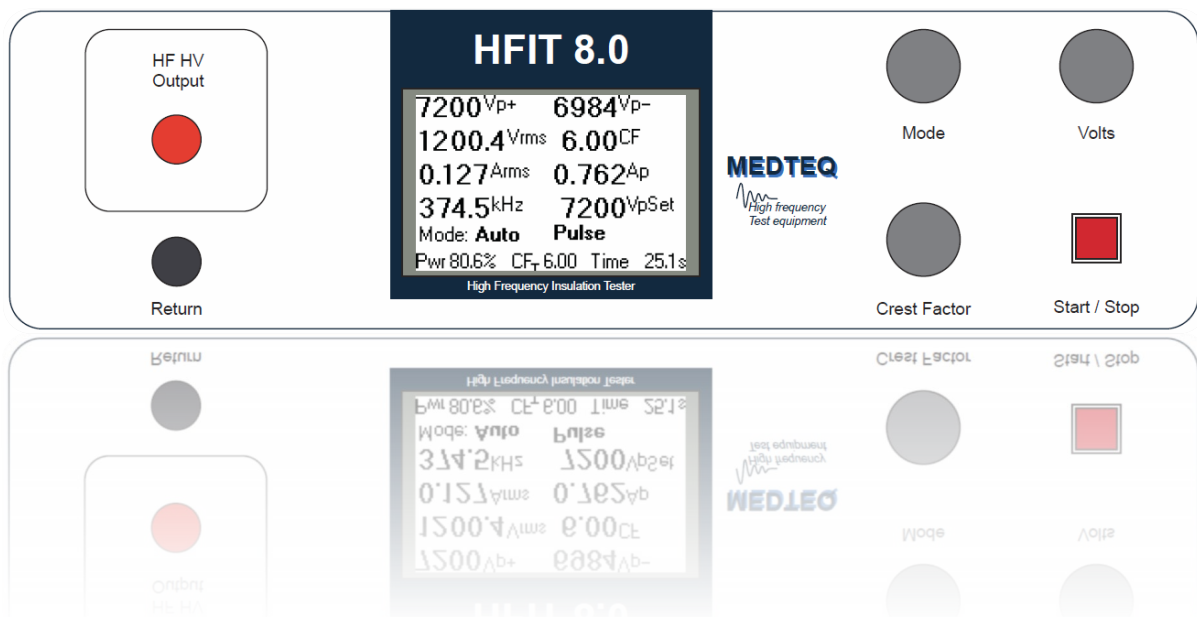


MEDTEQ

High Frequency Insulation Tester

HFIT 8.0



Operation Manual

Issue 3 March 2023

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CONTENTS

1	Overview	5
2	Significant Risks	6
3	Getting started	7
4	Functional Description	8
4.1	<i>Front panel controls, connections and display</i>	8
4.2	<i>Rear panel connections</i>	9
4.3	<i>Connection to external equipment and test load</i>	10
4.4	<i>Display</i>	11
4.5	<i>Modes of operation</i>	12
4.5.1	Off.....	12
4.5.2	Sine Mode.....	12
4.5.3	Modified Sine.....	13
4.5.4	Burst.....	14
4.5.5	Pulse.....	15
4.5.6	Auto Mode.....	16
4.5.7	Timer function.....	16
4.5.8	Settings Mode.....	16
4.6	<i>Warning messages</i>	17
5	Principle of operation	18
5.1	<i>Basic pulse</i>	18
5.2	<i>Pulse, crest factor modification</i>	20
5.3	<i>Basic sine wave</i>	20
5.4	<i>Modified sine, Burst modes</i>	21
5.5	<i>Effect of the test load (insulation under test)</i>	21
5.6	<i>Effect of test sample breakdown</i>	21
6	Operation	22
6.1	<i>HF Dielectric strength testing</i>	22
6.2	<i>Mode selection, load limit (based on rated voltage)</i>	23
6.3	<i>HF Leakage current testing</i>	24
7	HF insulation breakdown – theory and detection	25
7.1	<i>Thermal effects / dielectric dissipation factor (δ)</i>	25
7.2	<i>Dielectric breakdown</i>	26
7.3	<i>Purple (blue) corona</i>	26
7.4	<i>Orange corona</i>	27
7.5	<i>Limitations in IEC 60601-2-2</i>	27
8	HFIT Measurement methods, error analysis and validation	28
8.1	<i>Background</i>	28
8.2	<i>Voltage divider</i>	29
8.3	<i>Peak voltage</i>	29
8.3.1	Method overview.....	29
8.3.2	Error analysis.....	30
8.3.3	Validation (Oscilloscope method).....	31
8.4	<i>Vrms measurement</i>	32
8.4.1	Available methods.....	32
8.4.2	Background to the HFIT method.....	32
8.4.3	HFIT implementation.....	33
8.4.4	Validation.....	33
8.5	<i>Current measurement</i>	33
8.6	<i>Crest factor</i>	34
8.7	<i>Frequency</i>	34
8.8	<i>HFVM Traceability (production)</i>	34



9	Measurements by oscilloscope/probe.....	35
10	History of development.....	36
11	Calibration.....	37
11.1	<i>Voltage.....</i>	<i>37</i>
11.2	<i>Current monitor, BNC (1Ω shunt).....</i>	<i>38</i>
11.3	<i>Current monitor (display).....</i>	<i>39</i>
11.4	<i>Other displayed values.....</i>	<i>39</i>
12	Specifications.....	40
13	Contact details.....	40

1 Overview

The MEDTEQ High Frequency Insulation Tester (HFIT 8.0) is intended for testing insulation associated with high frequency surgical applications, in particular for testing insulation in active cables and electrodes to the requirements in IEC 60601-2-2 (which are also referred to in IEC 60601-2-18).

The specific tests from IEC 60601-2-2:2017/AMD1:2023¹:

- High frequency dielectric strength (Clause 201.8.8.3.103)
- High frequency leakage current (Clause 201.8.8.3.102)
- NE cord insulation HF dielectric strength, cable leakage (Clause 201.15.101.4)

Note: The HFIT cannot output mains or dc voltages for the test of 201.8.8.3.104. This test must be performed by a separate high voltage tester. The HFIT is designed for testing accessories only, and is not intended to be used as a HF generator in EMC testing.

The HFIT series has been designed to provide stable, reliable voltages with easily adjustable parameters. The equipment has four output modes: **Sine**, **Modified Sine**, **Burst** and **Pulse** designed to cover a wide range of crest factors and peak voltages as required by IEC 60601-2-2. Two of these modes (Burst and Pulse) feature adjustable crest factors.

For each mode the fundamental frequency ranges from around 330kHz (full rated load) to 470kHz (no load) depending on the capacitance of the test load. The variance of the fundamental frequency is due to the use of a high power resonant circuit to achieve the high peak and average loads associated with high voltage testing at high frequency. This equipment is designed for broad use with up to 100pF capacitive load and up to 150pF in many conditions.

The HFIT 8.0 achieves a new level in the series with in-built monitoring of V_{p+} , V_{p-} , V_{rms} , crest factor, I_{rms} , I_{peak} and frequency. Display of peak and rms utilize specially developed measurement systems designed to be intrinsically accurate at the frequency of interest, far exceeding the accuracy and reliability of existing measurement systems based on oscilloscopes and probes.

An **Auto** mode is also provided for which the user simply sets the target peak voltage, presses the start button and the system controls the rest: select the best mode, adjust the peak voltage and crest factor as required. A **timer** is also provided in both free running and set time modes. The Auto mode and timer make the equipment suitable for production testing.

System monitoring is included to indicate output overvoltage (peak and rms), low frequency, crest factor outside of target limits overload, short and internal temperature. Where appropriate the system will also actively reduce or stop the output.

In order to set up this equipment, the user should be a qualified electrical engineer or equivalent, familiar with principles of high frequency insulation and the use of oscilloscopes. The user should review the principle of operation of this equipment and the section on significant risks.

¹ The HFIT 8.0 is also suitable for tests to earlier versions of IEC 60601-2-2 and IEC 60601-2-18.

2 Significant Risks

As a result of risk assessment, the following significant risks/hazards were identified:

Potential risk	Information / Risk control
Burns	<p>If the output is touched by the user when activated a burn hazard exists, similar to that provided by electrosurgical equipment. It is considered a similar risk to use of a soldering iron (i.e. typically minor, non-permanent injury). The following risk controls have been implemented:</p> <ul style="list-style-type: none"> - The output controls are located well away from the output terminals - The output is disabled when the power is turned on or the mode is changed (avoids unexpected output) - In Auto mode, the user must press the Start button for 2s to enable the output, and no delay is used to stop the output. <p>In addition, the user should take care with the set up to minimize the likelihood of contact in the test area (leads and the like).</p>
Ozone	<p>If corona occurs during testing, it produces ozone which can be hazardous. Corona depends on the thickness of insulation and voltage. Thin insulation can produce corona and ozone at voltages as low as 2000Vp.</p> <p>Literature indicates that for most people, ozone should be avoided but small amounts should have little effect. For these people, the smell of ozone can be used as a good indicator of the need to take action. In rare cases, even small amounts of ozone, below that which can be detected by smelling, can cause adverse reactions. If ozone can be smelled, or in case of doubt, operate the test in a well-ventilated area, and/or limit the number of tests with time to reduce the volume of ozone.</p>
False positive	<p>If the equipment provides a false positive (pass test result when the insulation test should have failed), a potentially dangerous medical device could be released to market. This was determined to be the most serious risk associated with this equipment. The main risk control is user awareness and the following user actions:</p> <ul style="list-style-type: none"> ○ Investigate the material properties (dielectric strength, dissipation factor) to confirm the suitability of the material independent to the test (see Section 7) ○ Visually monitor the applied voltage throughout the test ○ Test at least 3 samples; consider testing the material also to destruction ○ Perform temperature study (determine dissipation factor) <p>As an additional risk control overload indicators are provided which detect if the sample is failing.</p>

Note: Although high voltages are involved, there is no significant risk of electric shock. The output is a tuned resonant circuit at high frequency, it is inherently unable to provide high currents at frequencies which are known to cause electric shock (<1kHz).

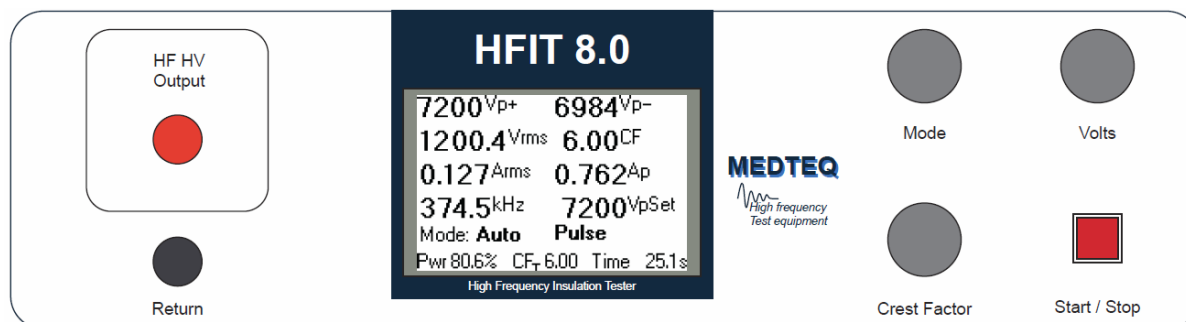
3 Getting started

This operation manual contains a significant amount of information. It is understood that users may wish to experiment with the controls prior to reading all the detail. In general the equipment is fairly robust and not easily damaged. The following key points should be checked before starting:

- The equipment is provided with internal monitoring. All warnings trigger an audible indication, with the warning type indicated on the display. The following warnings are used:
 - *Low frequency* (Sine, Modified Sine), indicates the output is below 300kHz and may be caused by too high capacitive load (typically >170pF). Output remains active.
 - *Overvoltage*: indicates an output in excess of 1225Vrms or 7250Vp. The output remains active. Once detected the system will prevent the user from increasing voltage. For voltages in excess of 1250Vrms and/or 7250Vp the system will slowly reduce the output power
 - *Overload*: indicates one of the following:
 - Current above 350mArms
 - Impedance (Vrms/Irms) below 2kΩ (approximately 200pF)
 - Output short circuit
 - *Overtemperature*: indicates over-temperature from internal parts. The output is stopped until the system cools down. It requires approximately 4min to cool down.
- As of February 2023, the units will limit the output to 60s max or 45s if high internal temperatures are detected.
- If using an external oscilloscope to monitor the waveforms, note that there are many sources of inaccuracy for peak and rms as determined by the oscilloscope (see [Section 10](#) for details). Refer to the [calibration section](#) for instructions how to check before use.
- Make sure to read the significant risks section (page before this one). To avoid burns do not touch the output when energized.
- At high frequency , the capacitance of the insulation is significant. The layout of the test sample and connecting leads should be done carefully to minimize the stray capacitance as much as possible. This equipment is designed for broad use up to 100pF load, and up to 150pF in most conditions.
- This unit is designed around a 40s test (10s ramp up + 30s testing time), and for use by R&D and third party test laboratories that will have several minutes break between tests, allowing the unit to cool down. For high demand use such as in production, or investigation, please contact MEDTEQ to determine the recommended duty cycle based on the test voltage and load, and also the possible methods to minimize the load.

