Development of an Automatic Mobile Measurement Tester for Medical Device Power Supplies

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Abstract: - The paper presents the process of constructing and programming an automatic measurement tester that can be operated remotely via the Internet. The proposed innovative tester can be used for rapid and automated verification of compliance of medical device components such as power supplies. The process of writing the program supporting the measurement tester is presented and the principle of its operation is described, along with the method of generating the developed measurement results.

Key-Words: - mobile tester, verification tests, power supply; medical device

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1 Introduction

Continuous technological development forces constant adaptation to new standards. These changes are particularly evident in the electrical and electronic device market, [1]. New solutions and components, the discontinuation of production of current ones, as well as changes in standards imposing ever more stringent technical requirements, create the need for systematic modifications to the designed and manufactured device, [2], [3]. The global COVID-19 pandemic, which has caused massive production delays and supply chain interruptions, has also had a huge impact on the market recently, [4].

Nowadays, companies cannot afford to be slow in upgrading and improving their products. For this reason, such companies employ entire teams dedicated to fine-tuning products and finding replacements for aging or missing components so that devices can continue to be sold and kept on the market, [5]. This requires a great deal of electronics knowledge on the part of the engineers, as the introduction of new solutions can result in changes to the performance characteristics of the device. An additional but major problem is also the replacement of subassemblies and components in such devices. This is because it is very rare to find a replacement that completely matches the characteristics of the component being replaced.

Any such change is a challenge for the personnel involved in verifying the correct operation of the manufactured device. The introduction of modifications means that the device must be retested and its performance confirmed against the specification, [6]. Documentation and test protocols must therefore be prepared against which the device is then tested. Once the tests are complete, a report is drawn up confirming the correct operation of the tested device. This is extremely important from the point of view of the manufacturer, who, by verifying the operation of the device, protects himself against financial penalties imposed by company inspection authorities and the return of defective products, which, besides generating additional costs, affect the reputation of the company.

In practice, the process of verifying a new subassembly in manufactured devices involves carrying out appropriate tests and evaluating the results obtained against the technical requirements. The traditional process consists of dozens of tests simulating the natural operation of a component placed in the device, [7]. The verification involves manual testing by the operator on three test objects to confirm that the possible correct operation of the device is not an isolated incident. It takes a very long time to perform all the tests in such a process due to the inefficiently designed test stand, which requires modifications for each successive test (involving, for example, changing measuring equipment or connecting cables). Particularly troublesome in the case of such verifications is the need to carry out tests under appropriate conditions, i.e. carried out in climate chambers with adjustable temperature and humidity settings. Manual testing also increases the risk of poorly executed verification, through the appearance of human error, [8]. Indeed, repetitive test procedures can significantly affect operator concentration.

The need to speed up and automate the entire verification process for electronic device components was the main motivation for the creation of this paper. The main aim of the paper is to design, manufacture, and program an innovative measurement tester for use in verifying the compliance of medical electrical device components against specifications carried out at Radiometer Solutions, [9]. Based on a review of the available literature, no similar solution for testing electronic device components was found on the market.

2 Materials and Methods

Medical devices such as blood analyzers, for example, help doctors and specialists to determine the state of health of patients and to make appropriate decisions about the course of their treatment, [10]. Consequently, human lives often depend on the correct functioning of such devices. If any changes are to be made to medical devices, it is necessary to draw up meticulous documentation and carry out numerous tests to confirm that the devices are safe to use and work to a strict specification. After all, medical devices need to be reliable. Introducing even minor modifications may result in changes to their performance characteristics, [11]. Conducting the most thorough verification tests at the stage of a new project is therefore crucial from the point of view of a medical device manufacturer. Efforts should be made to ensure that these tests can be performed efficiently and in the shortest possible time.

The research described in this paper is based on the example of one of the medical device manufacturers, which is Radiometer Solutions, [9]. To innovate a way of verifying the compliance of electrical components of medical devices with specifications, carried out manually, it was decided to design and manufacture an automated tester.

