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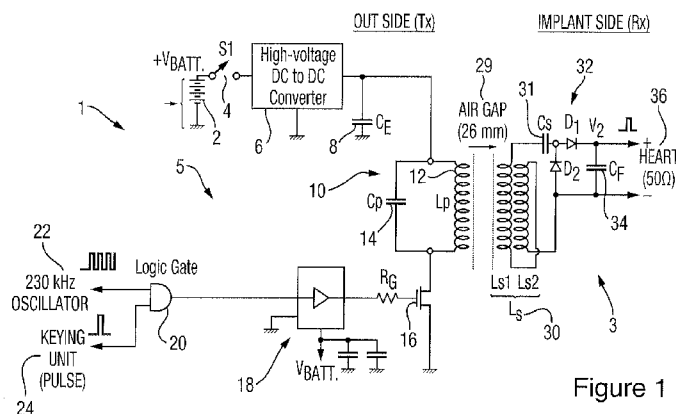


Figure 1

(57) Abstract: An apparatus and method for delivering an electrical defibrillation signal to a heart (36) transcutaneously. The apparatus (1) includes an external transmitter part (5) and implantable receiver part (3) arranged so that an RF pulse (22, 24) can be wirelessly transmitted through a barrier (29) and received internally to apply a defibrillating pulse to a heart (36). The oscillator (22) and the keying unit (24) are powered via a power source (2). The external transmitter (5) comprises a capacitor arrangement (8) connected to the power source (2) and a high voltage DC to DC converter (6). The capacitor (8) is connected through a resonant circuit (10) to circuitry (16, 18) operable to discharge the capacitor (8) through the resonant circuitry (10) and excite the primary coil (12) and cause RF pulse transmission. The primary coil (12) is inductively coupled to the secondary coil (30) of the implantable receiver (3), to enable instant wireless transmission of the RF pulse across the barrier (29). The receiver (3) further comprises a resonant circuit, rectification circuitry (32) and filtering circuitry (34).

Defibrillator Apparatus and Method

The present invention relates to cardiac defibrillation, and in particular to apparatus and methods for delivering an electrical defibrillation signal to a heart transcutaneously. While the present invention will be described by particular reference to atrial defibrillation, it will be appreciated that the apparatus and methods of the present invention in its various embodiments are equally applicable to ventricular defibrillation.

Atrial fibrillation (AF) is the most commonly encountered form of cardiac arrhythmia. The incidence and prevalence of AF increases with age. AF may have certain consequences including an increased risk of stroke.

Various techniques are used to treat AF, including pharmacological cardioversion, electrical cardioversion, pacemaker based therapies and atrial ablation techniques. Ablation procedures are still under development and require access to skilled practitioners and a specialised catheter lab.

Electrical cardioversion may be delivered in a number of different ways. While effective, one drawback of conventional electrical cardioversion is that it typically must be delivered under sedation. Automatic atrial defibrillators which automatically detect an episode of AF and deliver a defibrillation signal have also been used to treat AF. However, arrhythmia tends to recur frequently when such devices are used, and the administration of such shock-based therapy when the patient is not under sedation may be unpleasant, and can lead to anxiety or depression over time. Another problem with implanted automatic defibrillation devices is that they may have limited longevity, for example due to limited battery life, necessitating periodic surgical intervention. Such devices may also be relatively costly.

Recently a cardiac defibrillation apparatus has been proposed which includes an implanted receiver part and an external transmitter part. The implanted receiver is connected to electrodes implanted in the heart. A RF pulse is transmitted wirelessly from the external transmitter part through the skin to the implanted receiver part via induction between respective coils of the transmitter and receiver parts to cause the receiver to deliver a shock pulse via the electrodes to the heart. An apparatus of this type is described in US 7,110,812 B1, entitled "Cardiac defibrillation". Such devices relying upon transcutaneous energy transfer by induction are advantageous in that they may reduce or eliminate the need for the implanted apparatus to include active components, and hence an internal power supply.

These known transcutaneous defibrillation apparatus have certain limitations. The efficiency of energy transfer from the external transmitter part to the internal receiver part is relatively low. Typically, in order to be able to induce a sufficiently high voltage pulse in the

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implanted receiver to achieve defibrillation, the external part of the apparatus must be relatively heavy and bulky, and the external circuitry relatively complex. The external part typically includes many batteries in order to provide an adequate power level, for example at least ten 12V batteries may be required. As a result, known cardiac defibrillation apparatus relying upon transcutaneous energy transfer by induction have not been portable.

The Applicant has realised that there remains a need for an improved cardiac defibrillation apparatus which operates by transcutaneous energy transfer from an external apparatus to an implanted apparatus, and in particular for an improved external transmitter part for such an apparatus. The present invention seeks to provide such an apparatus.

In accordance with a first aspect of the invention there is provided an external transmitter apparatus for a cardiac defibrillator apparatus,

the external transmitter apparatus being operable in use to transmit a radio frequency (RF) pulse which may be received transcutaneously by an implantable receiver apparatus of the cardiac defibrillator apparatus and used by the implantable receiver apparatus to apply a defibrillating pulse to implantable electrodes connected to the implantable apparatus to enable a defibrillating pulse to be delivered to a heart when the electrodes are implanted in a heart in use;

wherein the external transmitter apparatus comprises a capacitor arrangement, and charging circuitry operable to charge the capacitor arrangement to thereby store energy in the capacitor arrangement,

and wherein the external transmitter apparatus further comprises a primary coil and circuitry operable to apply a RF pulse to the primary coil to energise the primary coil and cause the primary coil to transmit a RF pulse which may be received by a secondary coil of an implantable receiver apparatus when the primary coil of the external transmitter apparatus is in proximity to a secondary receiver coil of the implantable receiver apparatus in use, wherein the circuitry of the external transmitter apparatus is arranged to energise the primary coil for transmitting a RF pulse to the secondary coil using energy stored by the capacitor arrangement.

The external apparatus of the present invention forms part of a defibrillation apparatus in which a RF pulse is transmitted wirelessly to an implantable apparatus to enable a defibrillating pulse to be applied to the heart.

The present invention extends to a cardiac defibrillation apparatus comprising the external transmitter apparatus of the invention in accordance with any of the embodiments of the invention and an implantable receiver apparatus.

The implantable receiver apparatus comprises a secondary coil for receiving a RF pulse transmitted transcutaneously by the external transmitter apparatus when the secondary coil is in proximity to the primary coil of the external transmitter apparatus, and circuitry for using the

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received RF pulse to deliver a defibrillating pulse to a heart via implantable electrodes connected to the implantable apparatus.

In accordance with a second aspect of the invention there is provided a cardiac defibrillator apparatus comprising an external transmitter apparatus and an implantable receiver apparatus,

wherein the implantable receiver apparatus is arranged to receive a RF pulse transmitted transcutaneously by the external transmitter apparatus in use and to use the RF pulse to apply a defibrillating pulse to implantable electrodes connected to the implantable apparatus to enable a defibrillating pulse to be delivered to a heart when the electrodes are implanted in a heart in use,

wherein the external transmitter apparatus comprises a capacitor arrangement, and charging circuitry operable to charge the capacitor arrangement to thereby store energy in the capacitor arrangement,

the external transmitter apparatus further comprising a primary coil and circuitry operable to apply a RF pulse to the primary coil to energise the primary coil and cause the primary coil to transmit a RF pulse which may be received transcutaneously by a secondary coil of the implantable receiver apparatus when the primary coil of the external transmitter apparatus is in proximity to a secondary receiver coil of an implantable receiver apparatus in use,

wherein the circuitry of the external transmitter apparatus is arranged to energise the primary coil for transmitting a RF pulse to the secondary coil using energy stored by the capacitor arrangement,

and wherein the implantable receiver apparatus further comprises circuitry for using a RF pulse transmitted transcutaneously by the primary coil and received by the secondary coil to deliver a defibrillating pulse to a heart via implantable electrodes connected to the implantable apparatus.

The present invention also extends to a kit of parts for the defibrillator apparatus of the invention comprising the external transmitter apparatus and the implantable apparatus.

It will be appreciated that the present invention in accordance with the second aspect may include any or all of the features described in relation to any of the embodiments of the first aspect of the invention to the extent they are not mutually inconsistent therewith, and vice versa. Thus the apparatus of the second aspect may include an external transmitter apparatus in accordance with any of the embodiments described herein, and the apparatus of the first aspect of the invention in any of its embodiments may be used with an implantable receiver apparatus in accordance with any of the embodiments described.

It will be appreciated that the invention in its first aspect relates to the external transmitter part of the defibrillator apparatus, and does not, at least in some embodiments, require the presence of the implantable receiver apparatus. Thus while the features of the

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implantable apparatus are described herein for use in accordance with embodiments in which the implantable apparatus is provided, and in accordance with the second aspect of the invention, this does not imply that the implantable apparatus is an essential feature of the first aspect of the invention. The external transmitter apparatus of the first aspect is arranged to be suitable for use with the implantable apparatus in any of the embodiments described.

While, in embodiments in which the implantable apparatus is present, the apparatus is described as being connected to electrodes for applying a defibrillation pulse to a heart, the invention extends to an implantable apparatus providing an output defibrillation signal for application to electrodes implantable in a heart, and extends to an implantable apparatus which is connectable to electrodes implantable to a heart.

Accordingly, in embodiments of the invention, the energy required for the external transmitter apparatus to transmit a RF pulse for reception by an implanted receiver apparatus for use in providing a defibrillating pulse to the heart is provided by a capacitor arrangement of the external transmitter apparatus. The capacitor arrangement directly provides the power source for energising the primary coil. This enables the size and weight of the external transmitter apparatus to be reduced in comparison to prior art external transmitter apparatus which relied upon large numbers of batteries to power pulse transmission. The capacitor arrangement may be charged to a suitable level for delivering a RF pulse of a given energy level, and may store the energy until the external transmitter apparatus is operated to deliver a RF pulse. A power source such as a battery may be used to charge the capacitor which then powers the pulse generation circuitry. However the power source does not directly provide energy to the primary coil in contrast to prior art arrangements. In embodiments, by providing a suitable intermediate arrangement to convert the output of the power source to a level suitable for charging the capacitor, the power source may be of a relatively low voltage level, such as a relatively low voltage battery or relatively fewer batteries.

The primary coil is arranged to transmit a RF pulse to the secondary coil by induction. Thus the primary coil is an induction transmitting coil, and where provided, the secondary coil is an induction receiving coil. In embodiments the primary coil is arranged to inductively couple to the secondary coil when in proximity thereto for transmitting a RF pulse to the secondary coil. The primary and secondary coils may be arranged to inductively couple to one another at a resonant frequency as described below.

In accordance with the invention, the energy required to deliver a defibrillating pulse to the heart is provided by the capacitor arrangement, and preferably entirely by the capacitor arrangement. Preferably the primary coil is energised for transmitting a RF pulse to the secondary coil using only energy stored by the capacitor arrangement of the external transmitter apparatus. Thus, in embodiments all of the energy required to induce a RF pulse in the secondary coil of the implantable apparatus is obtained from the charged capacitor

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arrangement. The energy stored by the capacitor arrangement is used to directly power the primary coil.

During operation of the external apparatus to transmit a RF pulse to an implantable apparatus, energy is transferred from the capacitor arrangement to the implantable apparatus to enable a defibrillating pulse to be delivered to a heart via the implantable electrodes connected to the implantable apparatus when the electrodes are implanted in a heart in use. In embodiments the energy required to deliver a defibrillating pulse to the electrodes (and hence heart) is obtained solely from the external apparatus, and preferably solely from the capacitor arrangement thereof.

The capacitor arrangement is connected to an input of the primary coil or of a circuit e.g. a resonant circuit including the primary coil for supplying energy thereto.

The capacitor arrangement of the external transmitter apparatus may include one or more capacitors. Any arrangement may be used to result in a desired level of capacitance. The arrangement may consist of a single capacitor, or an array of two or more capacitors. The array is preferably an array of capacitors connected in parallel. In preferred embodiments the capacitor arrangement consists of a single capacitor or an array of from two to four, and most preferably two capacitors. Preferably the or each capacitor of the capacitor arrangement is an electrolytic capacitor

The capacitance of the capacitor arrangement may be selected to minimise the voltage drop experienced over the primary coil during the delivery of a RF pulse. The level of capacitance should therefore be selected by reference to the intended duration and energy level of the pulse that the external apparatus is to deliver, and the voltage or voltages at which the capacitor arrangement is to be charged.

In embodiments the capacitance of the capacitor arrangement is at least 1000 μ F, or at least 1200 μ F, or at least 1500 μ F, or at least 1800 μ F, or at least 2000 μ F. In embodiments the capacitance of the capacitor arrangement is less than 3000 μ F, or less than 2500 μ F or less than 2200 μ F. By choosing the capacitor arrangement to have a relatively high capacitance, the voltage drop over the primary coil when the capacitor arrangement provides energy thereto during RF pulse transmission may be kept relatively low, reducing the time required to recharge the capacitor arrangement after RF pulse delivery.

Preferably the external apparatus comprises a power source and the circuitry of the external apparatus comprises an intermediate arrangement to step up the voltage provided by the power source to a given level for charging the capacitor arrangement. The intermediate arrangement is preferably a DC to DC converter. In embodiments the DC to DC converter is a high voltage DC to DC converter.

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In embodiments the intermediate arrangement e.g. DC to DC converter has an input connected to the power source of the external apparatus and an output connected to the capacitor arrangement.

In embodiments the circuitry of the external apparatus is arranged such that the capacitor arrangement e.g. the input thereof is connected to the power source during charging of the capacitor and is not connected to the charging arrangement during RF pulse delivery. In some embodiments the output of the intermediate arrangement e.g. DC to DC converter is additionally connected to an input of a tuned circuit including the primary coil.

In accordance with the invention, the circuitry of the external apparatus is preferably arranged such that the capacitor arrangement is disconnected, preferably automatically, from the charging circuit when fully charged.

In embodiments the power source of the external apparatus is a DC power source. The power source may be a low voltage power source. In embodiments the power source has a voltage of less than 50 V, or less than 25V, or less than 20 V, or less than 15 V, and preferably less than 10V or less than 5 V. In preferred embodiments the power source comprises a battery, most preferably is a single battery. In some embodiments the or each battery is a lithium ion battery. In embodiments in which the power source comprises a battery, the battery is preferably a rechargeable battery.

In embodiments the charging circuitry of the external apparatus is operable to charge the capacitor arrangement at a voltage of at least 250V, at least 300V, or at least 400V or at least 500V.

The charging circuitry may be selectively operable to charge the capacitor arrangement at one or more voltages in a range or ranges of up to a maximum voltage of 50 V or greater, 100V or greater, 150V or greater, 200V or greater, 250V or greater, 300V or greater, or 400V or greater, or 500V or greater. By this it is meant that the maximum charging voltage available is e.g. 50V or greater. In some embodiments the charging circuitry of the external apparatus is selectively operable to charge the capacitor arrangement at one or more voltages in the range of from 20 V to 500 V, or in the range of from 50 V to 500 V, or from 50 V to 350 V, or in the range of from 150V to 300V. The voltage at which the capacitor is charged will define the voltage across the primary coil during RF pulse transmission. Selection of a voltage in these ranges may enable a shock pulse of up to 160V to be delivered to the heart.

Alternatively or additionally, the circuitry may be selectively operable to charge the capacitor arrangement at a voltage of less than 100V. Thus the circuitry may be selectively operable to charge the capacitor arrangement at a higher voltage e.g. 250V or greater in some situations, or less than 100V in other situations.

In some embodiments the charging circuitry of the external apparatus is operable to charge the capacitor arrangement at a voltage selected from two or more different voltages, and

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preferably three, four or five or more different voltages. The voltages may lie in any one of the above ranges. The voltage at which the capacitor arrangement is charged will be chosen with regard to the energy level of the RF pulses to be delivered by the external apparatus. Lower voltages may be chosen in some situations to reduce the likelihood of pain being experienced by the patient as a result of the corresponding shock pulse generated, or the need for sedation. In embodiments the voltage at which the capacitor arrangement is charged may be selectable by a user. It is of course envisaged that the charging circuitry might be operable at only a single charging voltage.

In some embodiments the charging circuitry is manually operable to charge the capacitor arrangement. For example a user may operate a switch or button to initiate charging or recharging. A single touch operation may be used. In other arrangements it is envisaged that the charging circuitry may be controlled by a microprocessor and the circuitry of the external apparatus may comprise a microprocessor for controlling charging of the capacitor arrangement. In these embodiments charging of the capacitor arrangement may proceed automatically after RF pulse delivery. Charging may be triggered automatically by the microprocessor. The voltage at which the capacitor arrangement is charged may be user selectable in embodiments in which the charging circuitry is controlled automatically or could be controlled automatically.

In embodiments the charging circuitry of the external apparatus and the circuitry operable to cause a RF pulse to be transmitted by the primary coil are independently operable. The charging circuitry and the circuitry operable to cause a RF pulse to be transmitted i.e. to apply a RF pulse to the primary circuit for transmission, may be operable to charge the capacitor arrangement or cause a RF pulse to be transmitted respectively in response to user intervention. For example the apparatus may comprise independently operable user operable controls for each purpose. The controls may be one touch operated controls. The controls may be buttons etc. In other embodiments operation of the charging circuitry may be controlled by a microprocessor as described above.

In embodiments the charging circuitry is arranged such that the capacitor arrangement may be fully charged from an uncharged condition in a time of less than 5 minutes at the or each available charging voltage, and preferably less than 4 minutes. In embodiments the charging circuitry is arranged such that the capacitor arrangement may be fully recharged subsequent to delivery of a RF pulse in a time of less than 45 seconds, or less than 30 seconds, or more preferably less than 20 seconds.

In particularly preferred embodiments the primary coil is an air core coil. Where provided, the secondary coil is preferably an air core coil. The term "air core coil" refers to an induction coil that does not use a magnetic core made of a ferromagnetic material. The term

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encompasses coils wound on plastic, ceramic, or other non magnetic forms, as well as those having air inside the windings of the coil.

The use of air core coils has also been found to be particularly beneficial, as it may result in greater levels of efficiency of transfer of energy from the primary coil to the secondary coil in use. In particular, in comparison to the ferrite cored coils used in the prior art arrangement of US 7110812 it has been found that the preferred embodiments of the invention using air cored coils may facilitate reduction in size and weight of the external apparatus, to provide further advantages in terms of providing a portable apparatus. Air core coils are small and lightweight in comparison to the conventional ferrite core coils. The air cored coils may also provide greater levels of efficiency of energy transfer than the ferrite cored coils disclosed in the US 7110812 arrangement, and may result in transfer with greater reliability over larger air gaps and hence skin thicknesses between the primary and secondary coils in use. By increasing the energy transfer efficiency, the frequency and energy of the RF pulse applied to the primary coil may be reduced while still resulting in a shock pulse of an energy level suitable for defibrillation being applied to the heart. The use of air core coil also provides a more biocompatible approach.

The primary and secondary coils together provide an RF transformer. Preferably the primary coil is arranged to provide a resonant coupling to the secondary coil at the operating frequency of the system i.e. at the frequency of the RF pulse applied to the primary coil.

In preferred embodiments the primary coil forms part of a tuned circuit of the transmitter apparatus circuitry. The tuned circuit is tuned to an operating frequency of the system. Thus the tuned circuit is tuned to the frequency of the RF pulse applied to the primary coil. These dual tuned arrangements may increase efficiency of energy transfer to the receiver apparatus.

In preferred embodiments the secondary coil forms part of a tuned circuit of the receiver circuitry. The tuned circuit of the receiver apparatus is tuned to an operating frequency of the system. The tuned circuit is tuned to the frequency of the RF pulse applied to the primary coil. Thus, in embodiments the transmitter and receiver apparatus tuned circuits are tuned to the same frequency.

The tuned circuit of the transmitter apparatus and/or the receiver apparatus may be a series or a parallel tuned circuit. In preferred embodiments the tuned circuits of the transmitter apparatus and the receiver apparatus are both parallel tuned circuits. The or each tuned circuit is preferably an LC tuned circuit.

The receiver apparatus may be arranged to carry out some processing e.g. rectification and/or filtering of the RF pulse received by i.e. induced in the secondary coil to obtain a defibrillating pulse suitable for delivery to a heart via the electrodes. In embodiments the circuitry of the receiver apparatus is arranged to provide a DC shock pulse for delivery to the heart via the electrodes. The shock pulse may be a rectilinear low tilt pulse.

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In embodiments the circuitry of the receiver apparatus comprises rectification circuitry for rectifying RF pulses received by the secondary coil from the primary coil. The circuitry of the receiver apparatus may further comprise filtering circuitry for filtering e.g. smoothing an output of the rectification circuitry. In some embodiments the circuitry of the receiver apparatus comprises a rectification circuit having an input connected to the secondary coil and an output driving the implantable electrodes for delivering defibrillation signals to the heart, optionally via filtering circuitry. In some embodiments the filtering circuitry is arranged to smooth the output of the rectifying circuit.

Preferably the circuitry of the implantable apparatus includes only passive components. In some embodiments the circuitry of the implantable apparatus includes only the secondary coil, rectification and optionally filtering circuitry. The circuitry of the implantable apparatus may include only small value capacitors required for example to carry out filtering. Preferably the circuitry of the implantable apparatus does not include a capacitor of greater than 1 μF capacitance. By powering the circuitry of the implantable apparatus from the external apparatus, the implanted apparatus may be made more robust, and may include a lower number of components, reducing the risk of malfunction. This is beneficial, reducing the likelihood of needing to carry out surgical intervention to replace or repair the implantable apparatus. Additional benefits are provided in terms of reduced material and manufacturing costs.

The secondary coil has a size constrained by the need for the receiver apparatus to be implanted in the body. In embodiments the secondary coil has an outer diameter of less than 60 mm, and preferably less than 50 mm or less than 40 mm. The secondary coil may be a double layer coil.

In embodiments the primary coil has an outer diameter within the same range as the ranges given for the secondary coil. The primary and secondary coils may be of equal outside diameter.

In use, the pulse transmitted by the primary coil of the external transmitter arrangement must be capable of being received transcutaneously by the secondary coil of the implantable receiver arrangement. It has been found that the apparatus of the present invention may transfer a pulse transcutaneously with greater efficiency than was possible in prior art arrangements, such as that disclosed in US 7110812. Such apparatus were typically limited to an air gap of no greater than about 15 mm. This makes it possible for a defibrillation pulse to more reliably be induced in the implanted apparatus through the skin, even for patients with relatively greater chest dermal thickness due to adipose tissue.

In embodiments the RF pulse transmitted by the primary coil is receivable by the secondary coil for providing a defibrillation signal via the electrodes when the primary coil and the secondary coil are separated by an air gap of at least 15 mm, or at least 20 mm or at least

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25mm. In embodiments the RF pulse transmitted by the primary coil is receivable by the secondary coil for providing a defibrillation pulse via the electrodes when the primary coil and the secondary coil are separated by an air gap in the range of from 15mm to 30mm.

It will be appreciated that the radio frequency (RF) pulse applied to the primary coil is of an energy level suitable for causing defibrillation of the heart. The RF pulse may then be received by the implantable receiver apparatus and used to apply a defibrillation pulse to a heart via electrodes connected to the receiver apparatus.

Preferably the frequency of the RF pulse is less than 1 MHz. Using RF in this range enables a smaller and simpler switching arrangement to be used as described below. This may further enhance portability of the external apparatus. In preferred embodiments the frequency of the RF pulse is less than 0.5 MHz, or less than 0.3 MHz. In some embodiments the frequency of the RF pulse is in the range of from 100 kHz to 400kHz, or preferably from 200kHz to 300kHz.