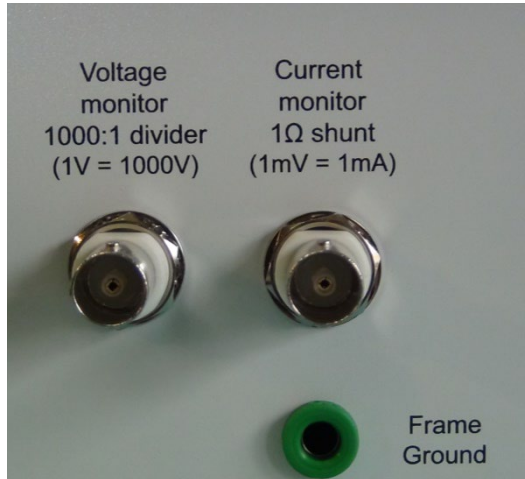
4 Functional Description

4.1 Front panel controls, connections and display



Part	Function
HF HV output	Output terminal with up to 7200Vp / 1200Vrms
Return terminal	Provides the return path and used to measure leakage current flowing through the test sample.
Mode control	Allows the user to select between the following modes: Off / Sine / Modified Sine / Burst / Pulse / Auto / Settings
Output voltage control	Off Mode: Not used Sine ~ Pulse Modes: Adjusts the output voltage Auto Mode: Adjusts the set voltage Settings Mode: Adjusts the display contrast
Crest factor Control	When the system is idle, the Crest Factor control can be used to set the timer. When the output is active: Sine, Modified Modes: Not used Burst, Pulse Modes: Adjusts the crest factor Auto Mode: Not used In Settings Mode the control adjusts the display brightness
Start/Stop button	Off Mode: Not used Sine ~ Pulse Modes: Stops output if pressed (no delay) Auto Mode: Starts output if pressed for 2s or more Stops output if pressed (no delay) Settings Mode: Not used Note: in Sine ~ Pulse modes, start button is not required
Display	Displays +Vp, -Vp, Vrms, Crest factor, Irms, Ipeak, Frequency, as well as warnings (see section on display for more detail)

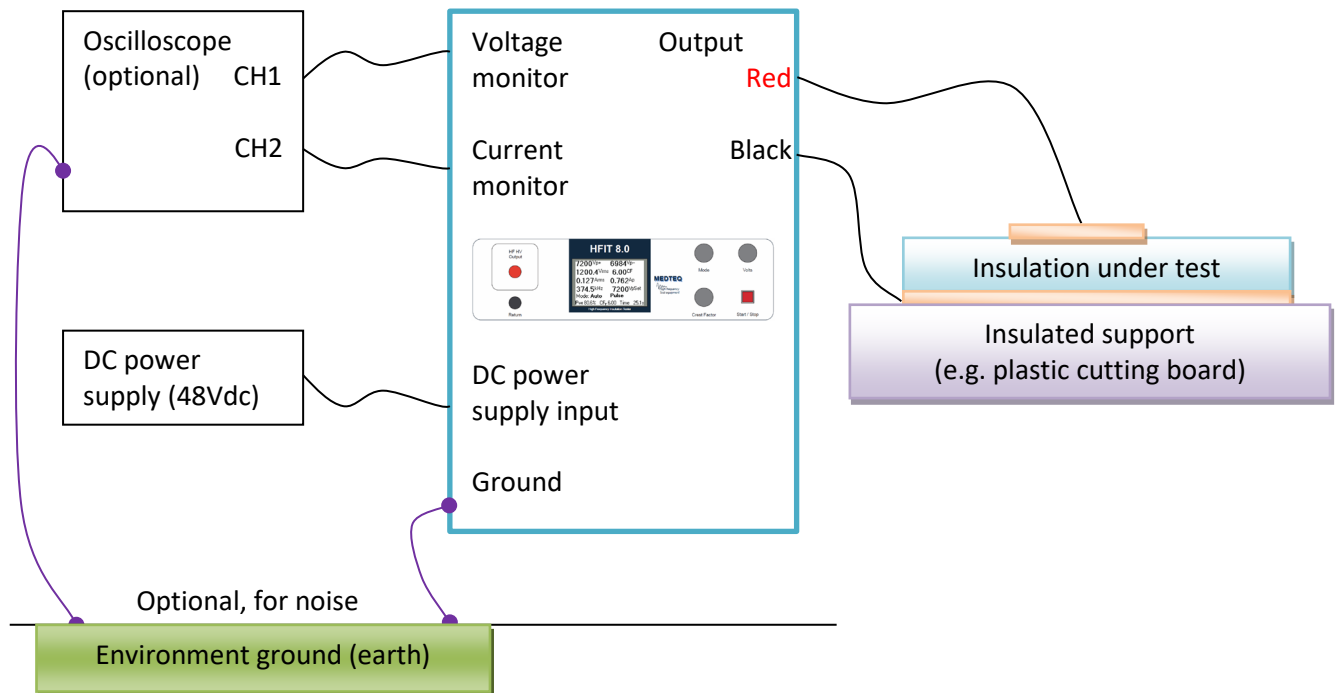
4.2 Rear panel connections



Part	Function
Voltage monitor output	BNC type connection for output to an oscilloscope. Output provides 1V/1000V of load voltage (1000:1 divider). Output is buffered with 50Ω source impedance.
Current monitor	BNC type connection for output to an oscilloscope. Output provides 1V/A of load current (1Ω shunt).
Frame ground	Connects to the frame and system ground. The frame ground is effectively the same potential as the Black HV return terminal (there is a 1Ω resistor internally which is used for current monitoring). Connection to this point is not required for testing. It could be useful to minimize noise.

4.3 Connection to external equipment and test load

The following is the typical connection of the equipment



Notes on the set up:

- For the HFIT 8.0, an oscilloscope is optional (tests can be performed stand alone).
- The common laboratory practice of disconnecting the oscilloscope earth should be avoided, as this creates high noise and affects any peak measurement on the oscilloscope
- All connections to the HV output (**red** terminal) should be minimized as far as possible, to keep the stray capacitance within the load limit. Use **short cables**, suspended **in air** from the red terminal to the test sample. The area tested (which connects to the red terminal) should be minimized as far as possible. For example:
 - in the wire wrap test, the wire wrap should be connected to the red terminal, while the core of the wire (active conductor) is connected to the black terminal
 - for samples wrapped in saline soaked cloth on a metal tray, the tray should be connected to the black terminal (being a large area), while the active electrode (smaller area) is connected to the red terminal. If the active electrode is connected to a cable, this cable should be neatly coiled (to minimize the area) and supported above any bench or metal parts (e.g. on a plastic box above metal table).
- The **insulated support** is necessary for the current monitor to work correctly. Otherwise, the return current may pass through environment ground rather than the internal 1Ω shunt.

4.4 Display

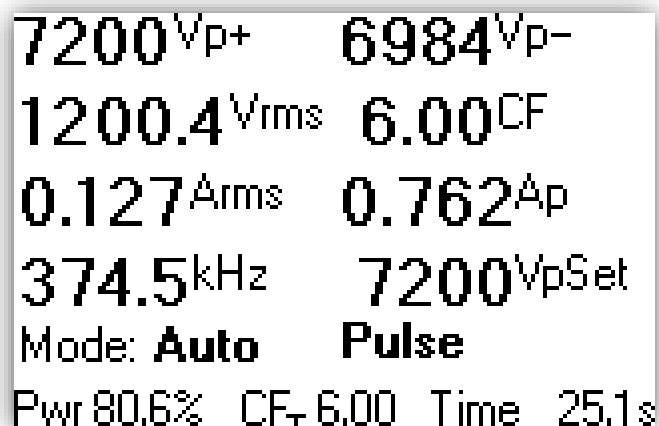


Figure 4-1: Typical display

The display includes the following items:

Vp+	Positive peak of the waveform, measured with range up to 8000Vp
Vp-	Negative peak of the waveform, measured with range up to -8000Vp
Vrms	Voltage rms, measured internally with range up to 1300Vrms
CF	Crest factor, calculated using the peak (max of Vp+ or Vp-) divided by the rms voltage
Arms	Current rms, measured internally with range up to 0.4Arms
Ap	Peak current, calculated by multiplying the rms current by the crest factor
kHz	Frequency measured internally (fundamental frequency) Only displayed for Sine and Modified Sine (Pulse, Burst modes do not have 100% duty cycle so the frequency cannot be measured)
VpSet	Auto mode only: indicates the target peak voltage for the test
Mode	Indicates the mode selected. In auto mode, also indicates the mode automatically selected.
Power	This indicates the system power from 0-99.9% (for reference only).
CF _T	Crest factor target. In Sine ~ Pulse modes, this displays the crest factor target based on the current measured peak voltage. In Auto mode, indicates the crest factor target based on the set peak. During testing, if the actual (measured) crest factor is not within ±0.2 of the target crest factor, the value will blink
Time	Timer function, which may be used in free running mode or set time mode
Warnings	The last line is also used to indicate any warnings (overload, overtemperature, frequency, over voltage)

Note: the above items are explained in more detail in the following sections

4.5 Modes of operation

4.5.1 Off

Off Mode provides a secure way to ensure the output off. The output is inhibited by two different methods and the voltage control is not effective.

4.5.2 Sine Mode

Sine Mode outputs approximate sine waves with values up to 1100Vrms (around 1600Vp.)

The sine wave is produced largely through the natural resonant frequency of the internal resonant circuit together with the external load.

As such, the frequency of the sine wave will depend on capacitance of the load. The system is designed to have approximately 460kHz at no load and 310kHz at 150pF load.

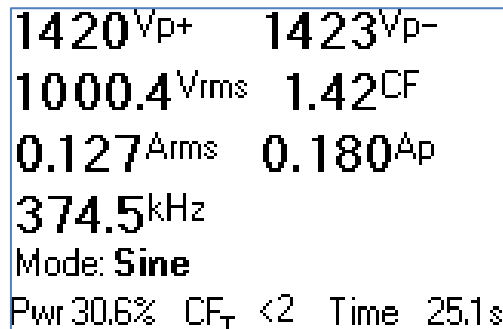


Figure 4-2: Sine Mode Screen

To maintain the sinewave, small top up pulses are added in the negative cycle. This can make the negative peak (Vp-) slightly higher than the positive peak (Vp+).

At very low voltages the sine wave mode will revert to Burst mode. This is because the sine mode relies on the natural frequency of the system and sufficient amplitude (around 50Vp) is required reliably adjust the timing of the system.

If the system measures more than 1100Vrms it will ignore any increase from the voltage control. If the system measures more than 1250Vrms, it will actively reduce the power.

As the waveform is 100% duty cycle the natural frequency can be measured with 0.1kHz resolution.

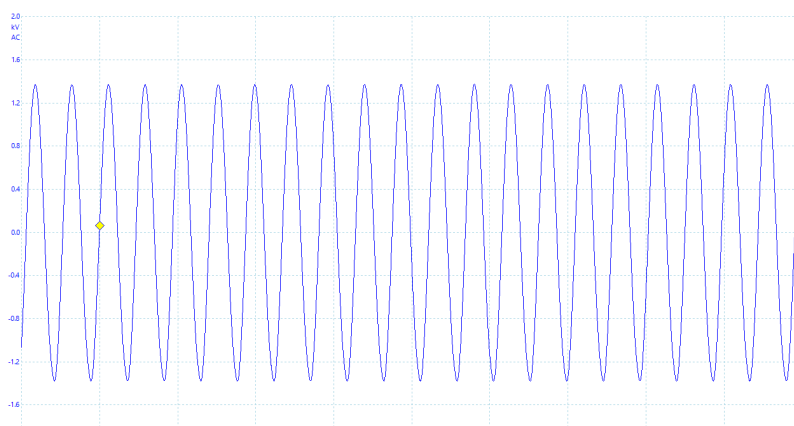


Figure 4-3 Sine Mode, typical waveform

4.5.3 Modified Sine

Modified sine is similar to Sine mode except that it includes a small amount of 12kHz amplitude modulation in order to achieve a slightly higher crest factor around 1.6-1.9 depending on the test load.

The purpose of this mode is to cover a small range of rated voltages from 1300Vp to 1600Vp (test voltages from 1560 to 1920Vp) where the use of a sine mode would create very high rms voltages, and the Burst mode may not reliably create crest factors of <2.

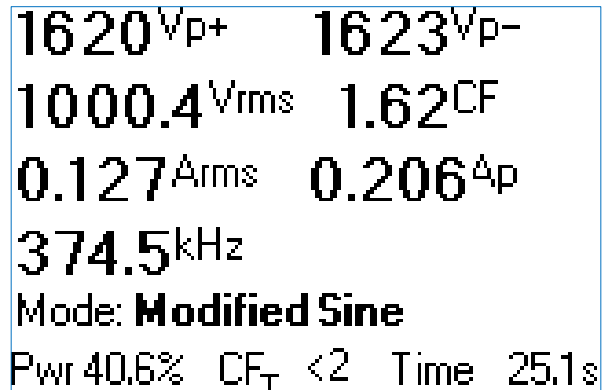


Figure 4-4: Modified Sine Sample Screen

As with Sine mode, the higher peak of Modified Sine can be in the negative cycle (Vp-).