2.1 Measurement Tester Construction Process

The following assumptions were made during its design phase:

- test stand will be automated as much as possible,
- tester will be built using existing equipment and solutions known on the market,
- modularity of the stand will be ensured to allow for future development,
- tester will be compact and mobile as well as easy to use.

Fulfillment of the above-mentioned assumptions will minimize operator involvement during the execution of test procedures and thus reduce the risk of human error. In addition, a significant reduction in verification time will be achieved, from several weeks to just a few days. A graphic representation of the measurement tester construction concept is shown in Figure 1.

A rack cabinet with dimensions of 1390 × 800 × 1000 mm and a mounting height of 27U was used to build the entire tester structure, [12]. The use of such a solution enables easy installation of devices inside the rack, as manufacturers offer ready-to-use mounting brackets adapted to the rack standard used. The base of the tester has been equipped with castors to enable it to be transported and connected elsewhere. To permanently seat the tester, the locks on the castors can be used, as well as the prepared stands.

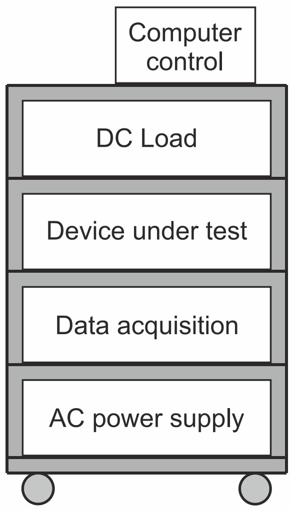


Fig. 1: Graphic representation of the tester construction concept

a)

b)

Fig. 2: Tester design elements to ensure adequate ventilation: a) perforated doors, b) ventilation system

The electronic devices installed in the rack cabinet get very hot, so the structure is equipped with perforated doors at the front and rear (Figure 2a), and fans with a temperature sensor are placed in the upper part of the tester (Figure 2b). The ventilation system activates when the set temperature limit is exceeded. The dimensions of the selected rack cabinet also allow adequate space to be maintained between the mounted measuring equipment, which facilitates heat dissipation. The space retained also allows modifications to be made to the tester construction.

The device under test is placed on a pull-out shelf. The retention of space allows larger electronic devices to be tested and further facilitates the assembly process inside the tester.

A power strip has been fitted to the rear of the tester's structure, to which the installed measuring equipment is connected. The power supply is routed outside the tester, allowing it to plug into a 230 V power outlet. The cabling inside the tester cabinet has been routed in suitably prepared troughs.

The device under test is powered by the IT7300 ITECH AC power supply (ITECH ELECTRONIC CO., LTD., New Taipei City, Taiwan). The power supply has the ability to adjust the output voltage up to 300 VAC, the frequency in the range of 45 to 500 Hz, and the setting of voltage and current limits. The power supply has been placed in the bottom of the measurement tester (Figure 1). The selected power supply allows remote operation and control of settings over a wide range. The power supply also has the ability to generate waveforms of individual parameters.

a)

b)

Fig. 3: Developed measurement tester: a) front view, b) rear view

The operation of the tested device is simulated using a DC electronic load with the eight-channel IT8700 ITECH equipment (ITECH ELECTRONIC CO., LTD., New Taipei City, Taiwan) modularly design to allow any system configuration. The appropriate configuration of load settings is intended to simulate the operation of the tested device under normal conditions.

The Keysight AG34972A data acquisition system (Keysight, Santa Rosa, CA, USA), equipped with twenty-two independent measurement channels, is responsible for recording all data during testing.

Communication between the equipment in the measurement tester takes place via a network connection. Triggering of the test sequences can be done via control from a computer connected to the tester or from any other location after a remote connection to the computer.

The developed measurement tester is shown in Figure 3.

