System for the evaluation of power supply transformers in medical equipment

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Abstract. The present work consists of the design and development of a prototype of equipment for the automatic testing of power supply transformers, following procedures and requirements of standard IRAM4220-1:2000 – IEC60601-1-1 “General requirements of safety for medical electrical equipment” [1], in order to fulfill certification of safety before commercialization. The device has a modular design thus facilitating modifications in case of updated requirements of standards or simply to improve performance. The equipment software, once the data of the transformer under testing is loaded, allows a friendly and simple interface with user while. It is worth mentioning that the equipment also contemplates the requirements of the international standard IEC 61010.1 (2) “Equipment for measurement, control, and laboratory use”

1. Introduction
The use of electrical energy in any device constitutes a potential risk for whoever makes contact with it. That is why diverse standards exist that establish methods to verify electrical safety, generally referred to certain field of application or group according to common characteristics and applications.

Electrical equipment for use in medical practice have the highest safety levels in comparison with almost every other application such as domestic appliances or office equipment. The reason behind such tough requirements is that they are often used in physical or electrical contact and/or transfer energy or substances to the patient, who may not be able to respond suitably to dangerous or painful conditions due to the absence of normal reactions (patient could be unconscious, anaesthetised, immobilized or simply have diminished physical capacities). Equipment designed for direct cardiac application have a direct connection to a vital organ so that a simple failure could lead to patient death.

It is worth saying that the safety of the operator might be jeopardized since even when he or she does not suffer any disease, in some cases the methods used by the devices represent a very high potential risk

The electrical safety of medical devices includes: safety of the equipment itself, of their installation in medical ambients and their application or use. It is required for normal use and also under the condition of first defect.

The reliability and quality of functioning is considered as an aspect of safety regarding vital assistance devices where the interruption of an examination or treatment is considered like a risk for the patient.
Standard IEC 60601-1-1, or its Argentine equivalent IRAM 4220-1, establishes the “general requirements of safety for AE” and details the corresponding tests to verify them.

From what has been described so far, we deduce that these devices must exhibit a high degree of reliability and quality of operation which need both to be verified before commercialization through quality certification.

An electro-medical equipment must have at least two independent means of protection against electric shock, both for operator and patient. There must always exist an element that provides safe isolation between parts under voltage, the accessible elements or that might enter in contact with who operates the equipment or the patient. In equipment class I, the second method of protection is the so called protection ground, meanwhile in those class II it is a second isolation known as additional.

The power transformer, besides its primary function of supplying the necessary voltages for the operation of the equipment, concentrates great part of the safety functions of the device, offering isolation between itself and the power network thru the correct insulation and separation of primary/secondary windings.

Thus it becomes essential to test its dielectric strength in order to verify integrity. Despite this, a fault in the equipment can originate an overload, and even a short circuit at the power supply area, causing a significant increase of temperature followed by degradation of the insulation.

For that reason it is necessary to determine the temperatures reached under overload and short circuit conditions, in order to evaluate if the materials used in the construction are apt.

Like in all systematic and repetitive process, its automatization allows simplification, thus diminishing the introduction of errors and the execution time.

For these reasons and following a line of work that the L.I.A.D.E (Applied Development and Research Lab), has pursued since long: development of equipment for testing biomedical equipment, is that we proposed the design, development and construction of a “SYSTEM OF EVALUATION OF OVERLOAD OF TRANSFORMING OF FEEDING FOR BIOMEDICAL EQUIPMENT” according to norm IEC 60601-1-1 /IRAM 4220-1.

2. Specifications

The testing system has the following specifications:

- Injection of a constant RMS current along the range 10mA – 5A +/- 5%, in transformers with secondary winding voltage range of 5 – 50V for a limit maximum power of 150W.
- Measurement of the winding coils resistance within the range 20mΩ to 200Ω with an accuracy better than 5%
- Calculation of the temperature of the windings
- Measurement of total testing time.
- Friendly software user interface
- Easy maintenance, in order to facilitate future modifications.
- Design according to standard IEC61010-1.