This mode again uses the natural resonant frequency of the system including the external load. As with Sine mode, the system needs sufficient amplitude to reliable timing. As such the system initially starts in Burst mode up to ~50Vp, then Sine up to ~400Vp before starting amplitude modulation.

If the output exceeds 2100Vp or 1225Vrms the system will ignore any increase from the voltage control. If the system measures more than 1250Vrms, it will actively reduce the power.

As with Sine mode, the duty cycle is 100% so the frequency can be measured with 0.1kHz resolution.

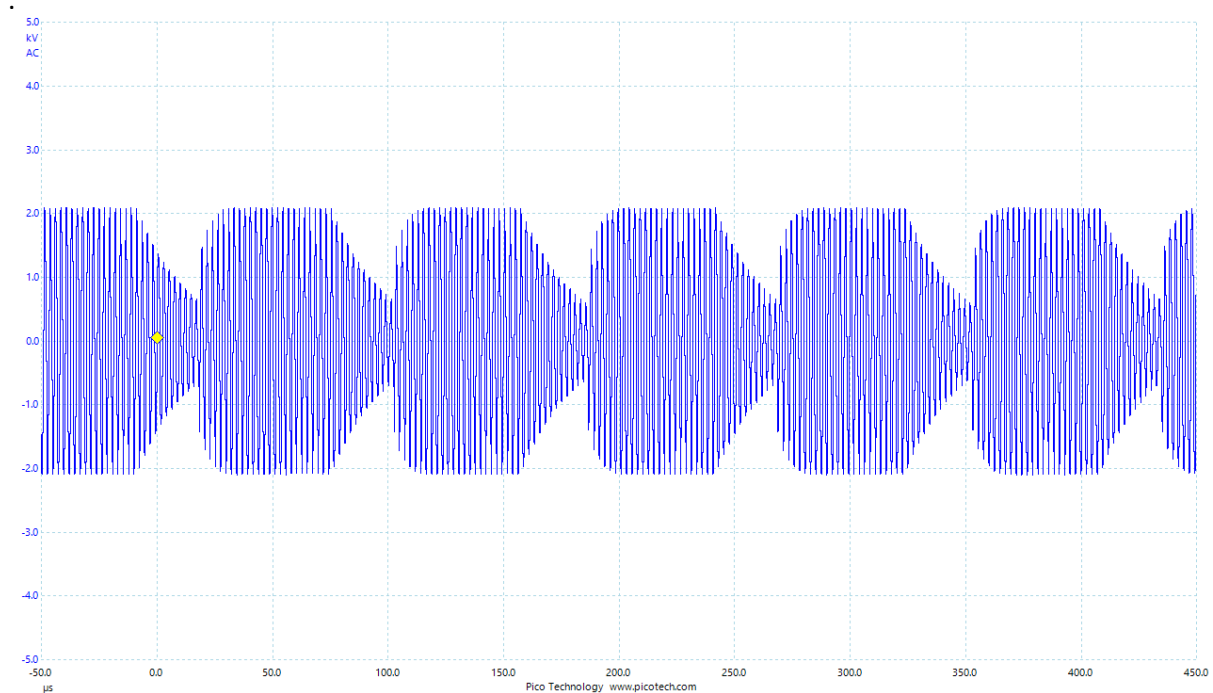


Figure 4-5: Modified Sine, typical waveform

4.5.4 Burst

Burst mode consists of bursts of sine waves at a 12kHz pulse repetition rate.

At the end of the burst, the main pulses are turned off and the output is “damped” by switching in a resistor to quickly discharge the energy in the resonant circuit. The timing of this point can be controlled to produce a variable crest factor.

Rotating the crest factor control clockwise increases crest factor. The mode can produce crest factors in the range of 1.9 – 7.0, depending on the load.

Burst Mode is designed to be used in the range of 1500 ~ 3600Vp which requires crest factor from around <2 to 4.3. In Burst mode the highest peak may be either positive or negative depending on the setting and load.

If the output exceeds 3700Vp or 1225Vrms the system will ignore any increase from the voltage control. If the system measures more than 1250Vrms, it will actively reduce the power.

As the waveform is not continuous, accurate measurement of frequency is not possible. If users wish to check the frequency in the burst is within the limits of the standard, use the Sine Mode for a spot check prior to the test.

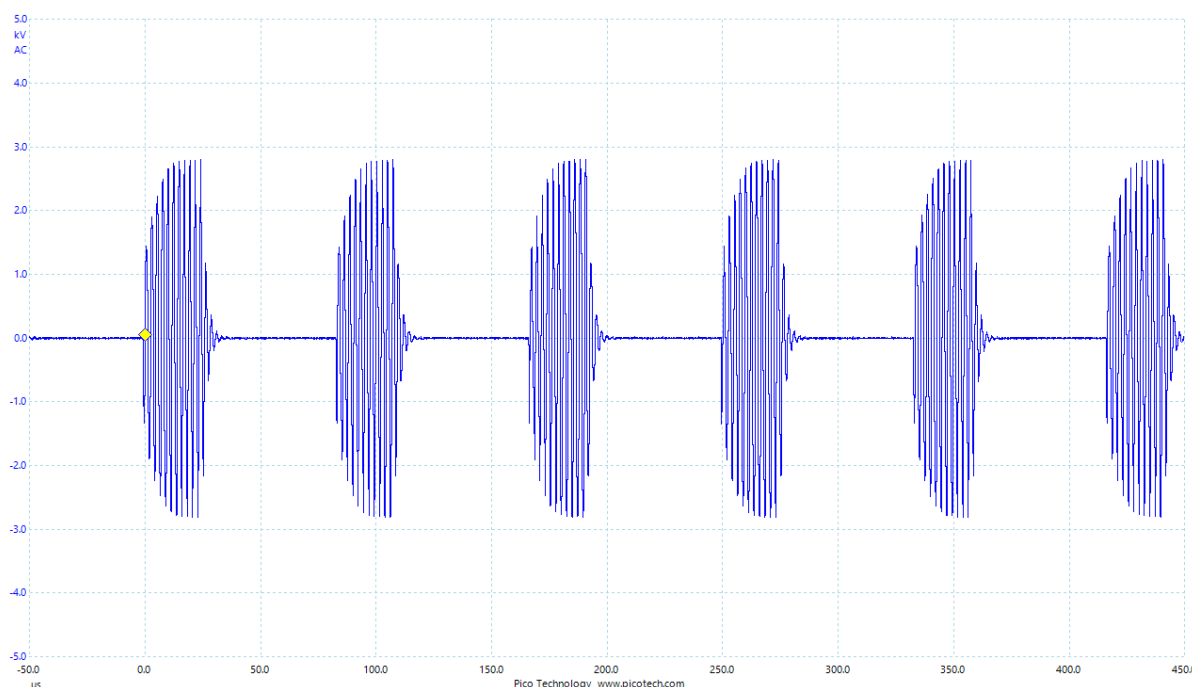


Figure 4-6: Typical Burst waveform

Note: for some units, the HFIT may be unable to maintain a crest factor of 2.0 or less under no load conditions in the region around 1700-2000Vp. If this occurs, it may be possible to re-arrange the test circuit so there is some capacitive load. Alternately, a capacitive load of 50pF high voltage capacitors can be used to create a minimum load in parallel to the test sample. The capacitors should be rated for both high voltage and high frequency (e.g. Polypropylene Pulse/High Frequency Capacitors), for example KEMET PPE capacitors, 2kV type, use 3 x 150pF in series to create 6kVp / 50pF capacitor.

4.5.5 Pulse

In Pulse mode, a high pulse is output which is then allowed to decay at the natural frequency of the circuit.

As with Burst, the crest factor can be adjusted by varying the timing in which a damping resistor is switched in to remove energy from the resonant circuit.

Rotating the crest factor control clockwise increases both the damping time and the crest factor.

This mode is designed for up to 7200Vp / 1200Vrms with crest factors varied from around 4.0 to 7.0. If the output exceeds 7250Vp or 1225Vrms the system will ignore any increase from the voltage control. If the system measures more than 7250Vp or 1250Vrms, it will actively reduce the power.

At this time, damping is only provided in the negative part of the waveform. Changes in damping timing in the positive part of the waveform do not change the crest factor. At high crest factors this effect is more noticeable. However, the crest factor can be easily adjusted to within the limits of the standard ($\pm 10\%$).

As the waveform is not continuous, accurate measurement of frequency is not possible. Users can check the frequency is within the limits of the standard using the Sine Mode.

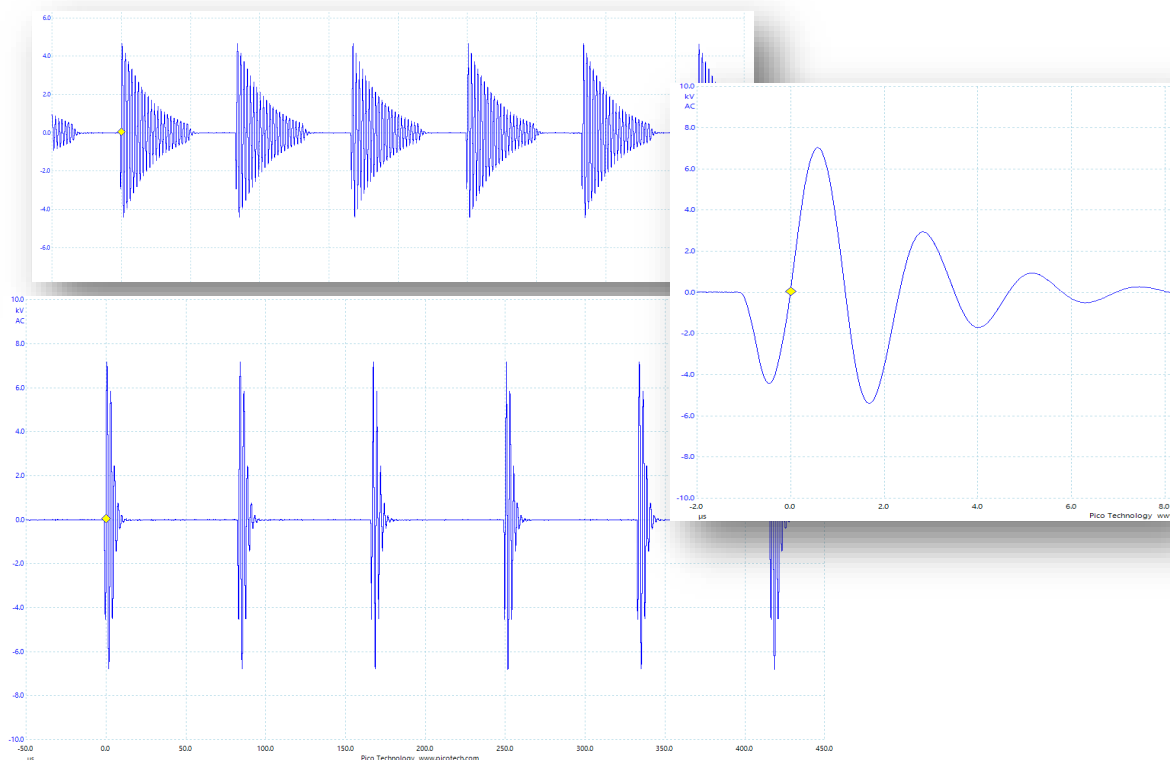


Figure 4-7: Pulse mode waveforms (high CF, low CF, expanded view)

4.5.6 Auto Mode

In Auto mode, the user sets the target peak value (VpSet) and presses the start button for 2s to start the test.

The system will then select the mode, and control the output to the required peak and damping to the crest factor required by the standard. The following modes are selected according to the target voltage:

200-1400:	Sine Mode
1410-3600:	Burst Mode
3610-7200:	Pulse Mode

```

7200Vp+   6984Vp-
1200.4Vrms 6.00CF
0.127Arms 0.762Ap
374.5kHz  7200VpSet
Mode: Auto Pulse
Pwr 80.6% CFr 6.00 Time 25.1s
  
```

During the test the user can still adjust the voltage. However, transients may occur especially around the change to different modes.

For safety the start button requires 2s push to trigger the output. There is no time delay to stop the waveform.

The value selected for VpSet is stored in permanent memory (retained with power off). This is intended for manufacturers that may have many tests at a particular voltage.

4.5.7 Timer function

For all output modes (including Auto) a timer function is provided at the bottom right corner of the screen.

Time 25.1s

At power on, the timer defaults to free running mode, in which the timer simply displays the actual test time. The timer is automatically reset when a new test is started.