2.2 Programming the Measurement Tester

Remote operation of the tester is possible via software developed in the LabVIEW environment (National Instruments, Austin, TX, USA). Meanwhile, TestStand (National Instruments, Austin, TX, USA) was used to generate reports on the verification sequences performed and to make all test data available.

Any number of verification tests can be created to carry out the tests. Each test is implemented using a block-structured program. An example program is shown in Figure 4. This is a test to check the output of the 5VSB power supply under load carried out in the following steps:

- setting the supply voltage to 230 VAC,
- measurement on the 5VSB line with a 0 A load,
- measurement on the 5VSB line with 1 A load,
- measurement on the 5VSB line with 2 A load.

The source code methodology is based on the operation of the subroutines controlling the measuring equipment installed in the tester. The following function blocks are included in the main program structure (Figure 4):

- PSU START – switching on the power supply,
- DC CURR – current load setting,
- DATA ACQ – measurement acquisition,
- DC STOP – switching off the load,
- PSU STOP – switching off the power supply.

The information displayed on the front panel is implemented based on the indicators from the data acquisition module. The system records successive measurements, displaying them in the form of a table and graph.

The design of the function block controlling the startup of the AC power supply allows the user to adjust the frequency value and the value of the supply voltage. The control of the AC power supply is done in a subroutine (Figure 5). When the test procedure is started, the program connects to the power supply via the configured remote connection, after which the output of the power supply is switched off so that the parameter setting does not take place on the power supply feeding the output voltage to the device under test. The next step is to set the parameters. The current limit is set to a fixed value of 2 A. When it is exceeded, the power supply will automatically switch off. Once the settings are set, there is a time delay of 5 seconds. This is the time needed for the power supply to stabilize its operation. The power supply output is then activated and the sequence proceeds to execute the next block.

The DC load control function block allows the current load to be set on each line of the power supply under test. The sequence of operation of the subroutine responsible for controlling DC loads (Figure 6) first implements the remote connection function. The next step is to drive the channel whose parameters are to be changed. Then, the program is informed which type of load is selected. In the next part, the preset load is set on the device. Depending on the number of channels to be driven, the program performs the same steps separately for each channel, after which it disconnects from the device and proceeds to the next block.

