Attachment XIII

November 16, 2005

Description of Magnetic Stimulation Coils for Bone Growth

[redacted]

Executive Summary

Measurements and calculations were made to characterize the magnetic field patterns and waveforms for the (1) EBI - FLX-2 coil powered by an EBI control unit and (2) Physio-Stim Lite Model MDL No. 202L coil.

The dB/dt waveforms were measured with a search coil and coil currents were measured by inserting a small sense resistor into the windings. Each coil produces a burst of pulses with overall parameters described in the table at the site of maximum dB/dt.

Description	Value for PhysioStim	Value for EBI
Burst period	0.067s	0.070 s
Number of pulse pairs in a burst	21	20
Average dB/dt of pulse 1	16.4 T/s	46 T/s
Average dB/dt of pulse 2	-4.6 T/s	-7.8 T/s
Duration of Pulse 1	66 μs	30 μs
Duration of Pulse 2	192 μs	200μs
Magnetic field at center for I = 1 A.	1300 μT	1010 μT

The overall waveform shapes are similar, but a principal difference is that the Physio-Stim device has a two times broader duration of "Pulse 1".

The EBI coil has no magnetic material and the dB/dt distribution can be calculated readily from a modeling of the coil winding pattern. The Orthofix coil has a magnetic core of approximate thickness 0.5 mm. The magnetic field pattern could be predicted with a finite element calculation. However, the qualitative geometry for the Physio-Stim field pattern can be obtained with an air-core calculation, since the magnetic material effectively multiplies the field produced by the air core.

An important difference between the two coils is the principal direction of dB/dt relative to the normal of the arc (y-direction) for the two coils. For the EBI coil, dB/dt is in the y-direction, whereas for the Physio-Stim coil dB/dt is in primarily in the x-direction. The differences in the dB/dt pattern are due to the very different winding patterns of the two coils.

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1. Introduction and General Considerations

A magnetic stimulation coil applies a time varying magnetic field to tissue. By Faraday's law of induction an electric field is induced in the tissue. Magnetic stimulation waveforms are essentially at audio frequencies, with effective pulse widths ranging from approximately 10 μs to 1 ms.

Current is applied to a magnetic stimulation coil. The time varying magnetic field at some point is expressed as

$$\frac{dB}{dt} = B_I \frac{dI}{dt}$$

where B_I is the magnetic field at a point due to unit current in a coil and $\frac{dI}{dt}$ is the derivative of the current. The magnetic field pattern B_I is entirely due to the winding pattern of the coil. Based upon the known winding pattern, B_I is determined by use of the Biot-Savart equation.

If there is magnetic material in the coil, then a finite element method may be needed for calculation of B_I.

In this report, we illustrate analysis of two magnetic stimulation systems for bone growth: (1) EBI - FLX-2 coil powered by an EBI control unit and (2) Physio-Stim Lite Model MDL No. 202L coil.

2. Coil Descriptions

2.1 EBI coil.

Figure 1 shows the EBI coil with part of the winding exposed. As an aid to understanding this coil, it is assumed that it is wrapped on a cylinder and to have rectangular dimensions. (A more refined approximation would be to use an ellipsoidal geometry.) The metal in the windings is apparently aluminum since it has a silvery color, can not be soldered and seems mechanically flexible. Aluminum would be a good choice for the metal in the wire since it has low density and high conductivity.

Figure 2 depicts the subtended coil with width 2W and height h. The z-direction is along the axis of the cylinder. The parameters describing the coil are

R_c - radius of curvature
Inner_θ - inner dimension of coil in the circumferential direction
Outer_θ - outer dimension of the coil in the circumferential direction
Inner_z - inner dimension of the coil in the z-direction
Outer_z - outer dimension in the z-direction

By geometry:

$$\frac{Outer_\theta}{2R_c} = \sin^{-1}\left(\frac{W}{R_c}\right)$$

Parameters for the EBI coil are summarized in Table 1. Figure 3 shows the modeled winding pattern. Figure 4 shows the calculated magnetic field pattern in the x-y symmetry plane of the simulated EBI coil in Fig. 3.

Parameter	EBI Coil
2W	140 mm
h	80 mm
Inner_θ	165 mm
Outer_θ	190 mm
Inner_z	110 mm
Outer_z	190 mm
R_c	72.5 mm
Number turns	100

Table 1. Parameters for approximating the EBI coil.

Figure 1. EBI coil with part of windings exposed. The resistors are for measurement of current through the coil. The x-direction is along the strap. The y direction is perpendicular to the plane of the strap. The z-direction is in the plane of the strap and perpendicular to the x-direction.

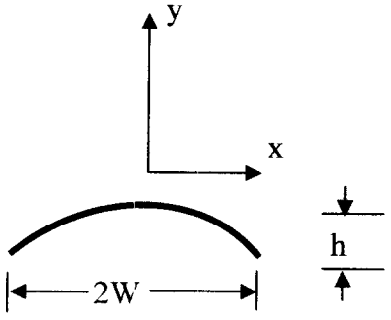

Figure 2. Dimensions of coil that is described as an arc on a cylinder. The x-direction is along the strap.

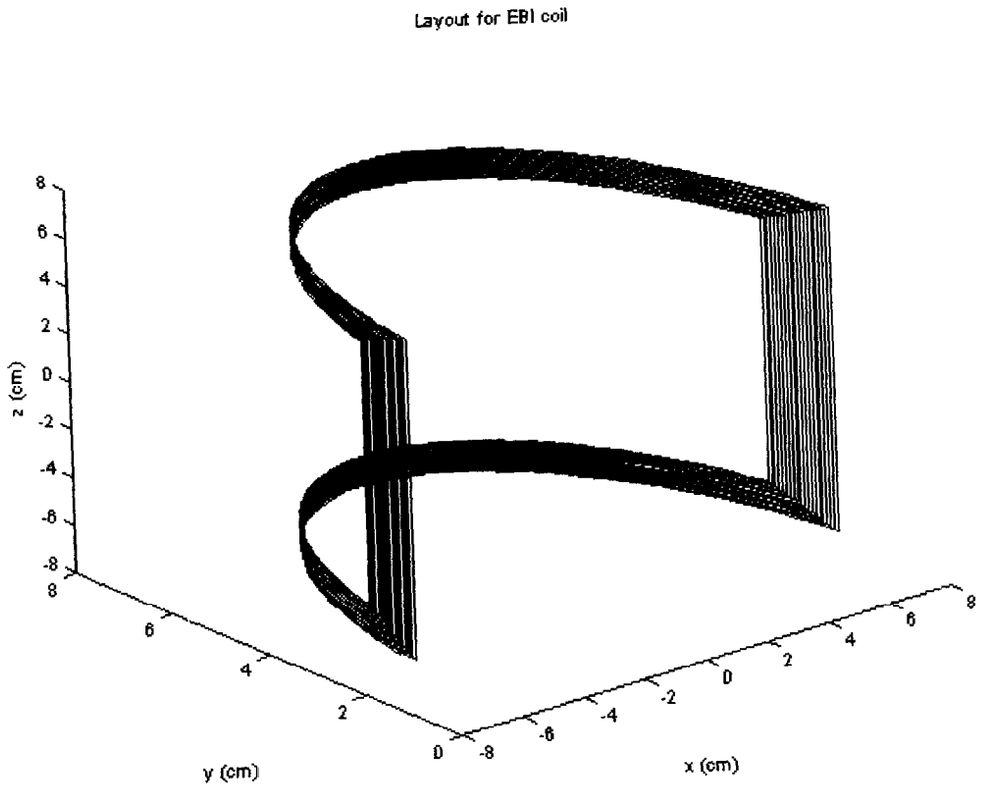

Figure 3. Model winding pattern for the EBI coil.

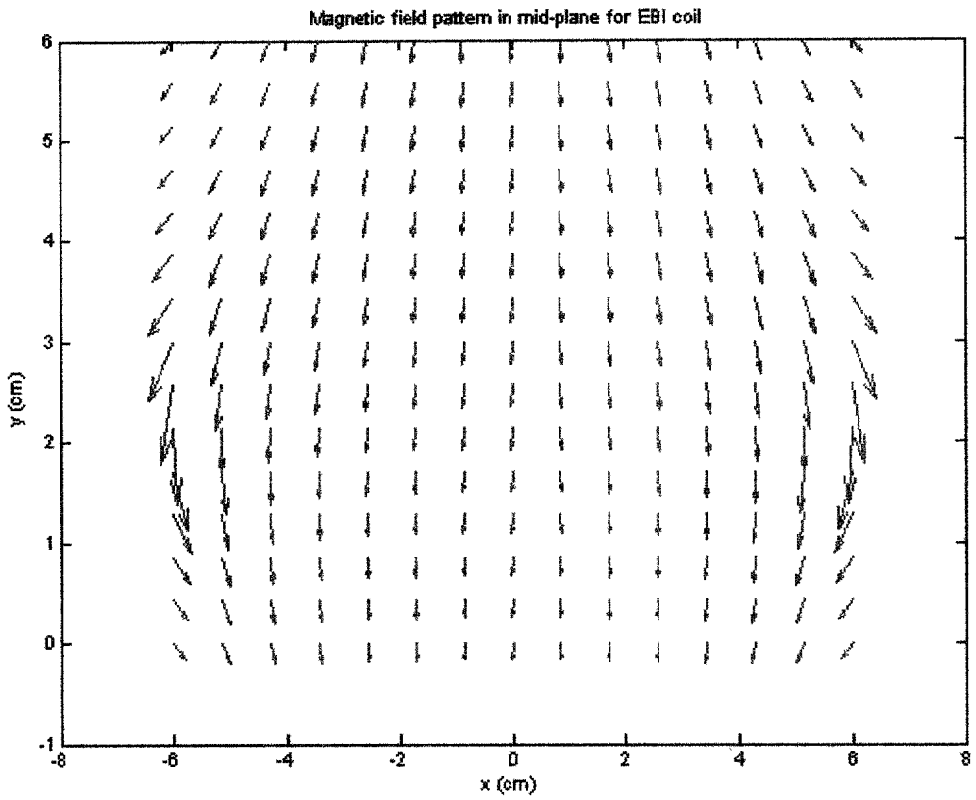

Figure 4. Calculated magnetic field pattern for EBI coil model coil geometry in Fig. 3.

2.2 Orthofix Physio-Stim Lite System.

Figure 5 shows the Orthofix Physio-Stim Lite coil with the windings partially exposed.

While the shape of outer shell of the Orthofix coil bears a resemblance to that of the EBI coil, the coil geometries are dramatically different. Each turn of the Orthofix coil has a racetrack geometry as depicted in Fig. 6. The coil has the approximate geometry of a half-circle with a diameter of 80 mm. There are approximately 100 turns in the entire coil. Figure 7 is a conceptual sketch of the magnetic field pattern. Effectively, the magnetic field is due to poles created as a result of the curvature of the windings.

Figure 8 shows a cross section through the Physio-Stim coil after cutting. There is a core made from sheets of metallic magnetic foil. The material has a silver metallic color, resembling the color of nickel. Analysis would need to be done to determine the exact material, but it appears to be amorphous magnetic material, which is known to have low loss. There are about 20 sheets of the material, each with a thickness of about 25 μm. Thus the total material thickness is thus about 0.5 mm. The width of the magnetic foil is 50 mm and the coil length is about 150 mm. Assuming a density of 8.5 gm/cm^3, the mass of magnetic material is then about 32 grams.

The magnetic core of the Physio-stim coil is surrounded by a hard plastic shell, which serves to provide mechanical rigidity, since the magnetic foil is brittle. Covering the plastic shell is a layer of soft fabric-like material. The thickness of the total core, consisting of magnetic material, plastic sheet, and soft cover is about 7 mm.

Figure 9 shows a model geometry for the Physio-Stim coil. The actual layout is elliptical, but this geometry should suffice for illustrating the nature of the magnetic field.

Figure 10 shows the calculated magnetic field pattern for the coil geometry shown in Fig. 9. Consistent with the measurement, the x-component of the magnetic field is the principal one within the coil.

Numerically for a 100-turn coil as shown in Fig. 9, the x-component of the magnetic field at a point (0, 2 cm, 0) = 24.2 μT/A. This is much less than the calculated field of 750 μT/A for the EBI coil. However, the measurements will show that the magnetic material serves to amplify the field that is produced by the core.

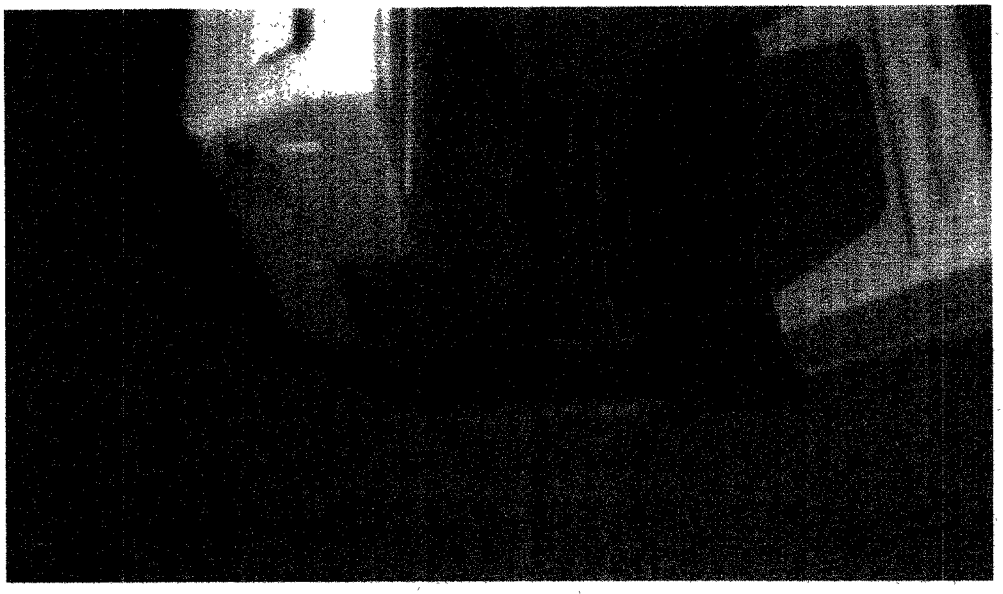

Figure 5. Physio-Stim Lite Coil. There are about 100 turns, each of which has a racetrack geometry as depicted in Fig. 6. There are sheets of magnetic foil, with total thickness about 0.5 mm, inside the windings.