When the system is idle, rotating the crest factor dial allows the user to set the test time. When this time is reached, the output will automatically stop. For testing to IEC 60601-2-2, in Auto mode it is recommended to use 35.0s or 40.0s which allows the system 5-10s to reach the target peak voltage and crest factor, and a further 30s for the actual test.

Setting the time to zero re-enables the free running mode.

As of Feb 2023, the output is limited to 60s regardless of mode or 45s if higher internal temperatures are detected. This is to prevent damage to the unit due to excessive test times. No off time is enforced, however users are recommended to allow about 2-3min off time depending on load.

4.5.8 Settings Mode

In the settings mode the user can adjust the display contrast using the Voltage Control and and brightness using the Crest Factor control.

These settings are stored in permanent memory (retained with power off).

Setting
 Volts ⇒ Contrast CF ⇒ Brightness

4.6 Warning messages

The following table shows the warning messages, meaning, system response and user action. All warnings are accompanied by a triple beep (may be repeated every 3s depending on warning).

Message	Meaning / System response	User action
Warning: Output under 300kHz	Due to high capacitive load, the output. This warning is only effective in Sine, Modified Sine Modes. Output remains on.	Reduce capacitance: - reduce amount of sample being tested - check if red/black orientation is best
Warning: Overload / short	Detected by either: - power circuit over current - output less than 2kΩ - output current > 350mArms Output remains on (current limited)	Check for short circuits in the test set up. If the overload is due to test sample breakdown, it is recommended to allow 5-10s to ensure permanent damage.
Warning: Output over 1200Vrms	Triggered when output Vrms exceeds 1225Vrms as measured by the system. Output remains on. If output exceeds 1250Vrms output will actively reduce.	Reduce voltage <i>or</i> for Burst/Pulse increase crest factor
Warning: Overvoltage >7250Vp	Triggered when output Vpeak exceeds 7250Vp Output remains on. Output will actively reduce while over 7250Vp.	Reduce voltage
Output stop (internal temperature)	Main internal heatsink is over 70°C. Output is stopped until the heatsink cools below 60°C.	Wait for message to clear. For continued use at heavy loads, allow 4-5 minutes for the system to fully cool.

Notes:

Overvoltage (Vpeak, Vrms) can be caused by fast increase in voltage setting such that the output increases faster than the system can measure. Vrms overvoltage can also be triggered by changes in the crest factor for Burst, Pulse modes.

Over temperature is most likely caused by long duration use or long duration short circuit. It should not trigger in normal testing.

5 Principle of operation

5.1 Basic pulse

The main output is created using a switched resonant circuit:

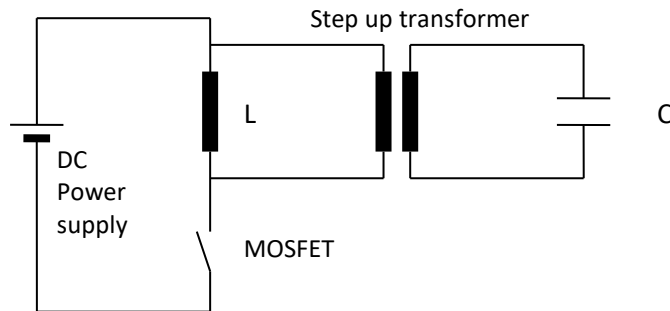


Figure 5-1: Simplified circuit of the HFIT 7.0

The MOSFET switch is pulsed (turned on) for less than 1μs during which energy is stored in both the capacitor C and inductor L. When the switch is turned off, the L and C form a resonant circuit, transforming the energy back and forth between magnetic and electrical forms, coupled by the transformer (N turns). The resonant frequency of the circuit is determined from:

$$f_R = \frac{N}{2\pi\sqrt{LC}}$$

Heat energy is lost in the inductor, capacitor and transformer, resulting in a decaying waveform with a frequency of approximately f_R , as follows:

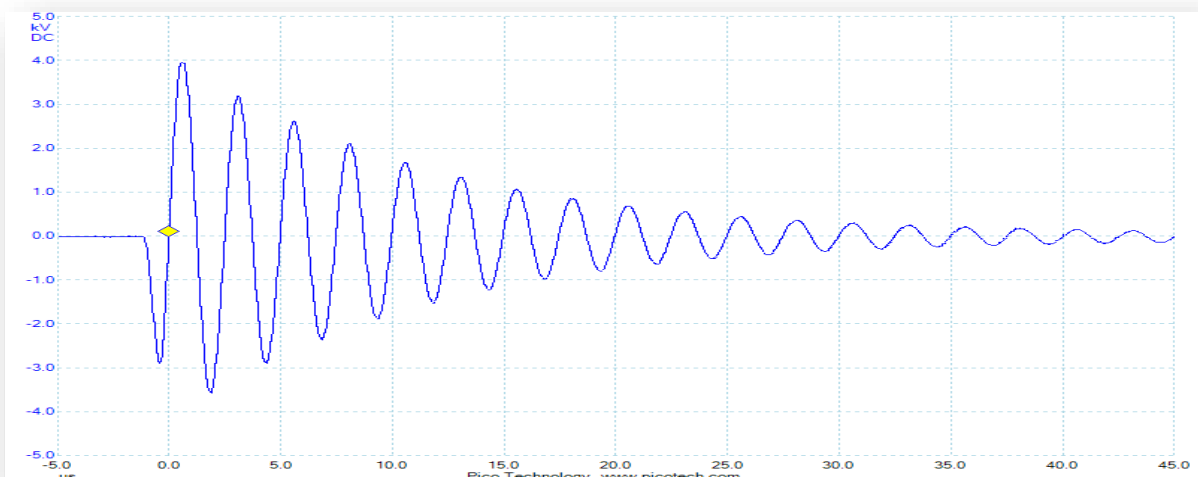


Figure 5-2: 4kVpeak decaying sine wave, 380kHz (1kV/div, 5μs/div)

If new MOSFET pulses are provided regularly, the result is a pulsed decaying waveform as follows:

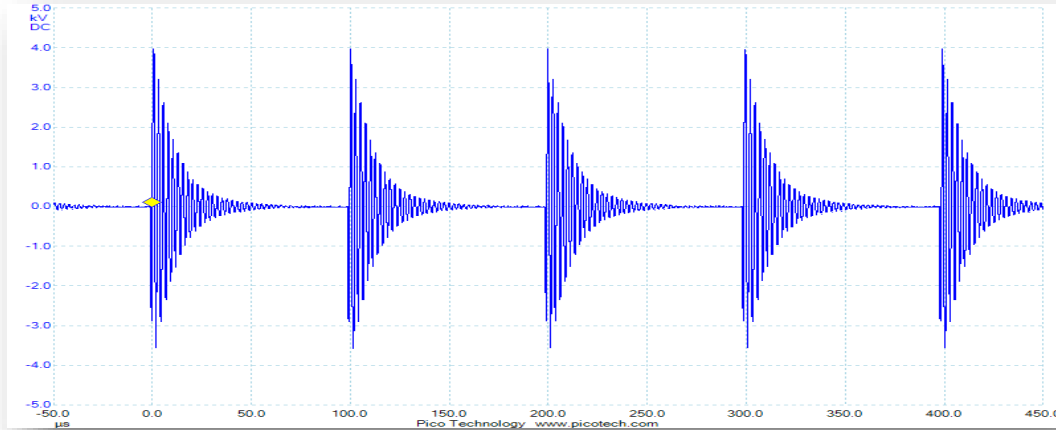


Figure 5-3: Repeated pulses of decaying sine waves (pulse repetition rate 10kHz)²

The crest factor of the output is determined from dividing the peak voltage by the rms voltage:

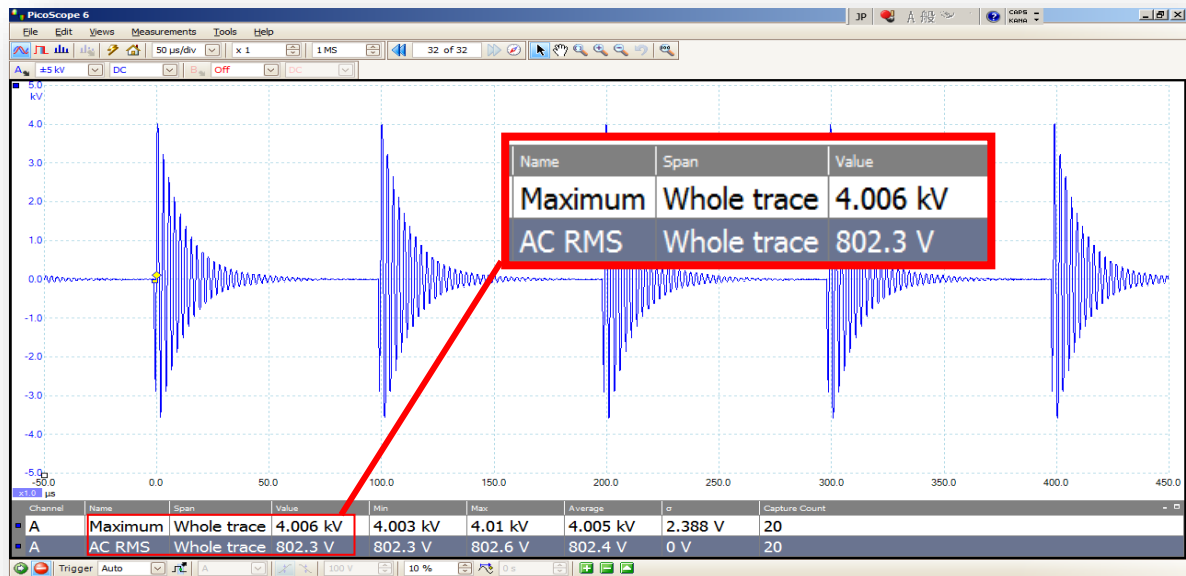


Figure 5-4: A 380kHz decaying sine wave, pulse repetition rate of 10kHz

The crest factor (CF) for the above waveform is calculated as:

$$CF = \frac{V_{peak}}{V_{rms}} = \frac{4006}{802} = 5.00$$

² Note that as of February 2014, the pulse repetition rate has been fixed at 12kHz.

5.2 Pulse, crest factor modification

The crest factor of the pulse waveform can be increased by switching in a “damping” resistor (after the peak) to absorb the energy of the pulse.

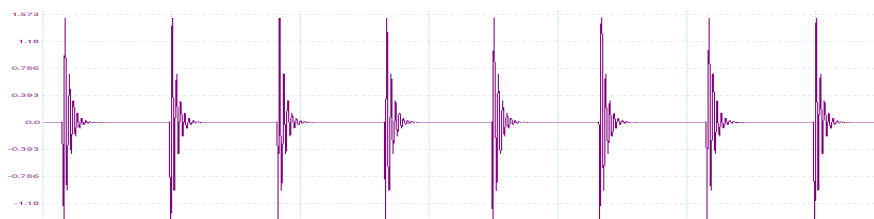


Figure 5-5: High crest factor pulse mode

The timing of this switching is controlled by the “Crest factor” control. The approximate crest factor range is 4.0 to 6.0, but the actual crest factor is affected by the load. The load is typically capacitive insulation, and increasing the capacitance will reduce the crest factor. However, the load may also have a high dissipation factor (see 7.1), in which case the crest factor will increase.

5.3 Basic sine wave

A sine wave mode can be created by adding a small amount of “top up” energy in the negative part of the each cycle in the waveform:

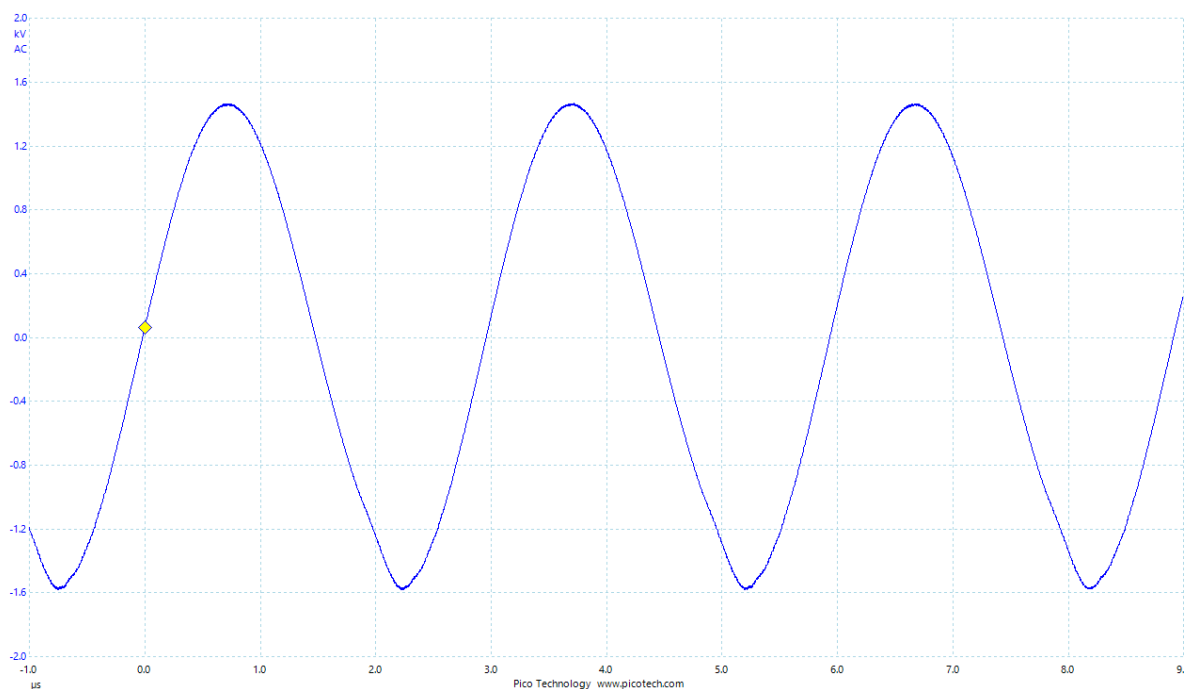


Figure 5-6: Sine wave mode

Because the resonant frequency depends on the capacitive load, the sine wave mode relies on feedback to trigger right timing of the top up pulse. To get the mode started, the equipment uses Burst mode until this feedback is effective. The minimum voltage which the feedback works reliably is around 50Vpeak.

