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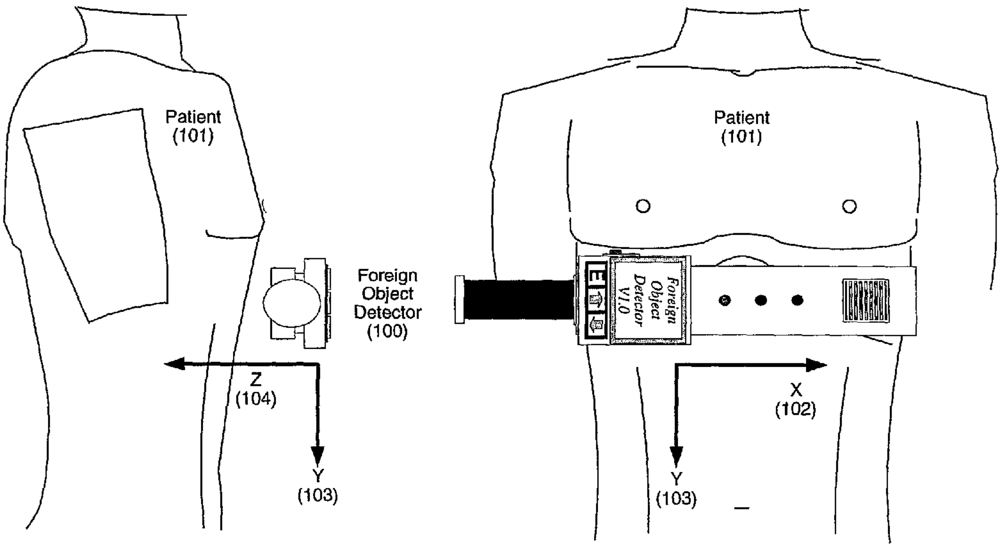

A: Side View

B: Top View

Coordinate System with Patient and Detector

**(57) Abstract:** A radar system uses an array of transceivers combined with signal processing techniques to provide a new type of medical imaging technology. The system detects foreign objects such as sponges, surgical tools, etc., based on the difference in the electrical properties between biological tissue and the foreign object. Advantageously, synthetic aperture radar (SAR) techniques are coupled with statistical filtering algorithms to detect, locate, and optionally also identify a foreign object.

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# SYSTEM AND METHODS FOR DETECTING FOREIGN OBJECTS AFTER SURGERY

## FIELD OF THE INVENTION

**[0001]** This Application claims priority to U.S. Provisional Patent Application Serial No. 60/515,216, filed October 27, 2003, and incorporated herein by reference.

**[0002]** The field of this invention is methods and apparatus for detecting objects in the body of a patient.

## BACKGROUND OF THE INVENTION

**[0003]** A recent study in “Annals of Surgery”, 1996 Jul; 224(1), 79-84, of medical mistakes found that out of approximately 28 million in-patient surgeries performed annually in the United States, operating room teams leave sponges, clamps and other tools or objects inside at least 1,500 patients every year. Due to lax reporting requirements and confidentiality agreements arising from settlements, many instances may go unreported, implying that the actual number of incidences could be significantly higher. These foreign objects pose a serious threat to post operative care and recovery as the foreign object may cause serious injury, infection, or death.

**[0004]** The current standard of care requires the surgical team perform a sponge and instrument count prior to and after an operation to insure all surgical materials and instruments are accounted for. Counts are labor intensive and errors are not uncommon. In fact, falsely correct post-procedure counts have been documented in over 75% of known cases where foreign objects were found in surgical patients. Postoperative x-ray checks may be ordered in suspected cases of foreign object retention. Unfortunately, radiological studies are infrequently employed due to the cost and difficulty associated with the procedure as well as the inherent harm ionizing radiation presents to the patient. Additionally, x-ray checks may not detect a foreign object because of the possibility that the object is obscured by an x-ray opaque internal structure or the object's composition makes it undetectable to x-ray. Therefore, there is a great need for a safe, reliable, cost effective and easy-to-use device that can be used to account for foreign objects, materials, or instruments used in surgery. Furthermore, the device should be able to detect a foreign object without making direct contact with the patient. Direct contact with the patient should be avoided because it can disturb the surgical site or any associated tubes, sensors, or wires connected to the patient, resulting in additional trauma or infection.