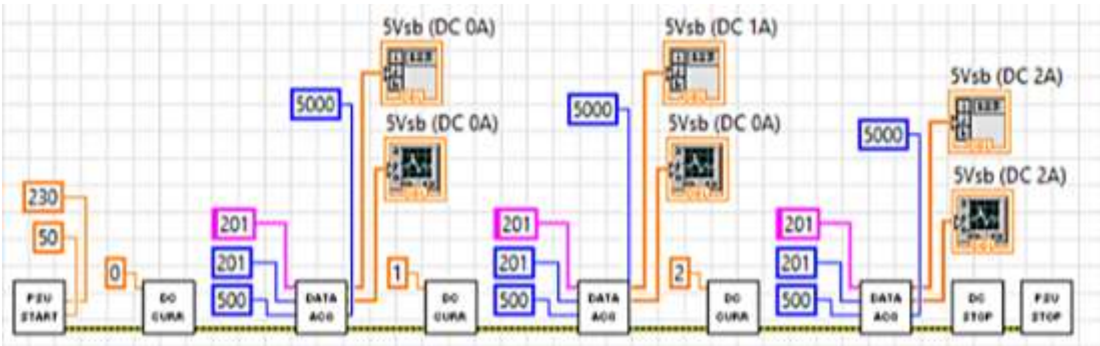


Fig. 4: Main program block diagram

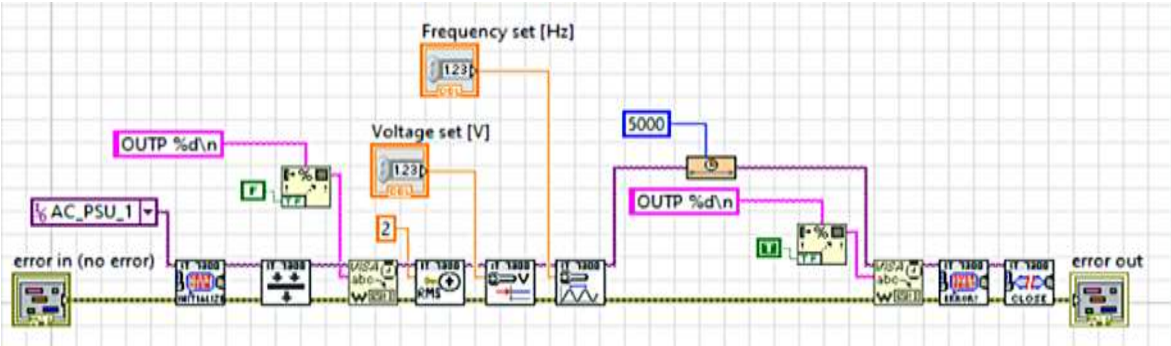


Fig. 5: Diagram of the AC adapter starting block

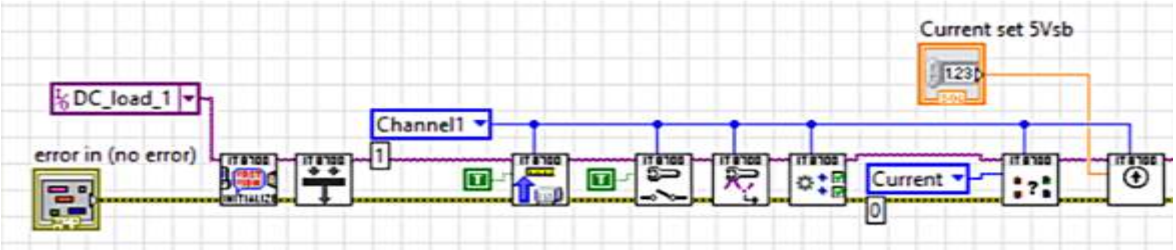


Fig. 6: Diagram of the DC load block

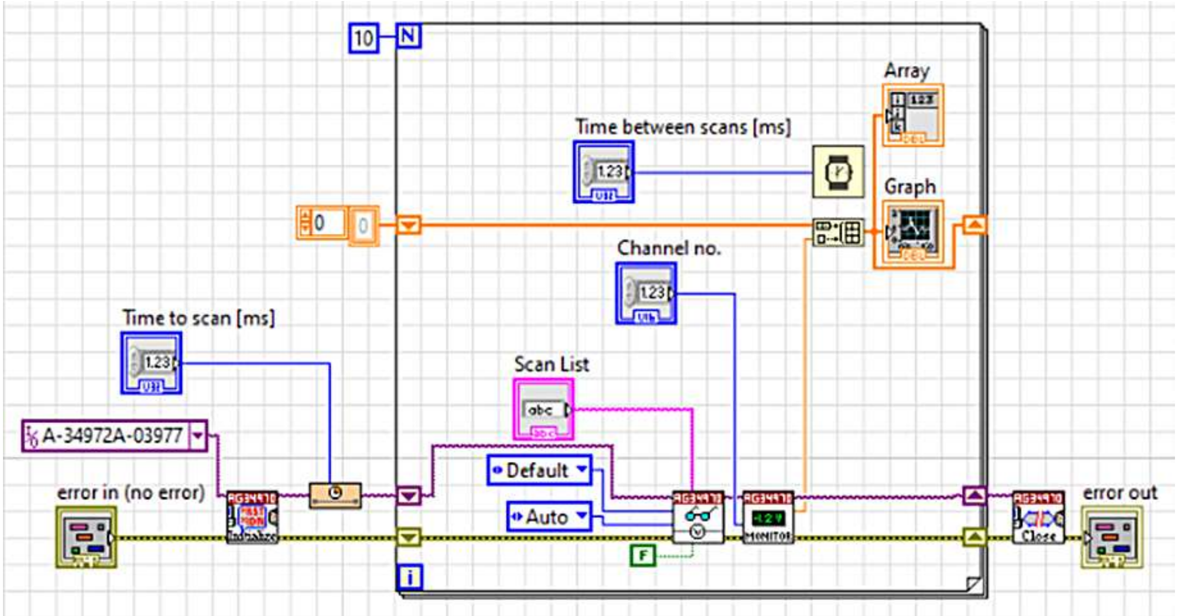


Fig. 7: Diagram of the block recording the measured parameters

The subroutine performing the collection of measurement results (Figure 7) first connects to the controlled device. Then the time delay function is implemented. These steps are followed by a sequence of measurement registration, which is closed in a loop and repeats 10 times. Once the data has been collected, the program disconnects from the device and moves on to the next block.

Deactivation of the set current loads takes place after all measurements have been taken. The subroutine responsible for the DC load disable function (Figure 8) connects to the DC load equipment and then resets the tested device and all its settings to nominal values.

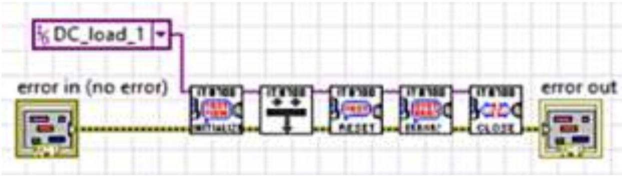


Fig. 8: Diagram of the DC load disable block

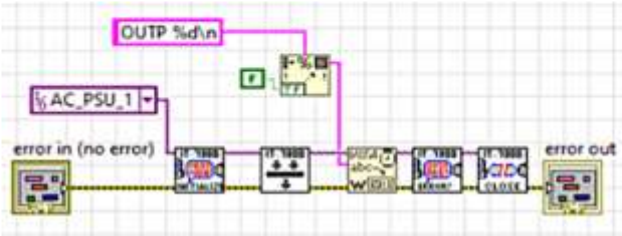


Fig. 9: Diagram of the block for switching off the output of the AC power supply

Each test sequence ends with a block to switch off the power supply output. A subroutine (Figure 9) configures the remote connection to the AC power supply and switches off the driven output, thus terminating the entire test.