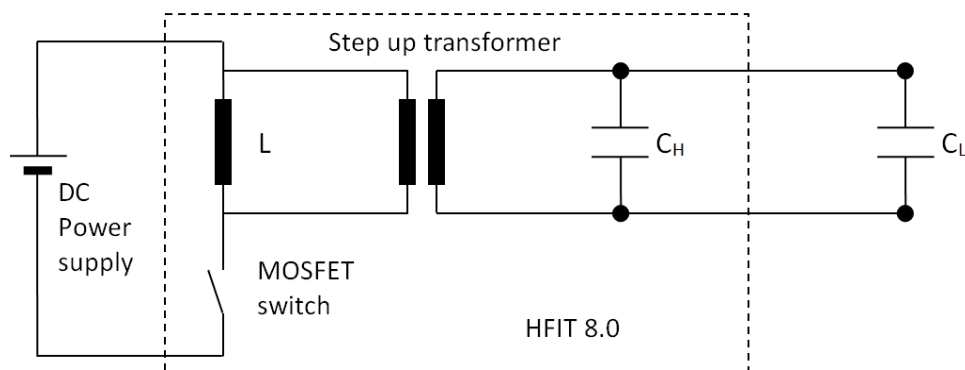
5.4 Modified sine, Burst modes

As described in Section 4.5.3 Modified Sine is a amplitude modified sine wave. It is created by temporarily turning off the top up pulses and allowing the waveform to decay naturally for a short period at the 12kHz repetition rate. The decay is limited so the waveform is still continuous.

As described in Section 4.5.4, Burst is essentially bursts of sinewaves at the natural frequency, which are truncated by switching in a damping resistor which removes the energy from the resonant circuit. The timing of the damping can be used to create an adjustable crest factor.

5.5 Effect of the test load (insulation under test)

The insulation under test will typically have a capacitance (C_L) in the order of 10-100pF. This combines with the internal capacitance C_H to form a resonant circuit:



As such, the capacitance C_L will affect the resonant frequency and the test frequency. The resonant frequency is proportional to:

$$f_R \propto \frac{1}{\sqrt{C_H + C_L}}$$

The internal capacitance C_H has been selected so that the under no load condition ($C_L = 0$), the resonant frequency is around 450kHz, while at maximum load ($C_L = \text{max}$), the resonant frequency is above 300kHz (within the limits of the standard, 400kHz \pm 100kHz). If a significantly larger load than rated is applied the resonant frequency may fall below 300kHz, the minimum allowed in the standard.

5.6 Effect of test sample breakdown

Although the equipment operates in a resonant mode, the HFIT can still provide a large amount of power in the form of heat, well in excess of what is needed to destroy the insulation in the case of dielectric breakdown. Tests with PVC insulation deliberately caused to breakdown result in arcing, burnt insulation and fire during which the HFIT output remains on.

The different types breakdown (dielectric strength, thermal, corona) are discussed in more detail in section 7, including ways to detect if breakdown has occurred.

6 Operation

6.1 HF Dielectric strength testing

Always use the standard (e.g. IEC 60601-2-2) as the primary reference.

The dielectric strength test should be performed according to the following procedure:

- Pre-condition the sample as required in the standard (e.g. sterilized, soaked in saline solution for 24hrs)
- Set up the equipment as shown in Section 4.3
- Select a suitable mode for the peak voltage or select Auto mode (see following page for guidance based on rated voltage)
- If performing the test of the handle and electrodes, it is recommended to use a metal tray as the return electrode, in which the the test sample wrapped in saline soaked cloth is used. The high voltage should be applied to the active electrode. The area tested should be minimized to keep capacitance within limits, see table below. If necessary sections with different design attributes (thickness, layers etc.) should be tested separately.
- If performing the wire wrap test, wrap the 0.4mm wire around the insulation as described in the standard. It is preferred to apply the high voltage to the wire instead of the active electrode (to minimize capacitance), and the active electrodes is the return path.
- If using Burst or Pulse mode, check the test frequency first by operating in Sine mode at 400Vp and confirming the frequency is >300kHz as required by the standard. The frequency can be used also to estimate the load:

Load	Typical frequency	Limitations for use (based on 25% duty cycle)
No load	460-470 kHz	Repeated use at 7.2kV may cause instability
50pF	385-395 kHz	None
100pF	360-370 kHz	None
150pF	325-335 kHz	Limited to 6kV
>150pF	< 325 kHz	HFIT may operate OK but is outside of ratings.

During the test, monitor the test frequency, peak voltage and the crest factor, and load current for signs of corona, non-linear current or breakdown. The HFIT 8.0 displays the target crest factor based on the current peak (for Sine ~ Pulse modes) or target peak (for Auto mode). Since the test voltage is 20% of rated voltage, the effective formula used is for the display:

$$CF_T = (V_p / 1.2 - 400) / 600$$

If the displayed number of CF_T is blinking, it indicates the value is outside the range allowed by the standard (If $V_p > 1920$, tolerance of $\pm 10\%$, otherwise < 2). In Auto mode the software will adjust the crest factor to within ± 0.03 if $V_p > 1920$ or 1.9 otherwise. This may take around 10s.

If warning / beeping occurs, check the [section on warnings](#) for meaning and action.

6.2 Mode selection, load limit (based on rated voltage)

According to IEC 60601-2-2:2009, the test voltage peak should be 120% of the rated peak voltage. The crest factor varies depending on the rated peak voltage and is allowed a moderate tolerance. The following table shows values based on rated voltages 6000Vp, and the allowable range of crest factors and rms voltages, recommended mode, and any limits based on load.

Vp (rated)	Crest Factor			Vp (test)	Recommended mode	Vrms			No Load	50pF	100pF	150pF
	Min	Nominal	Max			Min	Nom.	Max				
500	1.4		2	600	Sine	300	-	426	OK	OK	OK	OK
1000	1.4		2	1200	Sine	600	-	851	OK	OK	OK	OK
1200	1.8		2	1440	Burst	720	-	800	OK	OK	OK	OK
1300	1.8		2	1560	Burst	780	-	867	OK	OK	OK	OK
1400	1.8		2	1680	Burst	840	-	933	OK	OK	OK	OK
1500	1.8		2	1800	Burst	900	-	1000	OK	OK	OK	OK
1600	1.8		2	1920	Burst	960	-	1067	OK	OK	OK	OK
1700	1.95	2.2	2.38	2040	Burst	856	941	1046	OK	OK	OK	OK
1800	2.1	2.3	2.57	2160	Burst	842	926	1029	OK	OK	OK	OK
2000	2.4	2.7	2.93	2400	Burst	818	900	1000	OK	OK	OK	OK
2200	2.7	3.0	3.30	2640	Burst	800	880	978	OK	OK	OK	OK
2400	3	3.3	3.67	2880	Burst	785	864	960	OK	OK	OK	OK
2600	3.3	3.7	4.03	3120	Burst	774	851	945	OK	OK	OK	OK
2800	3.6	4.0	4.40	3360	Burst	764	840	933	OK	OK	OK	OK
3000	3.9	4.3	4.77	3600	Burst	755	831	923	OK	OK	OK	OK
3200	4.2	4.7	5.13	3840	Pulse	748	823	914	OK	OK	OK	OK
3400	4.5	5.0	5.50	4080	Pulse	742	816	907	OK	OK	OK	OK
3600	4.8	5.3	5.87	4320	Pulse	736	810	900	OK	OK	OK	OK
3800	5.1	5.7	6.23	4560	Pulse	732	805	894	OK	OK	OK	OK
4000	5.4	6.0	6.60	4800	Pulse	727	800	889	OK	OK	OK	OK
4200	5.4	6.0	6.60	5040	Pulse	764	840	933	OK	OK	OK	OK
4400	5.4	6.0	6.60	5280	Pulse	800	880	978	OK	OK	OK	OK
4600	5.4	6.0	6.60	5520	Pulse	836	920	1022	OK	OK	OK	OK
4800	5.4	6.0	6.60	5760	Pulse	873	960	1067	OK	OK	OK	OK
5000	5.4	6.0	6.60	6000	Pulse	909	1000	1111	OK	OK	OK	OK
5200	5.4	6.0	6.60	6240	Pulse	945	1040	1156	OK	OK	OK	OS
5400	5.4	6.0	6.60	6480	Pulse	982	1080	1200	OK	OK	OK	OS
5600	5.4	6.0	6.60	6720	Pulse	1018	1120	1244	OK	OK	OK	OS
5800	5.4	6.0	6.60	6960	Pulse	1055	1160	1289	OK	OK	OK	OS
6000	5.4	6.0	6.60	7200	Pulse	1091	1200	1333	LC5	OK	OK	OS

Key for load:

OK = does not trigger overtemperature alarm in 23°C room, normal air flow around the device, no sunlight, tested continuously with a 3min test cycle of 45s on 2min 15s off (25% duty cycle)

LCx = test as above, but limited to the number of cycles as indicated by “x” (longer cycles may trigger overtemperature, overload alarms and lead to damage).

OS = outside of specification (above 6000p, the unit is designed for maximum 100pF load)

6.3 HF Leakage current testing

For leakage current testing, use the following the procedure:

- Set up the equipment as shown in Section 4.3
- Select the auto mode and set to 400Vp (Sine mode is automatically selected).
- Mark off at most 30cm length of the test sample (e.g. using tape or marker) (see notes below)
- Immerse that section of the test sample in an insulated beaker, filled with saline solution
- Insert a return electrode into the saline solution
- Start the output (press the red start/stop button for 2s)
- Confirm the applied voltage is 400Vp
- Record the rms current (Irms) and the test frequency as displayed (or, on an oscilloscope if the required for according to laboratory procedure).
- Calculate the allowable limit using the formula in the standard

In Clause 203.1 of IEC 60601-2-2, Note 1 clarifies that the limit is based on rms current, which also aligns with the derivation of the limit from first principles. However, note that the voltage used in the formula is 400Vp (or as required for the test).

In the 2017 edition of IEC 60601-2-2, the limit has been raised by a factor of approximately 2.2.

The HFIT 8.0 has a resolution of 1mA for displayed values, and an accuracy of $\pm 3\%$.

Note regarding 30cm length: according to the standard the full length but not more than 30cm shall be tested. However, some endoscopic or trocar devices with thin insulation in the order of 0.1mm are likely to exceed the 150pF limit of the HFIT with a length of 30cm.

Since the test is ultimately based on current density (the limit is derived from 25mA/cm², see the rational), if the material under test is homogenous (same, consistent design) it is justified to test a shorter length as representative, provided that the actual test length is used in the formula. Alternatively, the full length can be tested in sections.

Note regarding IEC 60601-2-2:2017, Amendment 1(2023): This amendment clarifies that any handle should be included in the test. However, from basic design principles, only sections of thin insulation directly in contact with the active electrode can have measurable leakage. Examples are cables or heat shrink on a metal shaft. For a typical material with relative permittivity ($\epsilon_r = 2.0$), it would require a thickness $< 0.16\text{mm}$ to fail the test. Most accessible parts of a handle will have significantly thicker material and will not be adjacent to the active electrode. Therefore, while test data may be required for the handle, the priority in testing should be given to insulating materials of $< 0.5\text{mm}$ thickness and adjacent to conductive parts of the active electrode.

7 HF insulation breakdown – theory and detection

7.1 Thermal effects / dielectric dissipation factor (δ)

All insulating materials heat up when an ac voltage is applied.

At very low frequencies, such as 50/60Hz mains, this effect is tiny and requires very high voltages to become significant. However at electrosurgery frequencies around 400kHz, the effect is significant at even at relatively low voltages, with some materials having observed temperatures exceeding 100°C well below 1000Vrms.

The insulation under test can be modelled as an ideal capacitor in series with a resistor. The property of the material generally used is the “dissipation factor” or “loss tangent”, which needs to be measured around the frequency of interest.