## SUMMARY OF THE INVENTION

**[0005]** In a first aspect, a radar system is used to detect a foreign object in a patient. The system includes a detector including a radar transmitter and a radar receiver. A signal processor is linked to the radar receiver, for processing signals transmitted by the radar transmitter, reflected off of the patient's body, and received by the radar receiver. An indicator indicates the presence of a foreign object in the patient's body based on results of signal processing by the signal processor.

**[0006]** The system operates by transmitting a radar signal toward or at the patient, and then receiving a reflected radar signal from the patient. The reflected signal is processed to determine whether a foreign object is present in the patient. The system also advantageously , but not necessarily, provides information on the location of the foreign object in the patient, and the nature of the foreign object, for example, the material, size, or shape of the foreign object. In one version, an image of the object may be created and displayed. Alternatively, the processed reflected radar signal may be compared to radar reflection parameters of known foreign objects. When this comparison indicates that the processed reflected radar signal sufficiently matches the parameters of a known foreign object, the system indicates the presence of the known foreign object, e.g., metal, plastic, gauze, etc.

**[0007]** In a typical use, at the conclusion of a surgical procedure, before the surgical team closes the surgical site, a hand held radar device is held over the surgical site and activated. The device may optionally perform a self-test and signal the outcome of the test to the user. If the self-test is performed and is passed, the device begins active interrogation of the surgical site. The operator, typically a nurse, scans across the surgical site by sweeping or moving the device across the site. If an object is detected, the device signals the operator using audible tones or visual indicators, or both. The same indicators may provide information to the operator on the relative position of the object, allowing the operator to home in on the location of the object.

**[0008]** The radar, which advantageously is an ultra wide band (UWB) radar, generally emits a microburst of microwave energy, which propagates into the patient's body, illuminating individual tissues and organs. Reflections are created at the boundaries between different types of tissues and materials because of the differences in the electrical properties of the dissimilar materials. The reflections are received by the radar and processed, for example, by using statistical signal processing techniques, to extract information on the presence and location of a foreign object.

**[0009]** The invention resides as well in sub-combinations and sub-systems of the elements and method steps described. While the system here is generally described relative to a hand held device, the inventive concepts apply as well to a non-hand held system. These non-hand held systems can have a moveable radar element supported on a structure over or near the patient. The supported radar element can be moved or positioned manually or automatically (e.g., via a motor). Alternatively, a fixed, non-moving, electronically scanned radar, e.g., a phased array, may be used. The present system and methods are primarily intended for use in detecting foreign objects in a patient after surgery. However, they can also of course be used to detect foreign or stray objects in a patient due to injestion, penetration, or attempted concealment. The present system and methods can also be used to detect objects deliberately placed in the body, such as a stent, bone screw, etc.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0010]** Figures 1A and 1B are general representations of the coordinate system used to define the interactions between the system and patient.

**[0011]** Figure 2 is a block diagram of system architecture.

**[0012]** Figure 3 is a block diagram of a UWB transceiver.

**[0013]** Figures 4A and 4B are conceptual illustrations of the user interface of the system of Figure 1.

**[0014]** Figure 5 is a flowchart that illustrates general steps of signal processing.

**[0015]** Figure 6 is a block diagram of a clutter rejection filter used to attenuate the reflections caused by the air/skin boundary.