3. Development

In figure 1 we can observe that there exist four enslaved microcontrollers and four power stages, with their respective measurements of currents feedback, one for each secondary winding of the transformer, until a maximum of four, due to the adopted modularity principle.

Although the operating principle of the four is the same, we will describe the first one, because it has the control of the winding SBE (in overload) and the greatest current will circulate thru it, thus becoming the proper place to measure winding temperature. The others handle control of the current thru windings SCN and will only be mentioned whenever there are any differences.
3.1. Master microcontroller

The key component of the equipment is a Microchip microcontroller PIC16F877A working with a 20MHz clock utilized to perform the following tasks:

- Function selection: measurement of windings resistance (primary and SBE) or loading the transformer under testing for current flow.
- Digitalization of the resistance measurement signal.
- Store samples of that signal.
- Analyze samples and perform the necessary calculations for determining windings temperature.
- Store results.
- Measure of total elapsed time during testing.
- User interface thru a 16 keys keyboard and a 4x20 LCD screen.
- Data communication with the slave PIC’s thru I2C system.

As mentioned before, the system performs two main functions: measurement of resistances (primary winding and SBE) and circulation thru each winding of the transformer of a constant current. Selection of functions is made by communting three relays for the SBE case, as explained on table 1 and shown on figure 2.

| Relay1 | Relay2 | Relay3 | Function                                      |
|--------|--------|--------|-----------------------------------------------|
| NC     | NC     | NC     | Measure resistance of primary winding         |
| NC     | NC     | NA     | Measure resistance of SBE winding             |
| NA     | NA     | X      | Primary is connected to 220V and SBE is loaded for current flow test. |
Meanwhile in the SCN, the Slave PIC takes charge thru the PWM control and resistances bank selection.

For the digitalization of the resistance measurement, 50 data points are taken from the ADC and an average is then calculated. The digital analogic converter (ADC) works with 10 bits precision.

The variation of the resistance is utilized to calculate temperature. That is why the microcontroller samples winding resistance every 5 minutes.

\[
T = T_i + \Delta t
\]

\[
\Delta t = \frac{(R_{\text{medida}} - R_i)}{R_i} \times (234.5 + T_i)
\]

All the variables within the formula use 32 bits floating pint in the program thus achieving a greater resolution than specified for temperature.

The measurement of the total testing time uses an external clock of 32MHz in Timer 1.

For the communication, the Module I2C works as Master with a transmission speed of 100 kHz and I2C functions are forced by hardware. Data transfer is synchronous, that is the clock signal is sent to synchronize very bit in bit packets. La transferencia es sincronica, es decir envia la señal de reloj para sincronizar cada bit, en paquetes de bits.

Each slave device connected to the bus is assigned a unique 7 bits coded address.

3.2. Slave microcontroller

A microcontroller PIC16F877A from Microchip, working with a 16 MHz clock is utilized to perform the following tasks:

- Receive and transfer data to the Master
- Digitalize the signal coming out of measurement of current flow thru secondary winding.
- Store samples of that signal
- Analyze and perform the necessary calculations to compare with data received by Master
- Provide a PWM signal by means of a PI control[3],[4] in order to carry out the control of load current.
- Select the appropriate resistance according to nominal voltage and current of the test.

A PI control was implemented, figure 3, because our process of current control does not require a time of fast establishment time, since the duration of the test is of 30 min. Therefore the derivational one is not necessary, but still we need as low an error as possible.
\[ v(t) = MV(t) = K_p e(t) + K_d \frac{de}{dt} \quad (3) \]

We assumed \( K_i=0 \) to tune the controller. The gain \( K_p \) was increased until getting a proper response of the system to changes in setpoint without an excessive overshoot or oscillations. It was found \( K_i=0.1 \) to be an optimum value.

With this configuration the establishment time is achieved around 10 to 15 seconds depending upon setpoint, what is reasonably small as compared to total testing time.

The PI controller provides a PWM signal at 1 kHz with 10 bits resolution ranging from 0 to 100\%, thus the control in this case has an output between 20 and 90\% of the PWM.