A dissipation factor of 1% effectively means that 1% of the impedance appears as resistive component, and 1% of the apparent power will end up as heat. For example, if the capacitance of a test sample is 100pF, has a dissipation factor $\delta = 2\%$, and is tested at 1000Vrms, 400kHz, the calculations are:

$$\begin{aligned} \text{C impedance} &= 1/(2\pi \times 400\text{k} \times 100\text{p}) = \sim 4000\Omega \\ \text{Power (apparent)} &= 1000^2 \times 2\pi \times 400\text{k} \times 100\text{p} = \sim 250\text{VA} \\ \text{Resistive component} &= 4000\Omega \times 2\% = 80\Omega \\ \text{Heat in test sample} &= 250\text{VA} \times 2\% = 5\text{W} \end{aligned}$$

Generally, the physical volume of the insulation in the test sample is small, so power of 5W can easily produce very high temperatures. However, the actual temperature will vary greatly depending on the set up and the physical construction of the test sample. If the insulation is tested in water, water will cool the insulation. If the test sample has a large metal surface it can also cool the insulation. Thick material can sometimes end up worse than thin materials, as the heat cannot escape from inside the insulation as easy.

Different materials have different amounts of heating, for example Teflon has very low dissipation (δ typically <0.1%), while PVC has relatively high dissipation (1-3%).

The amount of heat produced is a function of the rms voltage squared, so a 10% increase in voltage can produce 21% more heat. The amount of heat is also a function of thickness squared (inverse), so a 10% reduction in thickness produces 21% more heat.

As such, accurate control of the rms voltage is important for the test. Also, if the insulation thickness varies in real production, testing of multiple samples is reasonable.

The HFIT has been tested with simulated high dissipation factor loads (100pF in series with 320 Ω , $\delta = \sim 8\%$, around 10W resistive load at 1000Vrms, 300kHz). The output remained stable and was able to reach all specifications. A factor of $\delta = \sim 8\%$ is expected to be well above all reasonable quality insulation at HF.

In many cases, high temperatures in the order of 100°C can be reached but the insulation does not break down if this is below the thermal limits of the material. This is allowed in IEC 60601-2-2 (and IEC 60601-2-18), but it may be undesirable particularly for insulation used in endoscopes or catheters (internal use).

If the thermal limits of the material are reached, the insulation usually falls into thermal runaway and complete breakdown. This may eventually exceed the limits of the HFIT and cause the overload indicator (beeping sound with output on).

It is recommended to research the dissipation factor for the material selected and confirm it is appropriate for use at the voltage specified (see more information on the [MEDTEQ website](http://www.medteq.net)).

Also, it is possible to perform experiments on the temperature of the insulation. A method used by MEDTEQ is to wrap the insulation in thin copper foil (0.05mm) with a thermocouple inserted. Apply the HIT HF HV terminal to the internal conductor, and the HFIT Return terminal to the copper foil (to avoid damage of the temperature monitor/logger). Apply 30s of the rated voltage and measure the temperature of the insulation at the end of test after the voltage is removed (during the test, the temperature monitor/logger may not accurately measure the temperature due to noise). It is recommended to avoid materials that have a temperature rise of more than 10°C at rated voltage³.

7.2 Dielectric breakdown

All insulating materials have a breakdown point which the applied voltage will cause permanent breakdown. At high frequency, for most materials this voltage will be higher than the other causes of breakdown documented here (thermal, corona).

The material's dielectric strength is normally easy to find in the material specifications, usually in kV/mm.

It should be noted that the high frequency test is to be followed by a mains frequency test at 1kV above the rated voltage, which may be significantly higher than the peak high frequency test voltage.

7.3 Purple (blue) corona

According to IEC 60601-2-2, blue corona can be ignored. However, test experience indicates this may be the main cause of breakdown, particularly for thin insulation.

Corona is the breakdown of air around the edges of the test electrode. Corona releases heat and ozone, both of which can damage the surface of the insulation. If the insulation is thin, this surface damage may be enough to cause permanent breakdown.

The presence of corona can be detected by a buzzing noise, the smell of ozone and the blue/purple light, which can be best seen in a darkened room. Small amounts of corona can be detected by oscilloscope (ns pulses in current monitor) and have been detected at voltages as low as 1200V, however intensity sufficient to damage insulation usually occurs at 1500V or higher.

³ In real clinical situations, there are likely to be heat sinks around the insulation to reduce the temperature, and the voltage is unlikely to be applied for 30s. More research is required to develop an appropriate limit.

The onset of corona can be fairly consistent, however, the onset of permanent breakdown is random, sometimes within 100V of visible corona, sometimes an additional 1000V causes no breakdown. Theoretical simulations indicate that the thinner the insulation, the lower the voltage at which corona occurs. Since the damage mechanism is surface damage, thinner insulation is also more likely to be permanently damaged from corona. Therefore, thin insulation is particularly vulnerable to the effects of corona.

It is recommended that if the insulation is thin (e.g. 0.2mm or less), there should be no visible corona at rated voltage.

7.4 Orange corona

Tests with saline soaked cloth have been found to cause random unexpected failures. The effect is suspected to be due to isolated drops of saline liquid which then sets up a voltage divider and causes dielectric stress along the surface of the insulation. If the surface is contaminated with residuals from saline, dust, fibers from the test cloth, a breakdown can occur which then burns off these materials, creating an orange colored corona. Orange corona indicates temperatures of 1000°C or more, and can easily burn through thin insulation. Since this is unrelated to the dielectric strength of the material, it should not be considered a test failure according to the standard. Test methods can take care to avoid isolated drops.

7.5 Limitations in IEC 60601-2-2

Currently the standard has the following limitations:

- No limit for the temperature of the material during tests. Material is in direct contact with the patient or devices that can transfer heat to the patient (e.g. cannula, endoscope, catheter), may cause burns if the insulation material heats up significantly.
- Dielectric heating is proportional to rms voltage squared and frequency. The standard has very relaxed controls for both these parameters. It is recommended the standard has a temperature rise test specially for dielectric heating. For example, test using an approximate sine wave at 300-500kHz with V^2f equivalent to 700Vrms at 400kHz, and a limit of 10°C rise.
- The standard ignores the effects of corona (purple and orange), which is significant for thin insulation. A minimum insulation of 0.2mm or 0.25mm is recommended.
- The standard only requires one sample to be tested. Variations in insulation thickness can have large impact for both thermal and corona effects, suggesting that a single test sample may not be suitable as a “type test” (representative of regular production).
- The standard refers to the use of oscilloscopes (and by implication, high voltage probes and current probes), even though these have high errors and lack traceable calibration in the frequency range of 300-500kHz.

For these reasons, it is strongly recommended that manufacturers research the material and ensure that the dissipation factor is appropriate, and thickness is controlled, and corona is minimized.

8 HFIT Measurement methods, error analysis and validation

8.1 Background

Measurements of peak and rms voltage are critical for the test, however at this time there exists no known ISO 17025 accredited third parties which can calibrate these values at the frequency and voltages used in this system. The combination of both high voltage and high frequency presents unique challenges for determining absolute values. National laboratories are normally limited to around 100Vrms/500kHz (far lower than the 1200Vrms/460kHz used in the HFIT), and there are no known accredited calibration services which can confirm peak values at high voltage/high frequency.

As such, a detailed description, error analysis and validation are provided to give users confidence in the measurement methods used in the HFIT.

These methods have been specially designed by MEDTEQ to be *intrinsically* or *inherently* accurate in the range of interest. Most accurate measurement systems are designed approximately and then adjusted against a higher accuracy reference system. For example the MEDTEQ HBTS (temperature) and PPS (pressure), IBPS (IBP simulator) are roughly accurate when assembled, and then adjusted in production against precision reference equipment.

Such an accurate “off the shelf” reference does not exist in for high frequency/high voltage region. However, one key advantage for the HFIT system is that there is no *transducer* which converts non-electrical parameters to electrical form. For this system, it is simply voltage in (as a waveform) and voltage out (peak and rms as dc values).

As such it is possible to design a system which intrinsically accurate *as assembled*, through the use of precision components such as 0.1% resistors, 0.1% DAC/ADC reference, and through the careful review of any parameters that may affect the frequency response of the system. In general the parts of the measurement system are designed to be well above the 11MHz 3dB bandwidth, a point which is calculated to have 0.1% effect at 500kHz.

This intrinsically accurate measurement system in the HFIT is then compared against an independent reference system. The reference systems developed by MEDTEQ include a mix of wideband thermal methods and 12 bit digital oscilloscopes which have been adjusted to be accurate at the frequency of interest, and common error sources investigated and minimized.

These reference methods are complex, however the key point is that they are independent of the HFIT measurement system. Thus when HFIT measurements are confirmed to match within around 1% of the reference system under a wide variety of conditions (range, frequency, crest factors), it provides a high level of confidence in the values displayed.

The reference methods are also traceable back to a calibrated, precision multimeter (Fluke 8845A) which has accuracy specifications better than 0.1% up to 50kHz. The wideband thermal method is used to extend this up to 500kHz.

8.2 Voltage divider

The system includes a 1000:1 capacitive voltage divider which uses a series of 150pF mica capacitors (15 in total, resulting in a 10pF load to the high voltage output).

Mica capacitors have been selected due to their high precision, reliability and stability, extremely low dielectric heating and constant capacitance with voltage and frequency. The divider output is filtered (3dB = 18MHz) and buffered, with the output available to users via the external BNC connector. The BNC output has an additional filter (3dB = 15.4MHz). Both of these filters have negligible effect at 500kHz.

The capacitors are sold with a tolerance of $\pm 5\%$ and as such the divider ratio requires a minor adjustment typically within $\pm 2\%$ of ideal values.

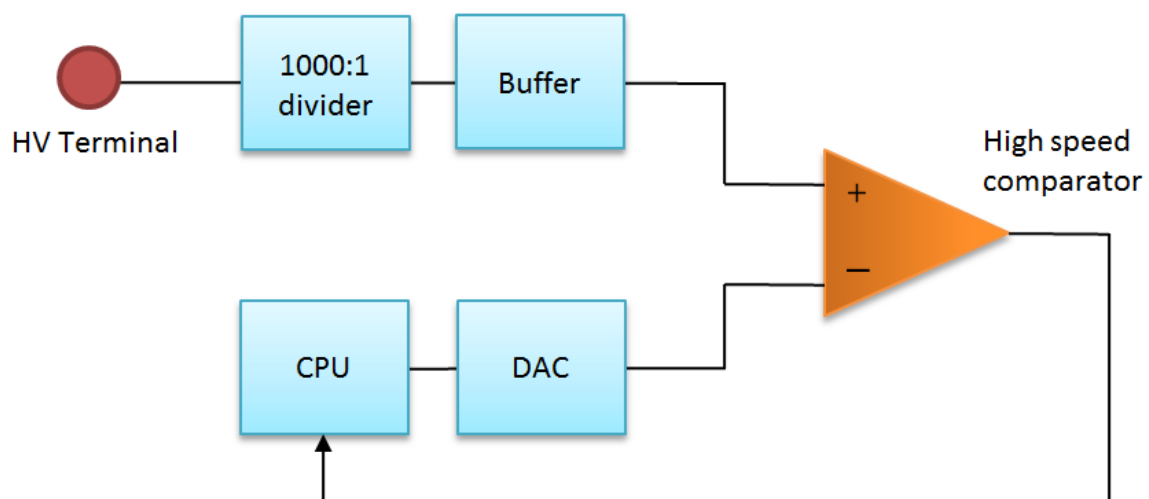
This adjustment is made using two wideband rms meters (one range 200Vrms, the other 200mVrms). A sine wave of 150Vrms at 400kHz is applied and monitored for low harmonic distortion ($< 0.3\%$ THD). The divider is then adjusted to within 0.1% of the ideal ratio (1000:1) at the buffer.

After adjustment the divider is checked at 300kHz, 400kHz and 460kHz and confirmed to be within 0.2% ($\pm 0.3V$) when tested at 150.0Vrms.

8.3 Peak voltage

8.3.1 Method overview

Peak voltage is detected by means of a software controlled comparator, as per the following simplified diagram:



One input to the comparator is derived from the divider output with 1000:1 ratio (e.g. 7200Vp is 7.20Vp at the comparator input). The other input is set by software via a precision DAC with 12 bit resolution. The DAC is set to a known voltage (e.g. 4.000Vdc), and the software watches the output of the comparator for 10ms.

Any trigger indicates the DAC is below the peak of the output waveform (i.e. the peak is >4000Vp), while no trigger indicates the peak must be <4000Vp. The software uses this indication together with successive approximation method to find the precise value of the actual peak. This requires 12 steps (one for each bit), making a total of 120ms for the full measurement process.

Positive and negative peaks are independently tested, thus the complete process takes 240ms. The measurement is repeated every 350ms (approximately 3 readings per second).

The measurement method is similar to successive approximation ADC, except that there is no sample and hold circuit and instead the comparator is used to watch for a trigger against the high frequency waveform over a fixed period (10ms).

