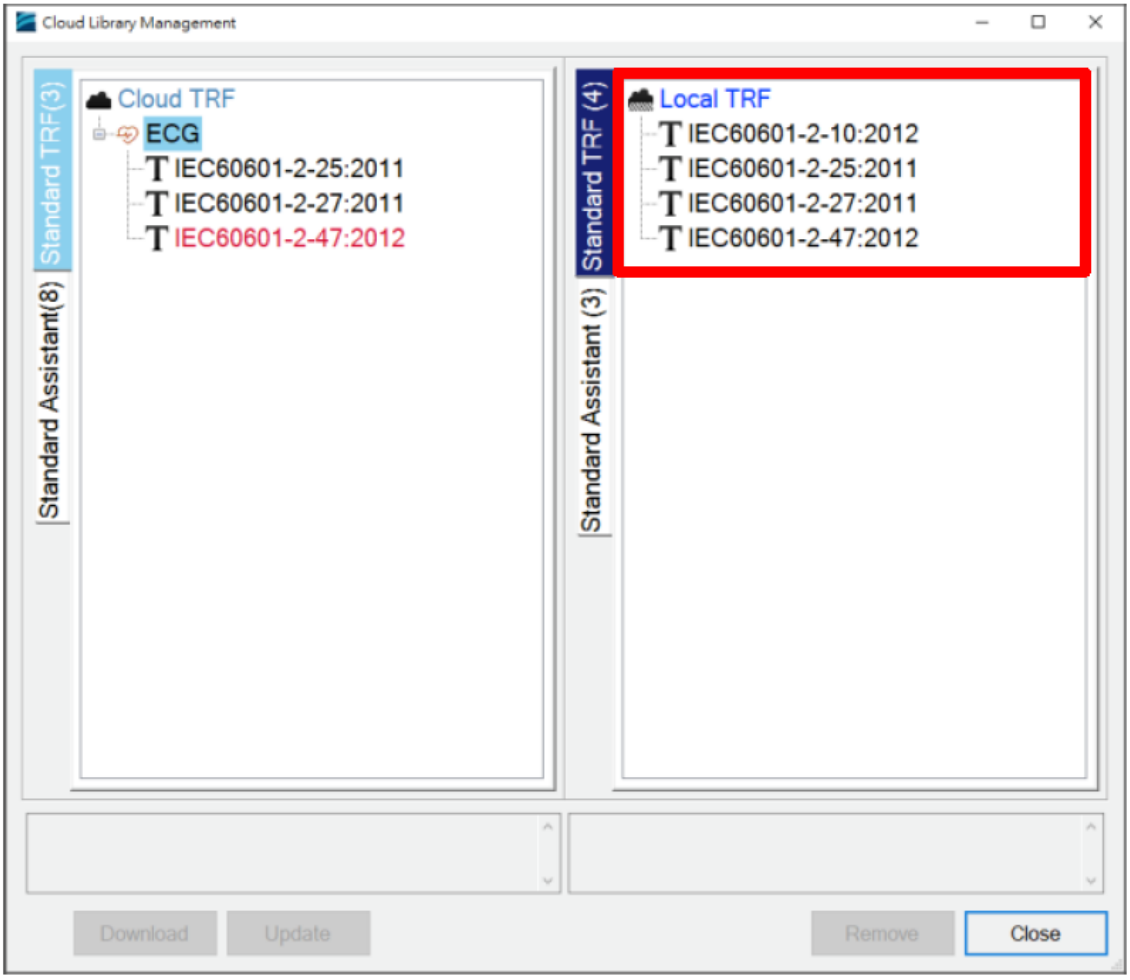


Figure 7: Download Project File for Different Medical Standards (Step 3)

Getting Started

Select the preferred medical standard. The instruction below uses IEC 60601-2-47 as an example.

Figure 8: Medical Standard Options

Click [IEC60601-2-47:2012]. You will see the details that consist of 4 parts:

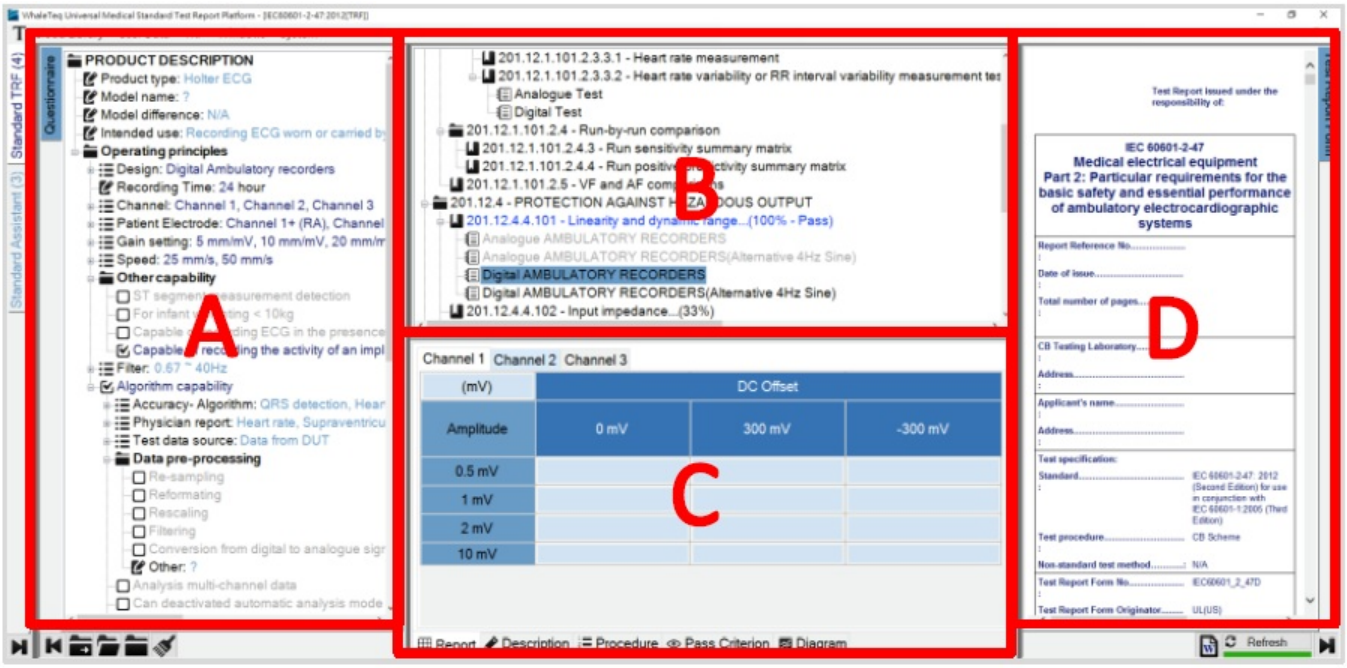


Figure 9: Medical Standard Compliance Test Screen

- A. Questionnaire: As we know, there are some questions in the body of the standards that need to be answered beforehand. Please answer these questions based on the attributes and the usage of the DUT. Some test projects will determine whether the tests need execution or parameter adjustment.
- B. Test Item: It consists of all the test clauses for the standards. Choose the test clause that you want to test.
- C. Test Record: Displays Report, Description, Procedure, Pass Criterion, and Diagram based on your selection for the test clause.
- D. Test Report Form: IEC Test Report Form with the test results and lets you see how the results display in the report form in real-time.