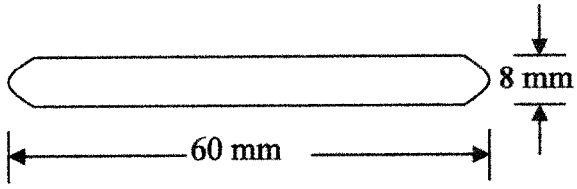

Figure 6. Approximate geometry of one turn of the Orthofix Physio-Stim coil. The radius of curvature of the end turns is about 3 mm.

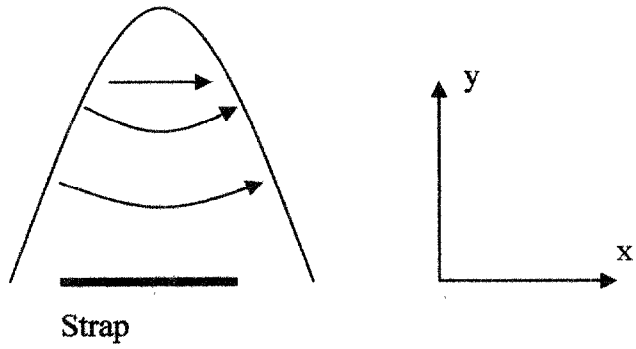

Figure 7. Schematic magnetic field pattern for the Physio-Stim coil in the mid-plane. The magnetic field is in the x-direction, which is perpendicular to the direction of the field of the EBI coil.

Figure 8. End view of the Physio-Stim coil after cutting. There is a magnetic core made from approximately 25 μm thick sheets of metal magnetic material with a total thickness of about 0.5 mm. The core is enclosed in a hard plastic cover this in turn is covered by a soft fabric-like material.

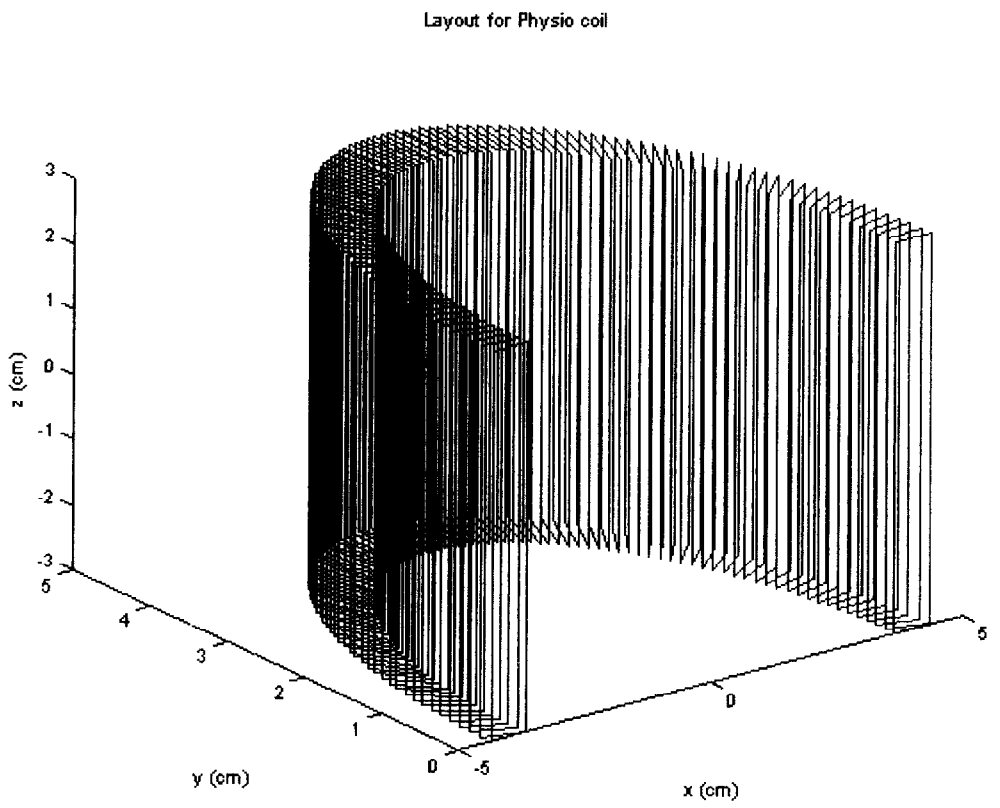

Figure 9. Approximate model for the Physio-Stim coil. The magnetic core is not included in the calculation.

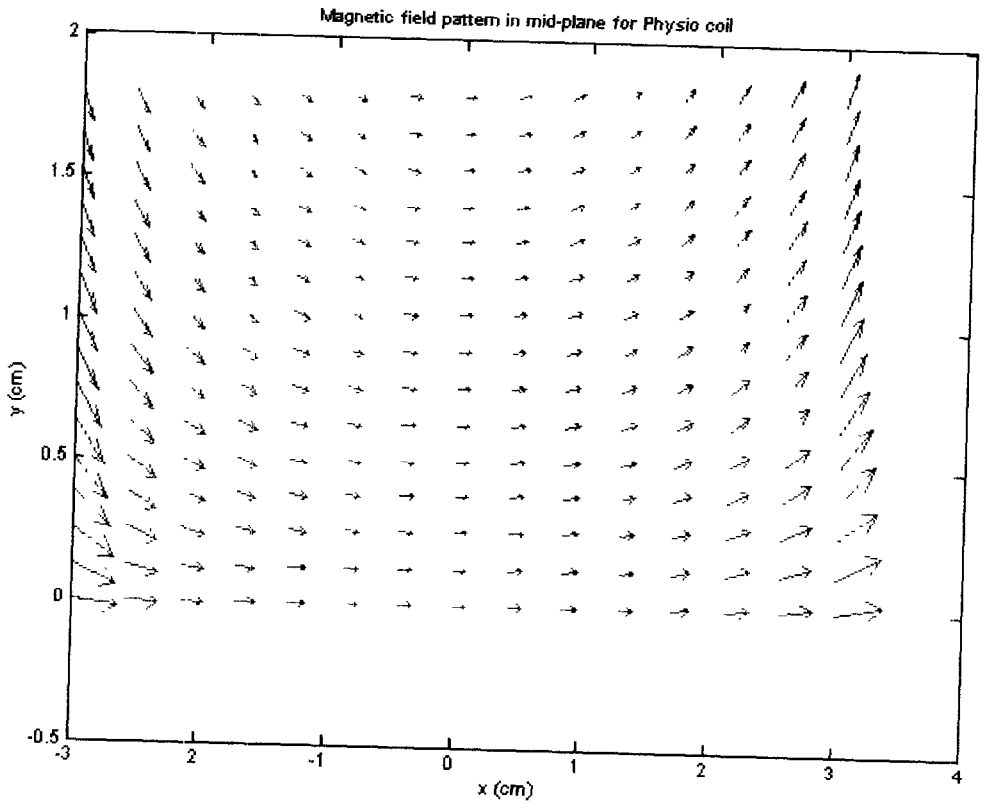

Figure 10. Magnetic field map inside the model Physio-stim coil shown in Fig. 9.

3. Sensing Coil and Calibration

Figure 11 shows the sense coil for measuring dB/dt and the calibration coil. The sense coil has an average diameter of about 11 mm and about 300 turns. Thus the effective area should be about 0.029 m^2.

To calibrate the sense coil, a current was applied to the calibration coil and the resulting voltage in the sense coil was measured. The calibration coil has ten turns with a diameter of 98.5 mm and a height of 13.5 mm. There is a series 48.8 Ω resistor for current measurement. The sense coil was aligned on the axis of the calibration coil and the center of the sense coil was a distance of 20 mm above the center of the calibration coil. At z=20 mm, the calibration coil is calculated to have a magnetic field of 1.01×10^{-4} T/A.

AC waveforms from 10 kHz to 80 kHz were applied to the calibration coil. The peak to peak voltage was constant at 4.91 V over this range and, neglecting inductance of the test coil, the current is 100 mA. Table 2 provides the measured voltages in the sensing coil as a function of frequency.

Frequency	Peak to peak sense coil voltage
10 kHz	19.8 mV
20 kHz	38.4 mV
30 kHz	57.5 mV
50 kHz	90 mV
70 kHz	124 mV
80 kHz	131 mV

Table 2. Voltage measured in sense coil as a function of frequency.

The voltage is approximately linear with frequency up to 30 kHz. The measurement at 20 kHz will thus be used for the calibration.

We seek the area turns product for the sense coil.

$$V_{sense} = 38.4\,mV = (N \times area)\frac{dB}{dt} = (N \times area)(2\pi)(20\,kHz)(0.1A)(1.01 \times 10^{-4}\,T/A)$$

Solving yields that N × Area = 0.030 m^2. This area is quite consistent with the estimated effective area of 0.029 m^2 based upon the sense coil diameter and number of turns.

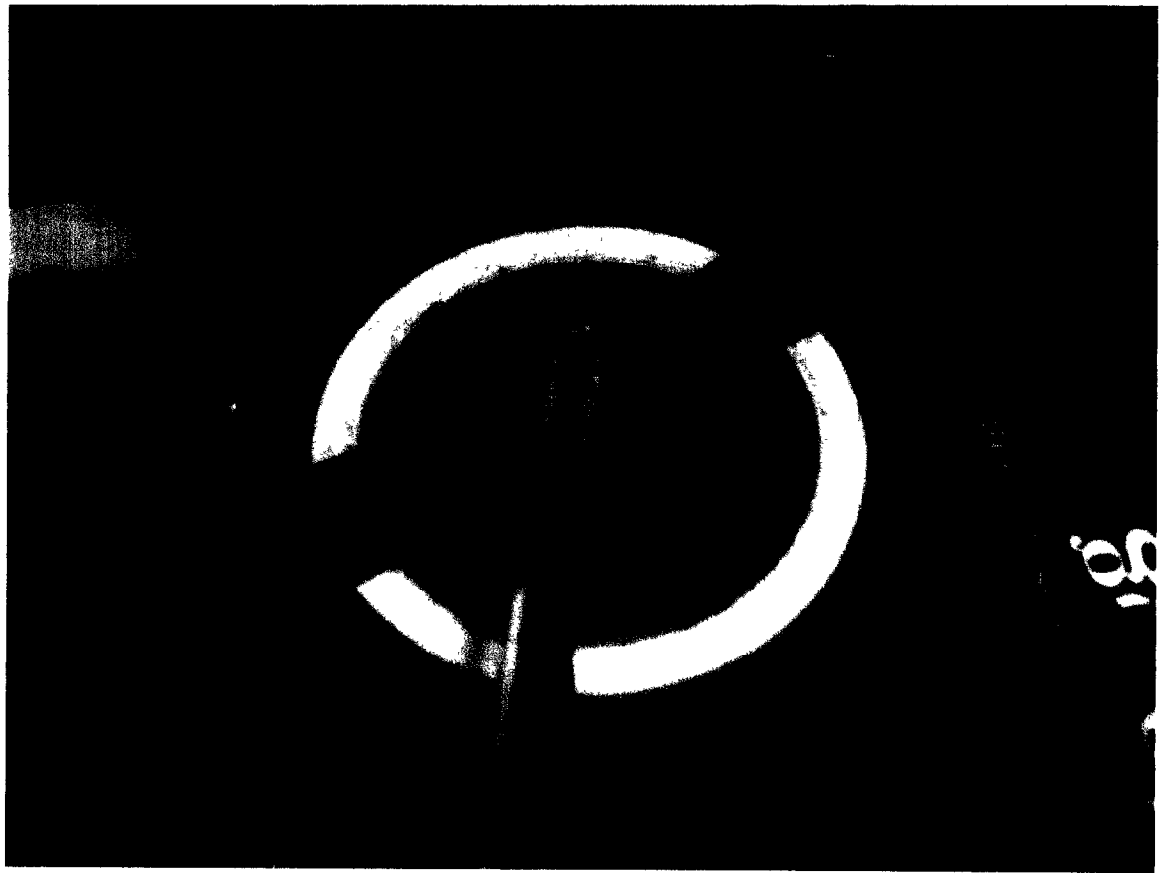

Figure 11. Sense coil and the larger coil for calibration of the sense coil. The diameter of the sense coil is about 11 mm and there are about 300 turns. The diameter of the 10-turn calibration coil is 98.5 mm.

4. Measurements on EBI coil

Figure 12 shows the EBI coil with the sense coil at y=4 cm and oriented along B_y. Consistent with Fig. 4, this orientation yielded a maximal induced voltage.