8.3.2 Error analysis

The system is designed to be intrinsically accurate through the use of precision components (0.1% resistors, 0.1% DAC reference voltage), bandwidth, response time, slew rate, are well above those required for the frequency of interest. No production adjustments are made for gain or frequency response of the measurement system after the main divider.

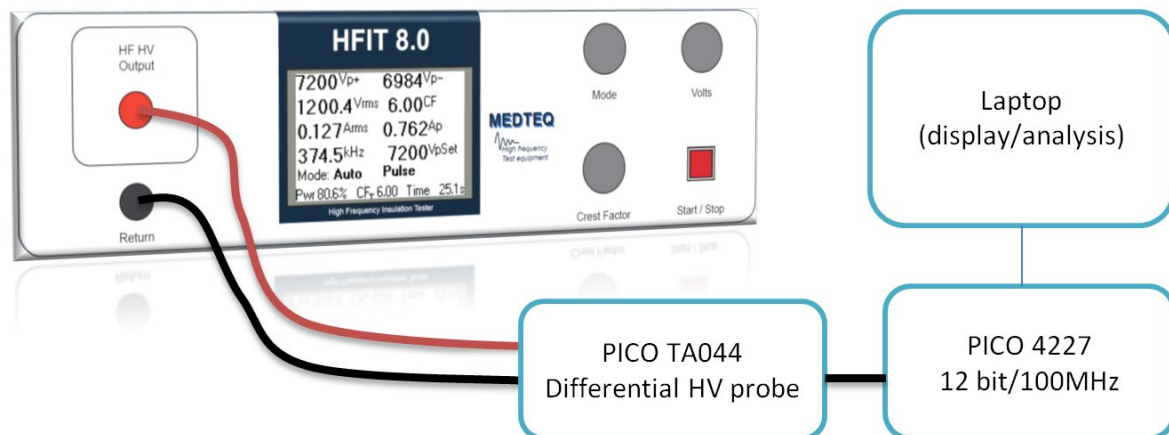
The following table shows the significant sources of error with analysis of the overall effect:

Item	Description	Value	Overall effect (with respect to output)
Buffer input filter	The buffer is filtered to minimize the possible effects of switching transients from the main output	18MHz (3dB)	<0.1%
Buffer bandwidth	The op amp bandwidth can affect the result if too low	>100MHz	<<0.1%
Buffer slew rate	The op amp slew can limit the peak	>4000V/μs	<<0.1%
Buffer offset	The high speed op amps have up to 10mV offset (10V at output). This is canceled by software by each individual unit	10mV, nulled to <2mV	<2V
Comparator speed	If the comparator is too slow, it can miss the true peak of the waveform.	25ns	<0.1%
Comparator input offset	Comparator has relatively high bias currents but a very low offset current. Circuit is carefully designed for balanced resistors to ensure minimal offset.	<1mV	<1V
Input filter	The input to the comparator is filtered to limit switching noise from the main drive system. Filter is positioned close to input pins, and an identical filter is used for DAC sourced input. Filter attenuation at 400kHz is 0.5%, compensated for in software.	3dB @ 4MHz	±0.5%
ADC resolution	A 12 bit DAC used to provide successive approximation. For Burst, Pulse the range is set to 8000V with respect to the output, and positive and negative sides are tested separately, which results in a resolution of 2V. For Sine, Modified Sine waveforms the range is set to 2400V	±2mV or ±0.3mV	±2V (Burst, Pulse) ±0.3V (Sine, Mod-Sine)
Overall limits	-	-	±1% ±4V (Burst, Pulse) ±1% ±1V (Sine, Mod-Sine)

Although the system is expected to provide ±1% overall, at this time a specification of ±3% is used.

8.3.3 Validation (Oscilloscope method)

The peak detection system was validated by an external 12 bit oscilloscope and active high voltage probe:



Prior to the test, the following steps were taken to ensure the accuracy of the reference system:

- A suitable range was selected for the particular test (e.g. $\pm 500\text{V}$ for Sine 400Vp test)
- A reference voltage 150Vrms, 400kHz, <0.3% THD sine wave was applied to the assembled reference system, monitored by wideband HFVM (high frequency voltmeter)
- Using math function, the scope was then adjusted to indicate 150.0Vrms (adjustment range was not more than $\pm 3\%$)
- The scope measurement “zero function” was applied
- With no input applied, the noise floor for peak measurements was recorded (+Vp, -Vp), e.g. typical value is +2V, -2V for 500V range

After the set up process is complete, the HFIT was then set to Auto mode and value selected, e.g. 400Vp, and set to output on and the values shown on the HFIT compared to the values shown on the reference system, with the reference system values corrected for the noise floor.

Tests were repeated at 1600Vp, 3600Vp and 7000Vp, in no load and 100pF load conditions. For each test, a new scope range was selected and the adjustment process above repeated.

Results of this test has found the peak detection to be within $\pm 1.5\%$ of the reference method, with most results within $\pm 1\%$.

8.4 Vrms measurement

8.4.1 Available methods

For rms/dc conversion, there are four well established methods:

- **Thermal/transfer** – uses the property that the heat produced in a wide band resistor will be the same from dc to high frequency; a dc or low frequency voltage can be found which produces the same temperature as the higher frequency voltage. Historically wide band meters were developed using this principle, but are not popular today, and the method is mainly used in calibration laboratories. There are also limits to voltage, for example 100Vrms at 500kHz.
- **Explicit** – this uses separate (explicit) circuits to implement each of the stages in a rms calculation: square (analogue multiplier) → mean (low pass filter) → square root (analogue root or by software). This method is not popular as the output of the initial square stage has a wide dynamic range, requiring special care for values at the low end of the range (e.g. 10% of full scale input is just 1% full scale after square stage). However, the method is known to have a wide bandwidth.
- **Implicit** – this uses a feedback loop to implement the full rms/dc conversion in a single stage; it requires a divider function to be included in the analogue multiplier. The method does not suffer the dynamic range issue from the explicit method, however the divider function limits the practical frequencies to around 10-50kHz. This is the most popular method for digital multimeters.
- **Digital sample/analysis:** the waveform is sampled at high frequency and the rms value calculated in software (oscilloscope). This is the most popular method for frequencies above the range of digital multimeters (e.g. >50kHz). However, at this time oscilloscopes are designed to prioritize bandwidth over vertical accuracy, with most systems having only 8 bit resolution, and the measurement systems being typically designed for ± 0.5 dB flatness in the pass band (equivalent to $\pm 6\%$). While future digital systems may provide more emphasis on amplitude accuracy, at this time digital based systems should only be trusted if they have been validated at the frequency of interest.

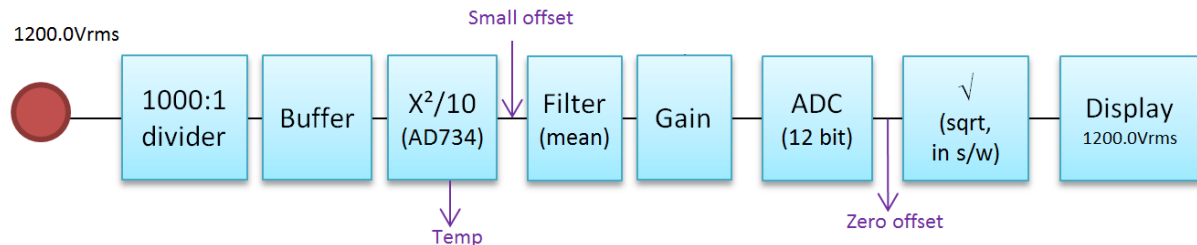
8.4.2 Background to the HFIT method

During 2010 – 2014 various implicit rms/dc circuits were trialed but were found to be unsatisfactory, particularly for the high crest factor waveforms found with the HFIT. However, in 2014 it was discovered that the Analogue Devices AD734 simple multiplier function (which can implement x^2) had an extremely flat frequency response up to 500kHz, better than the limits of the thermal reference system available at the time ($\pm 0.1\%$ detection threshold). This simple x^2 function allows the explicit mode method detailed above to be implemented.

As part of the HFVM (high frequency voltmeter) series, this method was then developed to handle the high dynamic range, with successful meters with accuracy better than 0.2% up to 500kHz being developed in 2015 and further refined in the HFIT system.

8.4.3 HFIT implementation

The implementation in the HFIT is as shown in the following diagram:



As per the explicit method, the system implements the discrete functions of square, mean and square root separately. The AD734 has a core multiplier bandwidth of 40MHz which is far above the needs of the test.

The AD734 has a small offset of around $\pm 3\text{mV}$ which is also temperature sensitive at around $0.04\text{mV}/^\circ\text{C}$. Due to the wide dynamic range at the output of the x^2 function, this offset can affect very low rms values (e.g. 250Vrms). To manage the AD734 offset, a small offset is added at the output to force it to be always positive, and then the zero offset is measured whenever the system is idle. To manage the temperature drift, a sensor is used to monitor the change in temperature during the test (note: this method has been borrowed from high precision 0.1% HFVM meters and may not be needed for HFIT due to the more relaxed specification of $\pm 3\%$). At higher voltages (500Vrms or more) these offsets have limited effect.

8.4.4 Validation

The HFIT rms measurement system is validated at the same time as the peak validation as described above. Under a wide variety of conditions (waveforms, crest factors, frequency), ranging from 275Vrms to 1200Vrms, the two systems matched within $\pm 0.5\%$.

8.5 Current measurement

Basic current measurement is made via a wideband 1Ω shunt which produces a voltage proportional to the current. It is filtered at 3.4MHz which is calculated to have an 1% effect at 500kHz (0.4% at 300kHz). This measurement is made accessible to users via the BNC socket without any further buffering. The measurement is also converted to a rms value using the same explicit rms/dc conversion system as for voltage monitoring.

Peak current is derived from the crest factor as determined from the voltage monitoring. Actual peaks may be higher due to transients in the system which are amplified for current due to the capacitive load. It is the opinion of MEDTEQ that these small transients are not relevant to the test target (thermal burns from HF leakage current) and are difficult to measure accurately.

8.6 Crest factor

Crest factor and crest factor targets are calculated by software based on the values measured above.

8.7 Frequency

Frequency is measured by sampling the number of zero crossings in a 10ms period every 350ms. As with most frequency measurements, the method is simple and highly accurate (much higher than is needed for the test).

Since only Sine and Modified Sine have 100% duty cycle, the measurement is only valid for these modes.

8.8 HFVM Traceability (production)

In production, three MEDTEQ HFVM (high frequency voltmeter) have been used to measure rms voltages from 100mVrms (at the divider, shunt BNC output) 1200Vrms, peak voltages from 400Vp to 7200Vp in the frequency range of 300-500kHz.

These devices have been validated in MEDTEQ Reports 58050 and 58051 which are available on request.

From February 2018, shipped products will include a formal calibration report and a traceability chart which provides an overview of how traceability at high frequency is achieved.

9 Measurements by oscilloscope/probe

Although it is common to use oscilloscopes (scopes) and high voltage probes for measurements at high voltage and high frequency, in actual case they are designed to prioritize bandwidth over absolute accuracy. As such, there are number of potential problems which are outlined in the table below. Users that are finding errors between the values displayed on the HFIT and the values shown via an independent scope/probe should review these items first.

Common issues with scopes/probes:

Issue	Details
Basic specification (at DC)	Most laboratory oscilloscopes (scopes) are 8 bit type, which has only limited resolution in the amplitude axis. As a result, a typical DC accuracy specification of $\pm 3\%$ <i>full scale</i> . This equates to a 4-6% error for typical readings in the range 50-80% of scale (e.g. reading 4200Vp @ 2kV/div). Probes have a typical specification of $\pm 3\%$ (DC only), meaning that the basic measurement system (probe + scope) already has a fairly weak basic specification of $\pm 6\%$ at DC
Noise	Many scopes have 2-3% noise in the baseline, which will add to peak measurements. Ensuring the scope is properly grounded and enable the bandwidth limit (e.g. 20MHz) can help to reduce the noise. The amount of noise should be recorded before starting the test. If the noise amplitude is constant it can be subtracted from any peak measurements (note: noise does not normally affect rms measurements)
Internal offsets	Offsets from probes and scope inputs can be around 2-3% of the peak measurement and can also drift with time (active HV probes are particularly prone to this). Setting a system to ac input can eliminate this issue, and/or compensating for the offset in the measurement (as for noise above).
No specification at high frequency (>1kHz)	Although scopes and probes are specified for wide bandwidth (e.g. 100MHz), this specification is the “3dB bandwidth”, or the point at which the error exceeds $\pm 30\%$. The formal accuracy statement is usually limited to dc only, and the flatness within this bandwidth is usually not specified. In practice manufacturers target $\pm 0.5\text{dB}$, equivalent to $\pm 6\%$. For legally traceability, probes and scopes setups should validated at the frequency of interest before use. It should be noted that the validation may be necessary for each range and channel of the scope used and may be time limited as frequency compensation systems are often highly temperature sensitive.
Probe compensation	At high frequency, HV probes normally use a capacitive divider (3pF:3nF). The divider needs to be adjusted as capacitance can drift with time, layout, and cabling and scope input. Failure to check or correctly adjust the compensation is a common cause of errors in excess of 10% . This should be included as part of the system validation above.
rms calculations: sample rate, sample length	For rms measurement, the system should have enough samples (cycles of the waveform) and fast enough rate for accurate measurement. For sine waves, generally 10 cycles are enough, for pulse waveforms up to 20 cycles may be needed. This can be checked by changing the time base (e.g. from $10\mu\text{s}/\text{div}$ to $20\mu\text{s}/\text{div}$) - if there is any significant change in the displayed rms values it indicates that sample length or rate is not sufficient.
Cycle rms calculations	Cycle rms calculations can be very accurate for simple waveforms with no duty cycle. However, for complex waveforms (such as modified sine, burst, pulse modes in the HFIT), the algorithm needs to be checked for accuracy before use.
Poor connections	At high frequency, a bad connection can still pass much of the signal, meaning the system can appear to work but could have high errors. BNC cables and connections often have poor connections due to the regular mechanical wear.