Select to start a test and fill in the records.
By selecting one of the test clauses, you shall see:

➢ Report

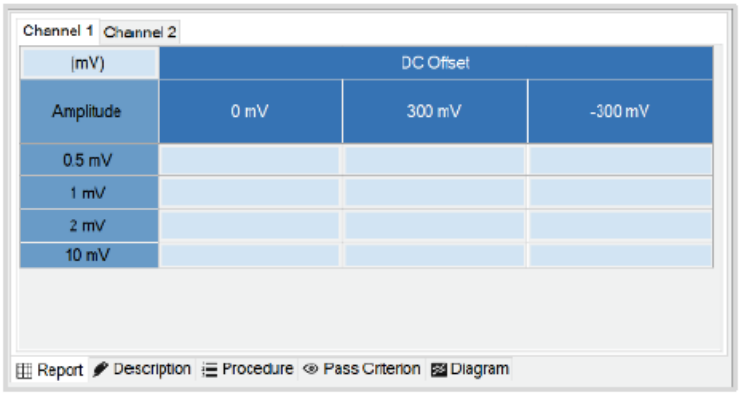


Figure 10: Report Tab

➢ Description

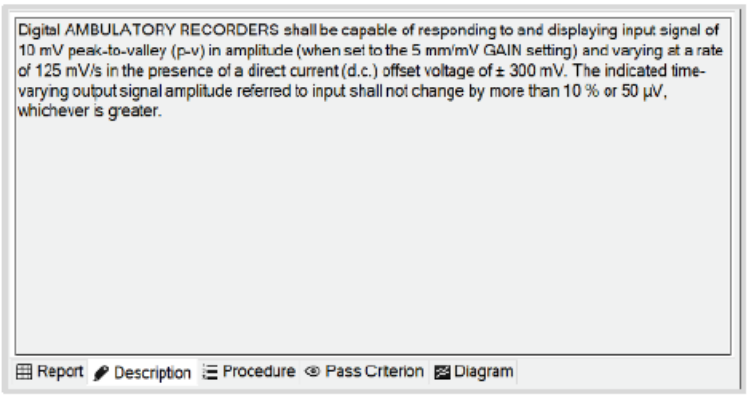


Figure 11: Description Tab

➢ Procedure

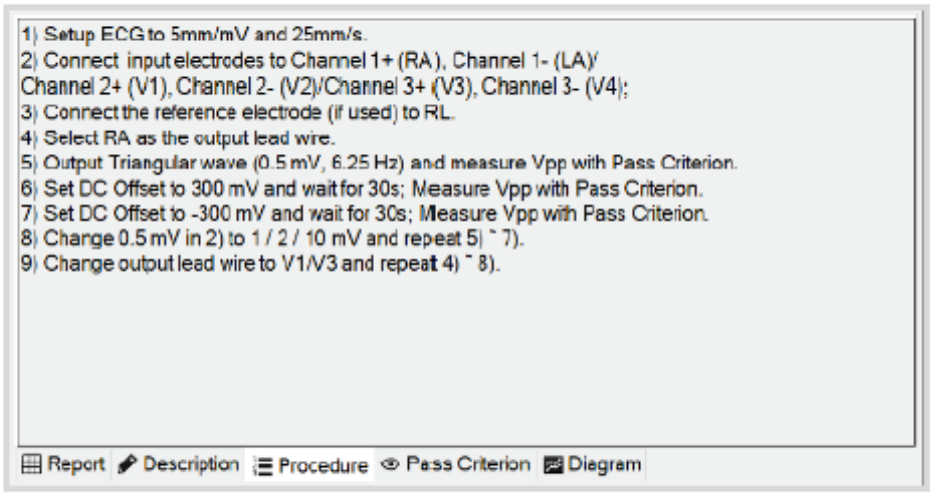


Figure 12: Procedure Tab

➢ Pass Criterion

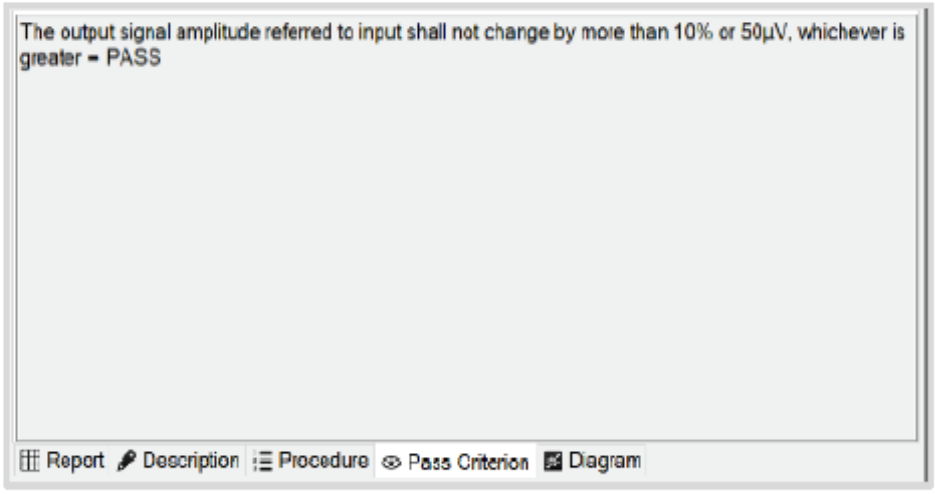


Figure 13: Pass Criterion Tab

➢ Diagram

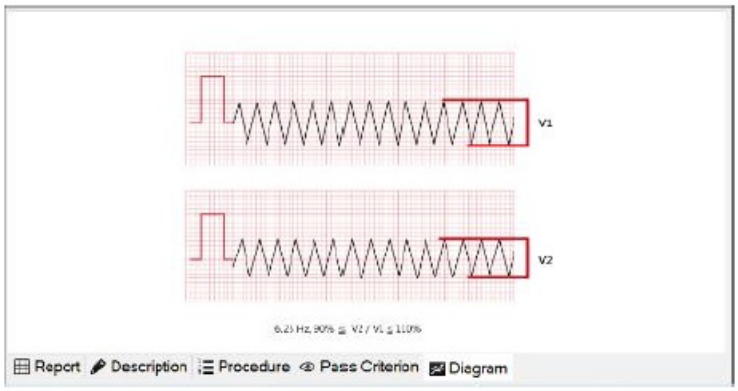


Figure 14: Diagram Tab

Select any fields in the report. Right-click to see [Start Test] and [Edit Result].