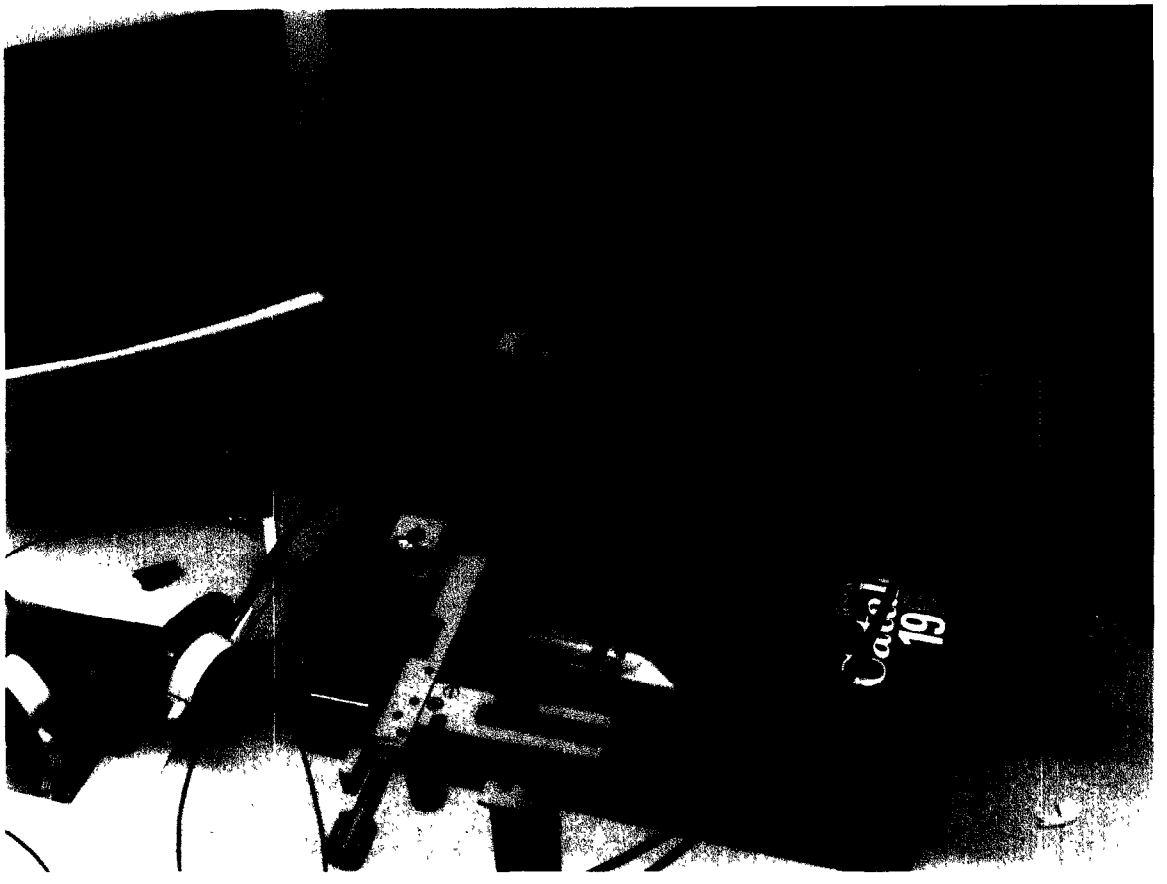

Figure 12. Test coil inside the EBI stimulator coil. As shown, the test coil is sensitive to B_y. This configuration yielded the maximum induced voltage. (The induced voltage will be greater near the windings, but that is not clinically relevant.)

4.1 EBI Waveform Characterization

The EBI stimulator outputs bursts of rectangular dB/dt pulses. The burst period is 70 ms, as is shown in Fig. 13. Within each burst (see Figs.14 and 15), there are 20 pairs of pulses. The durations of the pulses in a pair are about 30 μs and 200 μs. The dB/dt values are 46 T/s and 7.8 T/s. The average voltage in the pickup coil must be zero in accordance with Faraday's law of induction. The dB/dt ratio is 5.9 and the duration ratio is 6.7. The agreement is reasonable considering that the pulses are not perfectly rectangular.

In order to measure the current, a 5.1 Ω sense resistor was placed in the windings as shown in Fig. 16. Figure 17 shows the current waveform. The peak to peak voltage is 4.65 V, which corresponds to a current change of 0.91 A through the 5.1 Ω sense resistor. The current swing occurs over a duration of about 25 μs. Hence dI/dt = 36,400 A/s. From the calculation, the magnetic field at x=0, y=0.04, z=0 in the center of the EBI coil is about 750 μT/A. Then the predicted dB/dt = $(750 \times 10^{-6}$ T/A)(36,400 A/s) = 27.3 T/s. This compares with the measured dB/dt of 46.4 T/s. Measured and calculated dB/dt are in somewhat reasonable agreement given the approximation in estimating waveforms, coil geometry, and number of turns in the coil.

Figure 18 shows the dB/dt waveform with the sense resistor in place. The waveform is nearly the same as in Figs. 13, 14, and 15. The sense resistor thus results in minimal alteration of the dB/dt waveform. This is to be expected since the inductance of the coil requires the use of a high-voltage driver circuit and thus the voltage across the sense resistor is small compared to the overall voltage.

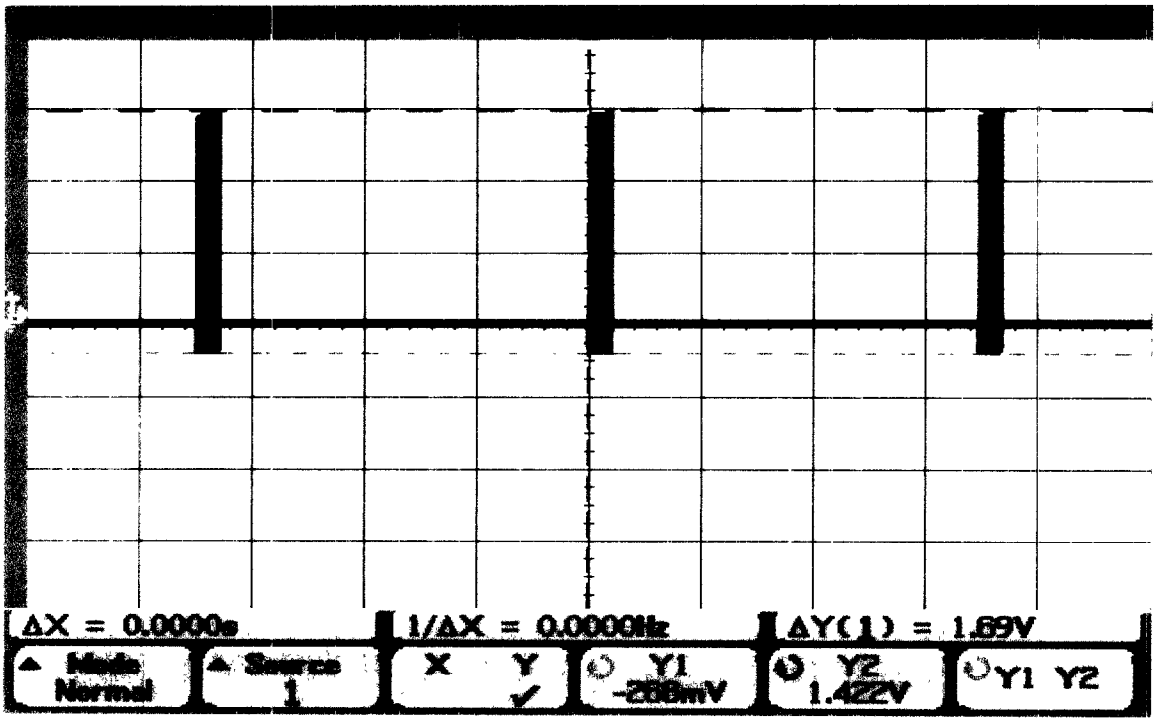

Figure 13. Oscilloscope trace showing burst period for the EBI coil. The time scale is 20 ms/division.

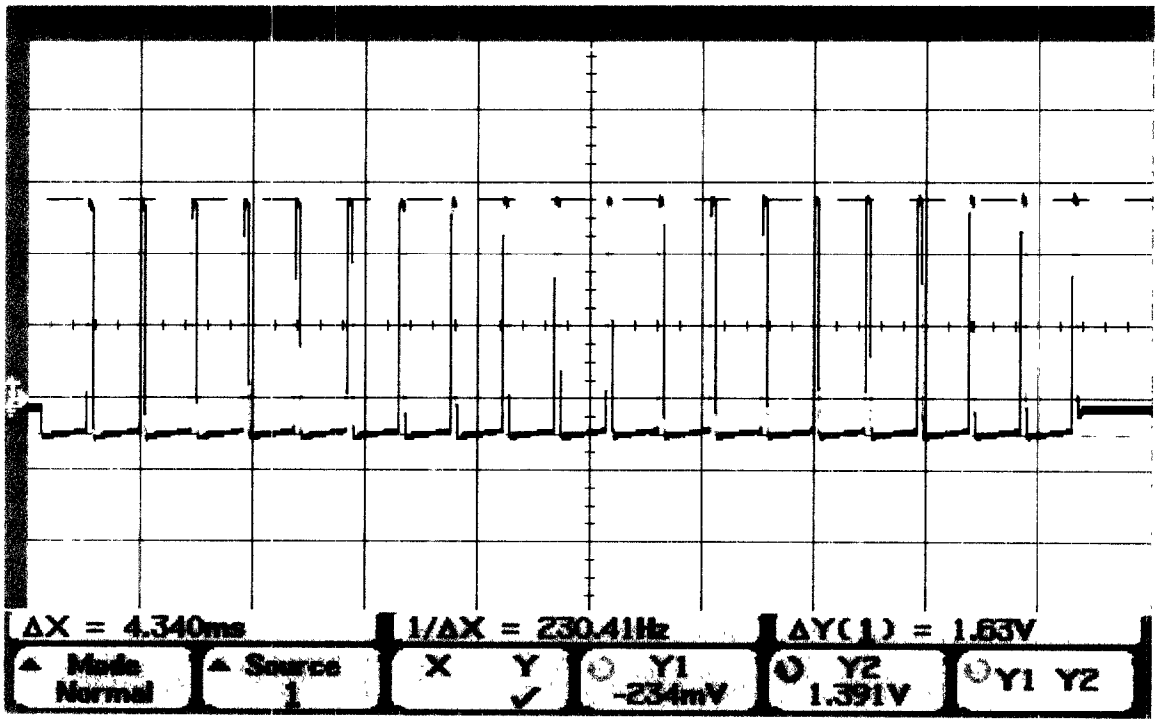

Figure 14. Oscilloscope trace showing dB/dt within a burst for the EBI coil. The positive voltage amplitude is 1.391 V and the negative voltage amplitude is 0.234 V, which correspond to dB/dt values of 46 T/s and 7.8 T/s, respectively.

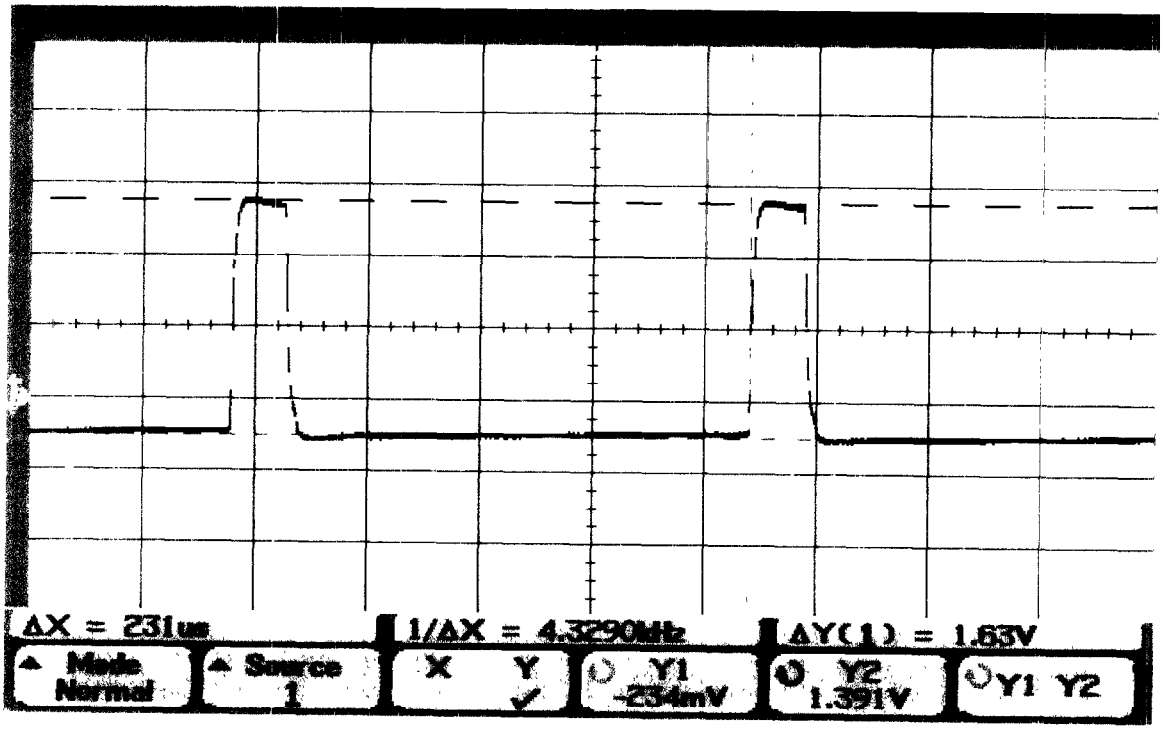

Figure 15. Detail of 2 waveforms in a burst for the EBI coil.

Figure 16. Exposed EBI coil with 5.1 Ω sense resistor to measure current.