Preferably the circuitry of the external apparatus is arranged to provide an RF pulse of energy less than 5 J, or less than 4J or less than 3J, and preferably in the range of from 0.2J to 5J for transmission to the implantable apparatus. Preferably the circuitry of the external apparatus is arranged to provide an RF pulse of energy at least 0.1J and preferably at least 0.25J for transmission to the implantable apparatus.

It has been found that the pulse transmitted by the external apparatus may be of lower energy in accordance with the invention than was possible with prior art apparatus due to the greater energy efficiency that the apparatus of the present invention provides. By way of illustration, the inventors have found that an efficiency of up to 55% can be achieved in some exemplary arrangements. In contrast, the inventors have found that the devices disclosed in US 7110812 may only have an energy transfer efficiency of around 10% from the primary coil to the secondary coil, with the result that the RF pulse applied to the primary coil must be of greater energy level e.g. at least 5 times greater than with the apparatus of the present invention, to result in a RF pulse of an energy level suitable for defibrillation being generated in the implantable apparatus.

Preferably the circuitry of the external apparatus is arranged to apply an RF pulse to the primary coil having duration of less than 15 ms. Preferably the circuitry of the apparatus is arranged to provide RF pulses having duration of at least 5 ms. In some preferred embodiments the duration of the RF pulse is in the range of from 6 ms to 12 ms. In some embodiments the circuitry of the external apparatus is selectively operable e.g. by a user to provide RF pulses having one or more different durations in the above range to the primary coil. In some embodiments the external apparatus is operable to provide a RF pulse having duration of one or both of 6ms and 12 ms duration.

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In preferred embodiments the RF pulse applied to the primary coil has a waveform i.e. an envelope waveform that is rectangular or rectilinear low tilt, preferably rectilinear low tilt. These may enable the implantable apparatus to deliver a corresponding waveform pulse to the heart. It has been found that such waveforms may reduce the pain experienced by the patient when the shock pulse is delivered e.g. at lower voltages, such as less than 75V, allowing defibrillation to be conducted under lighter sedation or without sedation.

In some embodiments the shock pulse delivered to the heart will be monophasic. This may correspond to a simple mode of operation. In other embodiments the shock pulse delivered to the heart may be biphasic. In these embodiments a timed polarity reversal circuit should be incorporated in the implanted apparatus.

In embodiments the circuitry of the external transmitter is arranged such that the capacitor arrangement discharges through the primary coil to energise the primary coil. In this way, the energy stored by the capacitor arrangement is used to energise the primary coil, and will be transferred to the secondary coil when in proximity to the primary coil.

In embodiments an input of the primary coil or of a tuned circuit including the primary coil is connected to the output of the capacitor arrangement.

It will be appreciated that the capacitor arrangement will provide a DC voltage. In embodiments of the invention the DC voltage is converted to a quasi AC voltage at the RF frequency for energising the primary coil.

In embodiments circuitry of the external transmitter apparatus comprises a switching arrangement drivable at the RF frequency of the RF pulse to be applied to the primary coil to alternately allow and not allow the capacitor arrangement to discharge through the primary coil for energising the coil over a period corresponding to the duration of the pulse to be applied to the coil to thereby apply the RF pulse to the primary coil. The switching arrangement may be such that the capacitor arrangement is connected to earth to allow it to discharge through the primary coil.

It will be appreciated that the frequency of the RF pulse to be applied and the duration of the RF pulse to be applied to the primary coil refer to the desired or intended frequency and duration of the defibrillating pulse to be applied. The period over which the switching arrangement is driven may be controlled by a keying pulse. The keying pulse will be chosen to have a duration corresponding to the desired duration of the RF pulse to be applied to the coil. That is, the term "keying pulse" refers to an RF pulse enabling time signal. The keying pulse determines the time duration of the RF pulse that is applied to the primary coil.

In embodiments the circuitry of the external apparatus thus comprises a switching arrangement switchable between a first configuration in which the capacitor arrangement may not discharge through the primary coil and a second configuration in which the capacitor arrangement may discharge through the primary coil for energising the coil. The switching

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arrangement is a high speed switching arrangement. The switching arrangement may comprise an Insulated Gate Bipolar Transistor (IGBT) or MOSFET or any other high speed power switching arrangement. In some embodiments the output of the primary coil or of a tuned circuit including the primary coil is connected to the switching arrangement.

The circuitry of the external apparatus further comprises driver circuitry for driving the switching arrangement at a frequency corresponding to the frequency of the RF pulse to be applied to the primary coil over a keying period corresponding to the duration of the pulse to be applied to the primary coil to thereby apply the RF pulse to the primary coil. The driver circuitry drives the switching arrangement between the first and second configurations to apply the RF pulse to the primary coil. The driver circuitry is arranged to drive the switching arrangement between the first and second configurations at the RF frequency of the RF pulse to be generated over a period corresponding to the duration of the pulse to be generated. In embodiments in which the switching arrangement comprises an IGBT or MOSFET, the driver circuitry may comprise an IGBT or MOSFET driver.

The driver circuitry may comprise an arrangement for generating an RF pulse for driving the switching arrangement. The driver circuitry may comprise an oscillator for providing a waveform of the RF frequency of the pulse to be applied to the primary coil and an arrangement for generating a keying pulse of the duration of the RF pulse to be applied to the primary coil from the output of the oscillator for driving the switching arrangement. It will be appreciated that some shaping of the RF pulse may be carried out.

In embodiments, operation of the external transmitter apparatus to apply the RF pulse to the primary coil for transmission to the implantable apparatus causes the driver arrangement to drive the switching arrangement to thereby initiate application of the RF pulse to the primary coil. In embodiments operation of the device to cause a RF pulse to be transmitted by the primary coil causes the driver circuitry to generate a pulse of the RF frequency and duration of the pulse to be applied to the primary coil.

In some embodiments the circuitry of the external apparatus is operable by a user to cause a RF pulse to be applied to the primary coil. In other embodiments the circuitry may be connectable to the output of an electrocardiogram apparatus (ECG) for providing a trigger signal for initiating shock pulse application in synchronisation with the ECG.

In some embodiments the primary coil is mounted to a paddle to facilitate placement on a patient's body.

Preferably the external apparatus is in the form of a portable unit, most preferably a hand held unit. In some embodiments, the external apparatus may comprise a housing for the circuitry of the external apparatus, the primary coil being located outside the housing for location on a patient's body and being connected to the circuitry within the housing. The primary coil

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may be connected thereto by a flexible connector. The components of the external apparatus other than the coil may be provided within a housing.

The present invention extends to an apparatus in accordance with the invention in which the implantable receiver apparatus is implanted in a body and the electrodes are implanted in a heart.

It is envisaged that a single external apparatus could be shared by multiple patients e.g. at an AF treatment centre.

It may be seen that the present invention provides an external apparatus for a defibrillation apparatus which may be made more compact and lightweight than could be achieved using prior art arrangements.

The present invention extends, in further aspects, to the use of the apparatus of the invention in accordance with any of its aspects or embodiments to deliver cardiac defibrillation.

The method comprises the steps of operating the charging circuitry of the external transmitter apparatus to charge the capacitor arrangement, locating the primary coil in proximity to the secondary coil of the implantable apparatus, and causing the circuitry of the external transmitter apparatus to apply a RF pulse to the primary coil to cause the implantable apparatus to deliver a defibrillating shock pulse via the electrodes. In embodiments the step of causing the charging circuitry to charge the capacitor arrangement is a separate step carried out prior to the step of causing the circuitry to apply a RF pulse to the primary coil. The shock pulse delivery operation may be carried out at a different time or place to the capacitor charging step. One or both of the steps may be initiated in response to a manual operation by a user or may be initiated automatically. The apparatus may be arranged such that one touch operations may be used to initiate one or both of the charging and shock pulse delivery steps.

When the steps are performed, the implantable apparatus is implanted in the body of a patient, and the electrodes implanted in a heart. The method may further include the step of implanting the implantable apparatus in the body of a patient, and may comprise the step of implanting the electrodes in the heart.

Although the invention has been described with particular reference to atrial defibrillation, the apparatus could be used to provide ventricular defibrillation. In this context higher levels of energy would need to be transmitted from the external apparatus to the implantable apparatus e.g. around 20 J.

It will be appreciated that, if not specifically stated, the pulse transmitted from the external transmitter apparatus to the implantable receiver apparatus is an RF pulse. The pulse applied to the primary coil to energise the primary coil is an RF pulse. Likewise, the RF pulse transmitted by the primary coil and which may be or is received by a secondary receiver coil of an implantable receiver apparatus is an RF pulse.

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The term "RF pulse" ("radio frequency pulse") refers to a burst of alternating current (AC) radio frequency signal. The pulse is typically of a relatively short duration, such as a few milliseconds. In some exemplary embodiments the RF pulse applied in accordance with the invention has a duration of from 6-12 ms.

The pulse caused by the implantable apparatus to be delivered to a heart via the implantable electrodes is a shock or defibrillating pulse. Thus, if not specifically stated herein, a pulse delivered to a heart will refer to a shock pulse. The terms "shock pulse" and "defibrillating pulse" are used interchangeably herein.

A shock pulse is a shock pulse which is intended to have a defibrillating effect when delivered to a heart. The term "shock pulse" refers to an "ON" state of a DC voltage applied to the heart. The DC voltage will be a high DC voltage. The shock pulse will typically be of relatively short duration. In some exemplary embodiments the duration of the shock pulse in accordance with the invention may be in the range of from 6 ms to 12 ms. The related energy of a shock pulse will be proportional to the square of the voltage level (V^2) of the shock pulse and the defibrillating pulse duration. For this reason, the shock pulse may sometimes be referred to as an "energy shock" delivered to a heart.

It will be appreciated that references to a "coil" herein refer to a complete coil assembly including its associated electrical connection terminals. A coil may also be known as an inductor L which may have a particular inductance value (in Henrys H). "Windings" refers to the wire turns of the coil i.e. to a building element of a coil.

Some preferred embodiments of the invention will now be described by way of example only and with reference to the accompanying drawings of which:

Figure 1 is a schematic diagram of an exemplary circuit arrangement of an experimental arrangement of a defibrillator apparatus in accordance with one embodiment of the invention;

Figure 2 illustrates schematically a system including the defibrillator apparatus in accordance with the invention;

Figure 3 illustrates the output voltage pulse obtained across a 50 Ohm load in one example arrangement;

Figure 4 illustrates schematically a prototype system used in a bench test with a 26 mm air gap;

Figure 4A is a photograph of a typical test set up;

Figure 4B shows the transmitter board used;

Figure 4C shows the receiver board used;

Figure 5 shows a typical IGBT gate signal at approximately 180 kHz switching frequency;

Figures 6-12 illustrate example waveforms obtained when the capacitor was charged at approx 340 V DC.

Figures 13-15 illustrate waveforms obtained when the capacitor was charged to approx 200V DC;

Figures 16-18 illustrate waveforms obtained when the capacitor array was charged to approximately 100V DC;

Figures 19 and 20 illustrate waveforms obtained when the capacitor was charged to approx 340 V Dc in open and short circuit conditions;

Figure 21 illustrates schematically a test set up used in bench testing of a prototype system using a body skin model;

Figure 22 illustrates the test set up showing the skin model;

Figures 23-31 show output voltage and current waveforms obtained at the 50 Ohm dummy load;

Figure 32 shows the output ripple on the output voltage and current in more detail;

Figures 33-35 illustrate the results of open and short circuit tests carried out at the output of the receiver;

Figure 36 illustrates a test set up used for bench tests using a skin model and a different prototype system;

Figures 37-45 show the output voltage and current waveforms obtained at the 50 Ohm dummy load;

Figure 46 shows the output ripple on the output voltage and current in more detail;

Figures 47-49 illustrate the results of open and short circuit tests.

Figure 1 is a schematic diagram of an exemplary circuit arrangement of a defibrillator apparatus 1 including an external transmitter part 5 and implantable receiver part 3 in accordance with one embodiment of the invention. The apparatus is a transcutaneous wireless instant power transmission system which may deliver a shock pulse internally into the heart. This Figure illustrates an experimental laboratory arrangement. Rather than being implanted in the body, the implantable apparatus is shown as being arranged such that its secondary coil is separated by an air gap from the primary coil of the transmitter apparatus. In reality, rather than there being an air gap, the skin of the patient would be present in this region separating the coils. In addition, the output of the implantable apparatus is shown as being applied over a 50 Ohm load, representative of the resistance of a heart. In practice the output would be applied to electrodes implanted in a heart for applying a shock thereto.

The defibrillator apparatus 1 includes an external transmitter part 5, which comprises the components to the left of the air gap 29 in Figure 1, denoted "outside Tx". The implantable receiver part 3 comprises the components located on the right-hand side of the air gap in Figure 1, being those parts on the side labelled "implant side Rx". The implantable receiver part 3 may be provided as a single implantable unit. Likewise, it is envisaged that the external transmitter part 5 would be provided as a single unit.

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The implantable receiver apparatus will be described first. The implantable receiver apparatus 3 includes a secondary coil 30. In the illustrated embodiments the secondary coil 30 L_S is configured as a double layer of spiral coils L_{S1} and L_{S2} . In the exemplary embodiment the spiral coils were arranged in parallel, being flat and close to one another, but electrically isolated by a thin non-conductive sheet between the coils. The coils were arranged side by side. The coils are air core coils. Such coils are believed to improve the operating efficiency of the apparatus as well as reducing the size and weight of the coils in comparison to ferrite cored coils. The secondary coil 30 forms part of a resonant circuit with the capacitor 31 C_S which is connected in series therewith. The receiver apparatus 3 also includes rectification circuitry 32 for rectifying the voltage induced in the secondary coil 30. The rectification circuitry 32 includes two rectifying diodes D_1 and D_2 in a voltage doubler mode with capacitor 31 C_S . The receiver apparatus 3 also includes filtering circuitry 34 for filtering the rectified output voltage. The filtering circuitry includes capacitor C_F which filters the rectified output voltage V_L to extract its DC component.

The output of the implantable receiver apparatus 3 would, in reality, be delivered to a heart via electrodes. In the laboratory test apparatus as illustrated in Figure 1, the output from the receiver circuitry is delivered to a nominal 50 Ohm dummy load 36 which simulates impedance of the heart.

The external transmitter part of the defibrillator apparatus is designated 5 in Figure 1. The external transmitter part 5 is intended to be located external to the body in use. In Figure 1 the implantable and external parts are shown to be separated by an air gap 29. The air gap in the example is of 26 mm and simulates a worst case skin thickness scenario in a laboratory setting. As mentioned above, in practice rather than there being an air gap, the skin of the patient would occupy this space between the primary and secondary coils of the external and implanted parts of the apparatus. Thus in practice energy will be transferred transcutaneously between the external and internal parts of the apparatus.

The external part of the apparatus includes a power source in the form of a battery 2. The battery has a comparatively low voltage as exemplified below. For example the battery may be a single 4.8 V battery. The battery 2 is connected via a switch 4 S1 to a high voltage DC to DC converter 6.

The output of the high voltage DC to DC converter 6 is connected to an energy storing capacitor arrangement C_E (8). The capacitor arrangement C_E will be referred to as the capacitor C_E herein for brevity but may comprise one or more capacitors. It has been found that one or two electrolytic capacitors in parallel providing may be suitable for providing the capacitor arrangement C_E . The capacitance C_E is, in one example, 2000 μ F. In practice, other values of the capacitance may be used, but it has been found that a capacitance of at least 1400 μ F is advantageous.

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The output of the capacitor C_E is connected to the input of a parallel LC resonant circuit 10. The resonant circuit includes a capacitor C_P (14) connected in parallel with a primary coil (12) L_P . The primary coil is an air core coil, and is located to facilitate placement on the body of a wearer e.g. by being located on a paddle. The resonant frequency of the resonant circuit 10 is the same as the resonant frequency of the resonant circuit of the implantable apparatus 3. The primary coil 12 is arranged to inductively couple to the secondary coil 30 when excited by an RF signal.

The output of the resonant circuit 10 is connected to a high speed switching arrangement in the form of a high performance switching IGBT transistor 16. It will be appreciated that other forms of high speed switch, e.g. MOSFETs may be used. The switch is movable between a position which enables the capacitor 8 C_E to discharge through resonant circuit 10 and primary coil 12 to earth and a position in which the capacitor 8 C_E may not discharge therethrough.

Driver circuitry is provided for driving the transistor 16 at an RF chopping frequency of the same value as the resonant frequency of the parallel LC circuit. The driver circuitry includes an IGBT driver 18 and a logic gate 20 for controlling application of an RF chopping signal to the IGBT 16. The RF chopping signal is generated in the following manner. The inputs of the logic gate 20, which is in the form of an AND gate, are connected to the output of an oscillator 22 and a keying unit 24 respectively. The oscillator 22 is arranged to provide an output in the form of an RF signal set at the resonant frequency of the circuit 10. The oscillator 22 is arranged to always be on from the time the apparatus is switched on. The oscillator and the keying unit 24 are powered via V_{batt} (2). The keying unit 24 is arranged to provide an output in the form of a keying pulse having a duration corresponding to the duration of a shock pulse to be applied using the defibrillator apparatus. In one example the keying unit was arranged to provide a 12 ms keying pulse for locating the chopping signal provided by the oscillator. Another suitable pulse duration would be 6 ms. An exemplary keying unit 24 is a monostable pulse generator, implemented with a 555 IC.

In this way, when the output of the keying unit is high, and the oscillator 22 is powered, a RF pulse of the RF signal output by the oscillator 22 will be passed through the logic gate 20. The RF pulse is arranged to be of a rectangular or low tilt RF waveform. A pulse of the RF signal will therefore be passed via the IGBT driver 18 to the switching arrangement having a duration corresponding to that of the keying unit pulse. The output of the oscillator 22 is set to provide an RF signal of less than 1 MHz, and suitably in the range of from 200 kHz to 300 kHz. In one exemplary arrangement the RF signal has a frequency of 230 kHz, and the operating resonant frequency of the resonant circuit 10 and the resonant circuit of the implantable apparatus 3 are set to the same value. It has been found that using an RF frequency below 1 MHz enables the switching electronics to be kept to a manageable complexity in size. The

keying unit 24 may be commanded by an ECG synchronised trigger as will be described in more detail below.

In the illustrated embodiment a spiral type of winding (disc-shaped) was used for both the primary coil 12 and the secondary coil 30. The overall secondary coil diameter was set at less than 60 mm to enable the implantable device to be made of a size suitable for implanting in the body. The overall inductance value of the secondary coil L_S was set to about 100 μH for operating resonant frequency of about 230 kHz. The inner diameter of each of the coils L_{S1} and L_{S2} of the secondary coil 30 was set to 20 mm. The primary coil 12 had the same inner diameter as each of the coils L_{S1} and L_{S2} . The air gap 29 i.e. distance between the primary and secondary coil discs was set to 26 mm.

Operation of the defibrillator apparatus in accordance with the embodiment of Figure 1 will now be described. In use, the implantable apparatus 3 is implanted in the body, and its output connected to electrodes implanted in the heart.

Before use of the apparatus, the charging circuitry of the external transmitter apparatus 5 is operated to charge the energy storing capacitor C_E (8). This may be done at any time, e.g. just before using the apparatus, or following use of the apparatus to deliver a shock pulse to ensure that the apparatus is ready for operation when next required, even if this is not or some time. The step of charging the capacitor may be carried out before or after the external apparatus is located in proximity to the body of a patient.

The switch S_1 (4) is closed to enable the battery 2 to charge the energy storing capacitor C_E (8) via the high voltage DC to DC converter 6. The output of the battery passes through the high voltage DC to DC converter 6 stepping up the voltage from the relatively low voltage output of the battery to a voltage of a level desired to be used to charge the capacitor C_E (8). In practice it is envisaged that the user may be able to select one of a number of voltages to use to charge the energy storing capacitor C_E (8) depending upon the energy of a shock pulse to be delivered to a patient. Some examples are given below. Once the capacitor C_E (8) is fully charged, the switch S_1 (4) is opened. This may occur automatically once the capacitor C_E (8) is fully charged.

In some embodiments, charging may proceed in response to a manual operation by a user to close the switch S_1 (4). The user may also manually select the voltage level for the charging process. It is envisaged that charging of the capacitor arrangement could alternatively be carried out under the control of a microprocessor. The microprocessor could automatically charge the capacitor C_E (8) when it is determined that it is not fully charged, or after delivery of a shock pulse etc. The microprocessor may control the DC to DC converter 6 to result in charging of the capacitor C_E (8) at a given voltage level, for example in response to a selection by a user, or in response to an automatic determination of an appropriate energy level for the shock pulse to be delivered, for example based on analysis of an ECG trace for a patient.

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When it is desired to deliver a defibrillating pulse to a patient, the primary coil 12 is located in proximity to the secondary coil 30 of the implanted apparatus 3. The primary coil 12 may be provided on a paddle to facilitate placement. In use, the primary coil 12 will be separated from the secondary coil 30 by the thickness of the skin of the chest surface. This will be located in the region designated "air gap 29" in Figure 1.

In order to initiate application of a pulse to the primary coil 12 for transmission to the secondary coil 30, the apparatus is switched on to energise the oscillator 22. The keying unit 24 is controlled to send a keying pulse to the logic gate 20 of a duration corresponding to the intended duration of the shock pulse to be administered via the implantable apparatus 3. This may be 6 milliseconds or 12 milliseconds for example. The keying unit 24 may be caused to provide such a keying pulse in response to a manual action by a user. For example the user may press a button to initiate delivery of a keying pulse via the keying unit, and hence a defibrillation shock pulse in this way. This may be a single touch operation. In other embodiments described in more detail by reference to Figure 2 below, operation of the keying unit 24 to deliver a keying pulse may be triggered automatically by the output of an ECG trace from a patient.

Activation of the keying unit 24 to deliver a keying pulse causes the logic gate 20 to be switched to an ON state as both of its inputs, from the keying unit 24 and oscillator 22 will be high. This allows the output of the oscillator to be passed through the AND gate. In this way, the oscillator provides an RF frequency signal output at the operating frequency of the system for the same time duration as the keying pulse duration. This is in the range of less than 1 MHz, and may be in the range of from 200 to 300 kHz in preferred arrangements, and in the example described herein is 230 kHz.

It will be appreciated that the logic gate 20, being an AND gate, will allow a signal to pass to the IGBT driver 18 when the output of both the keying unit 24 and the oscillator 22 are high. In effect this arrangement provides a RF pulse of a chopping signal for controlling the switching arrangement 16 with a RF frequency of the output of the oscillator e.g. 230 kHz. The duration of the pulse corresponds to the duration of a pulse provided by the output of the keying unit e.g. 12 milliseconds. This RF pulse of a RF chopping signal causes the IGBT 16 to move between a position in which the capacitor C_E 8 may discharge through the resonant circuit 10 and hence over the coil 12 and in which it is prevented from discharging therethrough at the frequency of the RF chopping signal e.g. 230 kHz over the duration of the pulse. In this way a pulse of quasi AC type voltage is applied to the primary coil 12 thereby energizing the coil at the resonant frequency of the resonant circuit 10. The voltage over the primary coil 12 corresponds to the voltage to which the capacitor C_E 8 was charged.