The creation of the test sequence is based on the use of a ladder diagram composed of the relevant functions in TestStand. The scheme of operation of each test sequence consists of the following two steps:

- Loading and executing a program built in the LabVIEW environment,
- Evaluation of measured parameters according to configured limits for each of the 10 measurements taken.

3 Measurement Results and Discussion

In order to illustrate the feasibility of performing studies with the developed tester, tests were carried out on the power supply unit placed in the blood analyzer, which serves, among other things, to measure the blood sample, print the results, rinse, or calibrate. As in Section 2, a test to check the output of the 5VSB power supply under load was considered.

An example of a measurement sequence performed for a current load of 2 A is shown in Figure 10. The limits for the 5VSB parameter are set from 4.75 to 5.25 V. Once the tester has started, the program provides real-time information about the test progress and the step currently being performed (yellow index in Figure 11). At the end of the sequence, the program generates a message about the result of the tests (passed or failed).

Once the research has been completed, it is possible to generate a report with full information on the results obtained. Figure 12 and Figure 13 show excerpts from the reports for a test that passed and a test that failed, respectively.

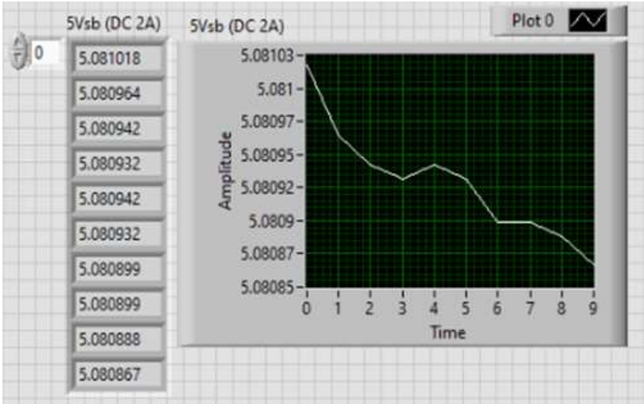


Fig. 10: Programme front panel with results in the form of a table and graph for a device loaded with 2 A.