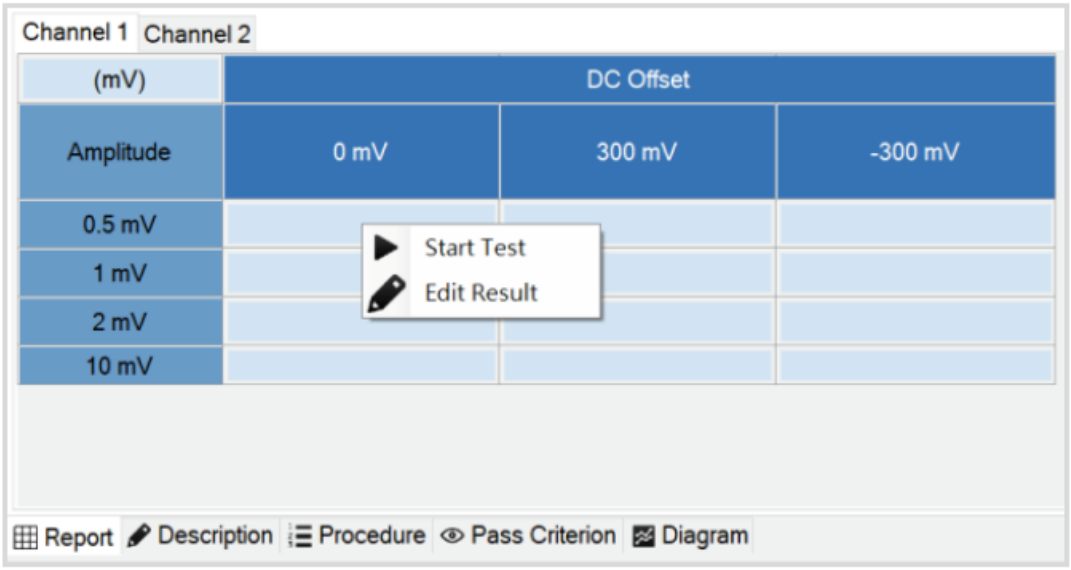


Figure 15: Start Test Function

Select [Start Test]. A window for controlling the test equipment and filling test results shows.
The window for controlling the test equipment

Figure 16: The Window for Controlling the Test Equipment

- A. Test Parameter: Shows test parameters required by the test clause.
- B. Executed SDK Routines: Controls the test equipment based on the selected test clause and outputs the corresponding waveform.
- C. Prompt Message: Prompts if manual intervention in the process is needed based on the requirements of the test clause. During the test, please pay attention to the messages and act on them accordingly.
- D. Waveform: Displays the waveform based on the test clause.

Test Result window
The window shows the Pass Criterion of the test clause. The text will be in Blue if the test results are within the scope of the criterion; Red if they are out of the range.

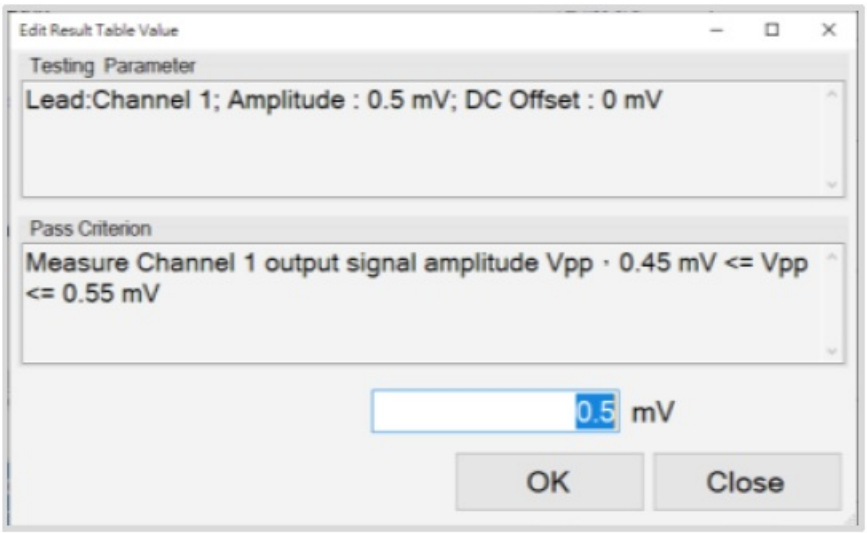


Figure 17: Test Result Window

Fill in the test report with the results according to the criterion of IEC Test Report Form to preview. The text will be in Green if the test results are within the scope of the criterion; Red if they are out of the scope.