The electromagnetic field induced in the primary coil 12 by the RF pulse applied thereto induces a voltage in the secondary coil 30. The induced voltage is rectified by rectification

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circuitry 32 and filtered by the capacitor C_F (34) to produce an output pulse for application to the heart as illustrated in Figure 1. In the arrangement illustrated in Figure 1, rather than being applied to the heart, the output pulse is delivered to the nominal 50 Ohm dummy load simulating the impedance of a heart. The RF waveform applied to the primary coil 12 advantageously is a rectilinear low tilt waveform to result in a shock pulse of a rectilinear low tilt shape.

In embodiments the high voltage DC to DC converter 6 is operable to convert the voltage of the battery 2 to a voltage for charging the capacitor at up to 400 volts. The charging voltage may be selectable to be at one or more different given voltages within this range. For example in some arrangements the charging voltage may be selected to be any one of a number of steps in the range of up to 400 volts, such as 25 volts, 50 volts, 70 volts, 100 volts, 150 volts, 200 volts, 250 volts, 300 volts, 350 volts and 400 volts. The apparatus may be arranged such that initial charging of the capacitor C_E (8) takes up to 3 minutes. The apparatus should be arranged such that subsequent recharging of the capacitor C_E takes no more than 15 seconds after delivery of a shock pulse.

It will be seen that in accordance with the invention the energy stored in the energy storing capacitor arrangement C_E (8) is used to deliver the DC shock pulse to the heart via the implanted apparatus. The energy stored in the capacitor arrangement C_E is used to energise the primary coil 12. Energy is then transferred subcutaneously to the secondary coil 30.

It will be appreciated that by replacing the many batteries required by previous transcutaneous energy transmission defibrillator devices by a low voltage supply with a high voltage DC to DC converter for charging an energy storing capacitor arrangement, which stores energy which is subsequently used to deliver a defibrillating shock pulse, the size of the external transmitter apparatus 5 may be reduced, allowing a more compact and lighter weight apparatus to be provided. The external transmitter apparatus may be provided as a portable, hand-held unit. It will be seen that the implantable apparatus 3 includes only passive components. All of the power requirements for applying a defibrillator shock pulse are supplied by the external transmitter apparatus 5, specifically by the energy storing capacitor C_E (8). This enables the complexity and size of the implantable apparatus to be reduced.

In practice the external transmitter components may be provided as a unit which will include all of the components shown in Figure 1, and will include oscillator 22 and keying unit 24. The primary coil will be provided on a paddle connected to the main circuit of the external unit.

A system including the defibrillation apparatus of the embodiment shown in Figure 1 but this time in an in- use rather than experimental situation will now be described by reference to Figure 2.

The system includes a radio frequency external transmitter apparatus (100) denoted "RFT" standing for Radio Frequency Transmitter, This corresponds to the external part 5 of the

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apparatus shown in Figure 1. As shown schematically in Figure 2, this transmitter apparatus 100 is in communication transcutaneously through a skin barrier 101 with an implanted part of the apparatus 102, labelled "PIAD". This stands for "passive implantable atrial defibrillator". The skin barrier 101 replaces the air gap of Figure 1.

Rather than being connected to a 50 Ohm load, the implanted part of the apparatus 102 is connected via defibrillation leads 104 including a right atrial lead (RA) and a coronary sinus lead (CS) to the heart 106 to enable an output shock pulse provided by the implanted part 102 to be delivered to the heart.

The system also includes an ECG monitor 108 connected to the body surface using standard disposable ECG electrodes. An R wave detector 110 is connected to the output of the ECG monitor 108, and an R-R interval/trigger device 112 is connected to the output of the R wave detector 110. When the interval of detected R waves is above a particular threshold which has been set the trigger device 112 is operable to cause a RF keying unit 114 connected thereto to deliver a keying pulse to initiate a defibrillating pulse delivery cycle. The keying pulse causes a RF power source 116 to energize the oscillator of the external transmitter device to result in a pulse of a radio frequency signal being applied to the primary coil of the external transmitter 100 e.g. by driving an IGBT switch of the transmitter with the RF pulse as described above. In this way the primary coil of the external transmitter 100 is energized over a duration corresponding to the keying pulse provided by the RF keying unit and at the RF frequency. A shock pulse is thus induced in the implantable device for application to the heart as described in relation to Figure 1, at a voltage set by the voltage to which the energy storing capacitor C_E of the transmitter 100 has been charged.

The defibrillator apparatus of the present invention does not require any battery or an energy storage device such as a capacitor of high voltage or large value in the implanted device. This is beneficial as such components are bulky, and tend to be expensive and have limited life longevity requiring surgical intervention for their replacement or maintenance. The implanted device part may function with just passive electrical components, such as a pick-up coil, rectifying diodes and small value capacitors of capacitance less than 1 micro farad. This may yield a more robust device with a lower number of electrical components and lower pull of relativity of malfunction. The inherent material manufacturing costs may also be reduced. The external hand-held device, which is relatively more complex may be shared among several patients for example at an atrial fibrillation treatment centre.

The defibrillation apparatus is arranged to deliver rectilinear low tilt defibrillation waveforms, which may be more efficacious, in particular at reduced voltage levels such as less than 75 volts, in that pain due to shock delivery has been found to be more tolerable under light sedation or even no sedation. The output pulse at the implanted circuit is also rectilinear low tilt.

Some testing has been carried out to determine suitable operating parameters for the defibrillator apparatus of the present invention, using an experimental apparatus having the circuitry shown in Figure 1. An exemplary arrangement will now be described.

Example 1

Coupled coils and implanted circuit (R_x)

A spiral type of winding (disc shape) was used for both the primary and secondary coils (12, 30). The primary and second coils were air cored. The distance between the primary and secondary coil discs (air gap (29, Fig. 1) was set to 26 mm. The secondary coil (30) (L_s) was configured as a double layer of spiral coils (L_{s1} and L_{s2}) of the same diameter as the primary coil (12) (L_p). Considering the restrictions for the secondary coil (30) diameter (<60 mm), the inductance value L_s of the secondary coil was set to about 100 μ H for an operating resonant frequency of about 230 kHz. The primary coil 12 and each of the coils making up the secondary coil had an inner diameter set to 20 mm. The rectifier circuitry of the implantable apparatus used rectifying diodes (D_1 and D_2) in a voltage doubler mode with C_s (see Fig. 1). The rectified output voltage (V_L) was filtered by C_F to extract its DC component.

Transmitter circuit (T_x)

This consisted of a simple LC parallel resonant circuit (10) (L_p and C_p), fed by the charged capacitor (8) (C_E) at the primary side, through a high-performance switching IGBT transistor (16), driven at a chopping frequency at the same value as the resonant frequency of the parallel LC primary circuit. The chopping signal (set to about 230 kHz) was logic gated via AND gate (20) by a 12 ms keying pulse from a keying unit (24) commanded by an ECG synchronised trigger. The capacitor C_E was provided by a capacitor array which had a capacitance of 2800 μ F. The power source was a single 15 V lithium ion battery pack.

Performance evaluation results

The following performance parameters were assessed in the proposed secondary circuit configuration (R_x) and are presented in Table 1:

V_{CEO} : Voltage at which the primary energy capacitor C_E is charged.

V_{LMAX} : Maximum voltage across the 50 Ω load (V_L) at the secondary side.

ΔV_L : Voltage drop of V_L after 12 ms.

% Tilt : Percentage of waveform tilt, calculated as $(\Delta V_L / V_{Lmax}) \cdot 100$

ΔE_{CE} : Total energy withdrawn from C_E during the transmission of energy (12ms).

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$E_{50\Omega}$: Total energy delivered to the 50 Ω load at the secondary side.

% Efficiency ; Energy transmission efficiency, calculated as $(E_{50\Omega} / \Delta E_{CE}) \cdot 100$

Table 1. Performance parameter measurements obtained.

V_{CE0} (V)	V_{Lmax} (V)	ΔV_L (V)	% Tilt (%)	ΔE_{CE} (J)	$E_{50\Omega}$ (J)	% Efficiency ($E_{50\Omega} / \Delta E_{CE}$).100
204.5	82.4	4.8	5.8	3.66	1.54	42.0%

The proposed circuit configuration of the secondary coil performed well and could provide high V_{Lmax} with a low number of components in the rectifying circuit. Efficiency assessment was carried out for different values of V_{CE0} , ranging from 51.5 V to 331.4 V. The results are presented in Table 2. The particular waveform of V_L obtained for $V_{CE0} = 267.8$ V, with a V_{Lmax} of 105 V, is shown in Figure 3.

Thus, a relatively simply power transmission circuit design was tested and evaluated on its energy transfer efficiency through air cored coupled coils at a separation distance of 26 mm. It provided a transmission efficiency of about 44% at higher voltages in the primary energy capacitor ($V_{CE0} > 268$ V).

Table 2. Performance parameters for the secondary circuit configuration, at different primary energy capacitor (C_E) charge voltages (V_{CE0}).

V_{CE0} (v)	V_{Lmax} (V)	ΔV_L (V)	% Tilt (%)	ΔE_{CE} (J)	$E_{50\Omega}$ (J)	% Efficiency ($E_{50\Omega} / \Delta E_{CE}$).100
51.5	23.0	2.2	9.6	0.32	0.115	36.3%
102.3	42.6	2.6	6.1	0.99	0.41	41.1%
153.7	61.6	3.8	6.2	2.1	0.86	40.7%
204.4	82.4	4.8	5.8	3.66	1.54	42.0%
267.8	105	5.0	4.8	5.78	2.52	43.6%
305.5	118	5.2	4.4	7.27	3.21	44.1%
331.4	127	6.4	5.0	8.39	3.7	44.1%

Figure 3 illustrates an output voltage pulse of 12 millisecond duration across the 50 ohm load (V_L) for a parameter capacitor (C_E) being charged with a voltage of 267.8 volts.

Bench Tests

Some bench tests were carried out with a prototype system with the primary and secondary coils being separated by an air gap and by a skin model respectively.

Bench tests with prototype systems using a 26 mm air gap**Test Setup**

Tests were carried out on a prototype system of the type shown schematically in Figure 4, upon which the test points referred to below are labelled.

The system included a transmitter board (200) including the IGBT electronic switch. This was connected to a primary coil (240) of a transformer prototype (270). The primary coil (240) was separated from secondary coil (260) of the transformer by a 26 mm air gap. The secondary coil (260) was connected to a receiver board (280) including rectifier and smoothing circuitry. The output of the receiver board (280) was connected to a dummy load (50 Ohm) to simulate impedance of the heart. The components of the transmitter board 200 correspond to the components of the external transmitter apparatus 3 shown in Figure 1 (excluding the primary coil which is illustrated as part of the transformer prototype). In contrast to the Figure 1 arrangement, the primary coil L_p (12) was located away from the transmitter board, being electrically connected thereto by a pair of wires. The primary coil would be located on a paddle for administering a shock pulse to the chest skin area localised over the subcutaneously implanted receiver apparatus in a patient in use. The capacitor C_E was in the form of a capacitor array of capacitance 1360 μF . The power source was a lithium ion battery of voltage 15V. The primary and secondary coils were air cored coils. The components of the receiver board 280 correspond to the components of the implantable receiver apparatus 3 shown in Figure 1 (excluding the secondary coil which is illustrated as part of the transformer prototype).

Figure 4A is a photograph of a typical test set up.

Figure 4B shows the transmitter board with test point **A** marked.

Figure 4C shows the receiver board with test points **B**, **C** and **D** marked.

Test Equipment

The following equipment was used to carry out the tests:

- Tektronix TDS 2024B Four Channel Digital Storage Oscilloscope (Serial No. TDS2024B C036725).
- FLUKE 80i-110s AC/DC Current Probe.
- Tektronix PS280 Laboratory DC Power Supply was used in some tests to power the transmitter board.

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- The transformer prototype was constructed using 0.75mm diameter copper enamel wire. The primary winding consists of one coil with 30 turns. The secondary winding consists of two coils, each with 30 turns, connected in a centre-tapped configuration.
- IRG4PH50PPbF (International Rectifier) IGBT was used in the transmitter board ($V_{CES\max} = 1200V$ and $I_{C\max} = 45A$).

Test Procedure and Theory

Embedded test code on the transmitter board allowed the charging capacitor array to be manually charged to the desired value. The final embedded code will allow the charging capacitor array to be charged automatically to the desired value.

Once the capacitor array is charged, the user could select another test option to switch the Insulated Gate Bipolar Transistor (IGBT) on/off over a 12 ms gating period. The switching frequency of the IGBT was approximately 180 kHz and this enabled the charging capacitor's DC voltage to be converted to a pseudo AC voltage. This action of converting a DC voltage to an AC voltage allowed the stored energy on the transmitter side to be transformed to the receiver side, i.e. wireless power transmission. In practice, not all the energy will be transferred over the wireless link due to losses in the system, e.g. magnetic coupling losses.

Figure 5 shows a typical IGBT gate signal at approximately 180 kHz switching frequency.

Output Test Results and Waveforms 1

The charging capacitor array was charged to approximately $340V_{DC}$. The IGBT was switched on/off at approximately 180 kHz over a 12 ms period. The following results and waveforms were obtained:

Figure 6 shows the output voltage measured across tests points C and D (figure 4), i.e. the 50Ω dummy load. The output voltage is approximately $102V_{DC}$ with a tilt of $2V_{DC}$.

Figure 7 shows the Collector-Emitter voltage envelope measured across the IGBT junction in the transmitter board. The peak-to-peak voltage is approximately 1.36 kV.

Figure 8 shows the Collector-Emitter voltage measured across the IGBT junction in the transmitter board. The time domain is expanded to show waveform detail (time division: $2.5\mu s/div$).

Figure 9 shows the current envelope measured at test point A on the transmitter side of the transformer. The peak-to-peak current is approximately 29.6A.

Figure 10 shows the current envelope measured at test point A on the transmitter side of the transformer. The time domain is expanded to show waveform detail (time division: 5 μ s/div).

Figure 11 shows the current envelope measured at test point B on the receiver side of the transformer. The peak-to-peak current is approximately 7.92A.

Figure 12 shows the output voltage (uppermost darker trace) measured across test points C and D (50 Ω dummy load) and the load current (lower lighter traces) measured at test point C. The output voltage is approximately 102V_{DC} and the load current 2.1A.

Output Test Results and Waveforms 2

The charging capacitor array was charged to approximately 200V_{DC}. The IGBT was switched on/off at approximately 180 kHz over a 12 ms period. The following results and waveforms were obtained:

Figure 13 shows the output voltage measured across test points C and D (figure 4), i.e. the 50 Ω dummy load. The output voltage is approximately 59V_{DC} with a tilt of 2.8V_{DC}.

Figure 14 shows the current envelope measured at test point A on the transmitter side of the transformer. The peak-to-peak current is approximately 18.6A.

Figure 15 shows the current envelope measured at test point B on the receiver side of the transformer. The peak-to-peak current is approximately 4.6A.

Output Test Results and Waveforms 3

The charging capacitor array was charged to approximately 100V_{DC}. The IGBT was switched on/off at approximately 180 kHz over a 12 ms period. The following results and waveforms were obtained:

Figure 16 shows the output voltage measured across test points C and D (figure 4), i.e. the 50 Ω dummy load. The output voltage is approximately 30.5V_{DC} with a tilt of 1.8V_{DC}.

Figure 17 shows the current envelope measured at test point A on the transmitter side of the transformer. The peak-to-peak current is approximately 9.28A.

Figure 18 shows the current envelope measured at test point B on the receiver side of the transformer. The peak-to-peak current is approximately 2.52A.

Output Test Results and Waveforms 4

The charging capacitor array was charged to approximately 340V_{DC}. The IGBT was switched on/off at approximately 180 kHz over a 12 ms period. The following results and waveforms were obtained:

Figure 19 shows the output voltage measured across tests points C and D (figure 4) during a no load condition, i.e. open circuit. It can be seen that the output voltage is limited to 150VDC by the transient voltage suppression (TVS) diode across the output terminals of the receiver, see figure 4C.

Figure 20 shows the current envelope measured at test point C/D during a short circuit condition, i.e. 50Ω load replaced by a piece of wire. The peak-to-peak current is approximately 10.4A.

Bench Tests with a body skin model (physiologic fluid)

Test Set-Up

This report describes the tests carried out on the prototype system and shows some of the oscilloscope traces obtained. The transmitter and receiver board prototypes were the same as those used in the air testing described above. Figure 21 shows a block diagram of the test set-up with the test points labelled.

The following test set-up was used throughout this section:

- The transmitter was used for the tests with a pulse width set to 12 ms.
- A SIGA Electronics Limited transformer was used for the test: 0.75 mm diameter enamelled copper wire wound around a 20 mm inner core. The primary winding consists of one coil with 30 turns encapsulated with Magic Rubber™. The secondary winding

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consists of two coils, each with 30 turns, connected in a centre-tapped configuration. The coils were encapsulated with polyurethane resin.

- A physiologic fluid media was modelled with a sodium chloride solution (at 0.9%) contained in a polyethylene bag (500 ml). This skin model was placed between the primary and secondary coils. The distance between the two coils was approximately $23\text{mm} \pm 3\text{mm}$. Cable ties were used to secure the bag between the coils (see illustrative photo in Fig. 22).
- The receiver circuit, prototype A, employed four MURS480ET3G rectifiers (RS: 463-511) and a $1\mu\text{F}$, 250V_{DC} (547-7247) filtering capacitor. The receiver circuit was encapsulated with ER1448 RF epoxy resin.
- A 50Ω resistive load (10W) was used to simulate the impedance of the heart. For the open circuit test, the 50Ω resistive load (dummy load) across test points **C** & **D** (Figure 21) was removed, i.e. no load condition. For the short circuit test, the 50Ω dummy load across test points **C** & **D** (Figure 21) was replaced by a piece of wire.
- Fluke current probe setting: 100mV/A .

Figure 22 is a photograph which illustrates the test set up showing the skin model.

Figures 23 to 31 show the output voltage and current waveforms obtained at the 50Ω dummy load.

Figure 32 shows the output ripple on the output voltage and current in more detail (time division: $2.5\mu\text{s/div}$).

Figure 23: Output voltage (CH2=5V/div (upper darker traces)) tilt = $26.6\text{V} - 25.4\text{V}$, voltage ripple = $26.6\text{V} - 25.0\text{V}$ and output current (CH3=0.5A/div (lower lighter traces) ripple = $0.56\text{A} - 0.47\text{A}$ approximately.

Voltage level switch setting on transmitter prototype = 20V

Figure 24: Output voltage (CH2=10V/div (upper darker traces) tilt = $39.2\text{V} - 37.6\text{V}$, voltage ripple = $39.2\text{V} - 36.8\text{V}$ and output current (CH3=0.5A/div (lower lighter traces) ripple = $0.82\text{A} - 0.70\text{A}$ approximately.

Voltage level switch setting on transmitter prototype = 30V .

Figure 25: Output voltage (CH2=10V/div (upper darker traces) tilt = $52.0\text{V} - 49.6\text{V}$, voltage ripple = $52.0\text{V} - 48.8\text{V}$ and output current (CH3=0.5A/div (lower lighter traces)) ripple = $1.08\text{A} - 0.92\text{A}$ approximately.

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Voltage level switch setting on transmitter prototype = 40V.

Figure 26: Output voltage (CH2=10V/div (upper darker traces)) tilt = 64.0V – 61.6V, voltage ripple = 64.0V – 60.0V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.34A – 1.14A approximately.

Voltage level switch setting on transmitter prototype = 50V

Figure 27: Output voltage (CH2=20V/div (upper darker traces)) tilt = 78.4V – 76.0V, voltage ripple = 78.4V – 72.8V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.62A – 1.40A approximately.

Voltage level switch setting on transmitter prototype = 60V.

Figure 28: Output voltage (CH2=20V/div (upper darker traces)) tilt = 90.8V – 88.8V, voltage ripple = 90.4V – 84.0V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.88A – 1.62A approximately.

Voltage level switch setting on transmitter prototype = 70V.

Figure 29: Output voltage (CH2=20V/div (upper darker traces)) tilt = 102V – 99.2V, voltage ripple = 102V – 93.6V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 2.10A – 1.80A approximately.

Voltage level switch setting on transmitter prototype = 80V.

Figure 30: Output voltage (CH2=20V/div (upper darker traces)) tilt = 112V - 110V, voltage ripple = 112V - 102V & output current (CH3=0.5A/div (lower lighter traces)) ripple = 2.32A – 1.98A approximately.

Voltage level switch setting on transmitter prototype = 90V.

Figure 31: Output voltage (CH2=20V/div (upper darker traces)) tilt = 124V - 122V, voltage ripple = 124V – 114V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 2.56A – 2.20A approximately.

Voltage level switch setting on transmitter prototype = 100V.

Figure 32: Output voltage (CH2=20V/div (upper darker trace)) ripple = 12V and output current (CH3=0.5A/div (lower lighter trace)) ripple = 0.44A approximately. Ripple frequency = 181 kHz approximately.

Voltage level switch setting on transmitter prototype = 100V

Open and Short Circuit Tests

Open and short circuit tests were carried out at the output of the receiver. For these tests the Voltage Level rotary switch on the transmitter prototype was set to 100V with the pulse width set to 12 ms.

Figure 33 shows the output current envelope measured at test point **C/D** (see Figure 21) during a short circuit condition, i.e. 50Ω load replaced by a piece of wire. Figures 34 (time: 2.5ms/div) and 35 (time: 250ms/div) shows the output voltage measured across tests points **C** and **D** during a no load condition, i.e. open circuit. It can be seen that the output voltage is limited to approximately $150V_{DC}$ (164V peak) by the transient voltage suppression (TVS) diode across the output terminals of the receiver. Once the short circuit and open circuit tests conditions were removed, the receiver circuitry operated as normal.

Figure 34: Output voltage (CH2 = 50V/div) approximately $150\text{--}165V_{DC}$ during an open circuit test (time: 2.5ms/div).

Figure 35: Output voltage (CH = 50V/div) approximately $150\text{--}165V_{DC}$ peak during an open circuit test (time: 250ms/div).

Laboratory Tests with a Skin Model (physiologic fluid) using a different receiver board prototype

All the previous skin model laboratory tests were conducted with a first receiver board and a first transmitter board prototype. The following tests were carried out with a new receiver board prototype and the same transmitter prototype used previously. Figure 36 shows the test setup. The following test set-up was used throughout this section:

- Transmitter prototype was as used in the skin model testing described earlier was used for the tests with a pulse width set to 12 ms.
- Perspex prototype transformer wound with 0.75 mm diameter copper enamel wire around a 20 mm inner core. The primary coil has one coil with 30 turns. The secondary coil consists of two coils, each with 30 turns, connected in a centre-tapped configuration. The coils were not encapsulated.
- The receiver circuit employed four MURS480ET3G rectifiers (RS: 463-511) and a 470nF, $630V_{DC}$ (547-7253) filtering capacitor. The receiver circuit was not encapsulated.
- A 50Ω dummy load was used to simulate the impedance of the heart. For the open circuit test, the 50Ω dummy load across test points **C & D** (Figure 21) was removed, i.e. no load

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condition. For the short circuit test, the 50Ω dummy load across test points **C** & **D** (Figure 21) was replaced by a piece of wire.

- Fluke current probe setting: 100mV/A.

Output Voltage and Current Tests (50Ω Dummy Load)

Figures 37 to 45 to show the output voltage and current waveforms obtained at the 50Ω dummy load. Figure 46 shows the output ripple on the output voltage and current in more detail (time division: $2.5\mu\text{s}/\text{div}$).