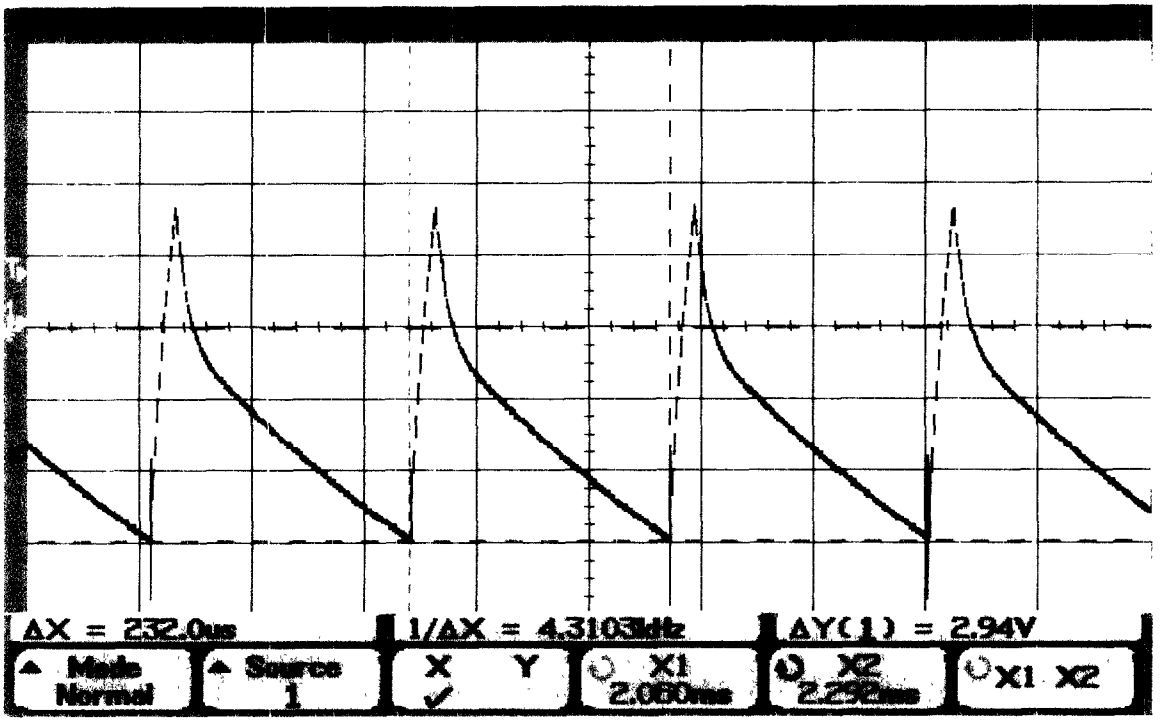

Figure 17 (a) . Voltage waveform across the 5.1 Ω sense resistor for the EBI coil shown in Fig. 16. . The peak to peak voltage is 4.65 V, which corresponds to a current change of 0.91 A through the 5.1 Ω sense resistor.

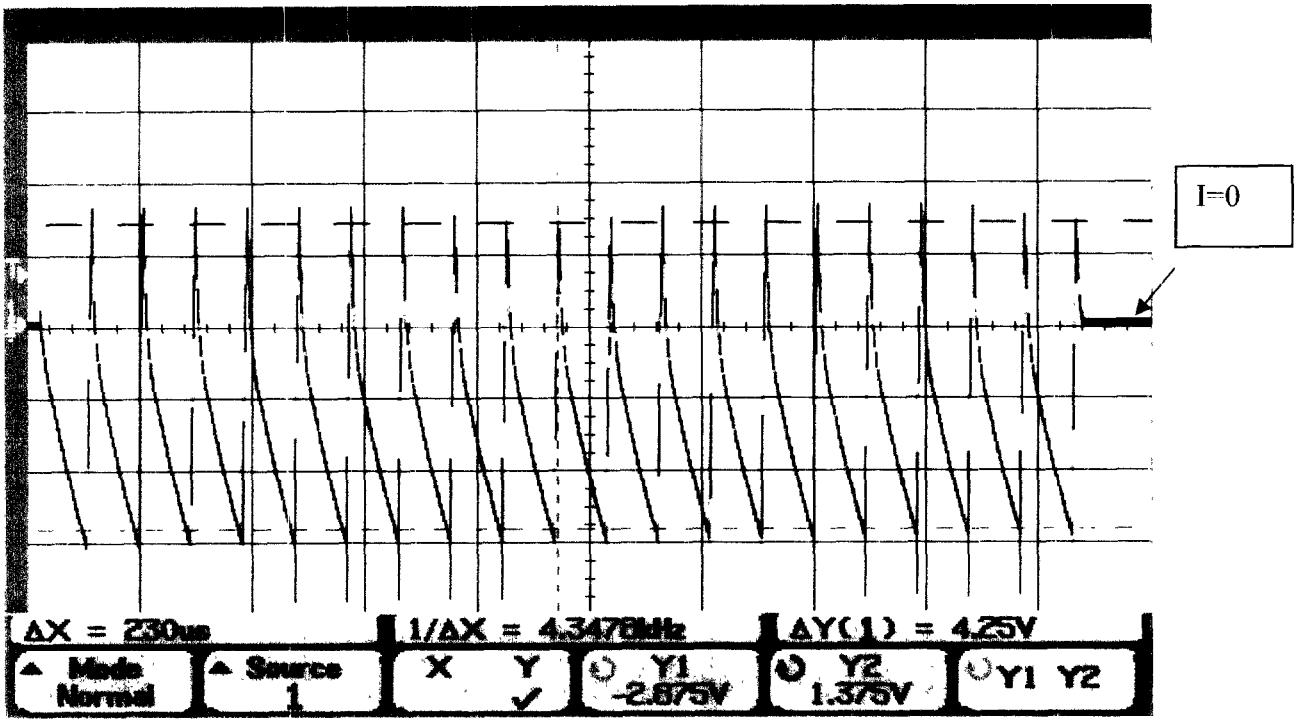

Figure 17(b). Current in entire burst for the EBI generator. There is a net DC current during the burst.

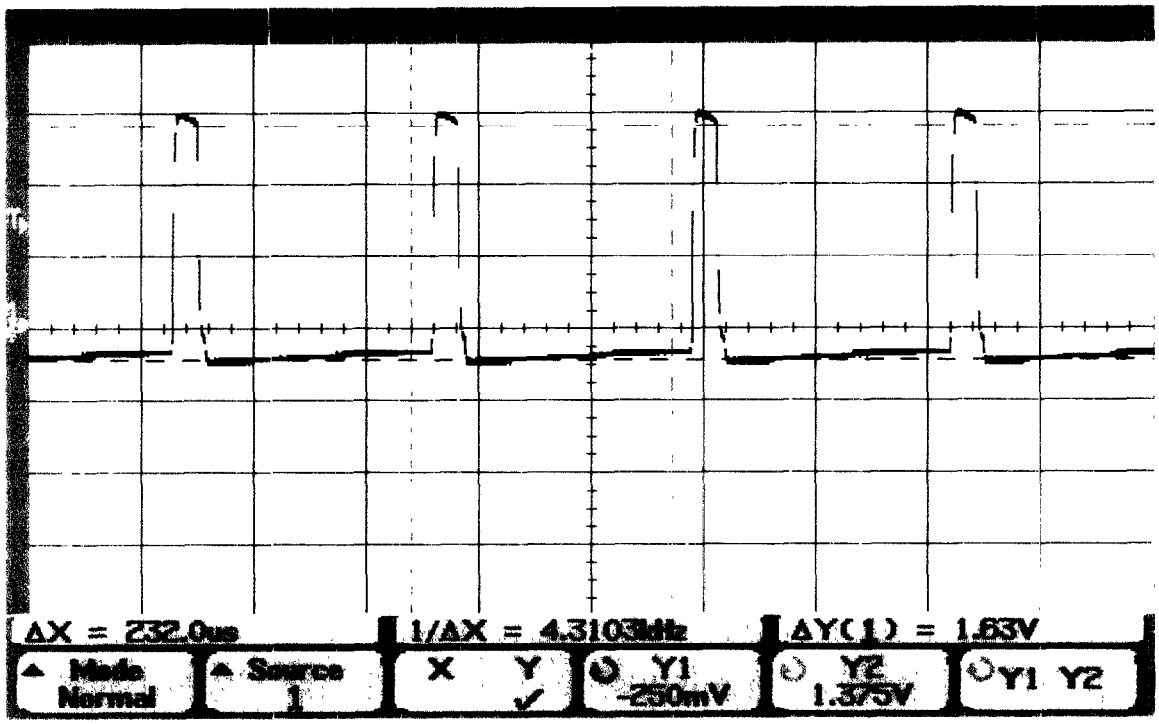

Figure 18. dB/dt waveform for the EBI coil with the sense resistor in circuit. The sense resistor has minimal impact on the waveform.

4.2 dB/dt Measurements for the EBI Coil

Figure 19 shows dBy/dt vs. y for the EBI coil for three values of z. in the x-y plane, By is approximately constant, consistent with the pattern in Fig. 4. Amplitudes of dBx/dt and dBz/dt are show in Figs. 20 and 21. As expected these latter two field components are much less than dBy/dt.

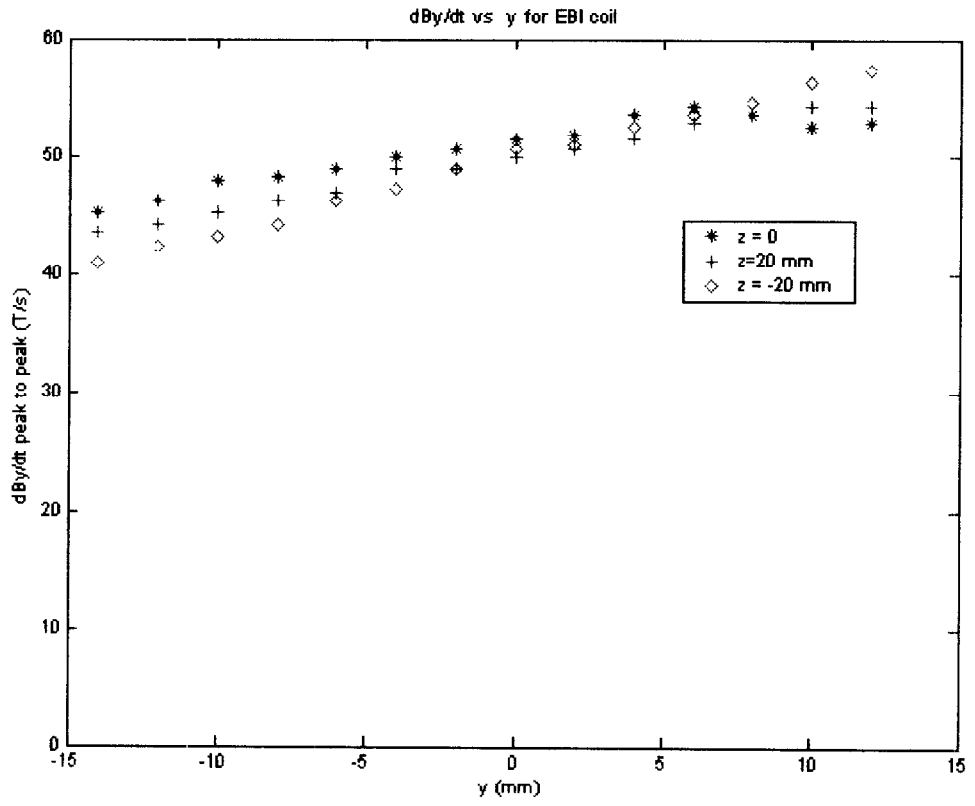

Figure 19. Peak to peak dBy/dt vs. y for EBI coil. x=0 and z is 0, 20 mm or -20 mm. (y=0 is in the plane of the strap. See Figs. 2 and 3 for coordinate definitions.)

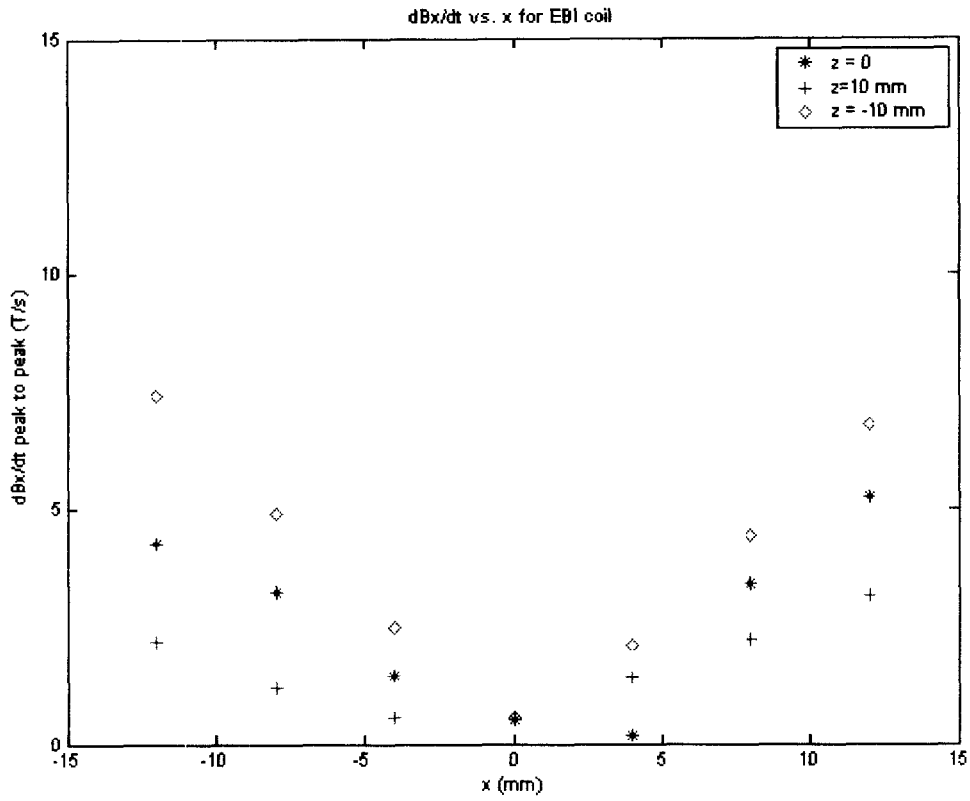

Figure 20. Peak to peak dBx/dt vs. x for EBI coil. y=0 and thus the measurements are made in the plane of the strap.