Thanks to a developed software procedure, it is possible to automatically generate a report of all measurements taken in PDF format. The measured data are compared with the limits set based on the test protocol. The report contains information about:

- computer from which the tests were started,
- serial number of the device under test,
- date and time when the tests were started,
- name of the operator,
- duration of the entire test procedure,
- final result of the entire sequence.

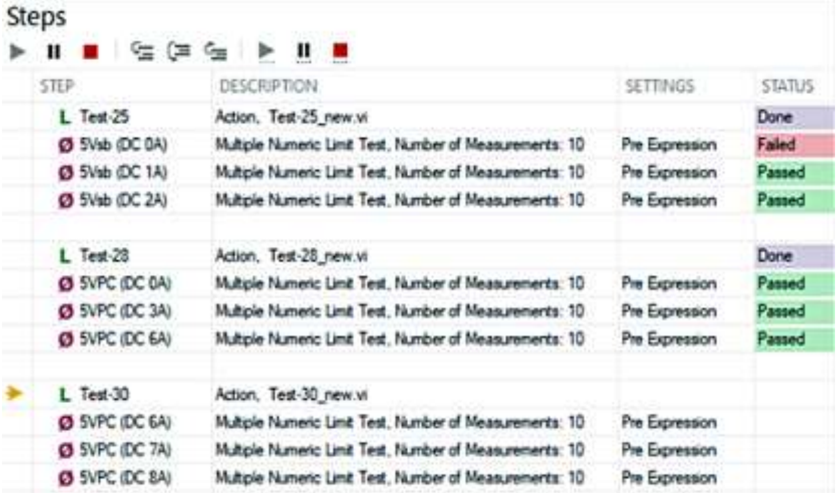
The measurement part of the report is divided into:

- type of test performed,
- parameter tested,
- ten measurements for the tested parameter.

The report with erroneous test results additionally contains information and a reference where the measurement is outside the set limits. This is particularly useful for an extensive report.

4 Conclusions

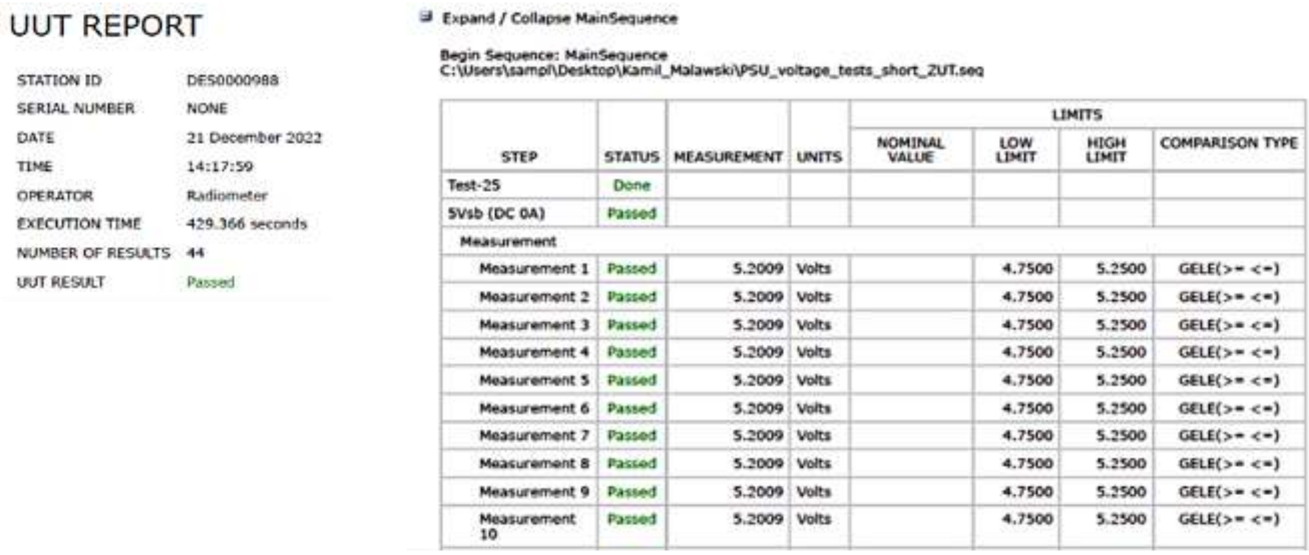
The implementation of modern technologies in industry is crucial to the smooth operation of a company. In addition to the use of automated machines and production robots, manufacturers also need to ensure development in the correct functioning of the devices being developed.