Figure 37: Output voltage (CH2=5V/div (upper darker traces)) tilt = 20.4V – 19.6V, voltage ripple = 20.4V – 19.6V and output current (CH3=0.2A/div (lower lighter traces)) ripple = 0.42A - 0.36A approximately.

Voltage level switch setting on transmitter prototype = 20V.

Figure 38: Output voltage (CH2=5V/div (upper darker traces)) tilt = 30.4V – 29.2V, voltage ripple = 30.4V – 29.2V and output current (CH3=0.2A/div (lower lighter traces)) ripple = 0.62A - 0.54A approximately.

Voltage level switch setting on transmitter prototype = 30V.

Figure 39: Output voltage (CH2=10V/div (upper darker traces)) tilt = 40.0V – 38.4V, voltage ripple = 40.0V – 38.4V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 0.80A - 0.74A approximately.

Voltage level switch setting on transmitter prototype = 40V.

Figure 40: Output voltage (CH2=10V/div (upper darker traces)) tilt = 49.2V – 48.0V, voltage ripple = 49.2V – 47.2V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 0.98A – 0.92A approximately.

Voltage level switch setting on transmitter prototype = 50V.

Figure 41: Output voltage (CH2=10V/div (upper darker traces)) tilt = 60.4V – 59.2V, voltage ripple = 60.4V – 58.4V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.2A – 1.14A approximately.

Voltage level switch setting on transmitter prototype = 60V.

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Figure 42: Output voltage (CH2=20V/div (upper darker traces)) tilt = 70.4V – 68.8V, voltage ripple = 70.4V – 67.2V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.38A – 1.32A approximately. Voltage level switch setting on transmitter prototype = 70V.

Figure 43: Output voltage (CH2=20V/div (upper darker traces)) tilt = 78.4V – 76.8V, voltage ripple = 78.4V – 75.2V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.56A – 1.48A approximately. Voltage level switch setting on transmitter prototype = 80V.

Figure 44: Output voltage (CH2=20V/div (upper darker traces)) tilt = 87.2V – 86.4V, voltage ripple = 87.2V – 83.2V & output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.72A – 1.64A approximately. Voltage level switch setting on transmitter prototype = 90V.

Figure 45: Output voltage (CH2=20V/div (upper darker traces)) tilt = 100V - 100V, voltage ripple = 100V – 96.8V and output current (CH3=0.5A/div (lower lighter traces)) ripple = 1.98A – 1.90A approximately.

Voltage level switch setting on transmitter prototype = 100V.

Figure 46: Output voltage (CH2=20V/div (upper darker trace)) ripple = 5.6V and output current (CH3=0.5A/div (lower lighter trace)) ripple = 0.14A approximately. The ripple frequency is approximately twice the IGBT switching (181 kHz) frequency. Voltage level switch setting on transmitter prototype = 100V

Open and Short Circuit Tests

Open and short circuit tests were carried out at the output of the receiver (Prototype B). For these tests the Voltage Level rotary switch on the transmitter prototype was set to 100V with the pulse width set to 12 ms.

Figure 47 shows the output current envelope measured at test point **C/D** during a short circuit condition, i.e. 50Ω load replaced by a piece of wire. Figures 48 (time: 2.5ms/div) and 49 (time: 250ms/div) shows the output voltage measured across tests points **C** and **D** during a no load condition, i.e. open circuit. It can be seen that the output voltage is limited to approximately 150V_{DC} by the transient voltage suppression (TVS) diode across the output terminals of the receiver. Once the short circuit and open circuit tests conditions were removed, the receiver circuitry operated as normal.

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Figure 47: Output current envelope (CH3 = 2A/div) during a short circuit condition across dummy load. The waveform has a current tilt = 8.64A – 7.36A with a ripple = 8.64A – 6.56A approximately.

Figure 48: Output voltage (CH2 = 50V/div) approximately 154V_{DC} during an open circuit test (time: 2.5ms/div).

Figure 49: Output voltage (CH = 50V/div) approximately 154V_{DC} peak during an open circuit test (time: 250ms/div).

Claims:

1. An external transmitter apparatus for a cardiac defibrillator apparatus, the external transmitter apparatus being operable in use to transmit a RF pulse which may be received transcutaneously by an implantable receiver apparatus of the cardiac defibrillator apparatus and used by the implantable receiver apparatus to apply a defibrillating pulse to implantable electrodes connected to the implantable apparatus to enable a defibrillating pulse to be delivered to a heart when the electrodes are implanted in a heart in use;

wherein the external transmitter apparatus comprises a capacitor arrangement, and charging circuitry operable to charge the capacitor arrangement to thereby store energy in the capacitor arrangement,

and wherein the external transmitter apparatus further comprises a primary coil and circuitry operable to apply a RF pulse to the primary coil to energise the primary coil and cause the primary coil to transmit a RF pulse which may be received by a secondary coil of an implantable receiver apparatus when the primary coil of the external transmitter apparatus is in proximity to the secondary receiver coil of the implantable receiver apparatus in use, wherein the circuitry of the external transmitter apparatus is arranged to energise the primary coil for transmitting a RF pulse to the secondary coil using energy stored by the capacitor arrangement.

2. The apparatus of claim 1 wherein the primary coil is an air core coil.

3. The apparatus of claim 1 or 2 wherein the frequency of the RF pulse is less than 1 MHz. and preferably less than 0.5 MHz.

4. The apparatus of claim 1, 2 or 3 wherein primary coil is energised for transmitting a RF pulse to the secondary coil using only energy stored by the capacitor arrangement of the external transmitter apparatus.

5. The apparatus of any preceding claim wherein the external apparatus comprises a power source and an intermediate arrangement to step up the voltage provided by the power source to a given level for charging the capacitor arrangement, preferably wherein the intermediate arrangement is a DC to DC converter.

6. The apparatus of claim 5 wherein the power source is a DC power source, and preferably comprises a battery, most preferably a rechargeable battery.

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7. The apparatus of claim 5 or 6 wherein the power source is arranged to provide an output voltage of less than 50V, preferably less than 25 V, and most preferably less than 15 V.
8. The apparatus of any preceding claim wherein the charging circuitry of the external apparatus is operable to charge the capacitor arrangement at a voltage of between 50V and 500V.
9. The apparatus of any preceding claim wherein the charging circuitry of the external apparatus is selectively operable to charge the capacitor arrangement at a plurality of different voltages, preferably under the control of a microprocessor.
10. The apparatus of any preceding claim wherein the capacitor arrangement consists of a single electrolytic capacitor, or is an array of two or more electrolytic capacitors.
11. The apparatus of any preceding claim wherein the capacitance provided by the capacitor arrangement is at least 1000 μ F, and preferably at least 1200 μ F, or at least 1500 μ F, or at least 1800 μ F .
12. The apparatus of any preceding claim wherein the primary coil forms part of a tuned circuit of the transmitter apparatus circuitry, wherein the tuned circuit is tuned to an operating frequency of the system.
13. The apparatus of any preceding claim where the external apparatus is in the form of a portable unit, most preferably a hand held unit.
14. The apparatus of any preceding claim wherein the circuitry of the external apparatus is arranged to provide a RF pulse of energy less than 5 J for transmission to the implantable apparatus.
15. The apparatus of any preceding claim wherein the external apparatus is arranged to apply a RF pulse to the primary coil having an envelope waveform that is a rectangular or rectilinear low tilt pulse.
16. The apparatus of any preceding claim wherein the external transmitter apparatus comprises a switching arrangement drivable at the RF frequency of the RF pulse to be applied to the coil to alternately allow and not allow the capacitor arrangement to discharge through the

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primary coil for energising the coil over a period corresponding to the duration of the pulse to be applied to the coil to thereby apply the RF pulse to the primary coil.

17. The apparatus of any preceding claim wherein the circuitry of the external apparatus comprises a switching arrangement switchable between a first configuration in which the capacitor arrangement may not discharge through the primary coil and a second configuration in which the capacitor arrangement may discharge through the primary coil for energising the coil, and driver circuitry for driving the switching arrangement between the first and second configurations at a frequency corresponding to the frequency of the RF pulse to be applied to the primary coil over a period corresponding to the duration of the RF pulse to be applied to thereby apply the RF pulse to the primary coil.

18. A cardiac defibrillation apparatus comprising the external transmitter apparatus of the invention in accordance with any preceding claim and an implantable receiver apparatus, wherein the implantable receiver apparatus comprises a secondary coil for receiving a RF pulse transmitted transcutaneously by the external transmitter apparatus when the secondary coil is in proximity to the primary coil of the external transmitter apparatus, and circuitry for using the received RF pulse to apply a defibrillating pulse to implantable electrodes connected to the implantable apparatus for delivering a defibrillating pulse to the heart when the electrodes are implanted in a heart.

19. A cardiac defibrillator apparatus comprising an external transmitter apparatus and an implantable receiver apparatus,

wherein the implantable receiver apparatus is arranged to receive a RF pulse transmitted transcutaneously by the external transmitter apparatus in use and to the RF pulse to apply a defibrillating pulse to implantable electrodes connected to the implantable apparatus to enable a defibrillating pulse to be delivered to a heart when the electrodes are implanted in a heart in use,

wherein the external transmitter apparatus comprises a capacitor arrangement, and charging circuitry operable to charge the capacitor arrangement to thereby store energy in the capacitor arrangement,

the external transmitter apparatus further comprising a primary coil and circuitry operable to apply a RF pulse to the primary coil to energise the primary coil and cause the primary coil to transmit a RF pulse which may be received transcutaneously by a secondary coil of the implantable receiver apparatus when the primary coil of the external transmitter apparatus is in proximity to a secondary receiver coil of an implantable receiver apparatus in use,

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wherein the circuitry of the external transmitter apparatus is arranged to energise the primary coil for transmitting a RF pulse to the secondary coil using energy stored by the capacitor arrangement,

and wherein the implantable receiver apparatus further comprises circuitry for using a RF pulse transmitted transcutaneously by the primary coil and received by the secondary coil to apply a defibrillating pulse to implantable electrodes connected to the implantable apparatus for delivering a defibrillating pulse to a heart when the electrodes are implanted in a heart.

20. The apparatus of claim 19 wherein the circuitry of the implantable apparatus includes only passive components.

21. The apparatus of claim 19 or 20 wherein the secondary coil is an air core coil.

22. The use of the apparatus of the invention in accordance with any preceding claim to deliver cardiac defibrillation.

23. A method of delivering cardiac defibrillation using the apparatus of any preceding claim, wherein the implantable apparatus is implanted in a patient, and the electrodes are implanted in the heart of the patient, the method comprising operating the charging circuitry of the external transmitter apparatus to charge the capacitor arrangement, locating the primary coil in proximity to the secondary coil of the implanted apparatus, and operating the circuitry of the external transmitter apparatus to cause a RF pulse to be applied to the primary coil to cause the implanted apparatus to deliver a defibrillating shock pulse via the electrodes.

24. An apparatus or method substantially as herein described and with reference to any one of the accompanying drawings.

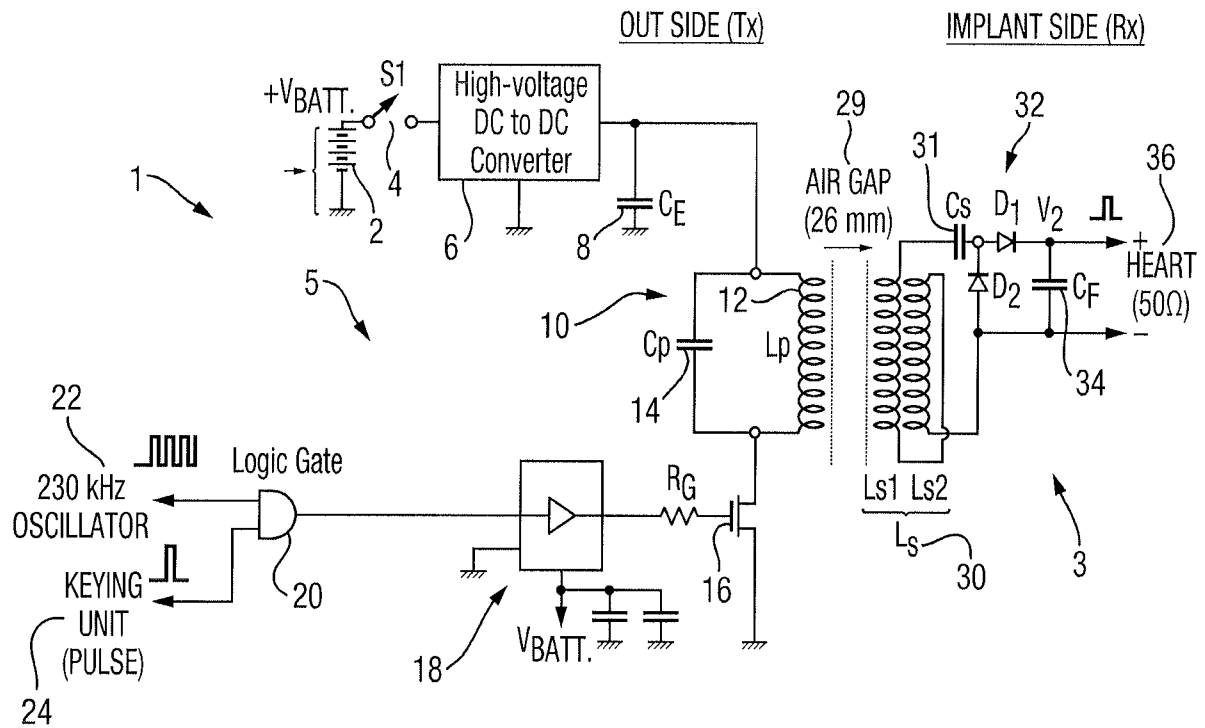
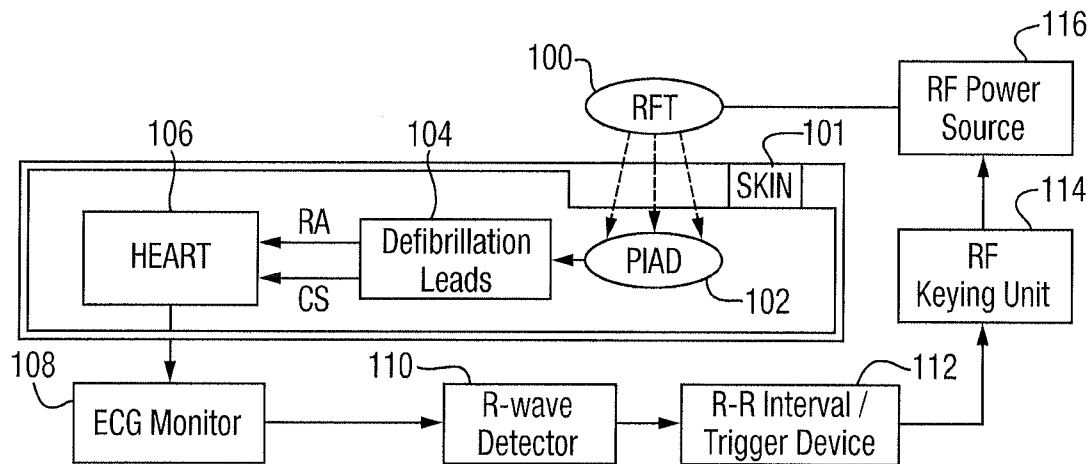


Figure 1



RA: right atrial lead
 CS: coronary sinus lead
 PIAD: passive implantable atrial defibrillator
 RFT: radio frequency transmitter (power)

Figure 2

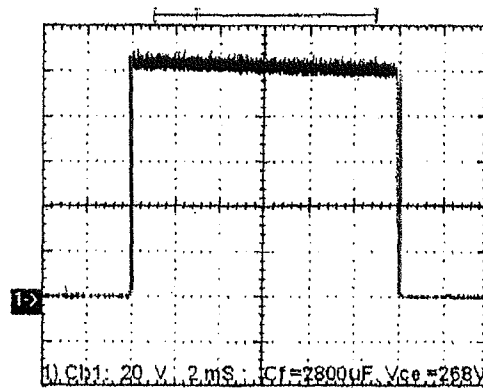


Figure 3 Output voltage pulse (12 ms duration) across the 50Ω load (V_L), for a primary capacitor (C_E) charge voltage of 267.8 V.

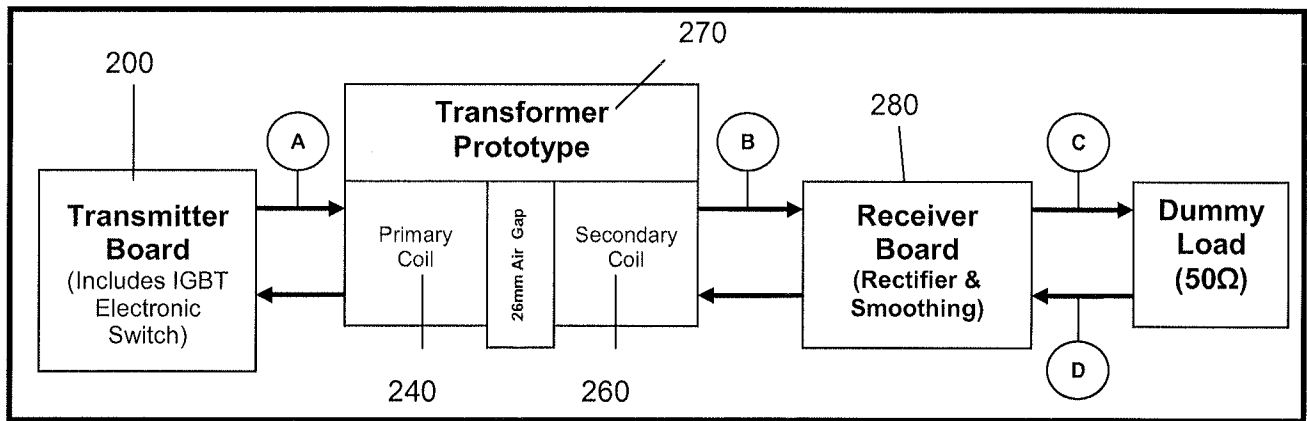


Figure 4

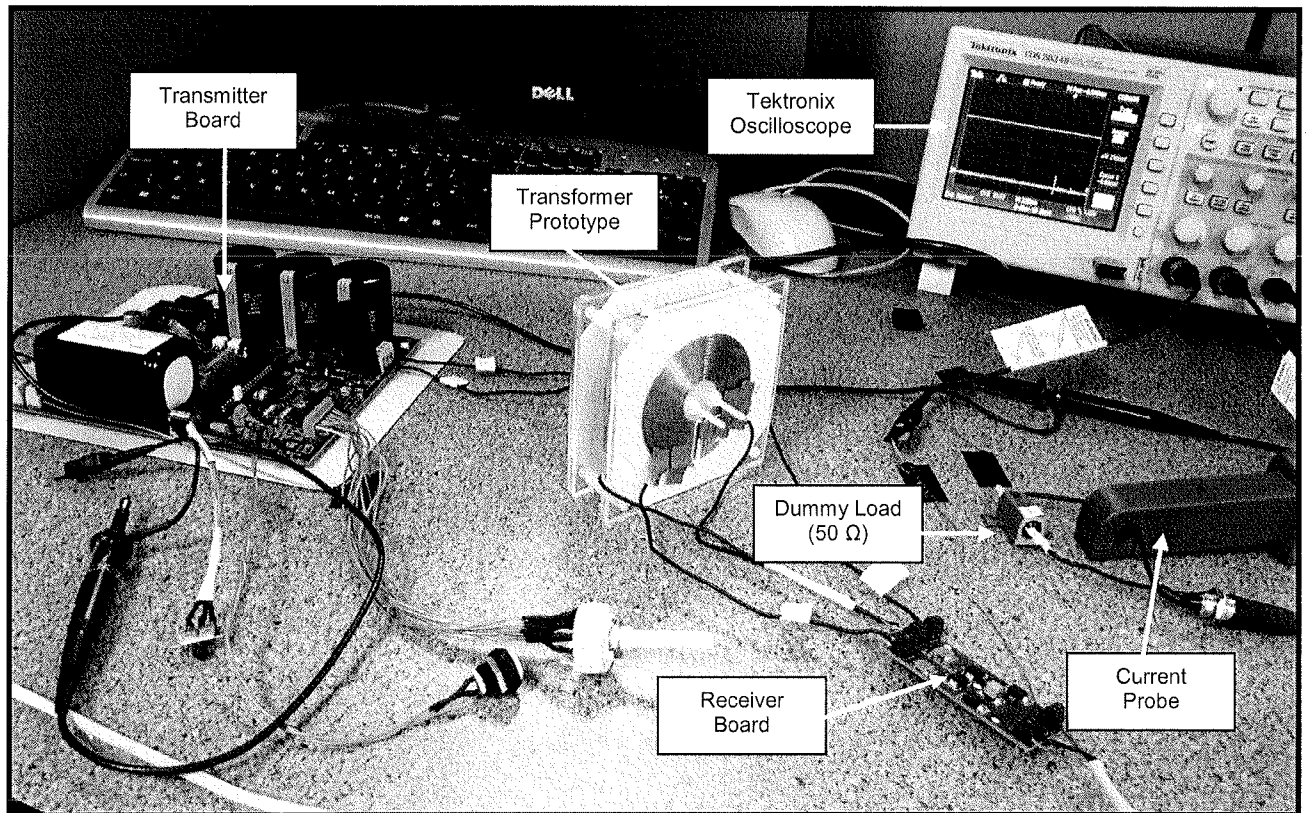


Figure 4A- photography of a typical test set-up

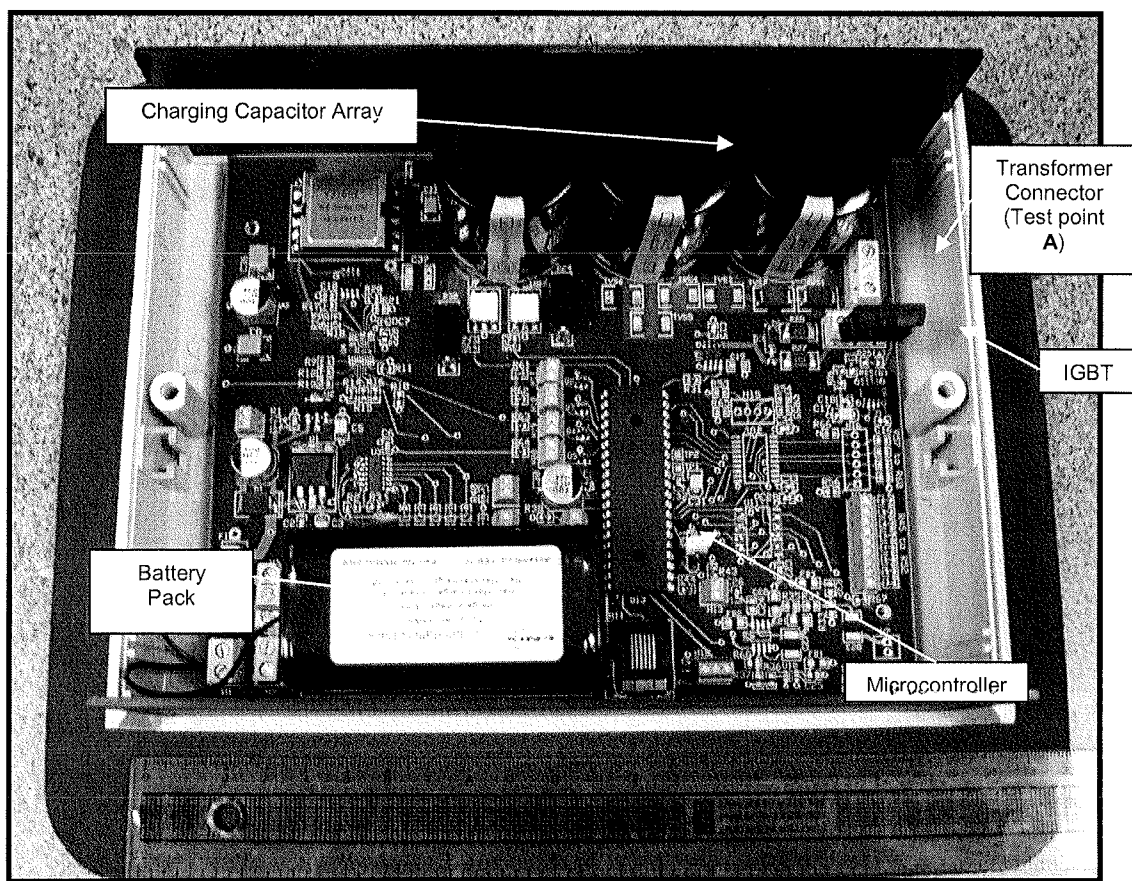


Figure 4B: Populated transmitter board with lithium-ion battery pack.