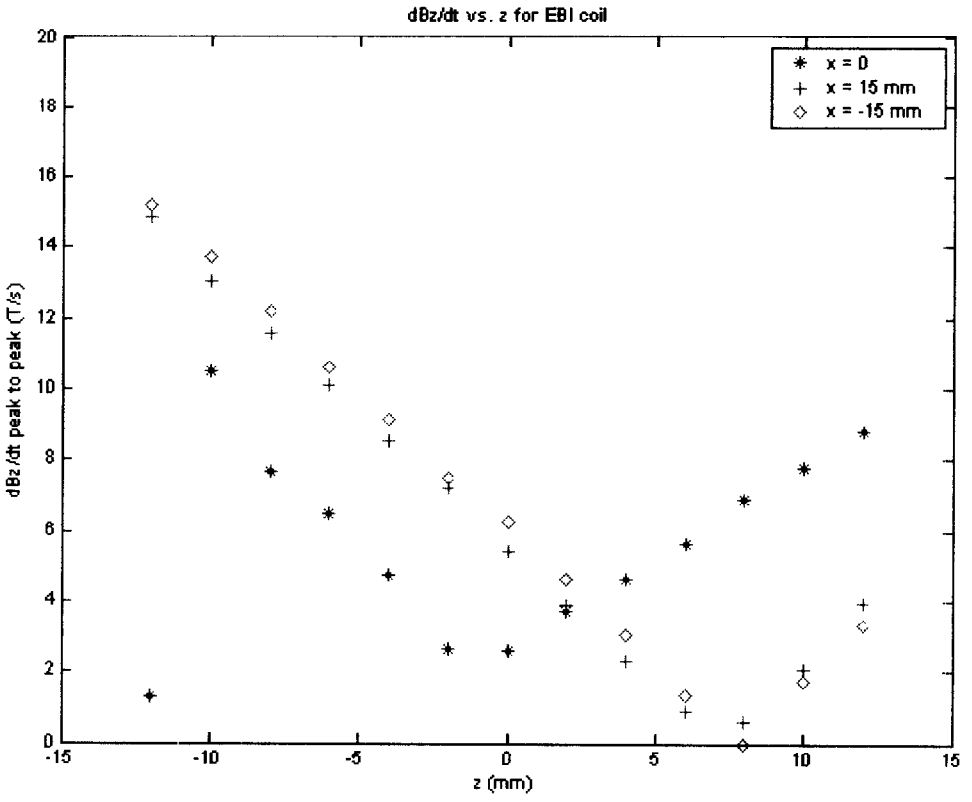

Figure 21. Peak to peak dBz/dt vs. z for EBI coil. y=0 and thus the measurements are made in the plane of the strap.

5. Measurements on the Physio-Stim Coil

5.1 Physio-Stim Waveform Characterization

Figure 22 shows the sense coil in the Physio-Stim coil and Figs. 23-25 show the waveforms. The burst period is 67 ms and there are 21 pulses in a burst. The dB/dt values are 16.4 T/s and -4.6 T/s and the pulse durations are 66 μs and 192 μs. The ratio of dB/dt and the pulse durations are equal to within 10%.

Figure 22. Physio-Stim coil with sense coil in a location that yields the maximal signal. Note that the maximal dB/dt is in the horizontal direction.

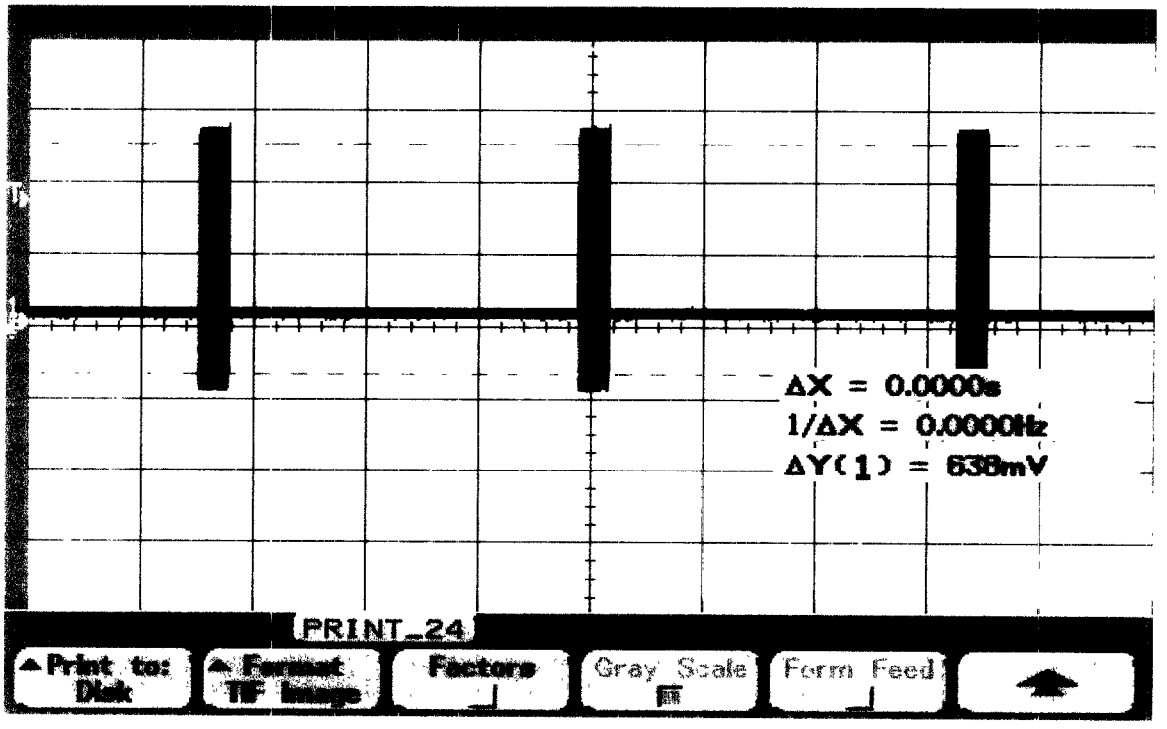

Figure 23. Burst dB/dt waveforms for the Physio-Stim coil for sense coil configuration shown in Fig. 22. The burst period is 67 ms.

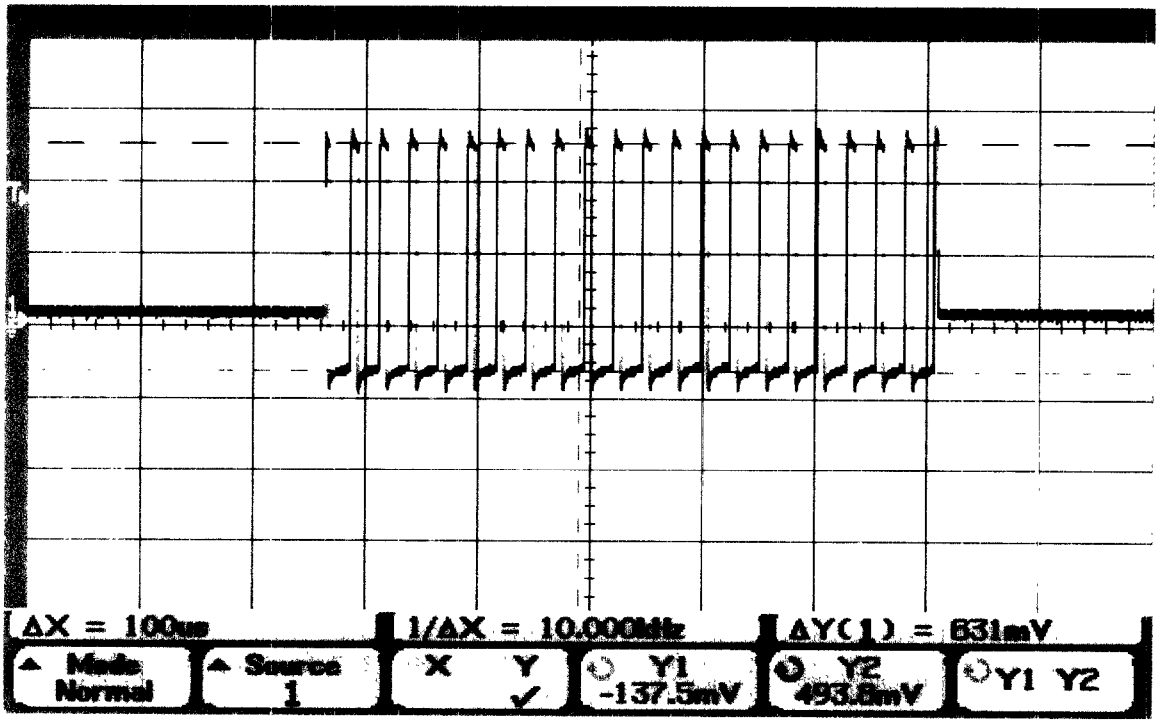

Figure 24. Train of dB/dt pulses for the Physio-Stim coil. The dB/dt values are 16.4 T/s and -4.6 T/s. Pulse durations are 66 μs and 192 μs.

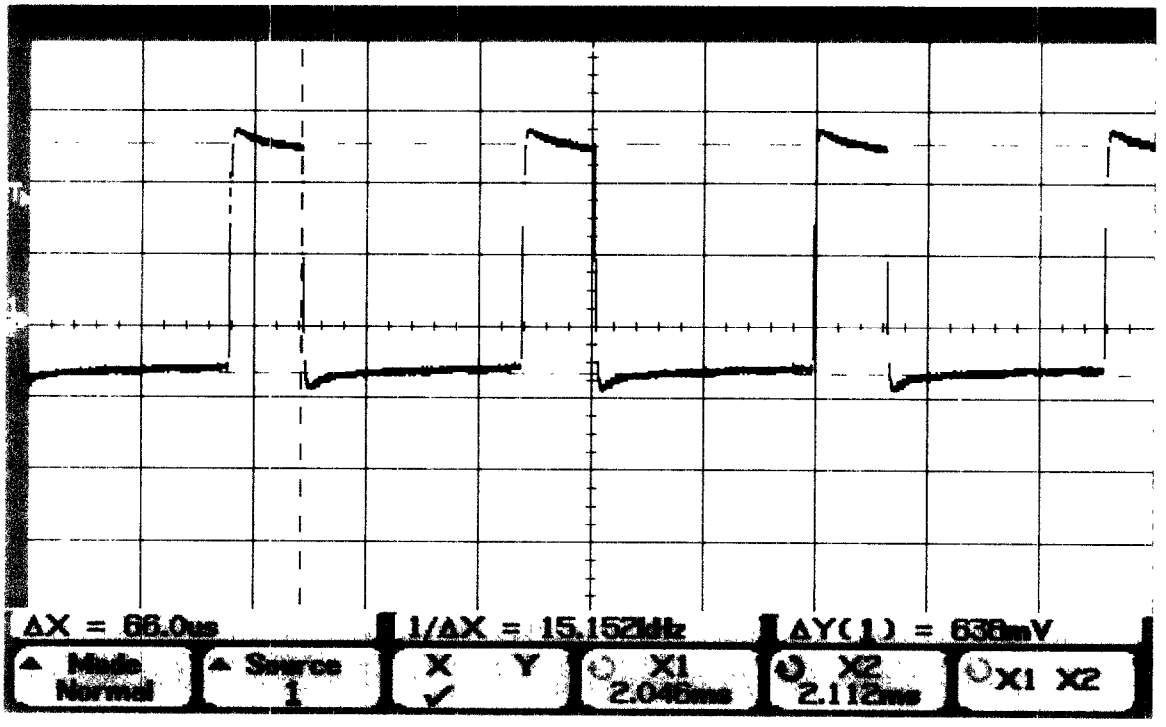

Figure 25. Detail for pulses in Fig. 24 for the Physio-Stim coil.

A 5.2 Ω resistor was placed into the Physio-Stim coil in order to measure the currents. Figure 26 shows the stimulator with the sense resistor in the windings.

Figure 27 shows the current pulses in a burst and Fig. 28 shows a detail of the current pulses for the first part of the waveform. The peak to peak current is 0.82 A, as determined from the voltage across the sense resistor. The current waveform is approximately symmetrical with a lower value of -0.373 A and an upper value of 0.45 A. The change in magnetic flux density is in the horizontal direction inside the coil is

$$\Delta B = \frac{dB}{dt} \times pulse_width = (16.4\,T/s)(65\,\mu s) = 1066\,\mu T \qquad)$$

The magnetic field per unit current is thus

$$B/I = \frac{1066\,\mu T}{0.82\,A} = 1300\,\mu T/A$$

Assuming an air core and the model geometry of Fig. 9, the calculated magnetic field is 24.2 μT/A. Thus the presence of the magnetic core increases the magnetic field by a factor of 1300/24.2 = 53.7. This number is the effective permeability.

Thus the magnetic material in the core increases the magnetic field per unit current by a factor of approximately 50. This has the effect of a considerable reduction in the power loss in the copper wire in the core.

Measured and calculated magnetic field per unit coil current are in much better agreement for the EBI coil since this coil does not contain ferromagnetic material. The flux density change of the EBI coil is 920 μT and the peak to peak current is 0.91 A. The magnetic field per unit current is thus 1010 μT/A. This compares with the predicted value of 750 μT/A.

Figure 30 shows the dB/dt for the Physio-Stim Lite with the sense resistor. The peak to peak voltage amplitude from the sense coil is 594 mV. This is essentially identical to the value of 639 mV shown in Fig. 25 for the intact coil. The sense resistor is thus concluded to have a minimal effect on the current flow.