Steps

STEP	DESCRIPTION	SETTINGS	STATUS
Test-25	Action, Test-25_new.vi		Done
5Vsb (DC 0A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	Failed
5Vsb (DC 1A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	Passed
5Vsb (DC 2A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	Passed
Test-28	Action, Test-28_new.vi		Done
5VPC (DC 0A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	Passed
5VPC (DC 3A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	Passed
5VPC (DC 6A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	Passed
Test-30	Action, Test-30_new.vi		
5VPC (DC 6A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	
5VPC (DC 7A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	
5VPC (DC 8A)	Multiple Numeric Limit Test, Number of Measurements: 10	Pre Expression	

Fig. 11: Running the test procedure



UUT REPORT

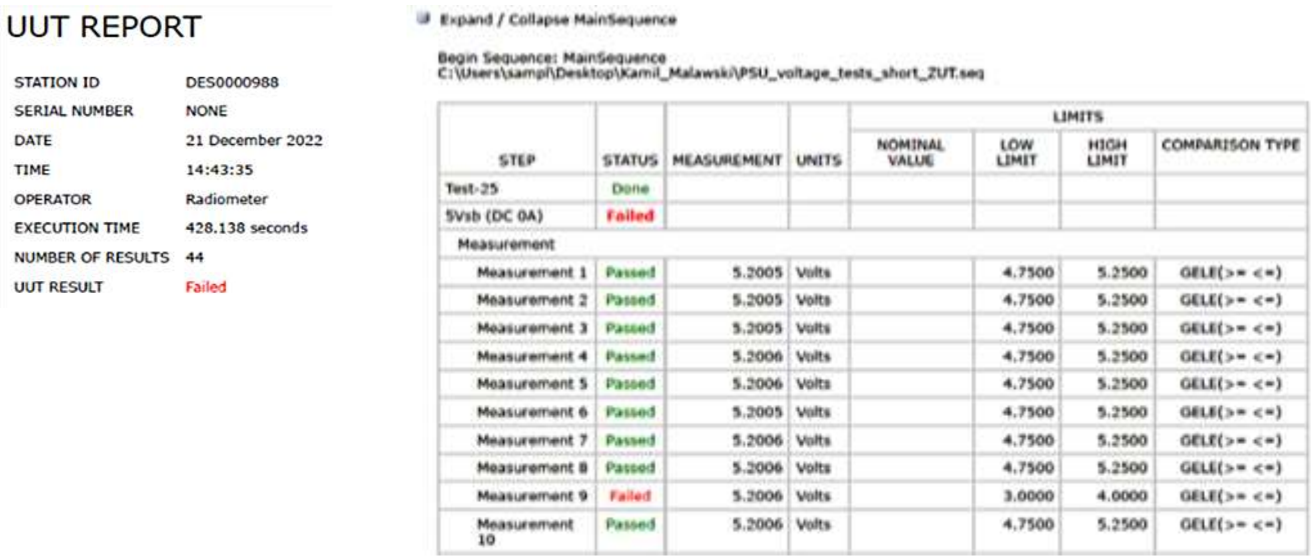
STATION ID	DES0000988
SERIAL NUMBER	NONE
DATE	21 December 2022
TIME	14:17:59
OPERATOR	Radiometer
EXECUTION TIME	429.366 seconds
NUMBER OF RESULTS	44
UUT RESULT	Passed