The digitalization of the current measurement (RMS) was calculated with the discrete values formula:

\[ I_{RMS} = \sqrt{\frac{1}{N} \sum_{i=1}^{N} x_i^2} = \sqrt{\frac{x_1^2 + x_2^2 + \ldots + x_N^2}{N}} \quad (4) \]

The converter acquires a total of 1000 samples of the signal, square each one and then adds them. The PIC configuration allows 170.4 \( \mu \)s sampling time. That means a time between samples of 171.4 \( \mu \)s or a sampling frequency of 5.8KHz.

Then the time needed for 1000 samples is 171.4 ms, that is, in one wave cycle (10 ms) pulsed at 1 kHz there are 58 samples, therefore fulfilling the sampling theorem.

The selection of resistance depends on voltage (V) and current (mA) data received from sampling. The program calculates the peak voltage of current flowing through the winding as:

\[ V_{pico} = V\text{(dato)} \times \sqrt{2} \quad (5) \]

Then the system determines the resistance to be selected simply with the Ohms law. Once determined, the closest value, always smaller than the calculated one, is selected. Otherwise the control would never reach the current preset.

3.3. Resistance measurement
A direct current supply pushes 25 mA current through the primary and SBE windings causing a voltage drop which is measured and signal-conditioned with an instrumentation quality differential amplifier with unit gain and then amplified with 4 possible pre-programmed values of gain automatically selected by the master PIC depending on signal amplitude.

It is worth noticing that if an alternate current were used instead, we would measure winding coil impedance instead of the pure resistance which is needed for temperature calculation.

3.4. Power stage
Here flows the current of the transformer under testing. We can partition this block in three for better understanding: rectifier circuitry, bank of load resistances and power commutation.

The rectifier circuit is simply a diode bridge that converts the sinusoidal alternating signal coming out of the transformer secondary into a full-wave rectified signal for further use.

The bank of load resistances is an array of 16 resistances for the SBE and 8 for the SCN, connected in parallel, that, when selected with help of the relays, will allow the flow of the proper current value according to the nominal voltage of the transformer.

The power switch[5] is made of a MOSFET transistor[6] and its corresponding snubber circuit for protection[7]. It will fix an average current according to the PWM signal injected in its gate which, in turn, will be measured and signal-conditioned by the following module.

3.5. Current measurement
This stage includes current sending and further signal conditioning. [8]
Current is detected by measuring the voltage drop across a shunt resistance in series with the MOSFET source. In the SBE case there exist two shunt resistances selected with relays meanwhile in the SCN, there is only one.

Voltage thus sensed is amplitude conditioned with a low noise differential amplifier which can be configured with either one of 5 gain values automatically selected by the slave PIC, depending on signal amplitude, with the help of a multiplexer.

This signal is then delivered to the A/D converter of the slave PIC for the calculation of the True RMS value.

3.6. User interface
It consists of a matrix keyboard 4x4, used to input nominal parameters, and a 4x20 LCD screen to visualize testing parameters and real values measured during testing and once finished.

4. Results
What follows is the presentations of results of performance tests of the equipment designed.

In order to realice them, 7 values were selected for each amplifying range of the instrument, as measured by a reference instrument, Hewlett Packard model 3478A for resistance and Fluke189 for current.

Those values were measured three times, in descending, ascending and descending order, respectively, in order to compare the average value with the reference one and thus obtain the percentage error, as shown in figures 4 and 5.

The lowest resistance values, between 150mohm and 20mohm, were constructed with a Nychrome wire of 1,3 ohm/meter, meanwhile commercial precision resistors were used for all other values. A 24V/6A transformer was used to excite input for the current measurement.

![Figure 4. Percentage error in resistance measurement for primary and secondary circuits of transformer.](image)
If we examine carefully the verifications realized by the equipment tester, we conclude that the mean error in measurements is smaller to the 5% required by the standards.

5. Conclusions

The accomplishment of a prototype that allows to perform the tests on supply transformers required by standard IEC 60601-1 and whose design also considers the requirements of the standard IEC 61010-1 for electrical safety of laboratory equipment.

Due to the principle of modularity employed, the equipment can be implemented partially according to particular requirements of transformers since during preliminary testing, every block was implemented and tested individually.

References
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