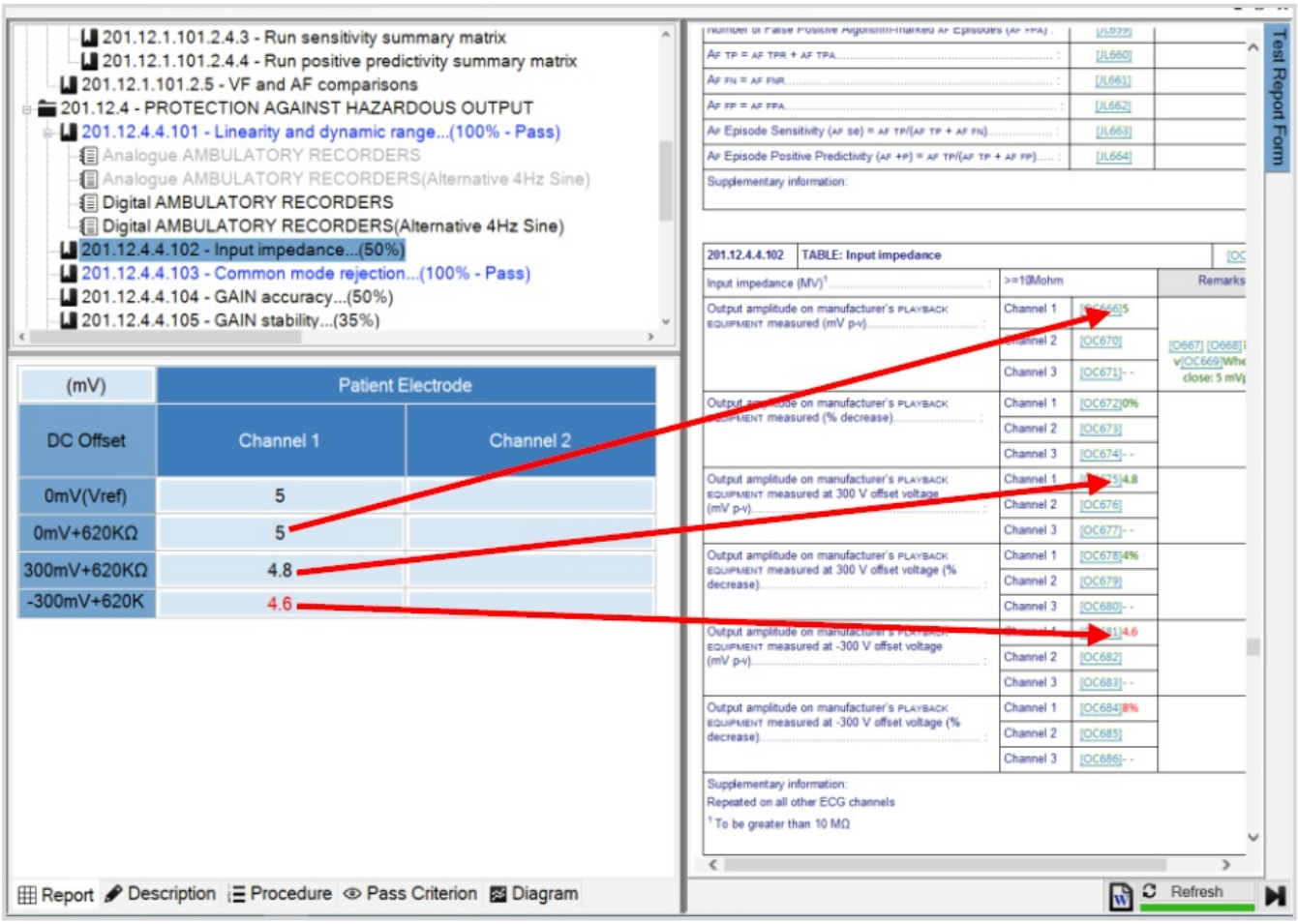


Figure 18: Test Report Preview

Test Progress: Current test progress is marked at the end of each item name for both the whole reports and single test items.

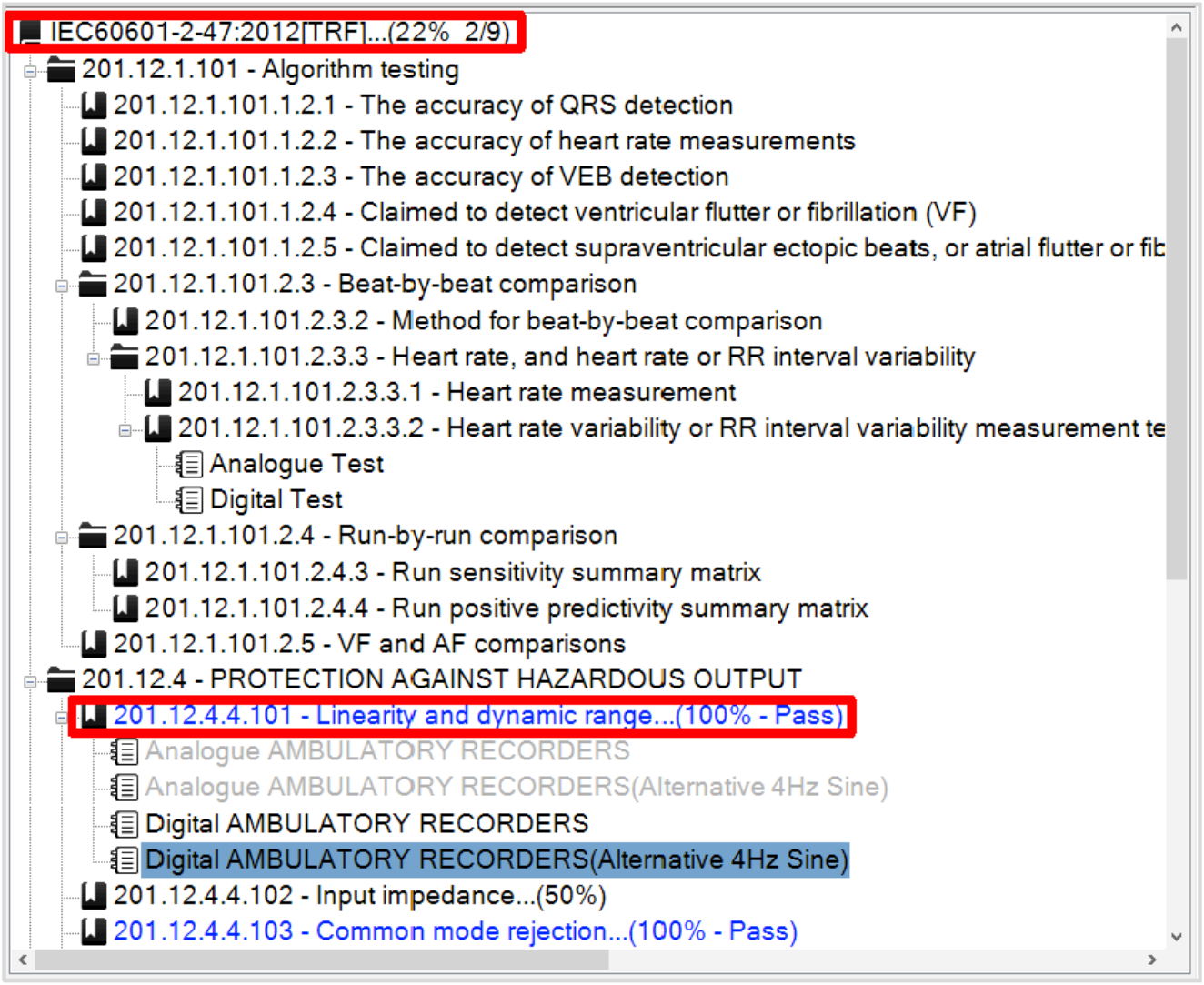


Figure 19: Test Progress

Actions in [User Data]

- Clean Questionnaire: Clean all the content in the questionnaire.
- Clean All Tables: Clean all the data in test table.
- Export User Data: Stores the test results in the selected folder.
- Import User Data: Imports the results from the last run to continue testing.
- Clean Result Table: Clean the test results of the selected test item.
- Export Table in Word: Exports the results of the selected test table to Word.