Expand / Collapse MainSequence

Begin Sequence: MainSequence
C:\Users\sampl\Desktop\Kamil_Malawski\PSU_voltage_tests_short_ZUT.seq

STEP	STATUS	MEASUREMENT	UNITS	LIMITS			
				NOMINAL VALUE	LOW LIMIT	HIGH LIMIT	COMPARISON TYPE
Test-25	Done						
5Vsb (DC 0A)	Passed						
Measurement							
Measurement 1	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 2	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 3	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 4	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 5	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 6	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 7	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 8	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 9	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 10	Passed	5.2009	Volts		4.7500	5.2500	GELE(>= <=)

Fig. 12: Excerpt from the test report that passed



UUT REPORT

STATION ID	DES0000988
SERIAL NUMBER	NONE
DATE	21 December 2022
TIME	14:43:35
OPERATOR	Radiometer
EXECUTION TIME	428.138 seconds
NUMBER OF RESULTS	44
UUT RESULT	Failed

Expand / Collapse MainSequence

Begin Sequence: MainSequence
C:\Users\sampl\Desktop\Kamil_Malawski\PSU_voltage_tests_short_ZUT.seq

STEP	STATUS	MEASUREMENT	UNITS	LIMITS			
				NOMINAL VALUE	LOW LIMIT	HIGH LIMIT	COMPARISON TYPE
Test-25	Done						
5Vsb (DC 0A)	Failed						
Measurement							
Measurement 1	Passed	5.2005	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 2	Passed	5.2005	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 3	Passed	5.2005	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 4	Passed	5.2006	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 5	Passed	5.2006	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 6	Passed	5.2005	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 7	Passed	5.2006	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 8	Passed	5.2006	Volts		4.7500	5.2500	GELE(>= <=)
Measurement 9	Failed	5.2006	Volts		3.0000	4.0000	GELE(>= <=)
Measurement 10	Passed	5.2006	Volts		4.7500	5.2500	GELE(>= <=)

Fig. 13: Excerpt from the test report that failed

The innovative measurement tester developed has eliminated all the difficulties associated with traditional manual verification testing. The duration of the full-scale test of the new power supply unit was reduced from around three weeks to just two days, including several hours of constant load and climatic chamber testing. A huge impact on the long duration of test procedures previously performed manually was the need to rebuild the test stand for each test. The new test stand does not require any modifications, and the execution of the prepared verification works on a ‘plug-and-play basis. An additional advantage of the tester is its size and mobility.

The full automation of the stand has also made it possible to eliminate the involvement of the operator during the measurement, and thus also the risk of human error. Such a solution also significantly affects the repeatability of the measurements performed. Programmed measuring devices are capable of performing operations several hundred or even several thousand times in a repeatable manner. The use of a measurement tester enables changes to be made to procedures and a larger number of measured values to be compared.

An extension of the tester is planned to allow battery and battery measurements, as well as tests involving time and frequency measurement and small-signal measurement.

The mobile measurement tester developed has allowed the entire process of testing electronic equipment at Radiometer Solutions to be accelerated and automated. Once it has passed the validation process, it will become an official verification tool at this company.

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Contribution of Individual Authors to the Creation of a Scientific Article (Ghostwriting Policy)

- Kamil Malawski was responsible for building the tester and writing the software, as well as conducting the research. He prepared the initial draft of the paper.
- Rafał Grzejda was involved in the visualisation of the tester concept and prepared the final version of the paper.

Sources of Funding for Research Presented in a Scientific Article or Scientific Article Itself

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Conflict of Interest

The author has no conflicts of interest to declare that are relevant to the content of this article.