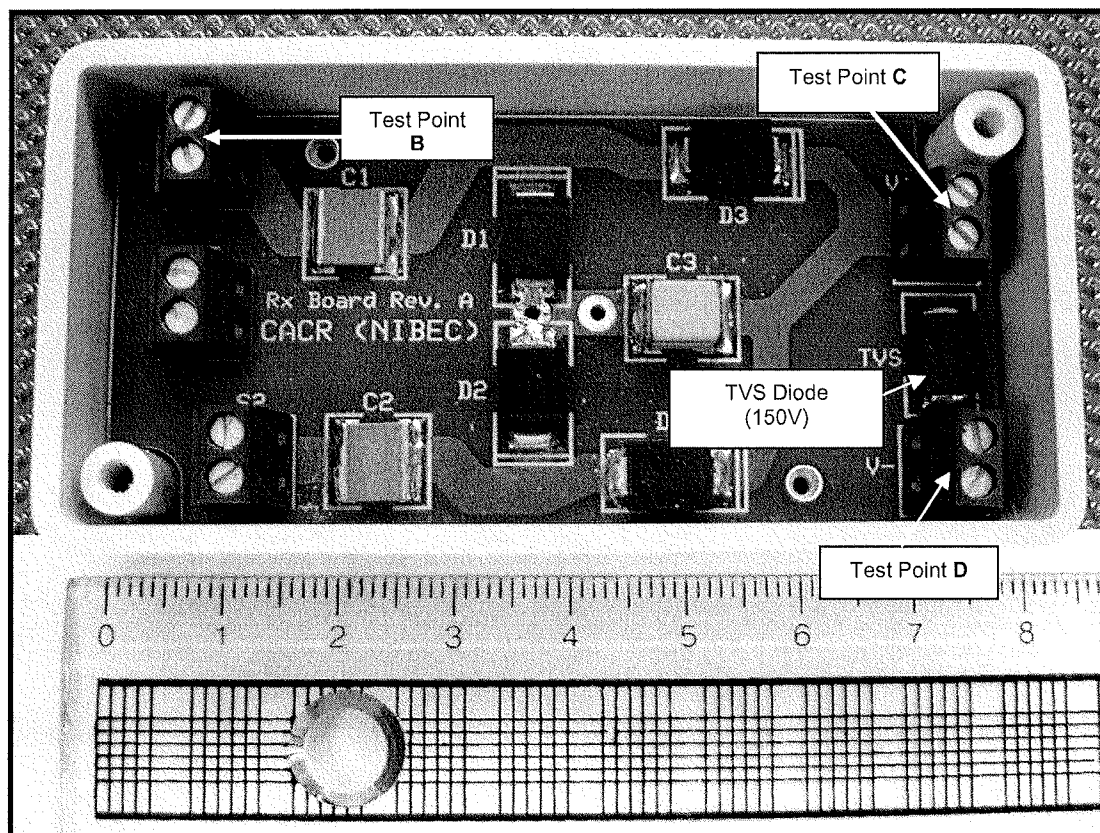


Figure 4C: Populated receiver board.

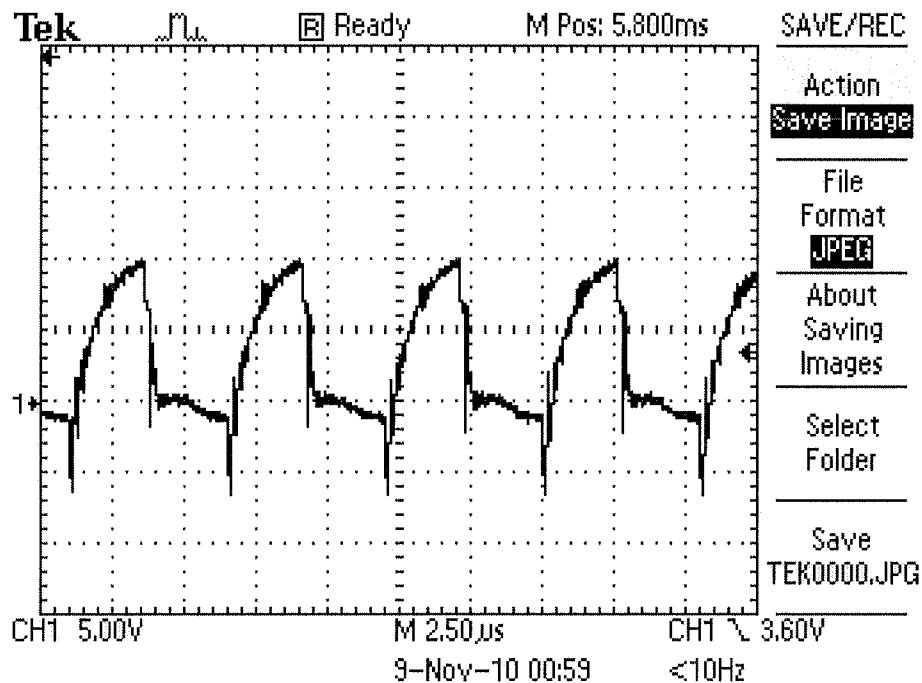


Figure 5 IGBT gate signal (approximately 180 kHz switching frequency).

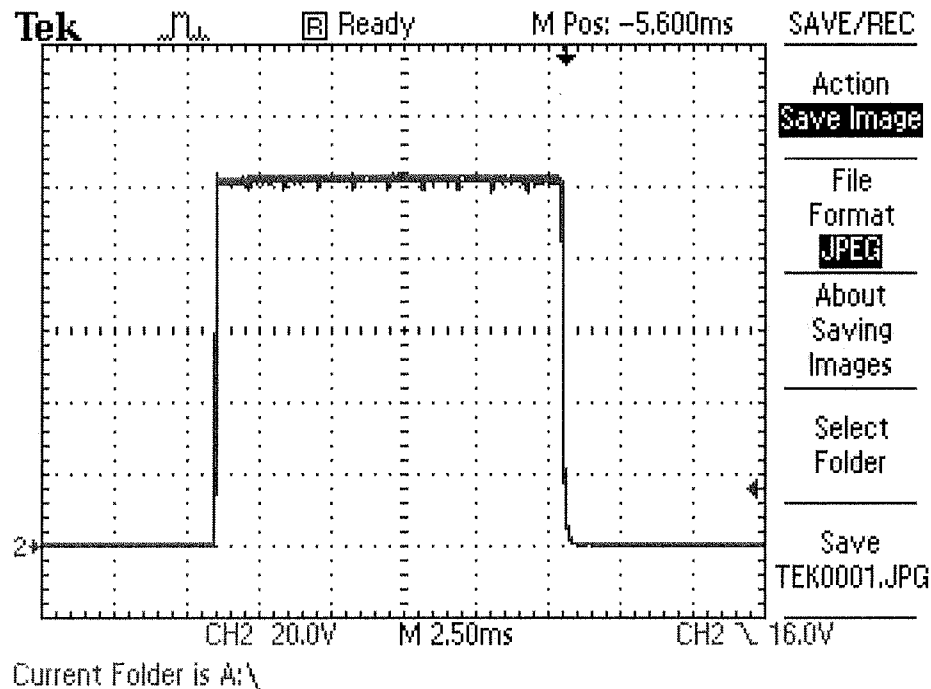


Figure 6 Output voltage (approximately 102V_{DC}) with a 2V_{DC} tilt measured across test points C & D.

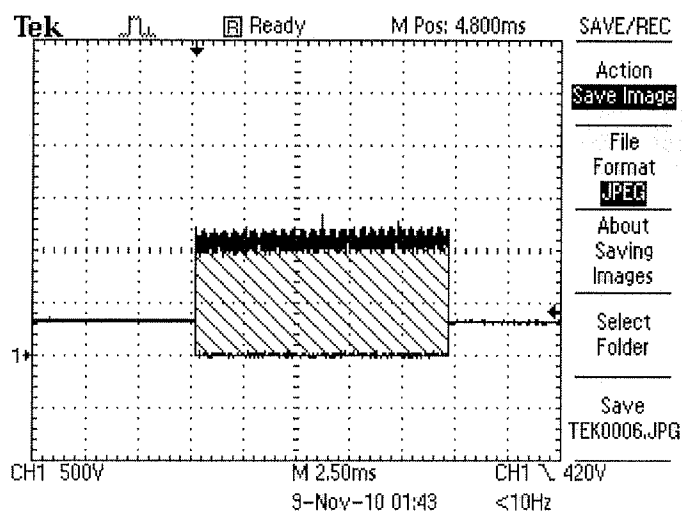


Figure 7: Collector-Emitter voltage envelope measured across the IGBT junction (1.36kV_{peak-to-peak}).

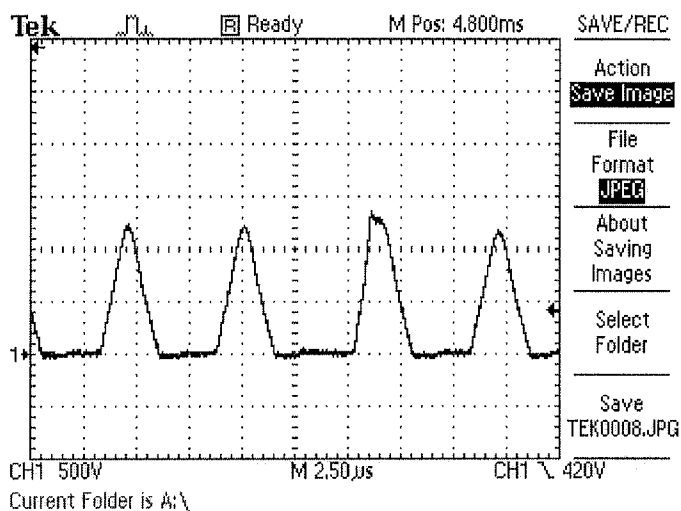


Figure 8: Collector-Emitter voltage measured across the IGBT junction (2.5μs/div).

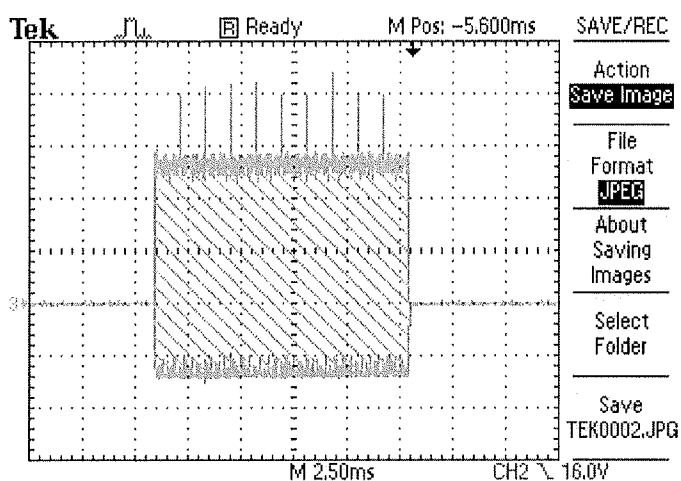
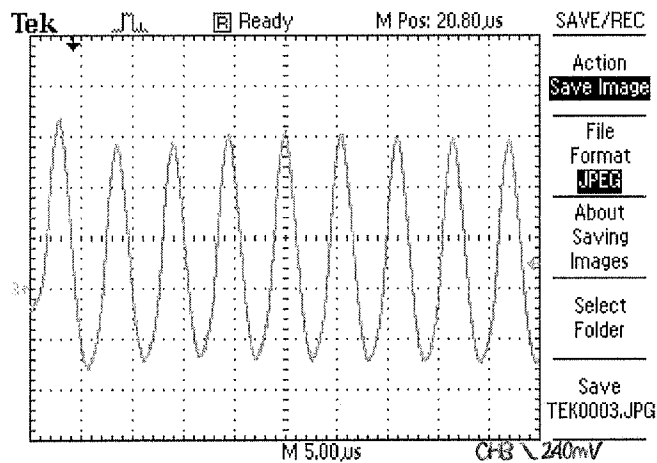
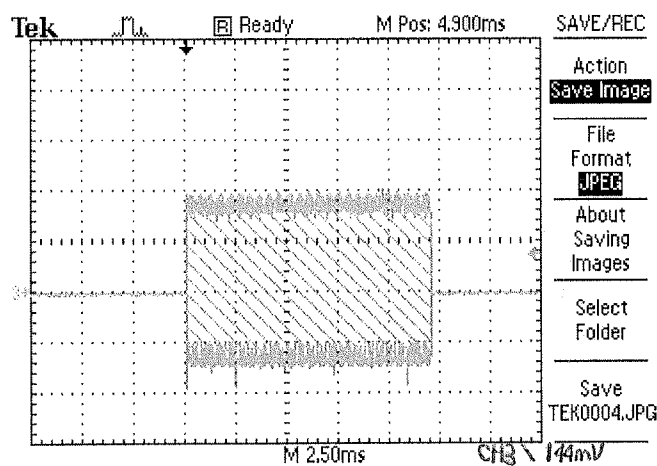


Figure 9: Current envelope (29.6A_{peak-to-peak}) measured at test point A on transmitter side of transformer.



Current Folder is A:\

Figure 10: Current envelope measured at test point **A** on transmitter side of transformer (5 μ s/div).



Current Folder is A:\

Figure 11: Current envelope (7.92A_{peak-to-peak}) measured at test point **B** on receiver side of transformer.

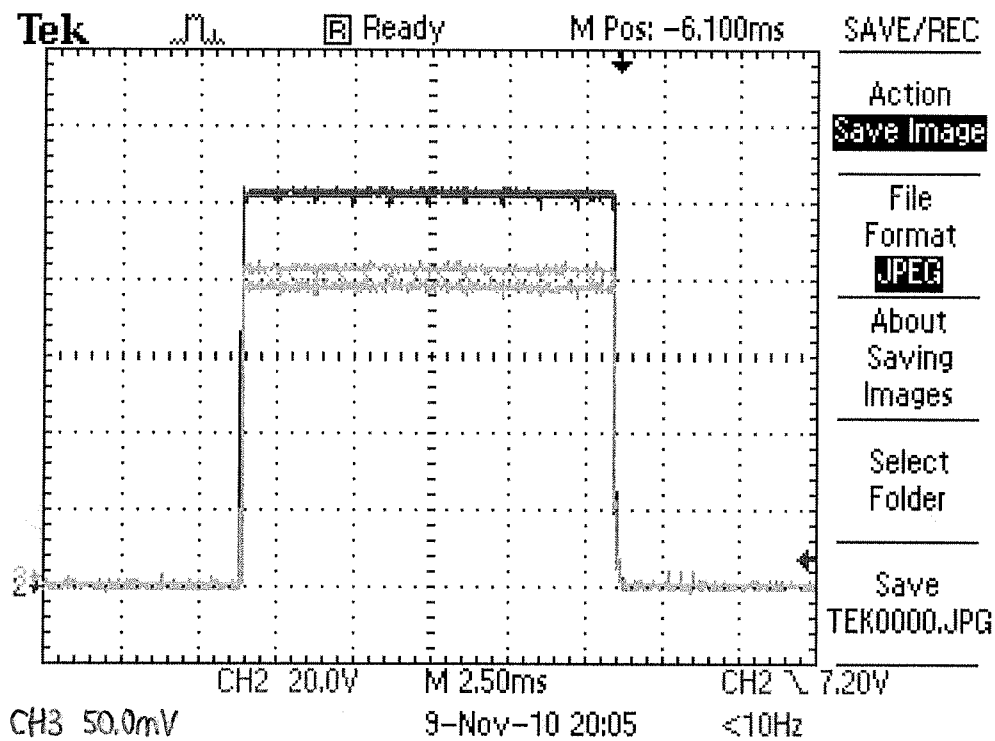


Figure 12: Output voltage (uppermost trace) and current (lower traces) measured at 50 Ω dummy load.

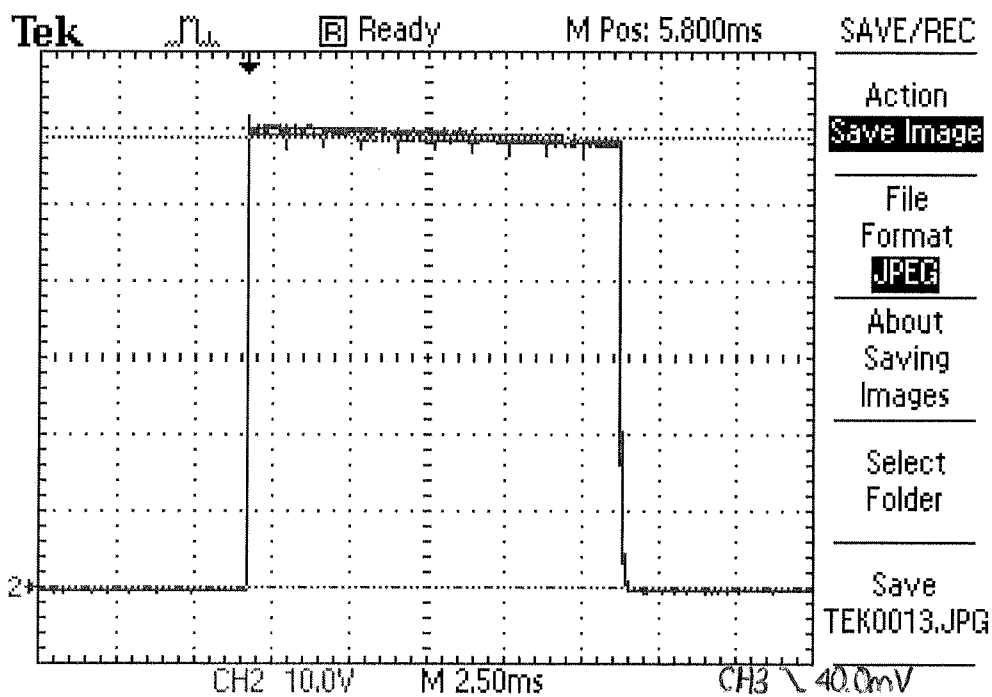
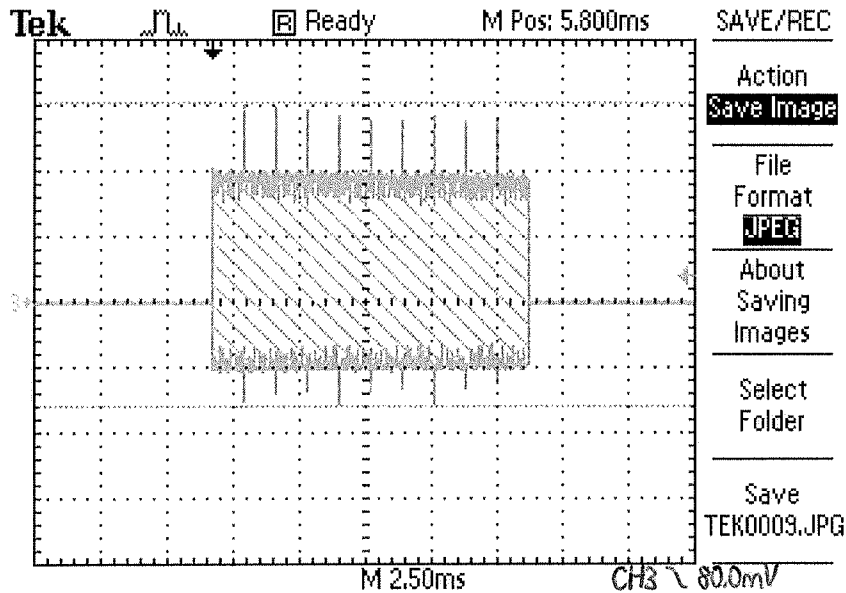
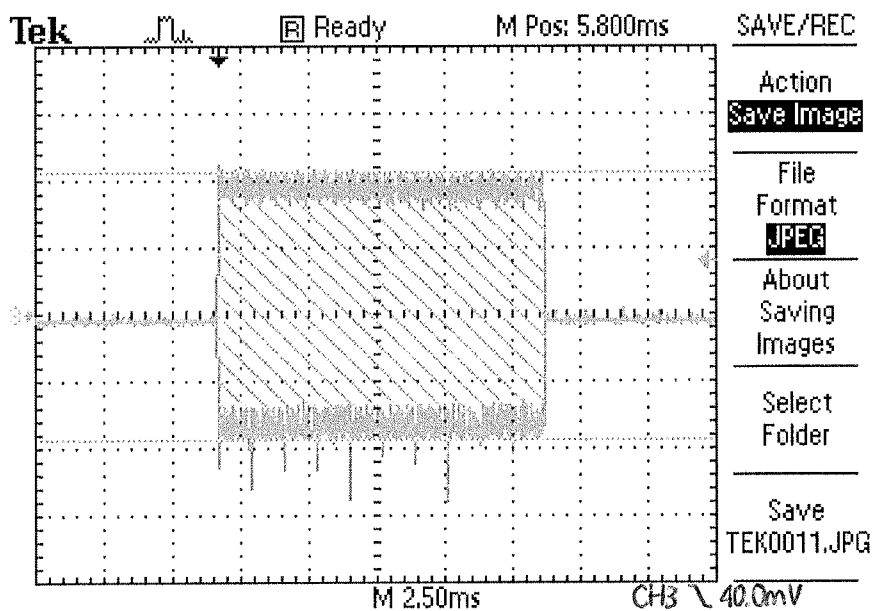


Figure 13: Output voltage (approximately 59V_{DC}) with a 2.8V_{DC} tilt measured across test points **C** & **D**.