**[0016]** Figures 7A and 7B are exemplary illustrations of the SAR geometry.

**[0017]** Figure 8 is a detailed illustration of the SAR geometry.

**[0018]** Figure 9 is a block diagram of the matched filter/correlator algorithm.

**[0019]** Figures 10-14 are screen shots in black and white showing test results. The original results were displayed in color.

## DETAILED DESCRIPTION OF THE DRAWINGS

**[0020]** A radar system uses an array of transceivers combined with signal processing techniques to provide a new type of medical imaging technology. The system can detect foreign objects based on the difference in the electrical properties between biological tissue and foreign objects. Synthetic aperture radar (SAR) techniques coupled with statistical filtering algorithms may be used to detect the presence of a foreign object within the patient's body, and to identify the object's position.

**[0021]** In one embodiment, multiple radar transceivers are arranged in a linear array. Operation of the transmitters and receivers are sequenced to allow collection of reflected energy from the patient's body across the length of the array. The reflected signals are coherently processed using SAR techniques to minimize the interference from undesired returns (clutter) and to enhance the desired returns. The desired returns are further processed using a matched filter/correlator approach to determine whether the return contains backscattered energy corresponding to one of many patterns of known foreign objects previously stored in a database. If there is a match between the return and a pattern in the database, indicating a foreign object has been detected, the operator is notified through audible and/or visual indicators. The patterns in the database can be modified or updated to accommodate the introduction of new surgical tools and supplies. Alternatively, the system can process the returns or received reflected signals, and then display an image directly. In this alternative design, no database of known object reflection characteristics, and no comparison step is needed or used.

**[0022]** The physical basis for microwave detection of foreign objects in biological tissue is based on the fact that when illuminated by electromagnetic energy, reflections will be created at the boundaries between dissimilar materials. The reflections are a direct result of the unique electrical properties associated with different materials types, and in this particular application, those electrical properties associated with biological tissue and surgical tools and supplies. For metal objects such as clamps, scissors, and needles, the pertinent electrical property is conductivity (designated by "$\sigma$"); while for non-metallic objects such as plastic tubing, gauze, sutures, tape, sponges, etc., the pertinent property is permittivity (designated by "$\varepsilon$").

**[0023]** Referring to Figures 1A and 1B, in order to be effective as a foreign object detector, the device (100) should be able to interrogate the entire volume encompassing the surgical site in the patient's body (101). This requires that the system gather information along three separate axes as defined by a Cartesian coordinate system. The X-Y plane is defined as the plane parallel to the surface of the surgical site on the patient's skin. As used here, the X-axis (102) corresponds to the linear array of transceivers internal to the device while the Y-axis (103) is defined as the direction of travel of the device. The Z-axis (104) corresponds to the range of the radar and is perpendicular to the surgical site surface in the direction internal to the body.

**[0024]** In one embodiment, the system (100) has a processor subsystem (105), multiple UWB transceivers (106) arranged in an array (107), and a user interface (108) as shown in Figure 2. The processor subsystem (105) is responsible for managing the operation of the device and processing the received reflections from the UWB array using the stored algorithms. In this embodiment, the processor subsystem includes a digital signal processor (109), memory, typically volatile storage SDRAM memory (110) and non-volatile storage Flash memory (111), a data port (112), an accelerometer (113), and associated support circuitry. The processor executes software code responsible for system level operation, housekeeping, and data processing. Run time code and data are stored in the volatile memory. Executable code is stored in the non-volatile memory. Non-volatile memory is also available for persistent storage of data or results for later use or analysis. The data port supports data transfer between the device and an external computer. The physical link could be either wired, for example a serial port, or wireless, for example a Bluetooth transceiver.