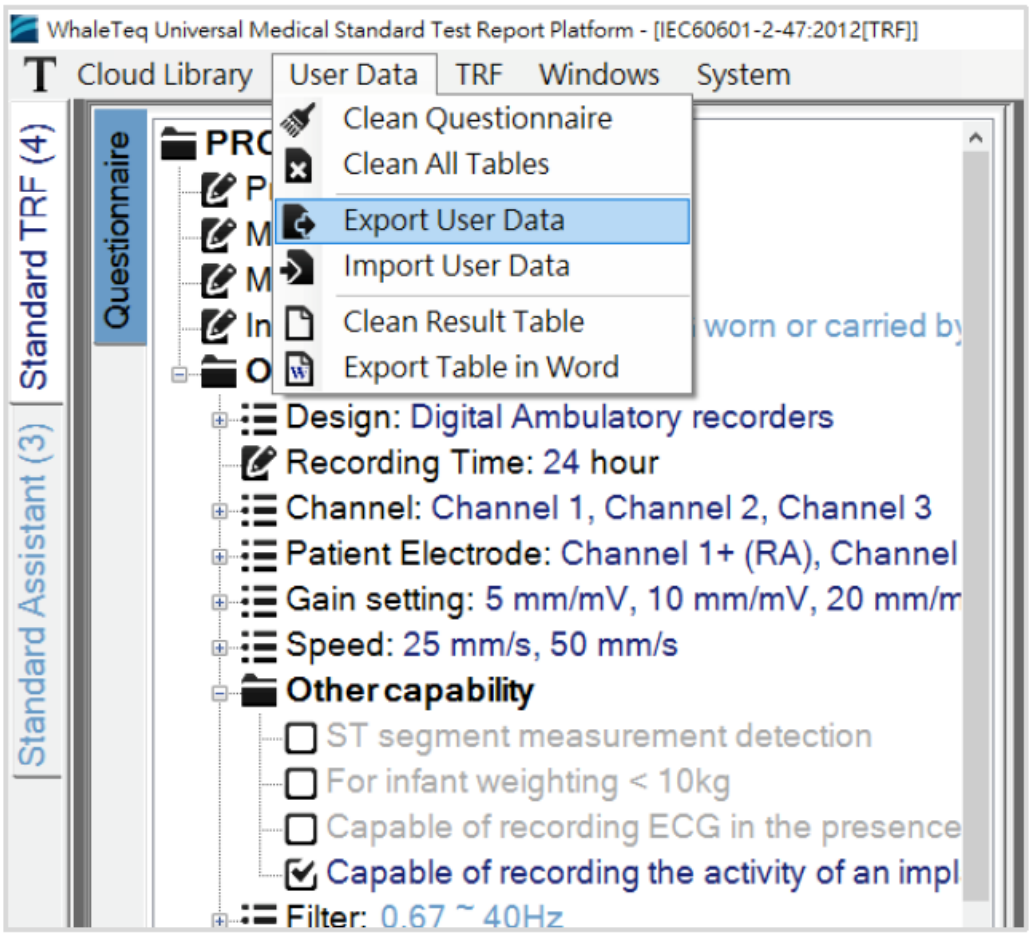


Figure 20: Functions in the User Data Tab

Generate Test Report

Select [TRF] and click [Generate Word TRF] to export the test report as a Word document to the folder you select. You can still edit the test report after it is generated.