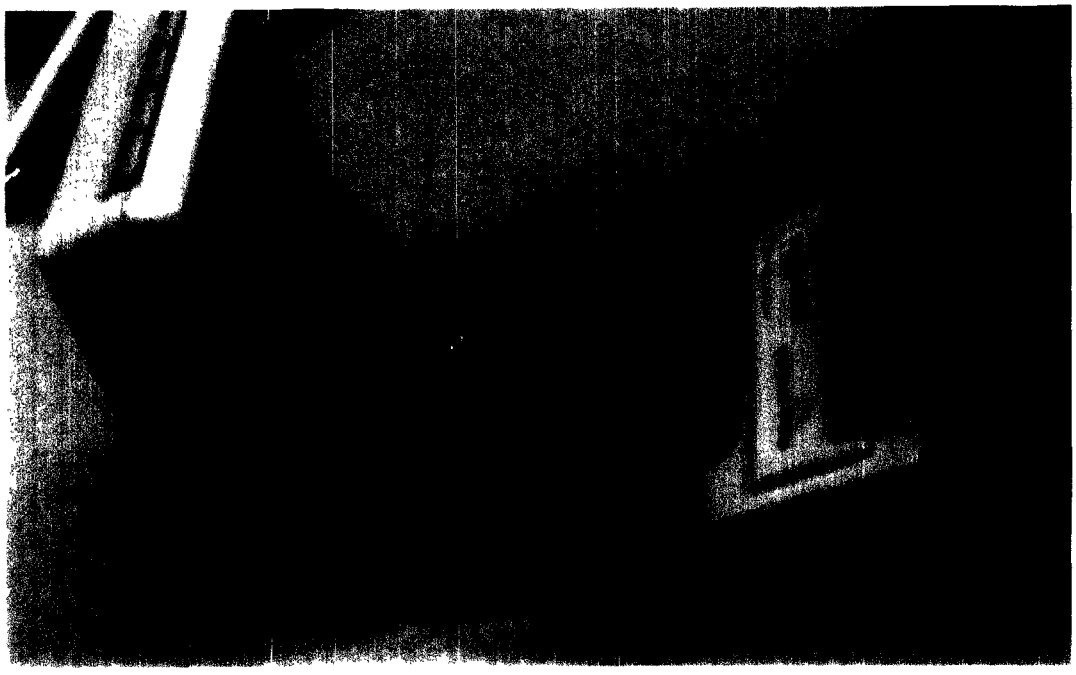

Figure 26. Physio-Stim lite with 5.2 Ω resistor inserted into the winding for measurement of the current.

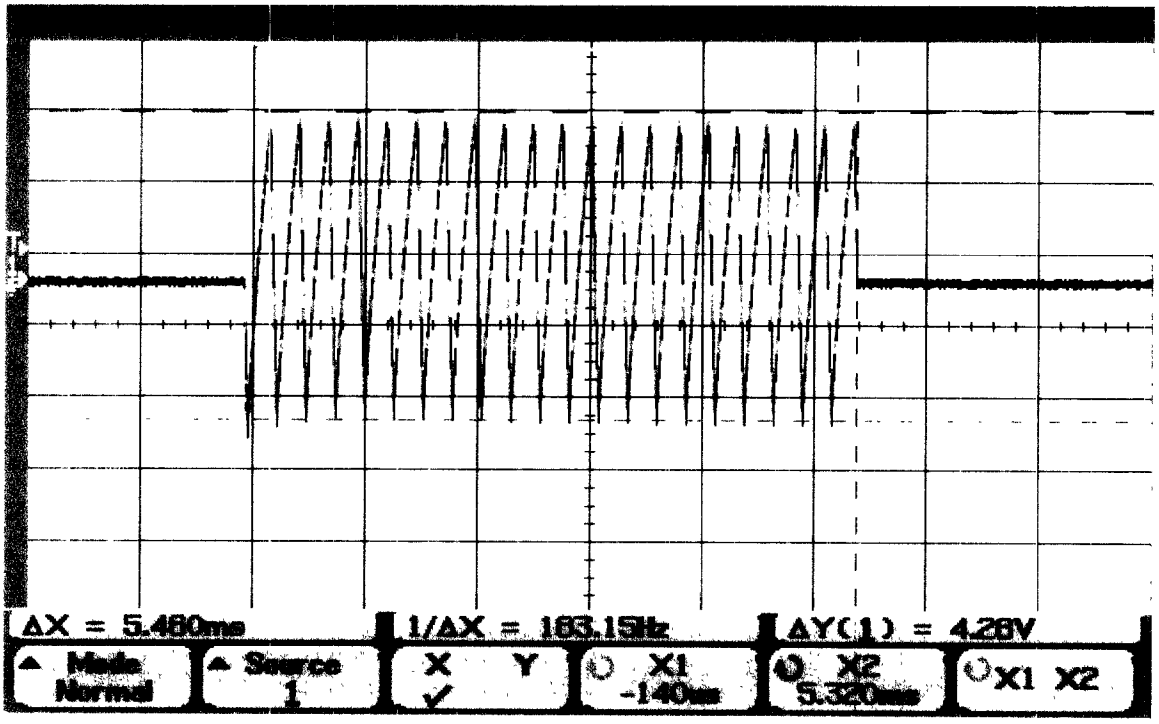

Figure 27. Current vs. time in the burst train for the Physio-Stim Lite. The peak to peak current is 4.28 V, which corresponds to a current of 0.82 A through the 5.2 Ω sense resistor. The current waveform is approximately symmetrical with a lower value of -1.94 V (-0.373 A) and a upper value of 2.34 V (0.45 A).

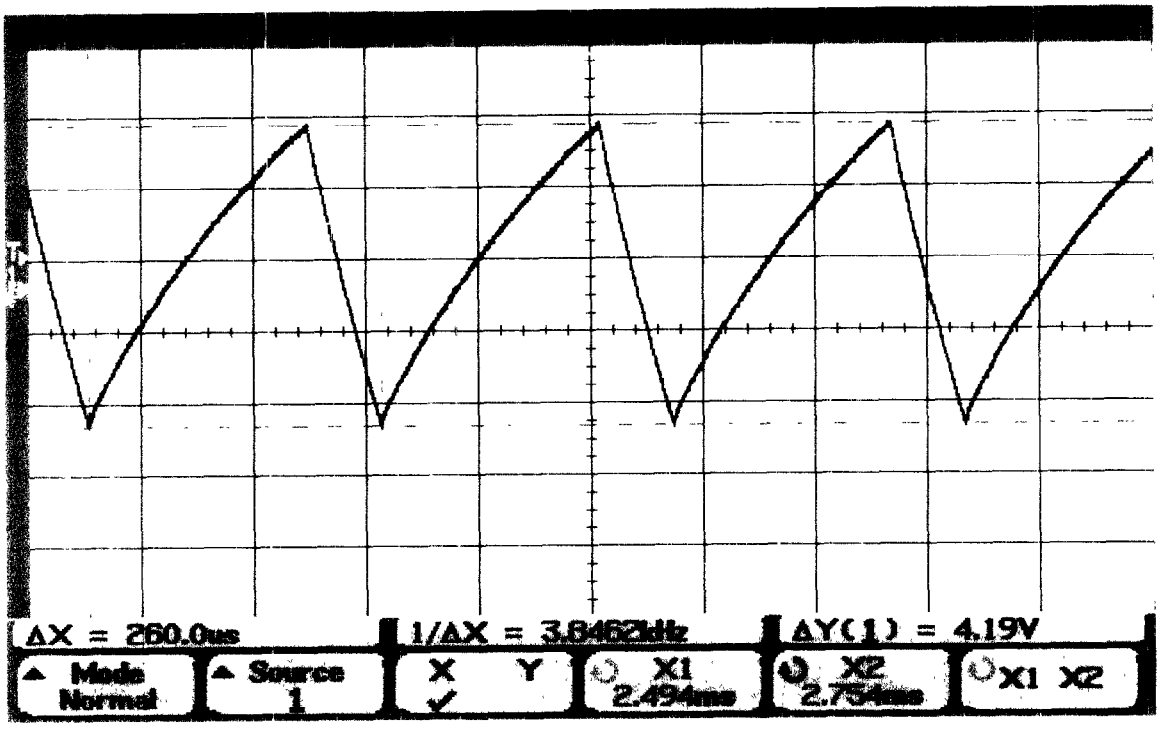

Figure 28. Detail of the current waveforms in Fig. 27. The rise time from minimum to maximum current is 192 μs and the fall time is 66 μs.

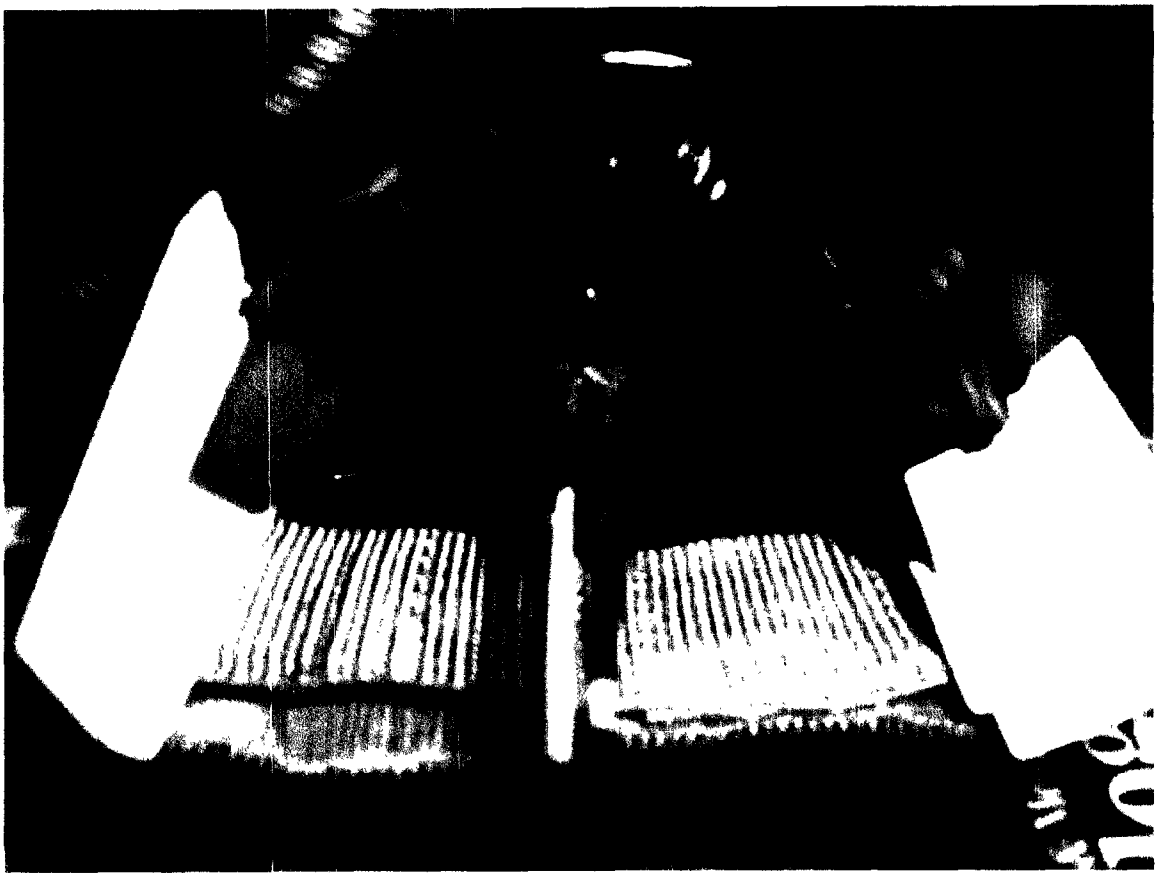

Figure 29. Location of evaluation of dB/dt for the Physio-Stim Lite with the sense resistor enclosed.

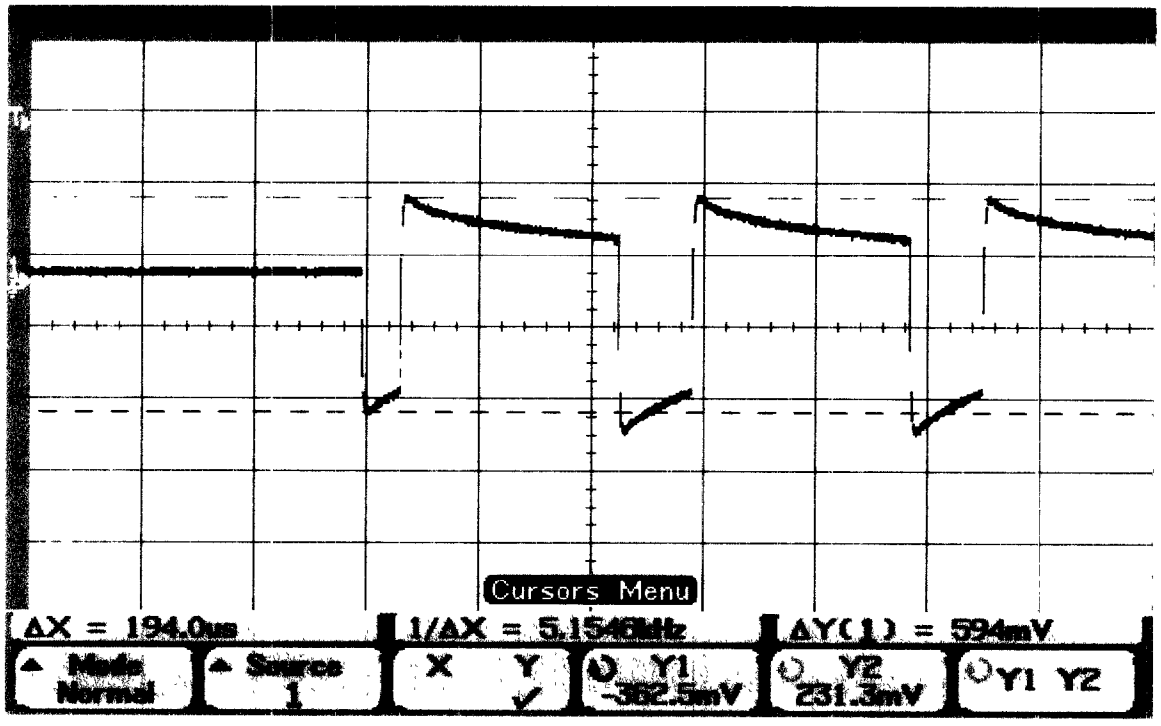

Figure 30. Measured dB/dt waveform for the first part of the burst for the Physio-Stim Lite configuration shown in Fig. 29. Note that the first pulse has a width half that of the other narrow pulses in the train.