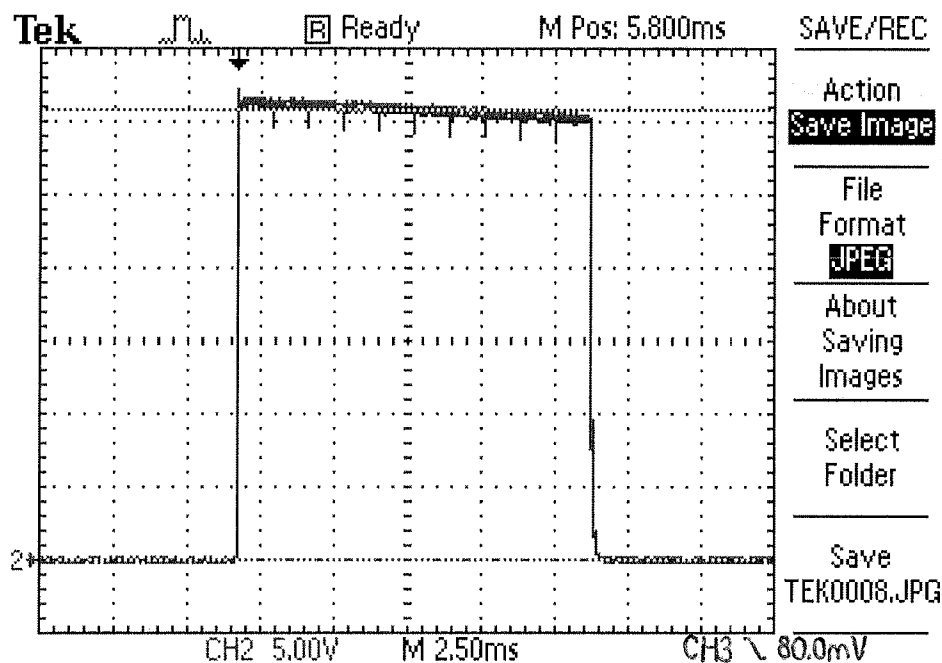
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Figure 14: Current envelope ($18.6A_{\text{peak-to-peak}}$) measured at test point **A** on transmitter side of transformer.



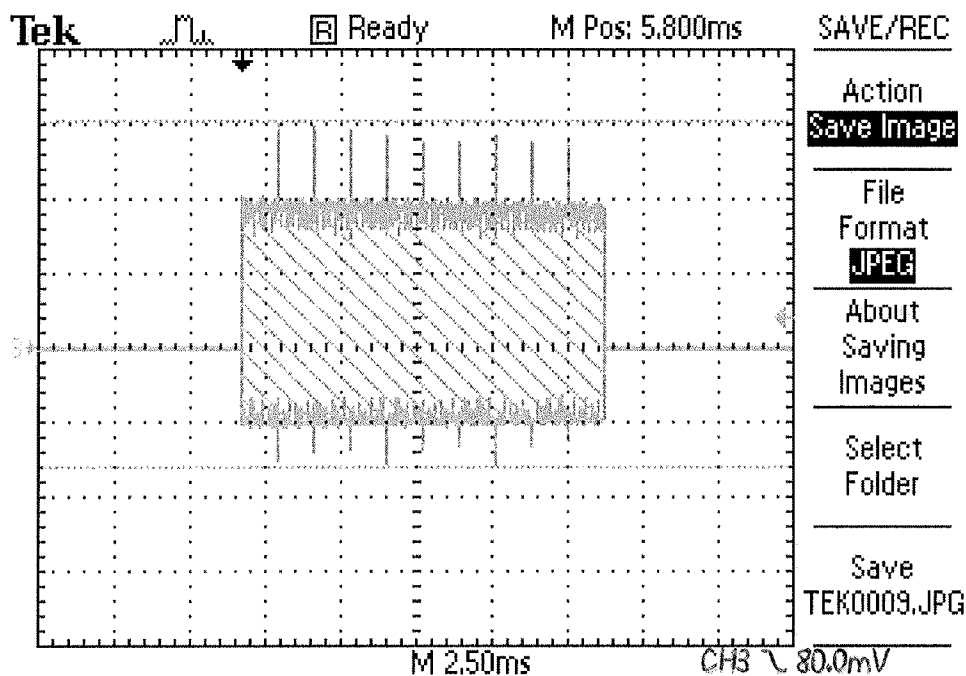
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Figure 15: Current envelope ($4.6A_{\text{peak-to-peak}}$) measured at test point **B** on receiver side of transformer.



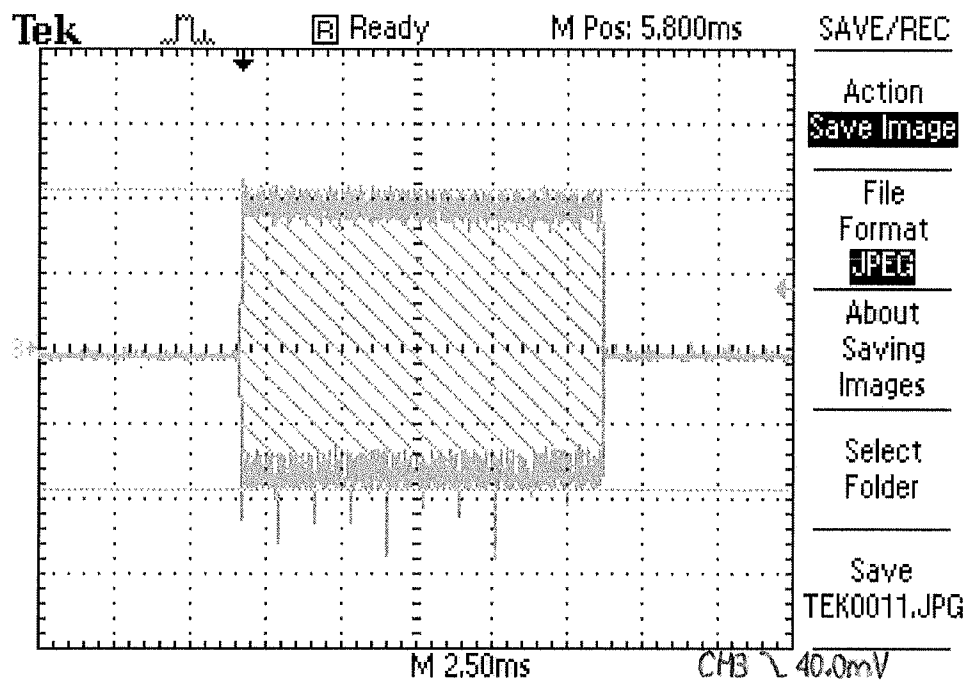
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Figure 16: Output voltage (approximately 30.5V_{DC}) with a 1.8V_{DC} tilt measured across test points **C** & **D**.



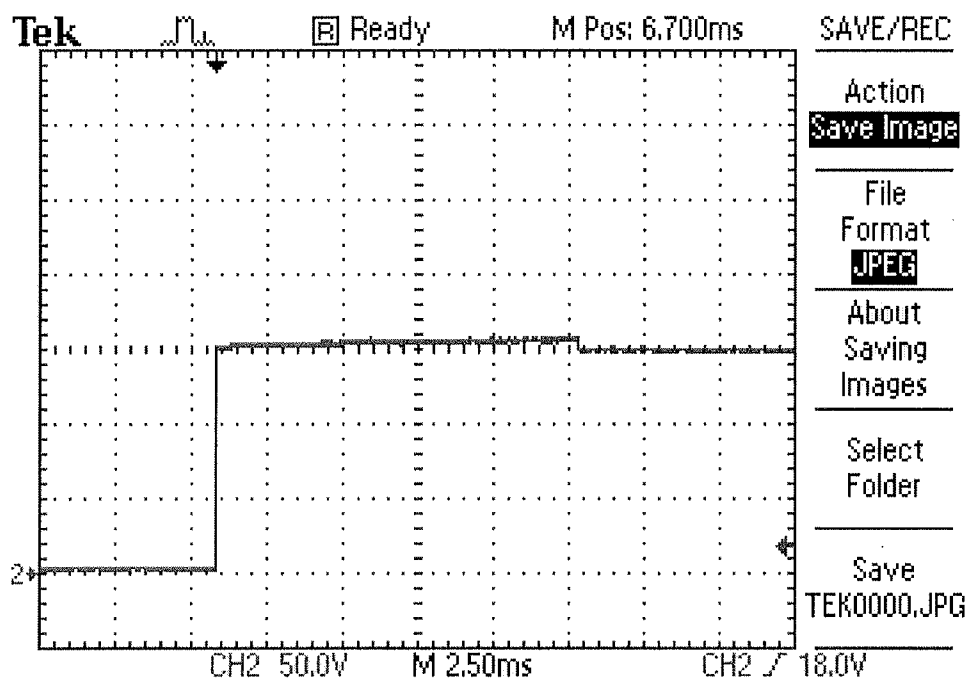
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Figure 17: Current envelope (9.28A_{peak-to-peak}) measured at test point **A** on transmitter side of transformer.



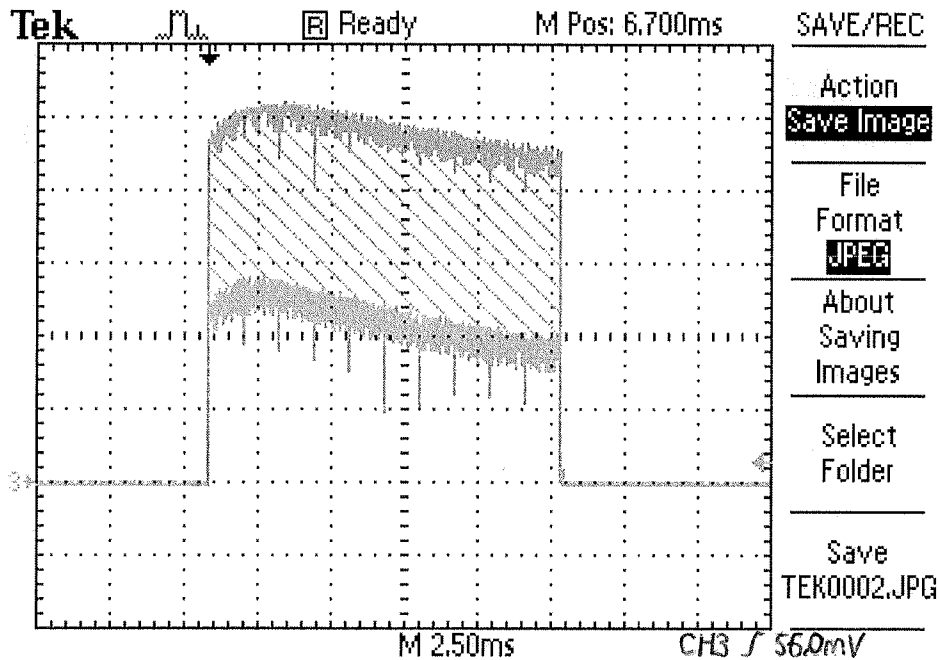
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Figure 18: Current envelope ($2.52A_{\text{peak-to-peak}}$) measured at test point **B** on receiver side of transformer.



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Figure 19: Output voltage clamped to $150V_{\text{DC}}$ during a no load condition, i.e. open circuit.



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Figure 20: Current envelope ($10.4A_{\text{peak to peak}}$) measured at test point C/D during a short circuit condition.

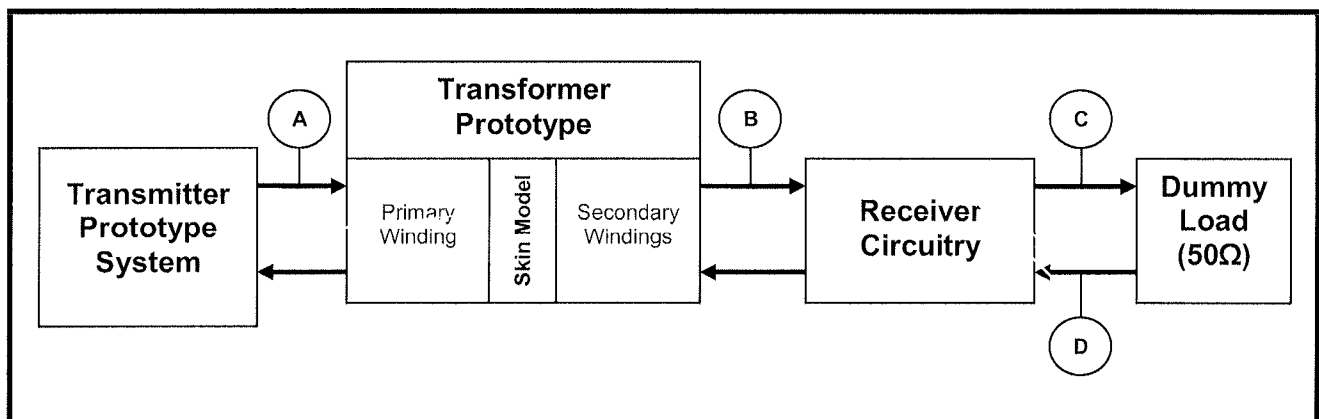


Figure 21- Test set-up for the prototype system with the test points labelled.

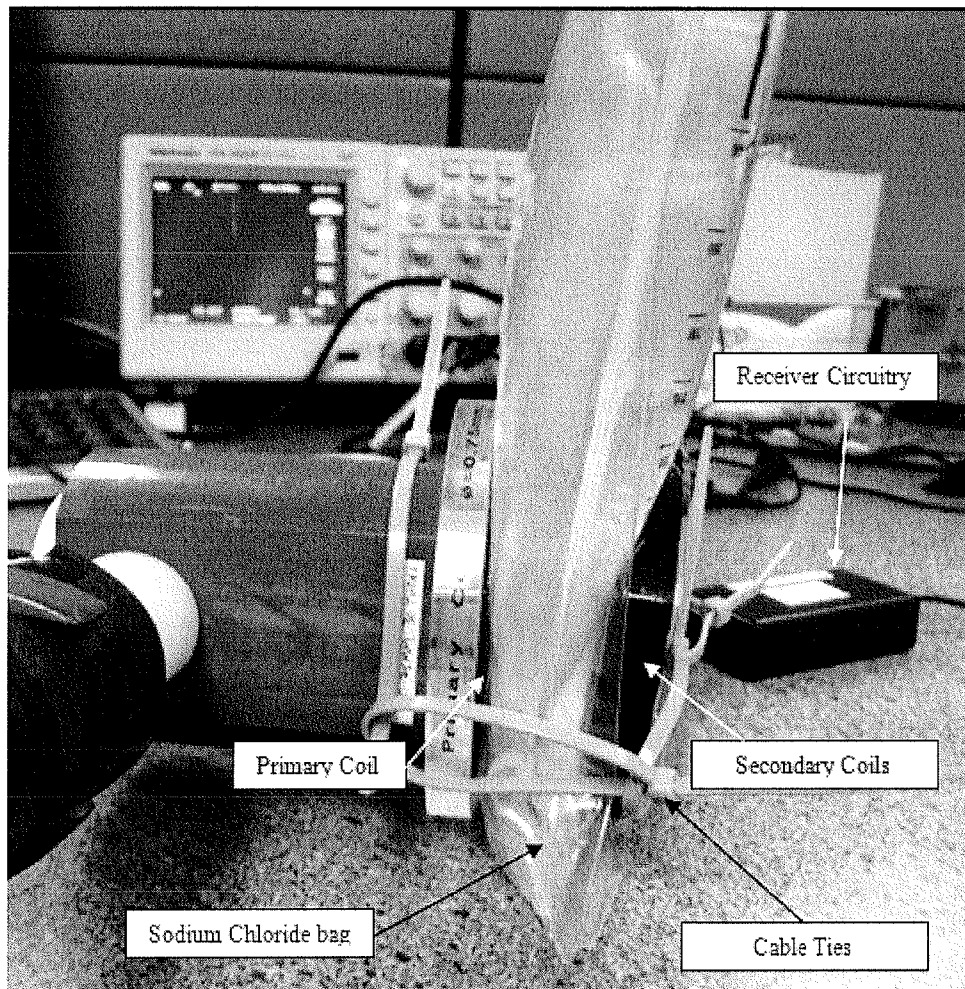


Figure 22 Test set-up using a sodium chloride bag (0.9%, 500 ml) positioned between coils.

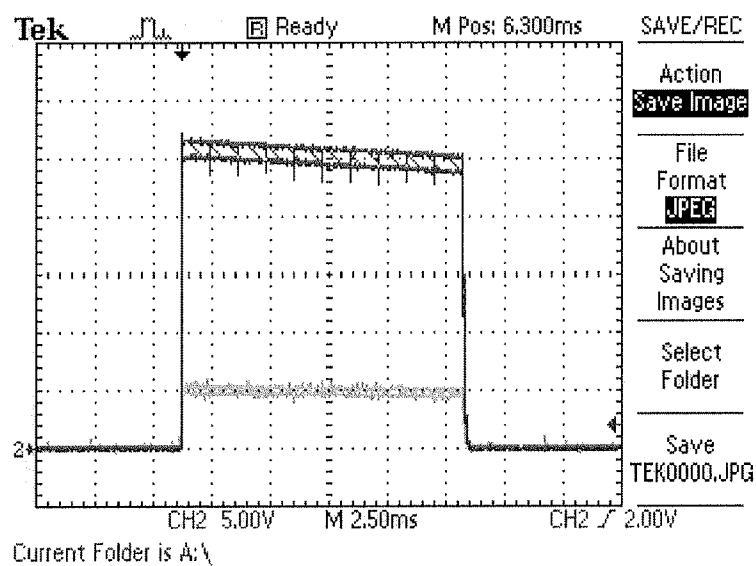
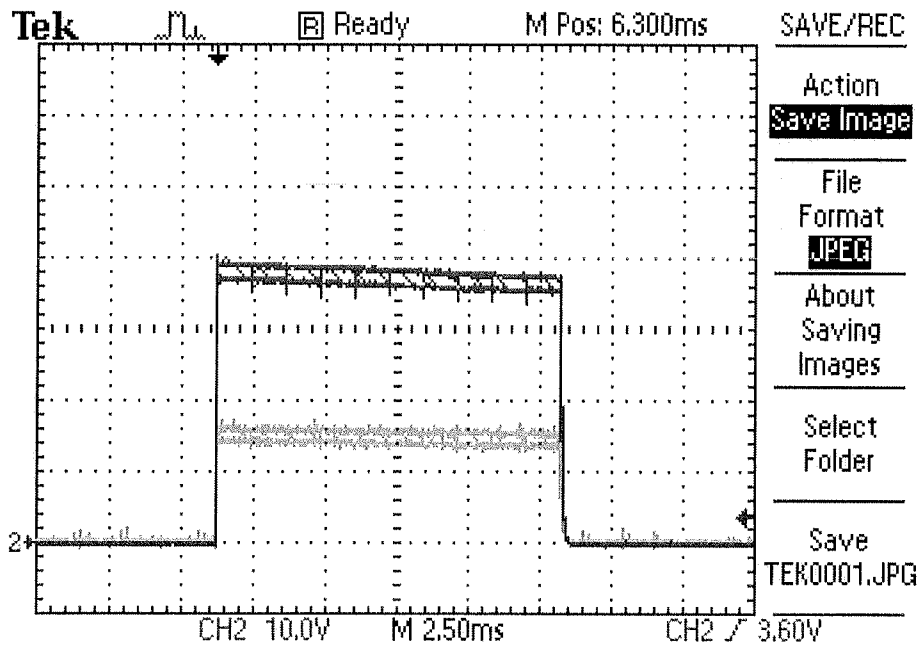


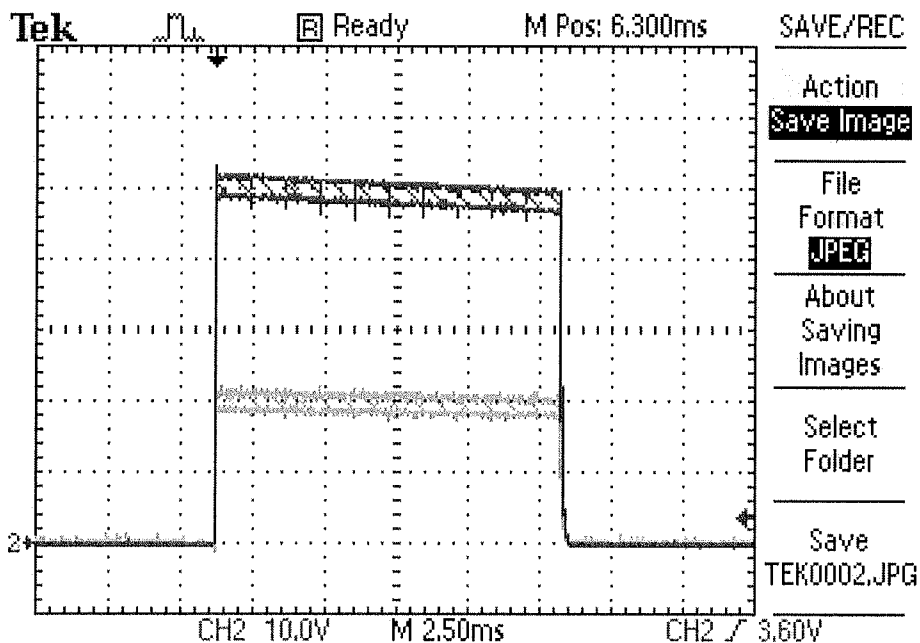
Figure 23: Output voltage (CH2=5V/div (upper trace)) tilt = 26.6V – 25.4V, voltage ripple = 26.6V – 25.0V and output current (CH3=0.5A/div (lower trace)) ripple = 0.56A - 0.47A approximately.
Voltage level switch setting on transmitter prototype = 20V.



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Figure 24: Output voltage (CH2=10V/div (upper trace)) tilt = 39.2V – 37.6V, voltage ripple = 39.2V – 36.8V and output current (CH3=0.5A/div (lower trace)) ripple = 0.82A - 0.70A approximately.

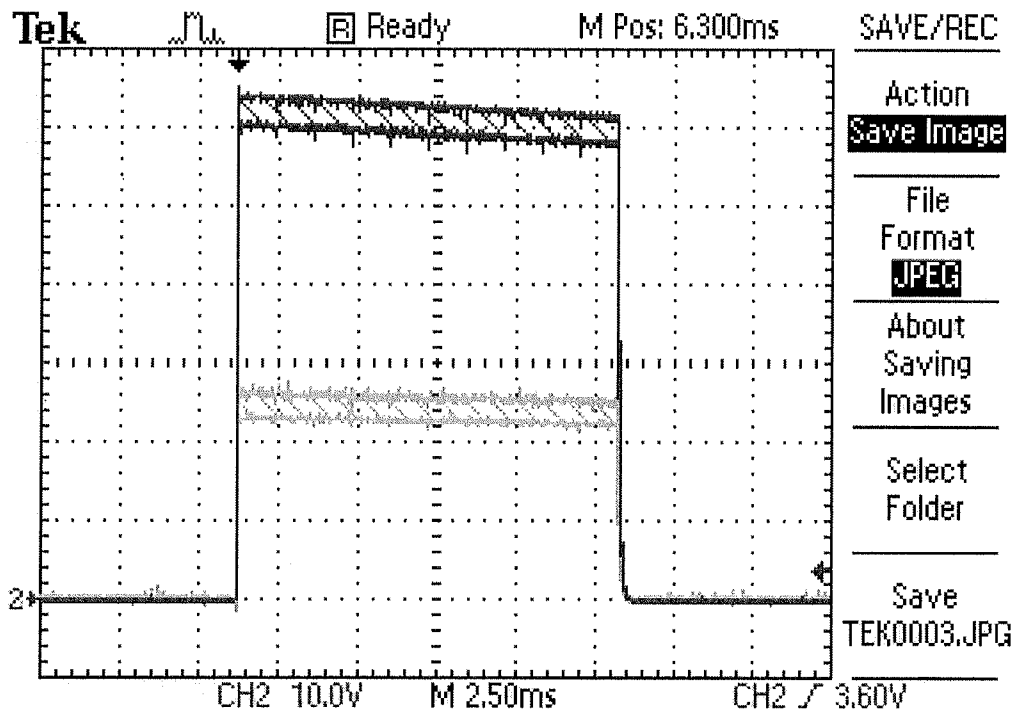
Voltage level switch setting on transmitter prototype = 30V.