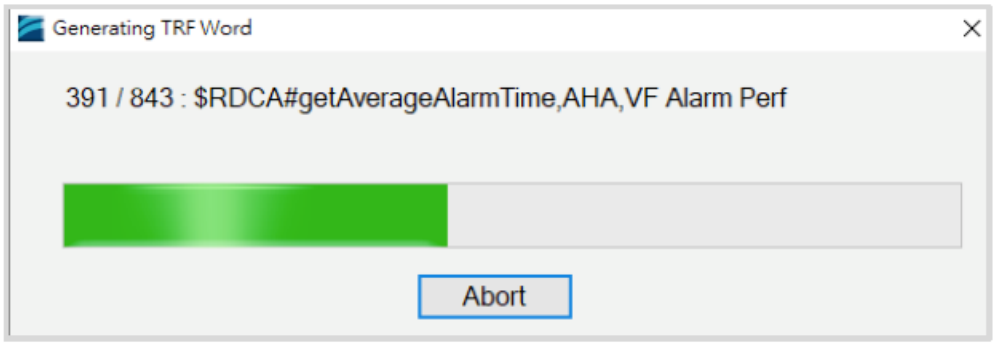


Figure 21: Export the Test Report as a Word Document

Supported Test Equipment

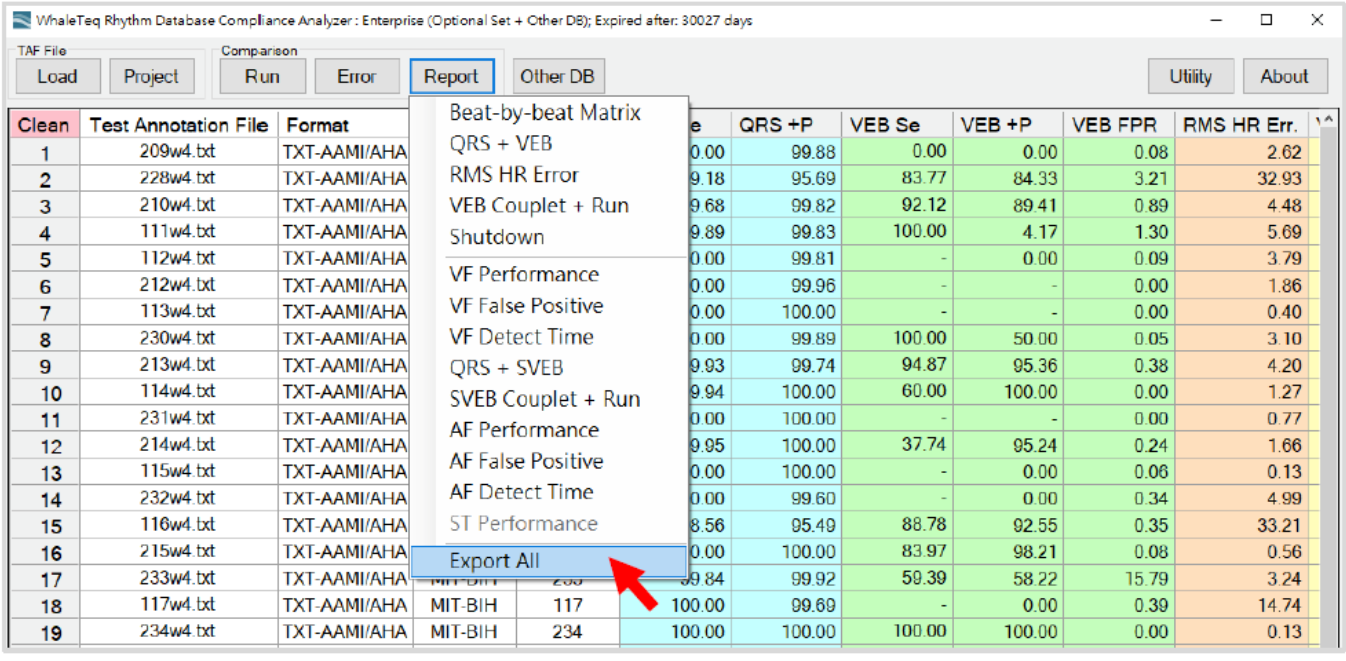
Table 1: Supported Test Equipment

Item	Equipment Name	Manufacturer	Medical Standards	IEC TRF Form
1	SECG 5.0 AIO SECG 4.0	WhaleTeq	IEC 60601-2-25 IEC 60601-2-27 IEC 60601-2-47 YY0782-2010 YY0885-2013 YY1079-2008 YY1139-2013	IEC 60601-2-25 IEC 60601-2-27 IEC 60601-2-47
2	CMRR 3.0+ CMRR 3.0	WhaleTeq	IEC 60601-2-25 IEC 60601-2-27 IEC 60601-2-47 YY0782-2010 YY0885-2013 YY1079-2008 YY1139-2013	IEC 60601-2-25 IEC 60601-2-27 IEC 60601-2-47

Import Database Comparison Results

Import Database Comparison Results from WhaleTeq RDCA

When using WhaleTeq RDCA for IEC60601-2-47 database compliance analysis, please import the test files of the 5 ECG databases to WhaleTeq RDCA by databases. It is recommended to name the folders with the name of the ECG databases, as shown in the image below.



Clean	Test Annotation File	Format			e	QRS +P	VEB Se	VEB +P	VEB FPR	RMS HR Err.
1	209w4.txt	TXT-AAMI/AHA			0.00	99.88	0.00	0.00	0.08	2.62
2	228w4.txt	TXT-AAMI/AHA			9.18	95.69	83.77	84.33	3.21	32.93
3	210w4.txt	TXT-AAMI/AHA			9.68	99.82	92.12	89.41	0.89	4.48
4	111w4.txt	TXT-AAMI/AHA			9.89	99.83	100.00	4.17	1.30	5.69
5	112w4.txt	TXT-AAMI/AHA			0.00	99.81	-	0.00	0.09	3.79
6	212w4.txt	TXT-AAMI/AHA			0.00	99.96	-	-	0.00	1.86
7	113w4.txt	TXT-AAMI/AHA			0.00	100.00	-	-	0.00	0.40
8	230w4.txt	TXT-AAMI/AHA			0.00	99.89	100.00	50.00	0.05	3.10
9	213w4.txt	TXT-AAMI/AHA			9.93	99.74	94.87	95.36	0.38	4.20
10	114w4.txt	TXT-AAMI/AHA			9.94	100.00	60.00	100.00	0.00	1.27
11	231w4.txt	TXT-AAMI/AHA			0.00	100.00	-	-	0.00	0.77
12	214w4.txt	TXT-AAMI/AHA			9.95	100.00	37.74	95.24	0.24	1.66
13	115w4.txt	TXT-AAMI/AHA			0.00	100.00	-	0.00	0.06	0.13
14	232w4.txt	TXT-AAMI/AHA			0.00	99.60	-	0.00	0.34	4.99
15	116w4.txt	TXT-AAMI/AHA			8.56	95.49	88.78	92.55	0.35	33.21
16	215w4.txt	TXT-AAMI/AHA			0.00	100.00	83.97	98.21	0.08	0.56
17	233w4.txt	TXT-AAMI/AHA			9.84	99.92	59.39	58.22	15.79	3.24
18	117w4.txt	TXT-AAMI/AHA	MIT-BIH	117	100.00	99.69	-	0.00	0.39	14.74
19	234w4.txt	TXT-AAMI/AHA	MIT-BIH	234	100.00	100.00	100.00	100.00	0.00	0.13

Figure 22: Import Database Comparison Results from WhaleTeq RDCA (Step 1)

Select to export the reports of 5 ECG databases to 5 folders respectively, as shown in the image below.

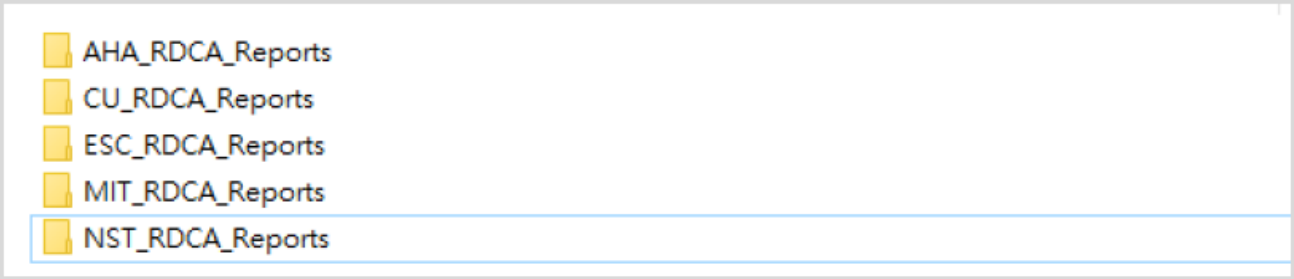


Figure 23: Import Database Comparison Results from WhaleTeq RDCA (Step 2)

Under [RDCA Reports] below the questionnaire of TRF Generator, click the database name and select the folder with database comparison results to import. Once imported, the reports of relevant test items will display, as shown in the image below.