5.2 dB/dt Measurements for the Physio-Stim Coil

Figure 31 shows the measured dBx/dt for different distances y from the plane of the base. The magnetic field was found to be primarily transverse in the cross section of the coil, consistent with the qualitative expectation of Fig. 7.

Figure 32 shows measured dBy/dt vs. y for different values of x. At x=0, the field is entirely transverse and dBy/dt is minimal. For an off-center scan, x= 20 mm and x = -20 mm, there is a significant value of dBy/dt. However, the maximal dBy/dt in Fig. 29 is less than half of the value of that dBx/dt in Fig. 28.

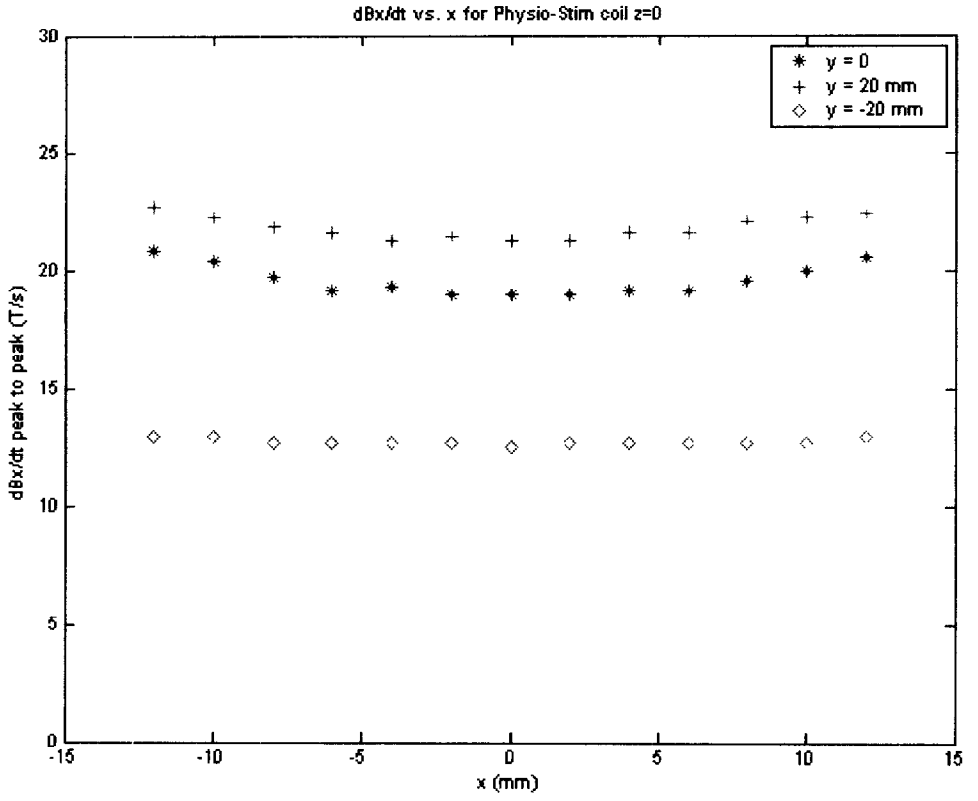

Figure 31. Measured dBx/dt vs x for the Physio-Stim coil. z=0. (See Figs. 7 and 9 for coordinate definitions.)

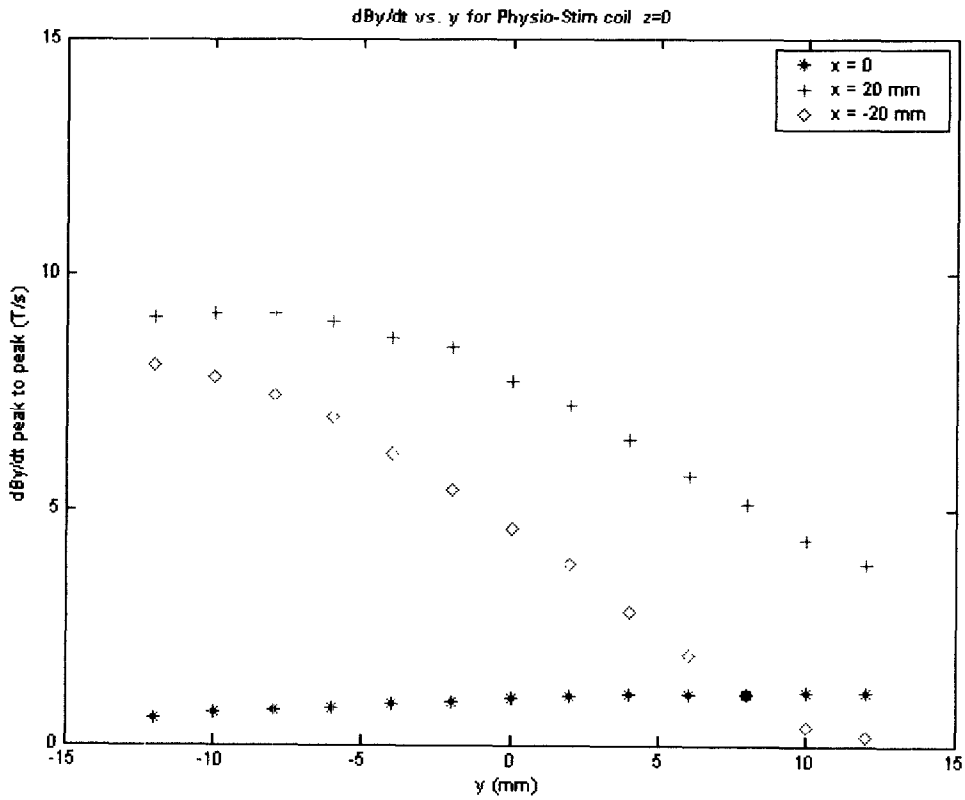

Figure 32 Measured dBy/dt vs. y for different values of x.

6. Waveform characterization

To describe the waveform, we use the current waveforms in Fig. 17 for the EBI coil and Figs. 27 and 28 for the Physio Stim coil. The ramps of the current waveforms can be described as exponential ramps. Consider first the PhysioStim coil since the current waveform is simpler. Figure 28 and repeated here for convenience. On Fig. 33 are annotated the current rise and fall times t_r and t_f, respectively.

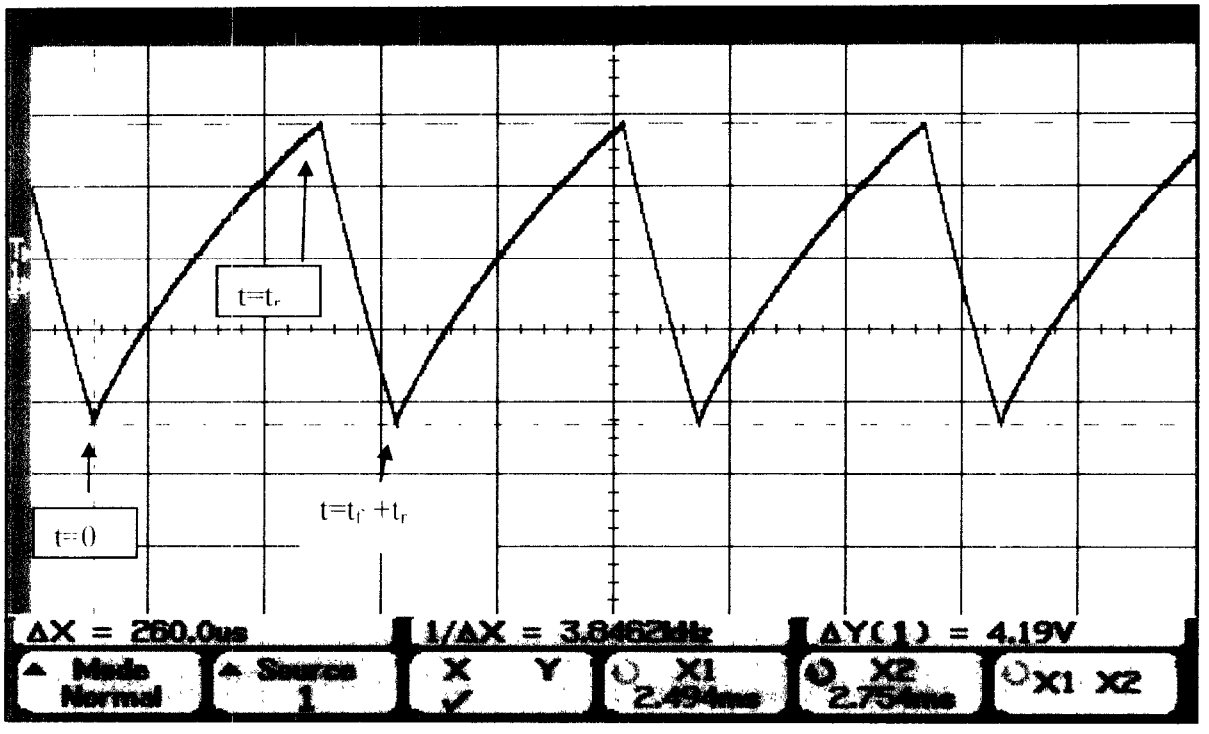

Figure 33. Current waveforms for the PhysioStim Stimulator. The peak to peak amplitude is 0.82 A. (This is the same graphs that is in Fig. 28.)

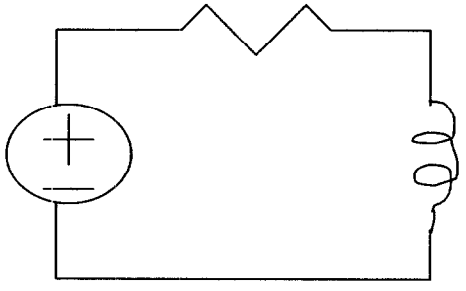

Figure 34. Equivalent circuit for the generator of the current waveforms. A voltage source is in series with a resistor and inductance.

From the equivalent circuit, we see that application of a uniform voltage will result in an exponential ramp of the current. We need a general expression for the current during an exponential ramp. Assume the current is I_1 at time t_1 and I_2 at time t_2. The time dependent current can be written as

$$I(t) = \Delta I(1 - \exp(-(t - t_1)/\tau)) + I_{off} \tag{6.1}$$

where τ is the time constant ΔI is current to fit the curve and I_{off} is an offset current. From the condition that the current is (I_1, I_2) at time (t_1, t_2), we obtain

$$I_{off} = I_1 \tag{6.2}$$

$$\Delta I = \frac{I_2 - I_1}{1 - \exp(-(t_2 - t_1)/\tau)} \tag{6.3}$$

We need general expression for the current during an exponential ramp. Assume the current is I_1 at time t_1 and I_2 at time t_2. The time dependent current can be written as The time derivative of the current is then

$$\frac{dI}{dt} = \frac{\Delta I}{\tau} \exp(-(t - t_1)/\tau) \tag{6.4}$$

$$\frac{dB}{dt} = B_I \frac{dI}{dt}$$

where B_I is the magnetic field per unit current, which will depend solely on the coil geometry.

From Fig. 28, for the PhysioStim coil, $t_r = 192\ \mu s$, $t_f = 66\ \mu s$. The minimum and peak currents are -0.372A and 0.451 A, respectively. Figures 35 and 36 show the calculated current and dB/dt waveforms.

The fitted current waveform in Fig. 35 is in good agreement with the measured current waveform in Fig. 27. Similarly, the fitted dB/dt waveform in Fig. 36 is in good agreement with the measured dB/dt waveform in Fig. 24.

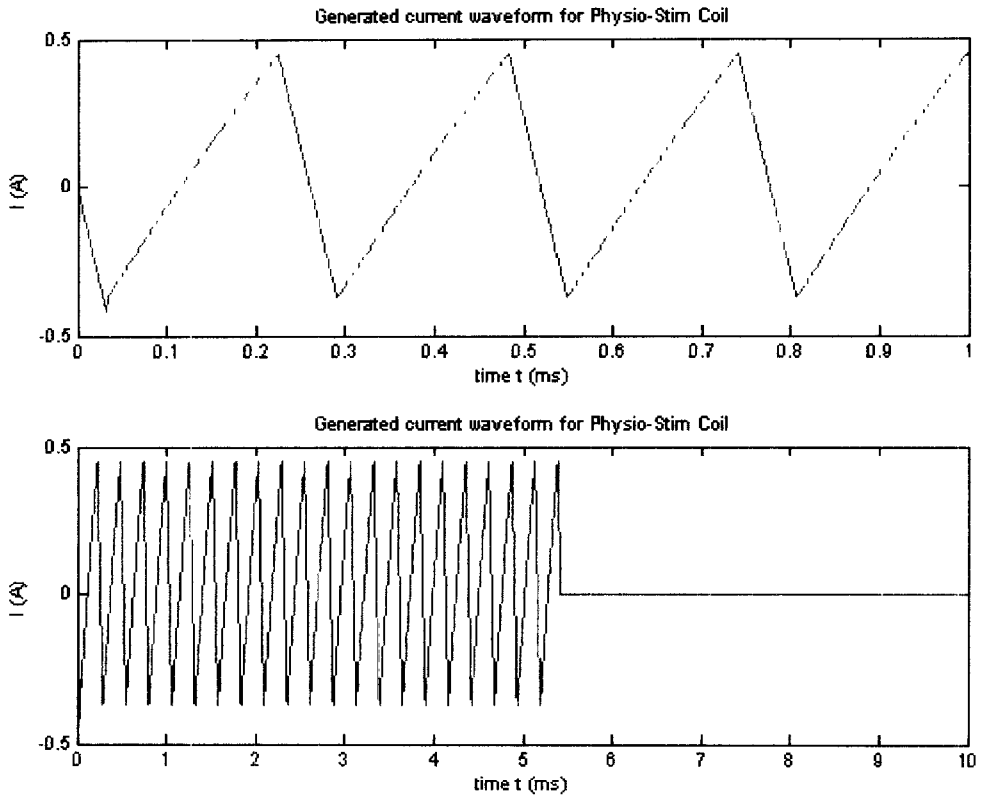

Figure 35. Approximated current waveform for the Physio-Stim coil using $t_r = 192\ \mu s$, $t_f = 66\ \mu s$, $\tau_r = 1$ ms, $\tau_f = 1$ ms, $I_1 = -0.372$ A, and $I_2 = 0.451$ A. Upper plot is an expansion of the lower plot.