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Figure 25: Output voltage (CH2=10V/div (upper trace)) tilt = 52.0V – 49.6V, voltage ripple = 52.0V – 48.8V and output current (CH3=0.5A/div (lower trace)) ripple = 1.08A - 0.92A approximately.

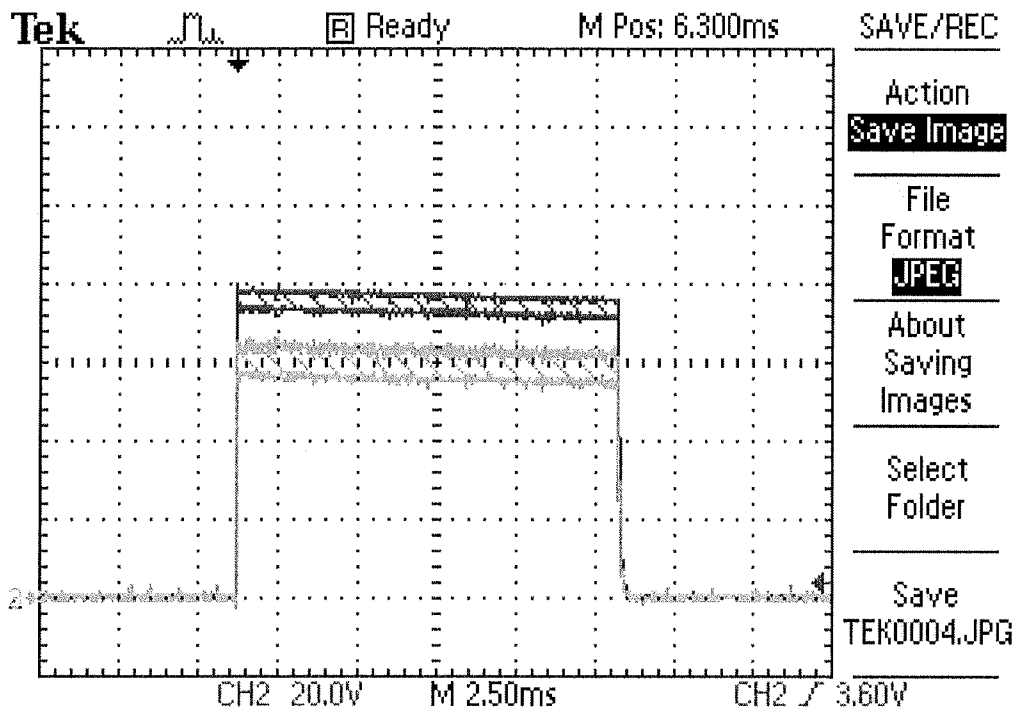
Voltage level switch setting on transmitter prototype = 40V.



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Figure 26: Output voltage (CH2=10V/div (upper trace)) tilt = 64.0V – 61.6V, voltage ripple = 64.0V – 60.0V and output current (CH3=0.5A/div (lower trace)) ripple = 1.34A – 1.14A approximately.

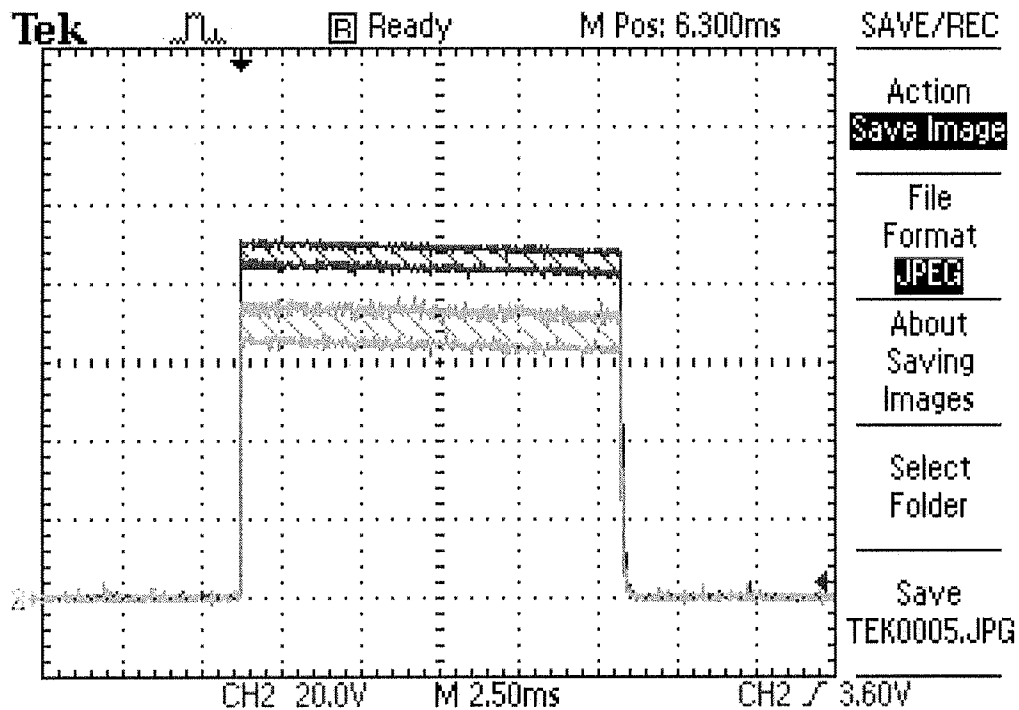
Voltage level switch setting on transmitter prototype = 50V



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Figure 27: Output voltage (CH2=20V/div (upper traces)) tilt = 78.4V – 76.0V, voltage ripple = 78.4V – 72.8V and output current (CH3=0.5A/div (lower traces)) ripple = 1.62A – 1.40A approximately.

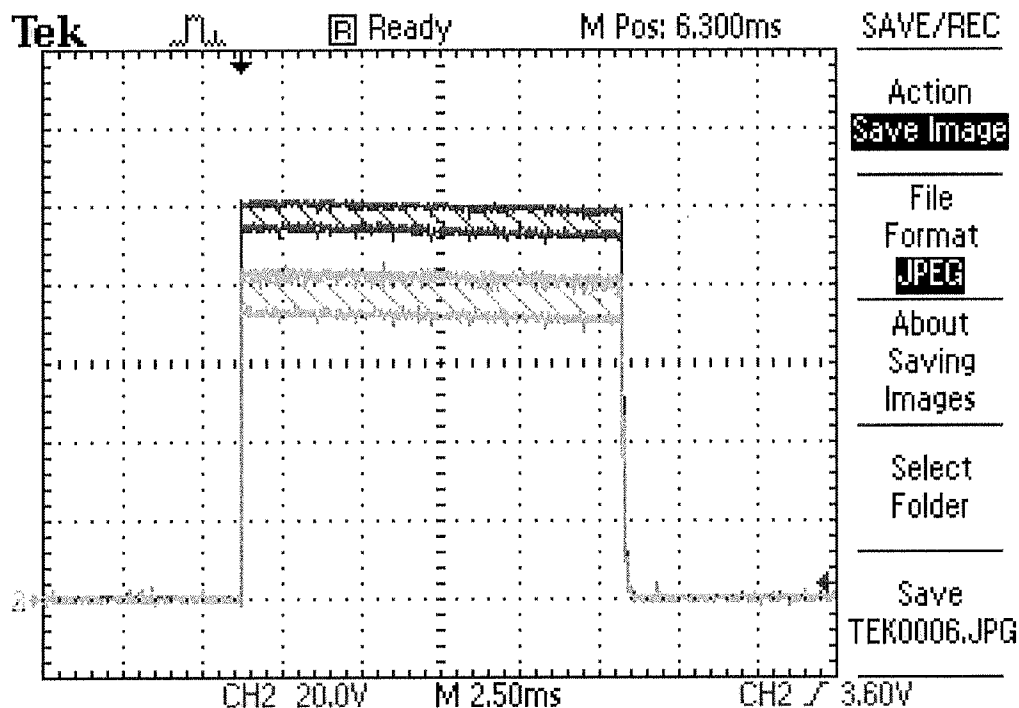
Voltage level switch setting on transmitter prototype = 60V.



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Figure 28: Output voltage (CH2=20V/div (upper traces)) tilt = 90.8V – 88.8V, voltage ripple = 90.4V – 84.0V and output current (CH3=0.5A/div (lower traces)) ripple = 1.88A – 1.62A approximately.

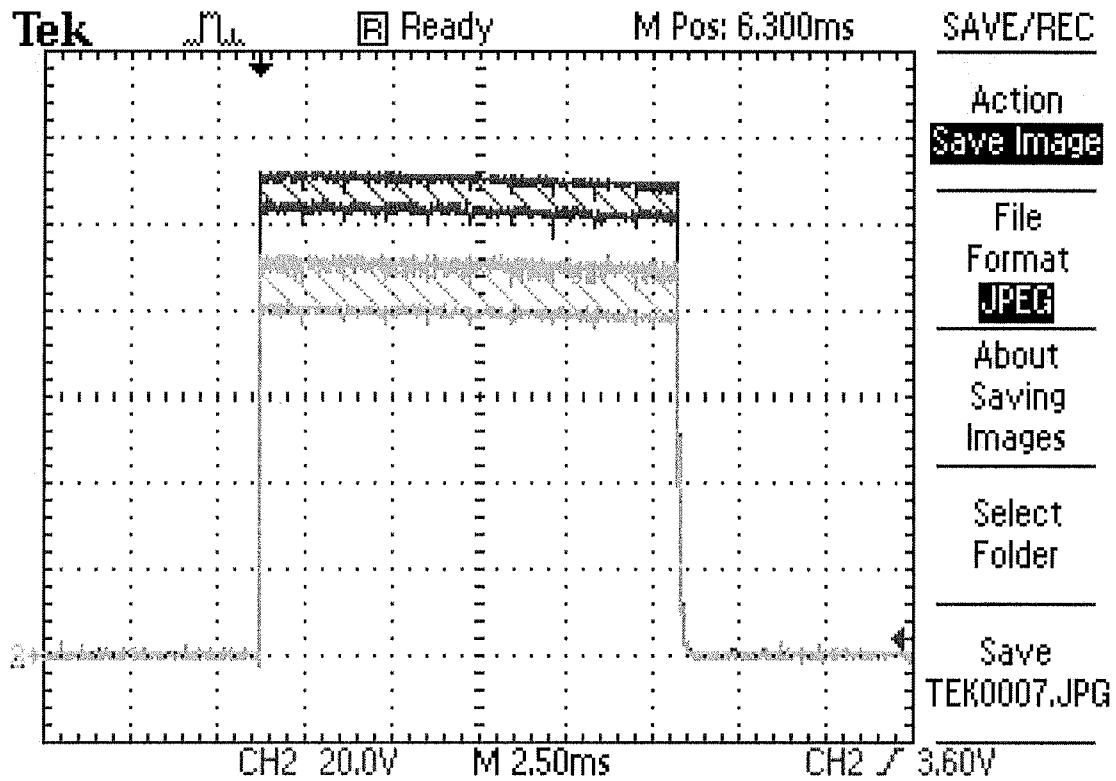
Voltage level switch setting on transmitter prototype = 70V.



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Figure 29: Output voltage (CH2=20V/div (upper traces)) tilt = 102V – 99.2V, voltage ripple = 102V – 93.6V and output current (CH3=0.5A/div (lower traces)) ripple = 2.10A – 1.80A approximately.

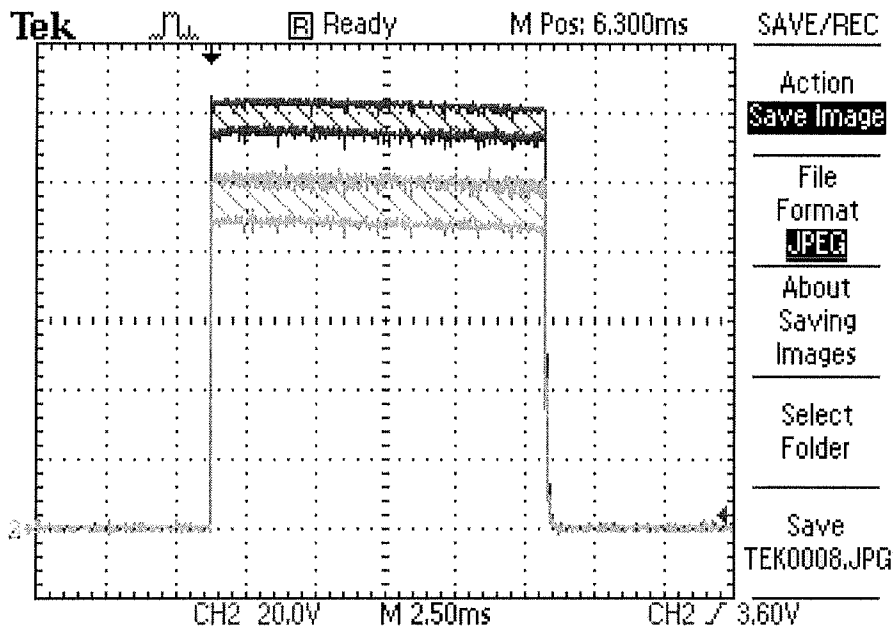
Voltage level switch setting on transmitter prototype = 80V.



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Figure 30: Output voltage (CH2=20V/div (upper traces)) tilt = 112V - 110V, voltage ripple = 112V - 102V & output current (CH3=0.5A/div (lower traces) ripple = 2.32A - 1.98A approximately.

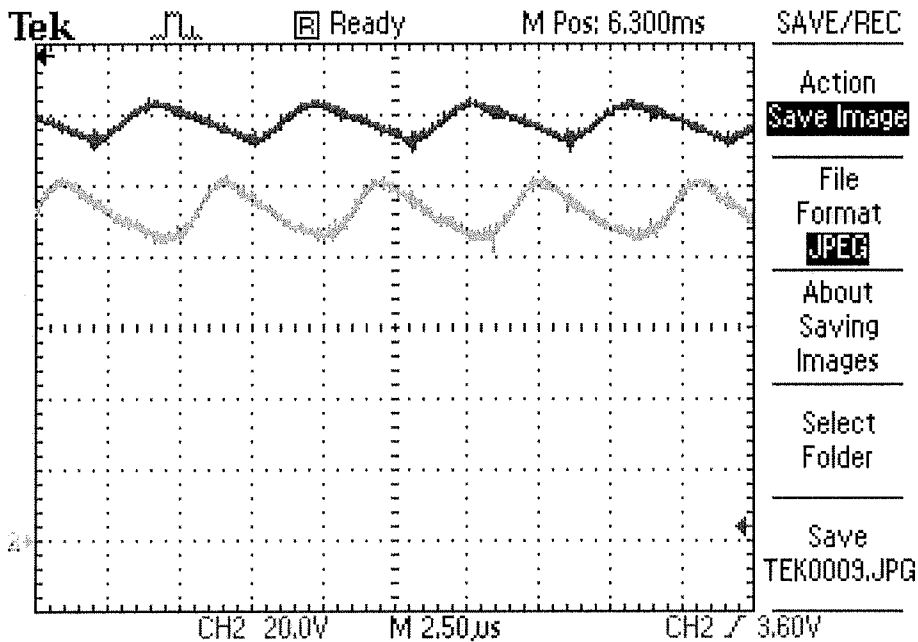
Voltage level switch setting on transmitter prototype = 90V.



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Figure 31: Output voltage (CH2=20V/div (upper traces)) tilt = 124V - 122V, voltage ripple = 124V - 114V and output current (CH3=0.5A/div (lower traces)) ripple = 2.56A - 2.20A approximately.

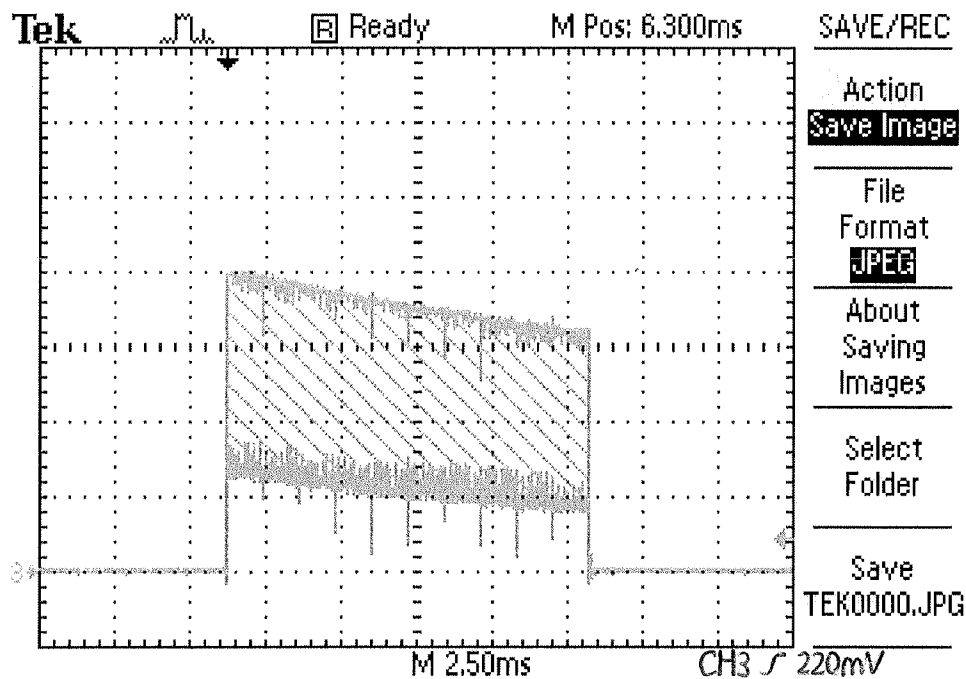
Voltage level switch setting on transmitter prototype = 100V.



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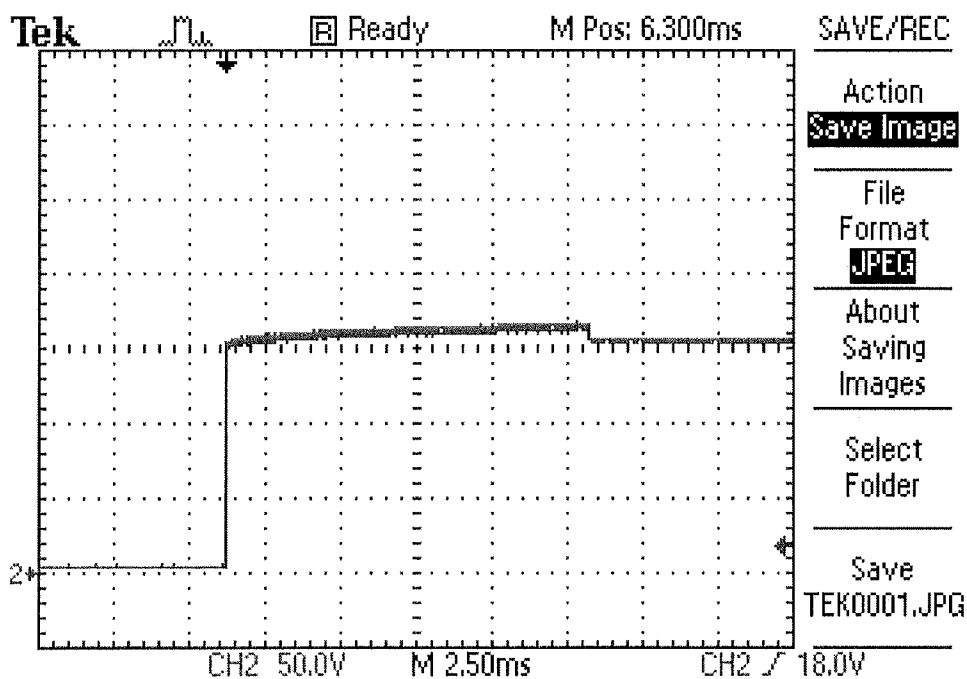
Figure 32: Output voltage (CH2=20V/div (upper trace)) ripple = 12V and output current (CH3=0.5A/div (lower trace)) ripple = 0.44A approximately. Ripple frequency = 181 kHz approximately.

Voltage level switch setting on transmitter prototype = 100V



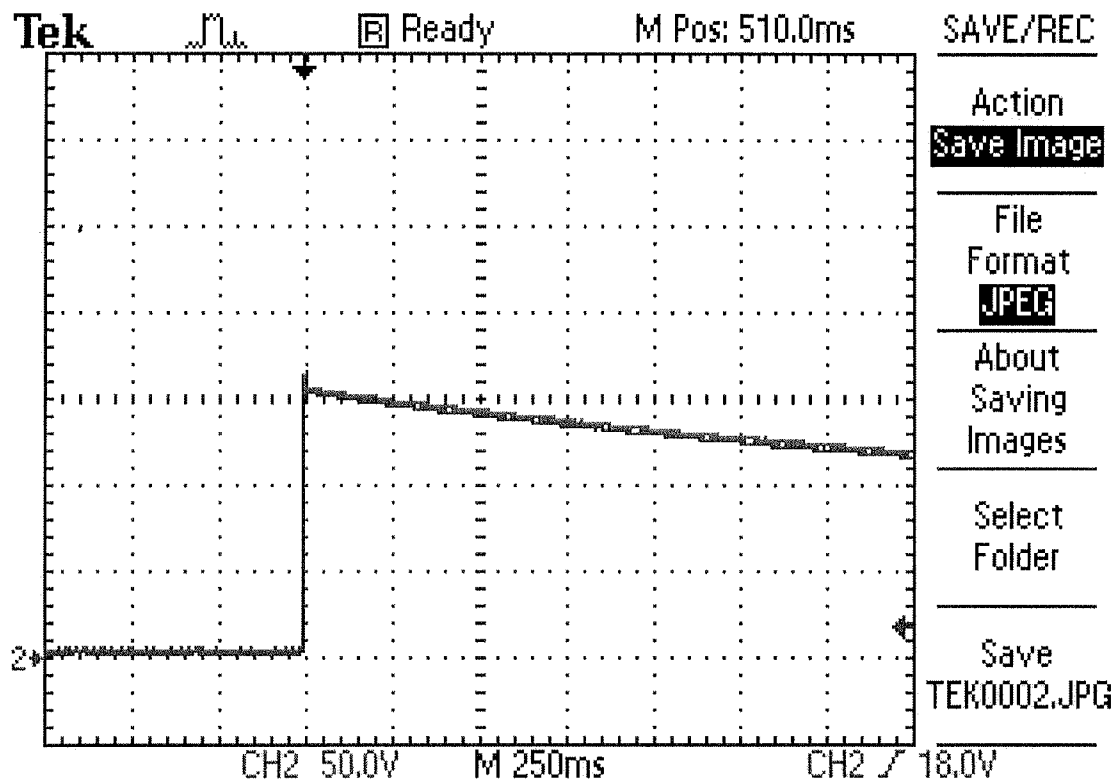
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Figure 33: Output current envelope (CH3 = 5A/div) during a short circuit condition across dummy load. The waveform has a current tilt = 20.0A – 16.2A with a ripple = 20.0A – 6.2A approximately.



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Figure 34: Output voltage (CH2 = 50V/div) approximately 150-165V_{DC} during an open circuit test (time: 2.5ms/div).



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Figure 35: Output voltage (CH = 50V/div) approximately 150-165V_{DC} peak during an open circuit test (time: 250ms/div).