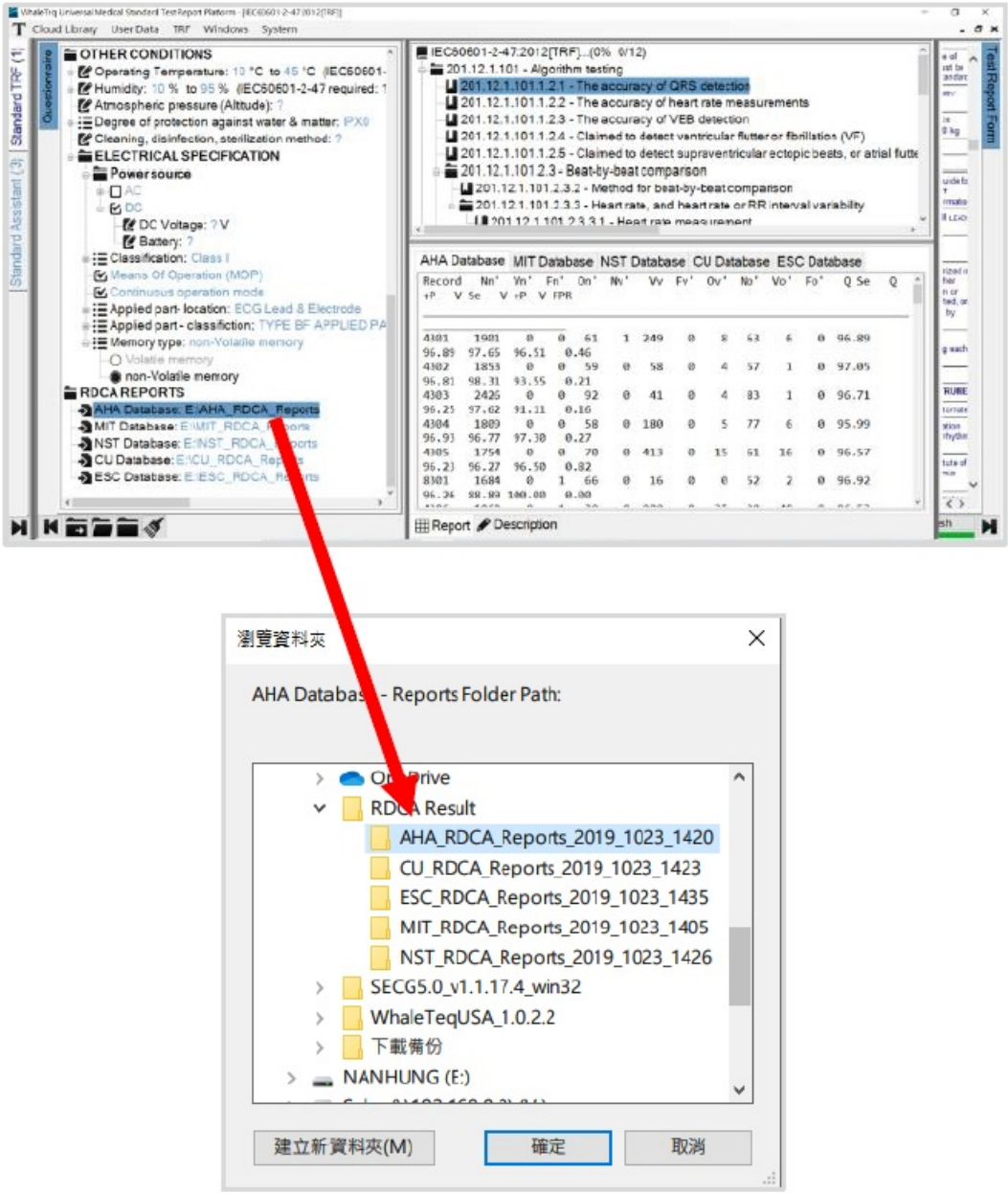


Figure 24: Import Database Comparison Results from WhaleTeq RDCA (Step 3)

Import Database Comparison Results from WhaleTeq CDCA

Use WhaleTeq CDCA for IEC 60601-2-25 database comparison and generates 3 different kinds of comparison results. Select [Export Result Report] to export them to the local storage, as shown in the image below.

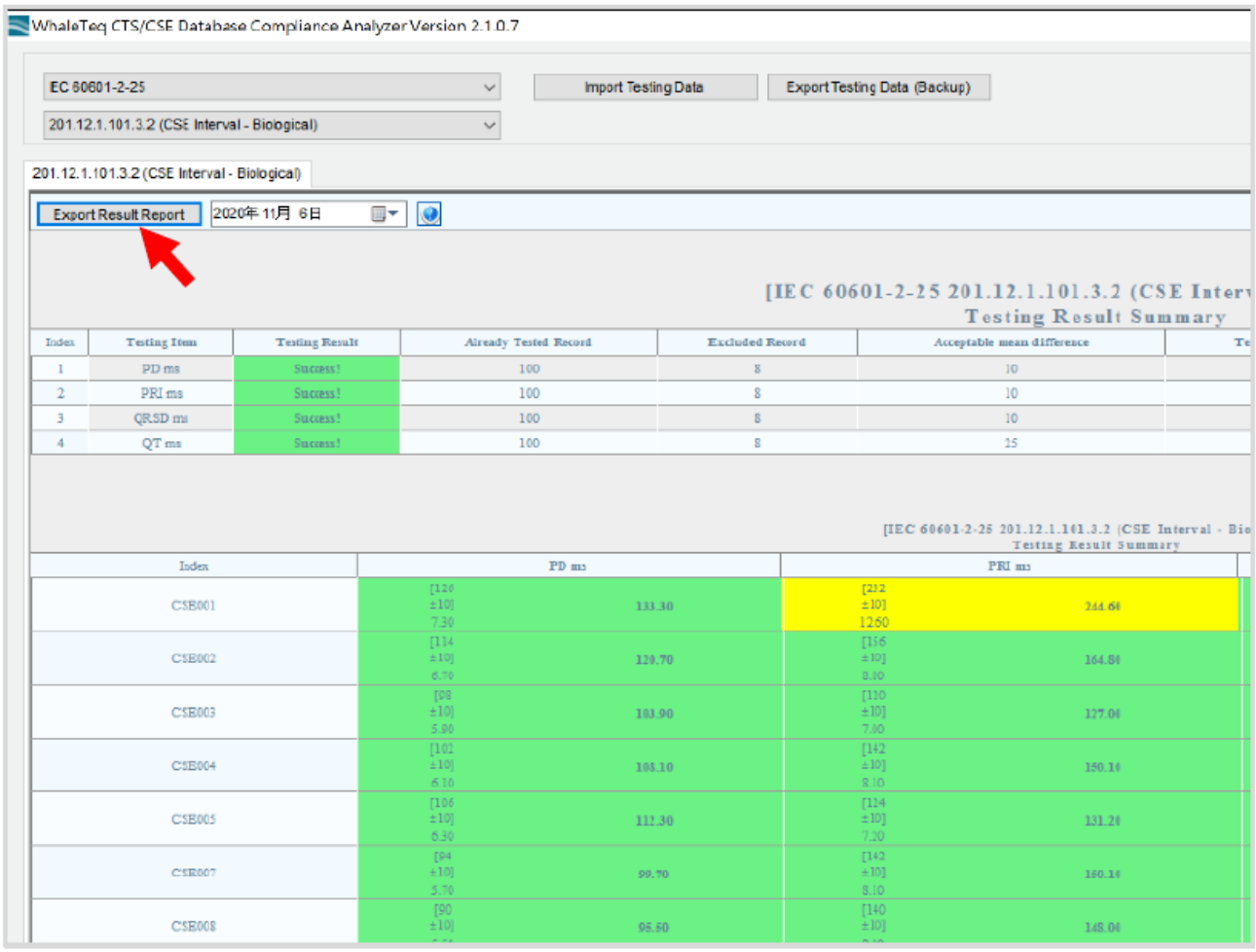


Figure 25: Import Database Comparison Results from WhaleTeq CDCA (Step 1)

Export the 3 reports to 3 RTF files individually, as shown in the image below.