Note: although this table covers voltage measurements, similar aspects also apply to current measurements.

10 History of development

Until now, high frequency insulation testing has been mostly performed using electrosurgical equipment (ESUs) together with transformers to gain higher peak voltages. High voltage probes (100M Ω , 1000:1) and oscilloscopes are typically used to monitor the voltage during the test, current probes for monitoring leakage current.

Complications with this set up include:

- Adjusting to obtain the peak voltage (ESUs are set by power and have limited resolution)
- Obtaining the crest factors required by the standard
- addition of transformers to the output creates multiple resonant circuits and other unexpected outcomes
- feedback loop of some ESUs is not stable
- the ESU can be damaged by the test for higher capacitive loads
- HV probes and scopes are often inaccurate at high frequency

These issues provided the incentive to develop a high frequency insulation tester with a stable output, adjustable peak voltage and crest factor, with a built in voltage and current monitor custom designed to fit with test requirements of IEC 60601-2-2.

Early in the design process, the impact of test sample's capacitance became apparent. A 15cm length of cable tested at 6000Vp at mains frequency (50-60Hz) would typically have around 100-200 μ A flowing in the insulation due to capacitance. The same insulation tested at 400kHz can easily have peak currents in the order of 1-2A, with peak loads in the order of 10kVA.

To handle this huge power, the HFIT employs a 20kVA resonant circuit.

As the load under test is part of the resonant circuit, the test frequency depends on the test sample. A test sample will typically have around 10-70pF capacitance. The MEDTEQ HFIT is designed to stay within the range required by the standard (300-500kHz) with loads of up to 100pF up to 7.2kVp and up to 150pF for 6000Vp.

An embedded 1000:1 divider was design using high quality mica capacitors which are extremely stable with frequency, voltage and temperature. This divider is accurate to better than 2% in the 300-500 kHz range. Similarly, a 1 Ω HF shunt ensures reasonably accurate monitoring of HF current.

The latest version (HFIT 8.0) incorporates an internal measurement system for peak voltage (positive and negative), Vrms, Irms, frequency and calculates crest factor and various alarms. The measurements are designed to be intrinsically accurate at high frequency providing confidence in the displayed values.

11 Calibration

11.1 Voltage

As discussed in previous sections calibration of high voltage at high frequency is difficult. Users should be aware that it is unlikely for ISO 17025 accredited calibration laboratories to offer traceable calibration at 300-500kHz for a 7.5kV 1000:1 divider for both peak and rms measurements. Although probes and scopes may be labelled at “calibrated”, this calibration is only valid for low frequencies.

However, it is understood that many laboratories and manufacturers may still consider their HV probes and oscilloscopes as being “calibrated”.

If these probes are used to verify the output of the HFIT, the following steps are recommended:

1. Obtain a good quality digital function generator (e.g. Wavefactory , Tektronix)
2. Set the generator to Sine wave output, 7.000Vrms, 10kHz
3. Verify the output as being 7.000Vrms using a good quality 6.5 digit multimeter which has good specifications at 10kHz (e.g. Fluke 8845A, which is better than 0.1%)
4. If necessary adjust the function generator so the output is 7.000Vrms \pm 0.1%
5. Connect the HV probe to the oscilloscope. If necessary, check the probe compensation adjustment according to the procedure recommended by the manufacturer. Set the scope input to “ac”, 1M Ω input and 1000:1 divider
6. Connect the HV probe to the output of the function generator
7. Select a suitable scale on the oscilloscope (e.g. \pm 20V [\pm 20mV] if available)
8. Turn the function generator output off
9. Verify that the residual noise reading is <0.5Vrms [$<$ 0.5mVrms]. If it is higher check set up ground etc to try to minimize the noise effect.
10. Turn the function generator output on
11. Verify the scope indicates 7.00Vrms [7.00mVrms] \pm 2%. If not, check the sample size (at least 10 cycles should appear on the screen), ac setting (dc offsets may be too high)
12. Without changing the function generator amplitude setting, increase the frequency to 300kHz, 400kHz and 500kHz
13. Verify the scope indicates 7.00Vrms [7.00mVrms] \pm 3%. If not, check the probe compensation.
14. For precise reference (when checking the HFIT), set the function generator to 400kHz and on the oscilloscope use a math function so that the displayed indication is 7.00Vrms \pm 1%

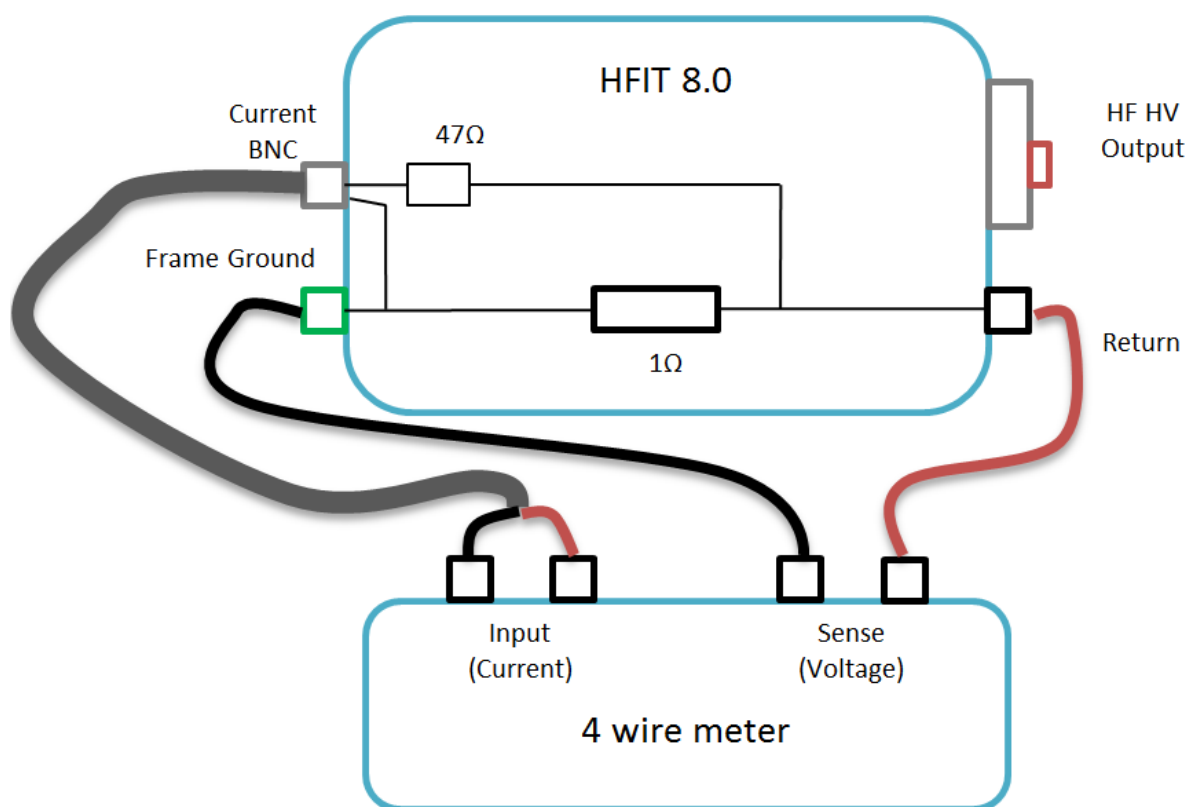
Once the above HV probe and oscilloscope have been confirmed at 400kHz, the same set up can then be used to monitor the output from the HFIT and verify the voltages (peak and rms) displayed. To comply with IEC 60601-2-2, it is recommended that the values match within \pm 3%.

Notes:

- the above pre-check/adjustment may be time limited due to the temperature sensitivity of many frequency compensation systems. It is recommended to allow the system to warm up for 30 minutes before checking, and to repeat the check at 30-minute intervals.
- Even good quality scopes may have 1-2% variation with different ranges as different frequency compensation may be required for different ranges. If this is suspected, it can be separately checked by applying the function generator directly to the scope input in a method similar to above (verify at 10kHz using the DMM, then increase to 400kHz and check for any variation). Remember to remove the DMM before increasing the frequency.

11.2 Current monitor, BNC (1Ω shunt)

The resistance of the current monitor shunt can be confirmed using a 4 wire resistance method or equivalent (e.g. passing a known current and measuring the voltage drop), as per the following diagram:



Notes on the test:

- A BNC to 4mm cable is needed for the above test
- The above set up has the current path through the 47Ω and voltage sense through the 1Ω. This configuration makes sense for low current meters such as Fluke 8848 that may only use 1mA for measurement, in order to minimize noise that may come from the 47Ω.
If equipment with 20mA or more is used, the current path should flow through the 1Ω only and the BNC used for voltage sense. This avoids the possibility of damaging the 47Ω resistor.

As the current shunt is a simple wide band resistor, the value at DC can be considered representative of the value at 500kHz. The output is low pass filtered at 3.4MHz which has approximately 1% effect at 500kHz (0.4% at 300kHz).

11.3 Current monitor (display)

The displayed current (Arms) can be verified by comparing the value measured by external oscilloscope at the BNC current terminal with the value shown on the display, or alternately using a current probe (note: current probes can suffer similar problems to HV probes). A variable capacitive test load can be created from placing variable lengths of insulated wire in liquid container.

11.4 Other displayed values

The displayed frequency can be confirmed against the frequency indicated on a reference oscilloscope. This function is only applies for Sine and Modified Sine modes. The digital nature of the measurement is that the accuracy far exceeds the requirements of the test.

The crest factor and crest factor target are calculated values and hence do not need to be calibrated. Users may wish to confirmed these independently by calculation.

The peak current is also a calculated parameter based on the voltage crest factor. In actual case, the peak current can be higher as the load is capacitive and may amplify some of the higher frequency transients that occur in the test waveform. It is the opinion of MEDTEQ that such transients should not be considered based on the principles of the leakage current tests (rms effect).

If required, the timer can verified against an external calibrated stopwatch. The digital nature of the measurement is that the accuracy far exceeds the requirements of the test.

12 Specifications

The following key specifications are provided:

Parameter	Specification	Notes
Sine mode output	50-1100Vrms, 0-150pF load, CF 1.4-1.6	
Modified Sine	400-2100Vp, 0-150pF load, CF 1.6 -1.8	
Burst mode	0-3600Vp, 0-150pF load, CF 2.0 – 6.0	
Pulse mode	0-6000Vp, 0-150pF load, CF 4.0 – 6.5 0-7200Vp, 0-100pF load, CF 4.0 – 6.5	
No load frequency	455 ~ 475kHz	
Full load frequency (150pF)	325 ~ 335kHz	
Load dissipation factor	Up to 5%	Design tests to 8%
Output current limit	0.350Arms (up to 2A peak)	
Voltage divider (BNC)	1000:1±2% Buffered output to BNC socket (50Ω)	Adjusted to ±1% from 300-430kHz during production.
Current monitor (BNC)	1Ω ± 2% (HF resistor), Buffered output to BNC socket (50Ω)	
Peak voltage (Vp+, Vp-) indication	Sine, Modified Sine: 50-2400Vp ±3% ±1V Burst, Pulse 100-8000Vp ±3% ±4V	Vp, Vrms and Irms are intrinsic measurement system designed 0.3%, true rms, no frequency compensation applied
Vrms indication	100 - 1200Vrms ±3% ±2Vrms	
Irms indication	0.010 – 0.400Arms ±3% ±0.002Arms	
Crest factor indication	1.00 ~ 9.99 ± 4% (Calculated from Vp, Vrms)	These indications are calculated from above measured values
Peak current (Ap) indication	0.000-2.000Ap ±4% ±0.005Arms	
Frequency indication	0-500.0kHz ±0.2kHz	Only for Sine, Modified sine (other modes are pulse which prevents measurement)
Protection	Under frequency Overload / short circuit Overvoltage (Vrms, Vpeak) Over temperature	(See Section 4.6 for more details)
Power supply	48Vdc 160W (approximately 3.3Amax) 100-240Vac, worldwide approvals.	Dedicated power supply

13 Contact details

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