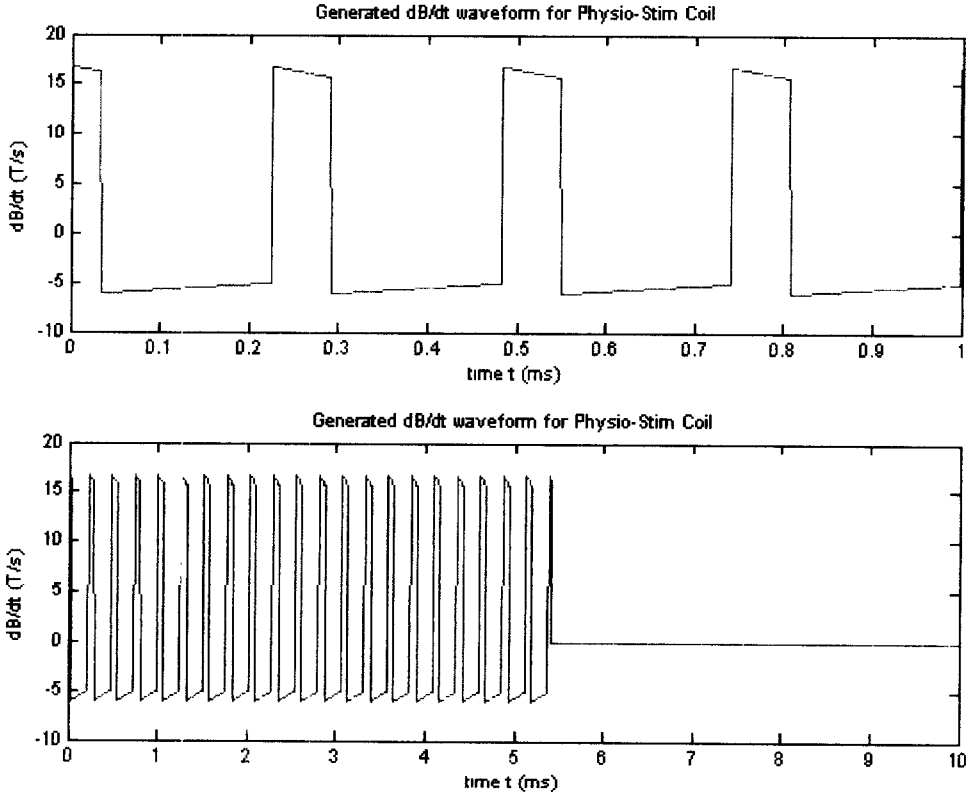

Figure 36. Approximated current waveform for the Physio-Stim coil using $t_r = 192\ \mu s$, $t_f = 66\ \mu s$, $\tau_r = 1$ ms, $\tau_f = 1$ ms, $I_1 = -0.372$ A, $I_2 = 0.451$ A, and $B_I = 1.3 \times 10^{-3}$ T/A. Upper plot is an expansion of the lower plot.

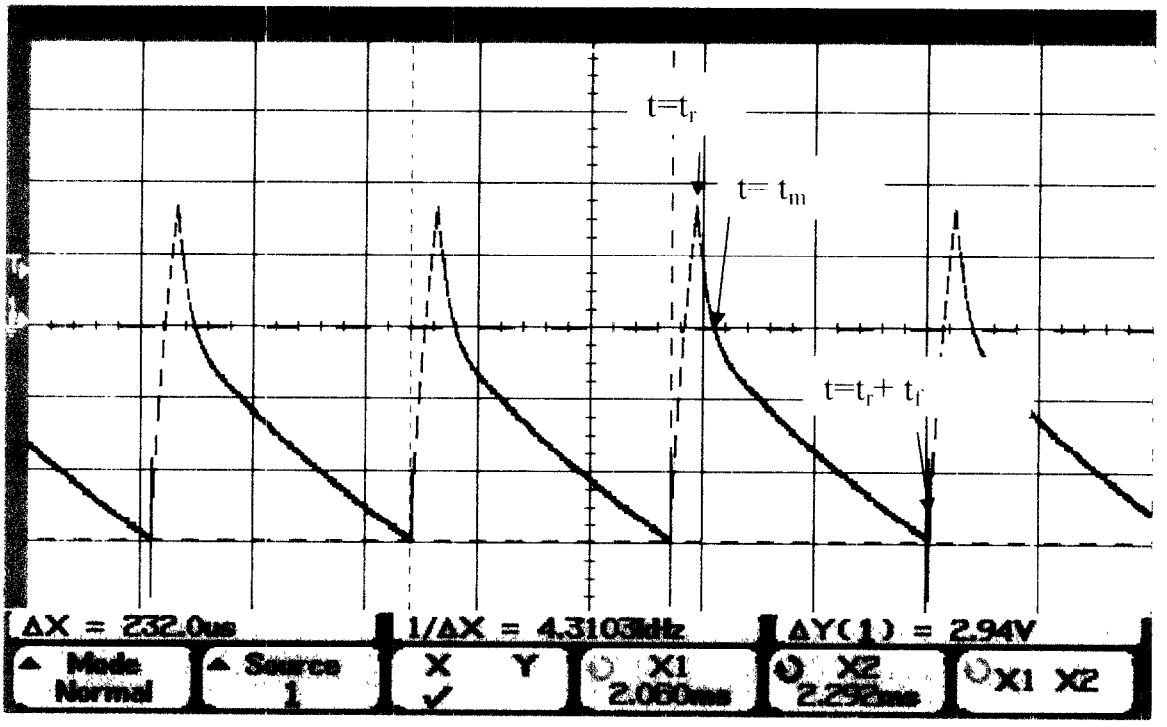

Figure 37. Current waveform for the EBI coil. Times are t_r = 26 μs, t_f =208 μs, and t_m = 40.5 μs. Voltage levels at t=(0, t_r, t_m, t_r+t_f) = (-3.0 V, 1.594 V, 0 V, -3V). The sense resistor is 5.1 Ω and thus the currents are (-0.588 A, 0.3125 A, 0 A, -0.588 A)

Figure 37 shows part of the current waveform for the EBI coil. There are three critical times (t_r, t_m, t_f) and the corresponding time constants are (τ_r , τ_m, τ_f). Figure 38 shows generated current waveforms for the EBI coil. The general shape matches the currents in Figs. 17(a) and 17(b). However, the transition at the zero crossing is more abrupt in the model than in the measurement. Figure 39 shows the generated dB/dt waveform. The positive pulses are in good agreement with Figs. 17 and 18. However, the negative spike in the calculated dB/dt waveform is more pronounced than in the measured one. Part of the reason is the imprecision in the approximating the downward going part of the dB/dt waveform by sections of exponentials. Another factor would be the low pass filtering effects of the inter-winding capacitance of the sense coil and the EBI coil. Eddy currents in the winding could also result in loss pass filtering of the dB/dt waveform.

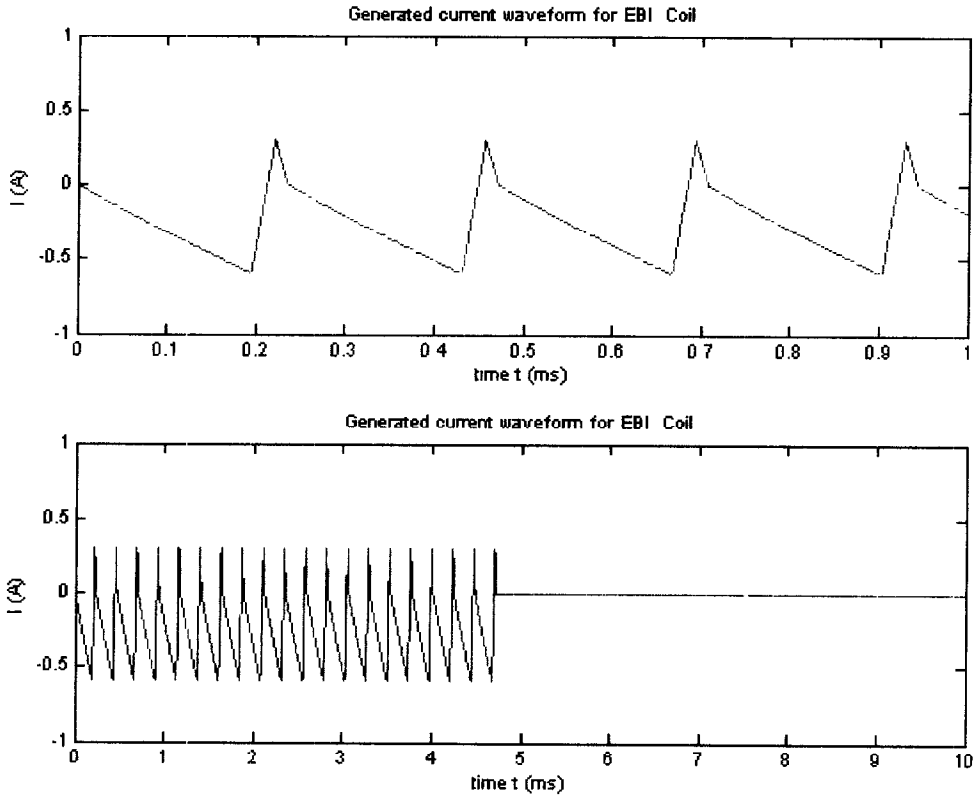

Figure 38. Approximated current waveforms for the EBI coil.

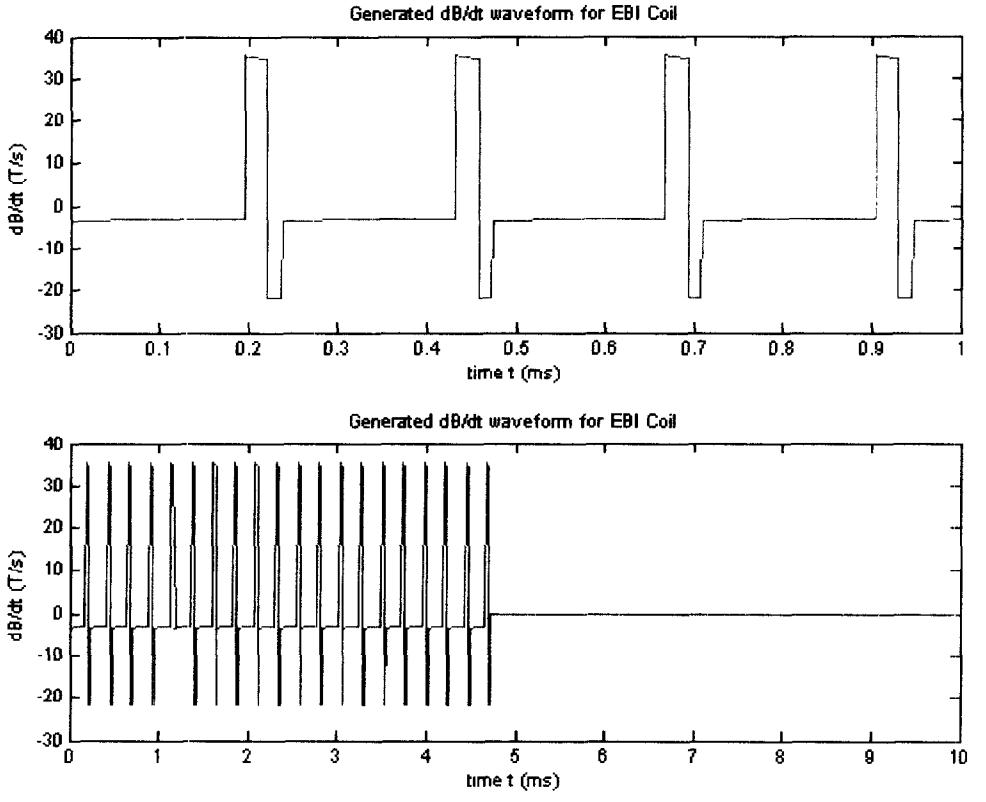

Figure 39. Approximated dB/dt waveforms for the EBI coil. Times are t_r = 26 μs, t_f =208 μs, and t_m = 40.5 μs. Voltage levels at t=(0, t_r, t_m, t_r+t_f) = (-3.0 V, 1.594 V, 0 V, -3V). The sense resistor is 5.1 Ω and thus the currents are (-0.588 A, 0.3125 A, 0 A, -0.588 A). $B_I = 1.01 \times 10^{-3}$ T/A and time constants are 1 ms. The negative tail on the dB/dt waveform is low pass filtered by the EBI coil and the pick-up coil.