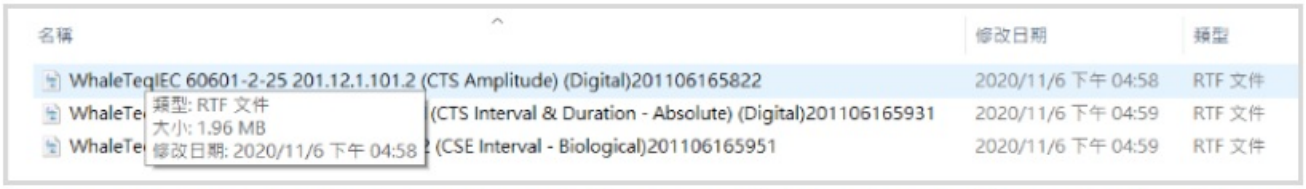


Figure 26: Import Database Comparison Results from WhaleTeq CDCA (Step 2)

Import the 3 RTF files into TRF Generator. Once imported, the reports of relevant test items shall display, as shown in the image below.

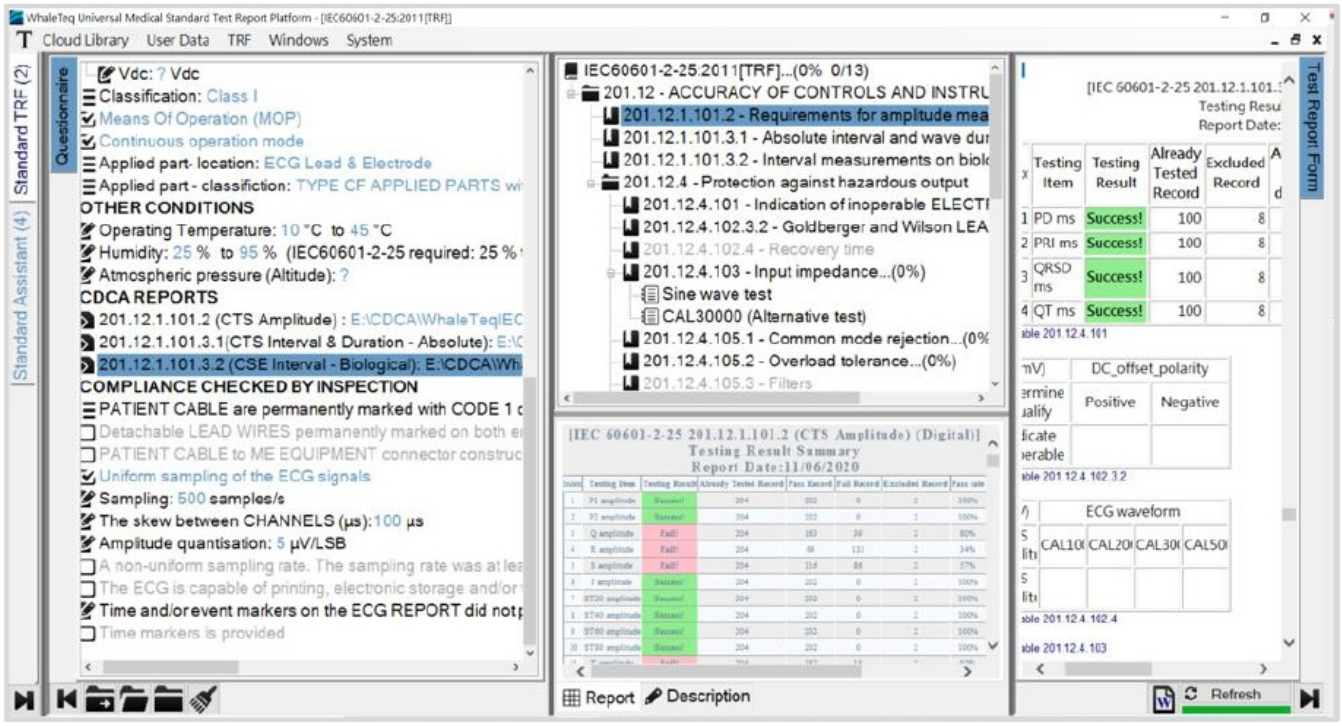


Figure 27: Import Database Comparison Results from WhaleTeq CDCA (Step 3)

Troubleshooting

Q1: What if the test equipment cannot be controlled and output test signals?
A: Please use the test equipment supported by TRF Generator. In case the equipment cannot output signals as expected, reconnect the equipment. Close and reopen TRF Generator software. Do not worry, the data you filled in will be retained when you open it next time. If you would like to save it to local storage, click [User Data] and select [Export User Data].

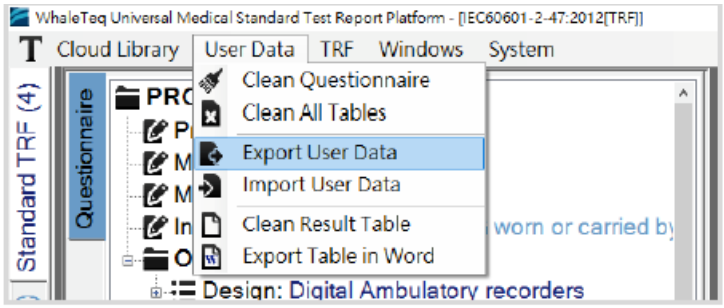


Figure 28: Save Test Results to a Local Computer

Q2: The test is completed, but I cannot export the report to Word.
A: Please check if Microsoft Word 2016 or higher is correctly installed on the PC. If yes, close any Word instances and try to generate the report again.

Q3: What to do when a message shows that the license is invalid?
A: It means your account has expired and become invalid. Please contact us if you want to keep using it.

Q4: The version of IEC Test Report Form is found not to be the latest one.
A: Please let WhaleTeq know your software version and the environment under which it runs. We will help you with the issue as soon as possible.

Ordering Information

Table 2: Ordering Information

Part No.	Description
HB0-TR00001	TRF Report Generator for IEC 60601-2-25:2011
HB0-TR00002	TRF Report Generator for IEC 60601-2-27:2011
HB0-TR00003	TRF Report Generator for IEC 60601-2-47:2012

Revision History
Table 3: Revision History

Version	Modified Contents	Issued Date
2020-12-23	First release	2020-12-23
2024-05-08	• Update Figure 3 and 4 • Add 5 Ordering Information 6 Revision History	2024-05-21

Contact WhaleTeq

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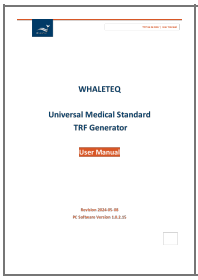
Documents / Resources

	WHALETEQ TRF Generator Software [pdf] User Guide TRF Generator Software, Software

References

- User Manual