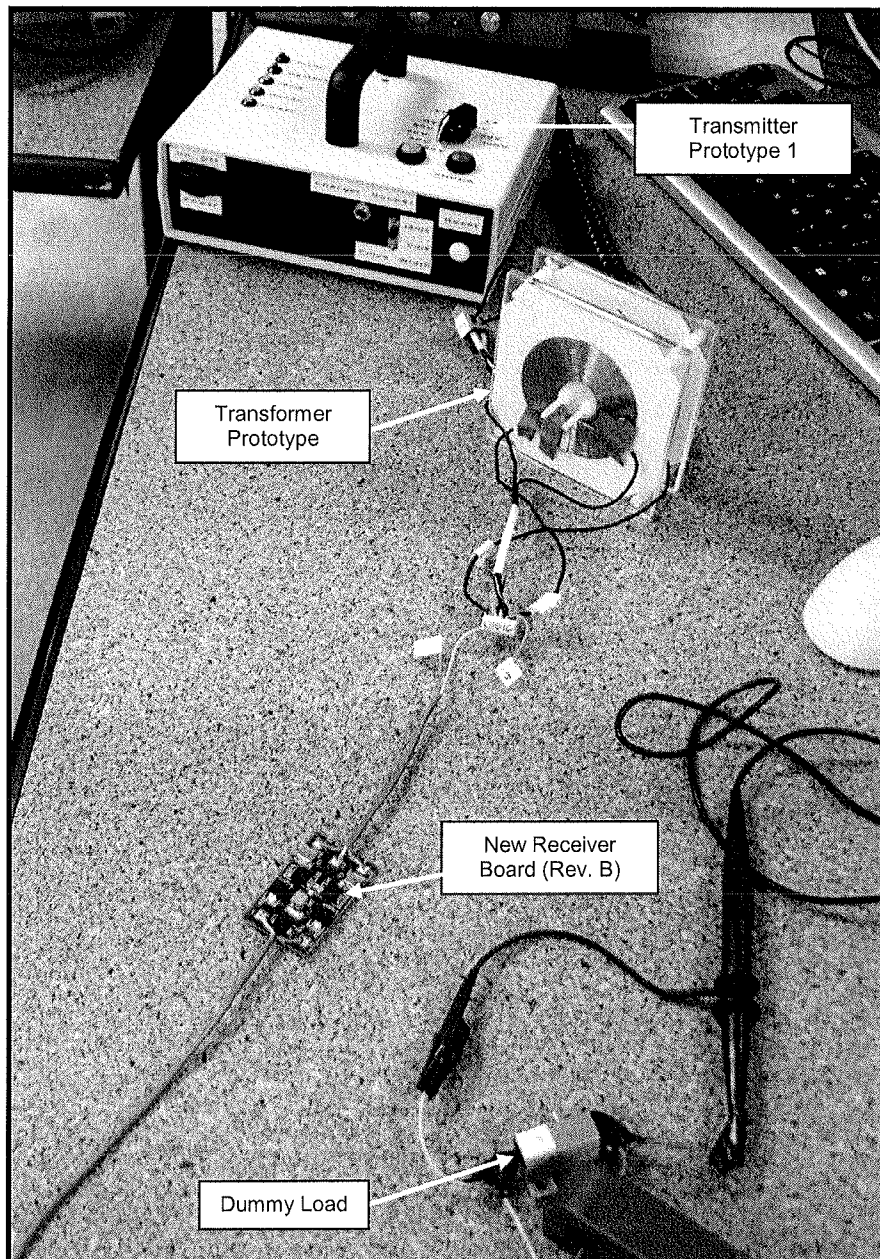


Figure 36- Test set up for skin model testing with receiver prototype B

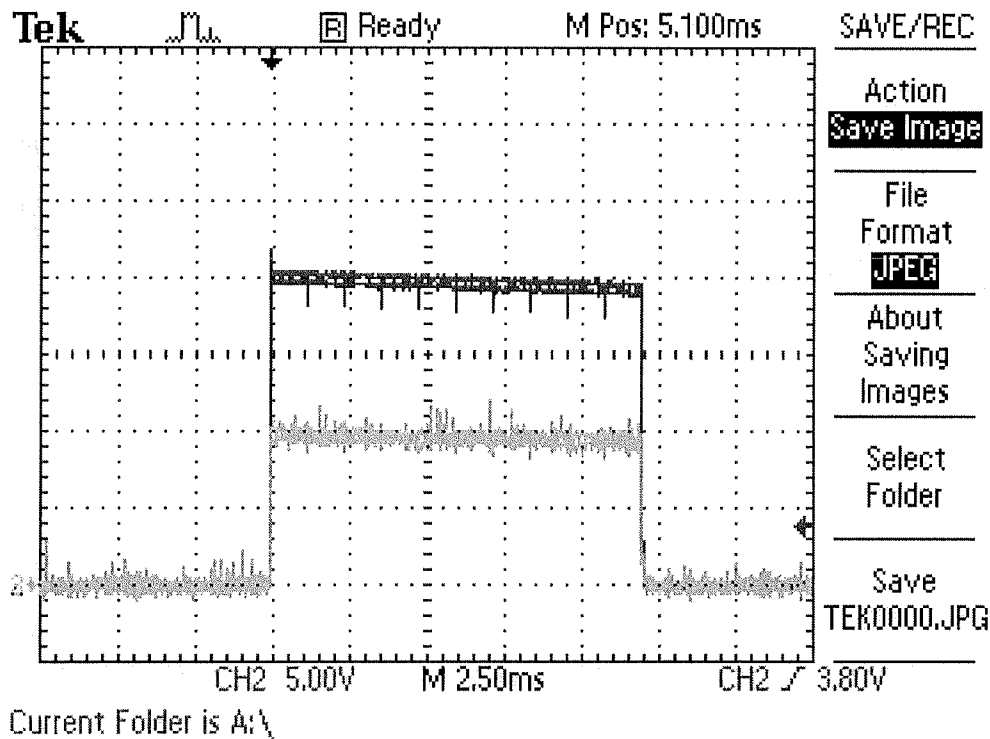


Figure 37: Output voltage (CH2=5V/div (upper trace)) tilt = 20.4V – 19.6V, voltage ripple = 20.4V – 19.6V and output current (CH3=0.2A/div (lower trace)) ripple = 0.42A - 0.36A approximately. Voltage level switch setting on transmitter prototype = 20V.

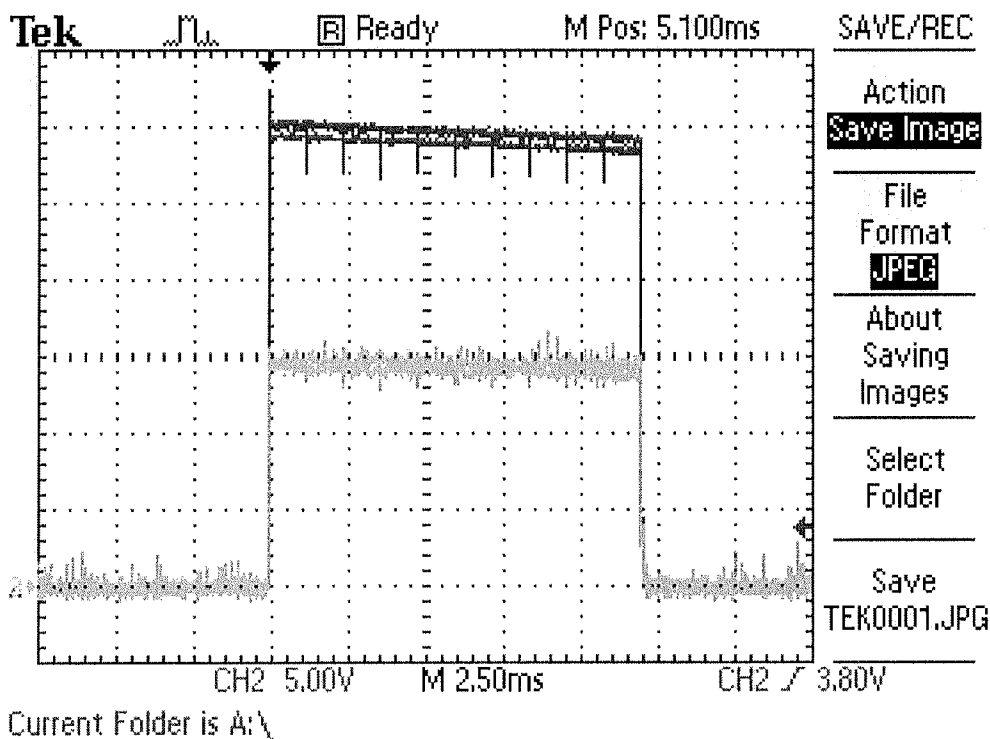


Figure 38: Output voltage (CH2=5V/div (upper trace)) tilt = 30.4V – 29.2V, voltage ripple = 30.4V – 29.2V and output current (CH3=0.2A/div (lower trace)) ripple = 0.62A - 0.54A approximately. Voltage level switch setting on transmitter prototype = 30V.

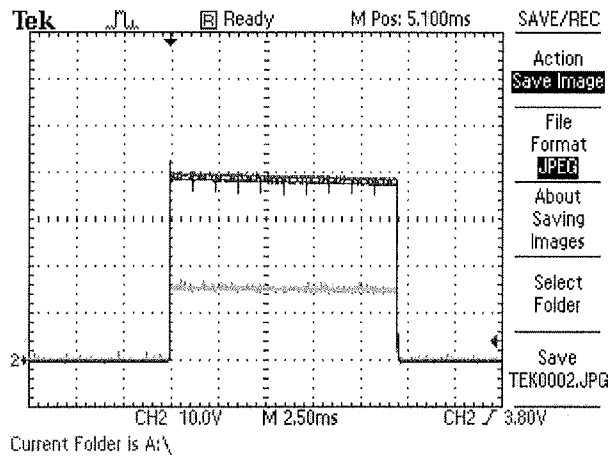


Figure 39 Output voltage (CH2=10V/div (upper trace) tilt = 40.0V – 38.4V, voltage ripple = 40.0V – 38.4V and output current (CH3=0.5A/div (lower trace) ripple = 0.80A - 0.74A approximately. Voltage level switch setting on transmitter prototype = 40V.

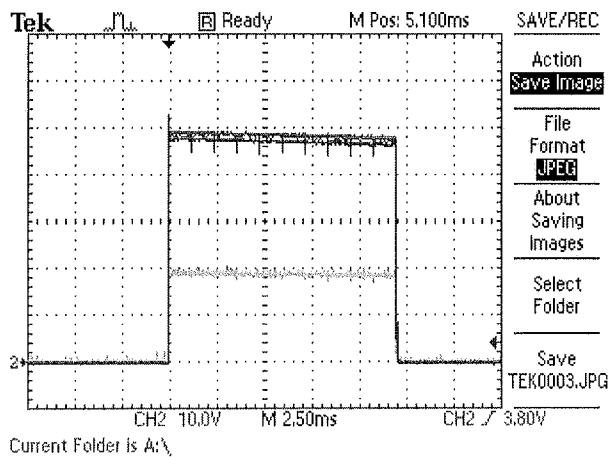


Figure 40: Output voltage (CH2=10V/div (upper trace)) tilt = 49.2V – 48.0V, voltage ripple = 49.2V – 47.2V and output current (CH3=0.5A/div (lower trace)) ripple = 0.98A – 0.92A approximately. Voltage level switch setting on transmitter prototype = 50V.

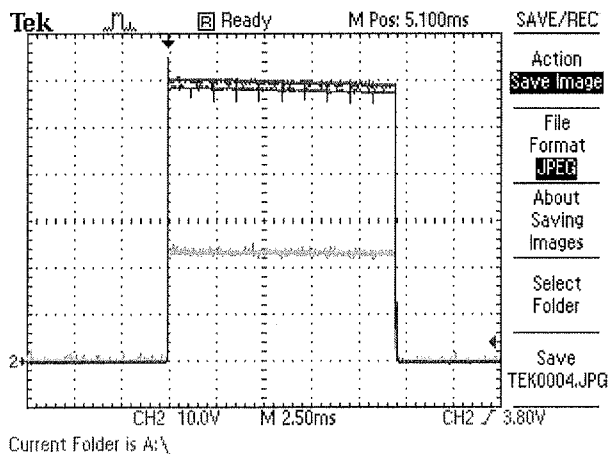
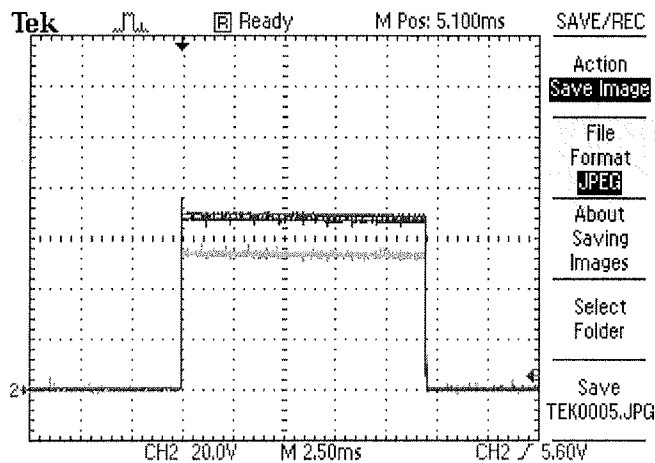
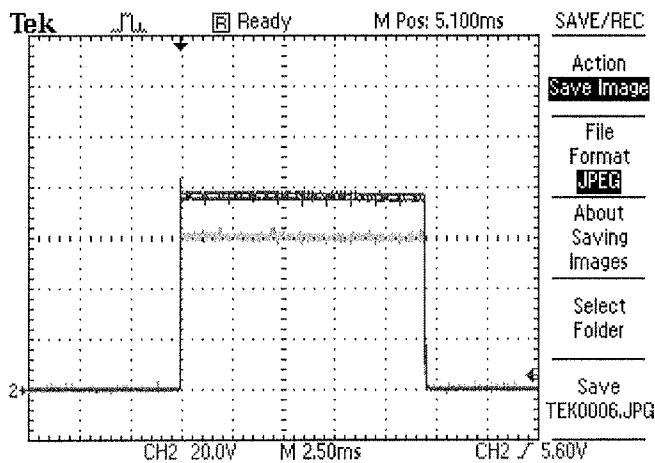


Figure 41: Output voltage (CH2=10V/div (upper trace)) tilt = 60.4V – 59.2V, voltage ripple = 60.4V – 58.4V and output current (CH3=0.5A/div (lower trace)) ripple = 1.2A – 1.14A approximately. Voltage level switch setting on transmitter prototype = 60V.



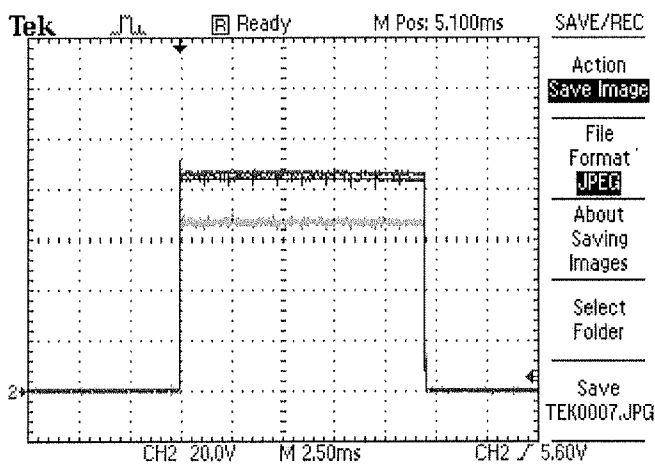
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Figure 42: Output voltage (CH2=20V/div (upper trace)) tilt = 70.4V – 68.8V, voltage ripple = 70.4V – 67.2V and output current (CH3=0.5A/div (lower trace)) ripple = 1.38A – 1.32A approximately. Voltage level switch setting on transmitter prototype = 70V.



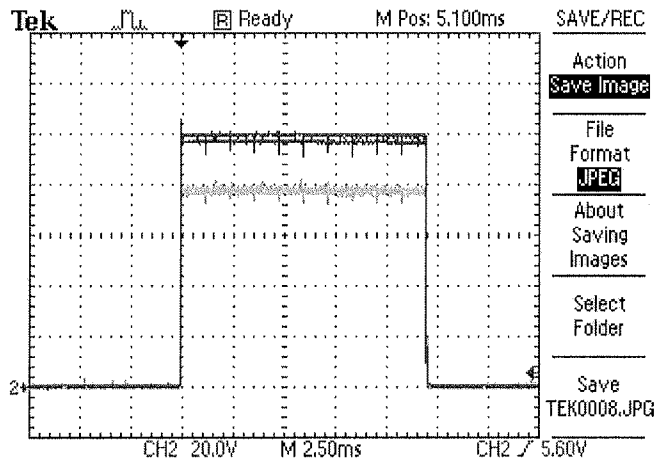
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Figure 43: Output voltage (CH2=20V/div (upper trace)) tilt = 78.4V – 76.8V, voltage ripple = 78.4V – 75.2V and output current (CH3=0.5A/div (lower trace)) ripple = 1.56A – 1.48A approximately. Voltage level switch setting on transmitter prototype = 80V.



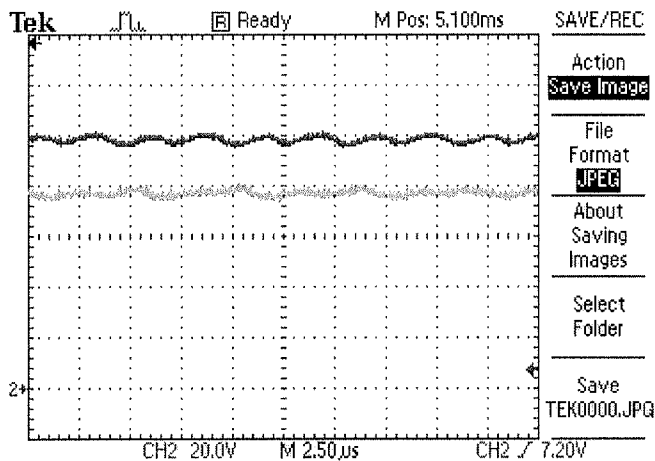
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Figure 44: Output voltage (CH2=20V/div (upper trace)) tilt = 87.2V – 86.4V, voltage ripple = 87.2V – 83.2V & output current (CH3=0.5A/div (lower trace)) ripple = 1.72A – 1.64A approximately. Voltage level switch setting on transmitter prototype = 90V.



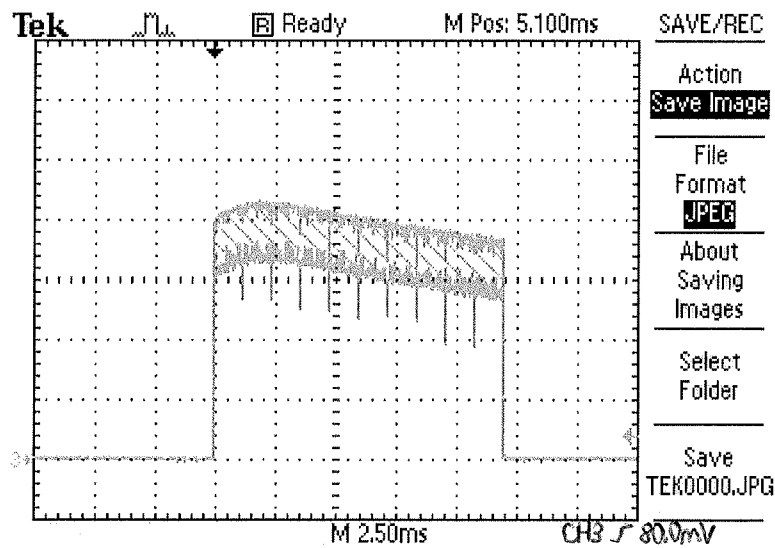
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Figure 45: Output voltage (CH2=20V/div (upper trace)) tilt = 100V - 100V, voltage ripple = 100V - 96.8V and output current (CH3=0.5A/div (lower trace)) ripple = 1.98A - 1.90A approximately. Voltage level switch setting on transmitter prototype = 100V.



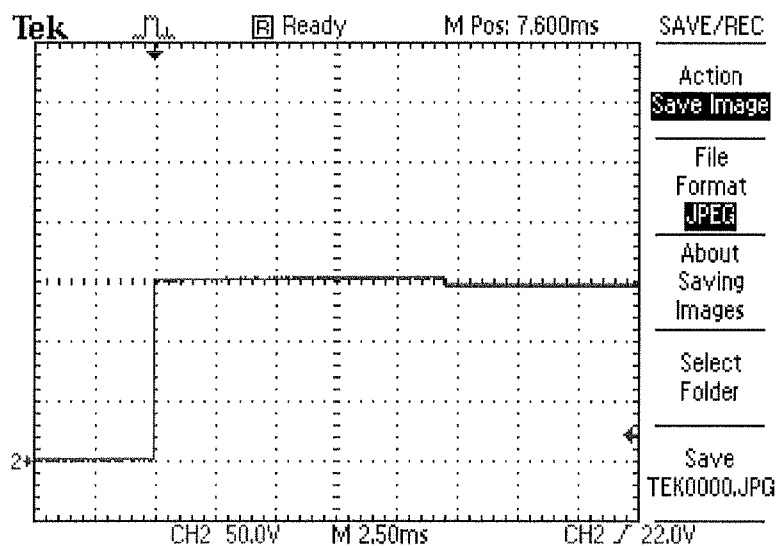
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Figure 46: Output voltage (CH2=20V/div (upper trace)) ripple = 5.6V and output current (CH3=0.5A/div (lower trace)) ripple = 0.14A approximately. The ripple frequency is approximately twice the IGBT switching (181 kHz) frequency. Voltage level switch setting on transmitter prototype = 100V



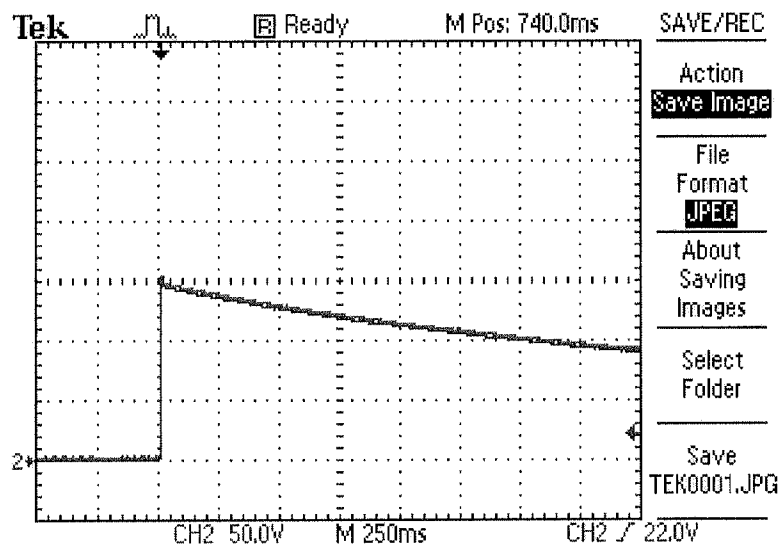
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Figure 47: Output current envelope (CH3 = 2A/div) during a short circuit condition across dummy load. The waveform has a current tilt = 8.64A – 7.36A with a ripple = 8.64A – 6.56A approximately.



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Figure 48: Output voltage (CH2 = 50V/div) approximately 154V_{DC} during an open circuit test (time: 2.5ms/div).



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Figure 49: Output voltage (CH = 50V/div) approximately 154V_{DC} peak during an open circuit test (time: 250ms/div).