**[0025]** The processor subsystem (105) also receives and processes data from the internal accelerometer (113). The accelerometer data serves two purposes – it is used to assist in identifying the relative position of a detected foreign object and to monitor the manual scan rate to ensure that the scan rate does not exceed the maximum allowable rate. The maximum allowable rate is a function of the array size, processor speed, and algorithm complexity. If the maximum rate is exceeded, the resolution in the direction of travel will decrease below the range of interest, resulting in the device potentially failing to detect certain objects. In an alternative design, the accelerometer can be omitted. Movement of hand held unit can be monitored using optical or doppler techniques. Optionally, detecting or measuring movement of the device can be omitted entirely, although the performance or versatility of the device may then be degraded.

**[0026]** The UWB transceivers and antennas comprising the array (107) are responsible for generating the UWB transmitted signals and receiving the reflected signals. Each transceiver (106) is composed of a transmitter and a receiver, as shown in Figure 3. The transmitter (114) operates in the microwave spectrum and preferably complies with applicable electromagnetic radiation rules, such as, in the United States, FCC Rules and Order 02-48 pertaining to UWB medical devices. There are several common approaches used to generate the UWB transmit signal, including direct impulse, sweep synthesis, and pulse compression. A direct impulse generator (115) driven by the PRF oscillator (116) running at 10MHz to control the pulse repetition frequency (PRF) is used in the Fig. 3 embodiment. The PRF is chosen to balance the requirements imposed by the desired unambiguous range while maximizing the amount of transmitted energy illuminating the surgical site.

**[0027]** From Equation 1 below, an approximation of the unambiguous range is calculated from the two-way time delay between a transmitted and received pulse, for example: the pulse repetition interval (100nsec for 10MHz), the pulse width (250ps), the speed of light (c= 3e8m/s) and the average dielectric constant of the medium (30 for a combination of air and body tissue).

**[0028]** In this embodiment, the unambiguous range is approximately 2.7 meters.

**[0029]** This unambiguous range is more than sufficient to accommodate the largest possible patient as well as a reasonable air gap between the device and patient.

Equation (1): $$\mathit{Unambiguous\ Range} = \frac{c}{2\sqrt{\varepsilon_{r(average)}}}\left(t_{period} - t_{pulsewidth}\right)$$

**[0030]** The receivers in this embodiment use a swept-range architecture similar to that employed in traditional radar, sonar and ultrasound systems, allowing the receivers to collect reflections across a range of depths within the patient's body. Each receiver (117) in the array here has a sample and hold (118), an integrator (119), a combination low pass filter/variable gain amplifier (120), and an analog-to-digital converter (121).

**[0031]** The sample and hold (118) is triggered by a signal that is based on a delayed version of the transmitter PRF and a ramp waveform from a pattern generator (122). The delayed version of the transmitter PRF synchronizes the transmitter and receiver and controls the minimum range of the device. The ramp waveform causes the receiver sample window to monotonically sweep from the minimum range to the maximum range, where the amplitude of the waveform is proportional to the delay between the transmitter pulse and the sampler. The choice of the sweep rate is chosen to balance the desire to collect reflection from a large number of pulses at a single position of the device with the desire to collect reflections from a large number of device positions. In this embodiment, the sweep rate of the receiver as defined by the ramp waveform was set at 60Hz. The amplitude of the ramp was set to a value that resulted in a receiver sample window sweep range of 18.5ns, corresponding to a maximum usable range or depth of 50cm per Equation 1. The integration process improves the signal-to-noise ratio by coherently summing the reflections from numerous transmitted pulses at a fixed range. This compensates for the extremely low transmitted power levels of the UWB transmitter.

**[0032]** The low pass filter/variable gain amplifier (120) is responsible for two operations – restricting the bandwidth of the received signal in preparation for conversion from an analog to a digital format and amplifying the filtered signal. The filter bandwidth is designed such that the cutoff frequency is sufficiently below the critical Nyquist frequency as defined by the sampling rate to prevent aliasing of the data. The variable gain amplifier is employed to help compensate for the loss in reflected energy resulting from increased range. The gain of the amplifier is also controlled by the ramp waveform, increasing the gain as the range of the receiver sample window increases. The analog-to-digital converter (121) receives the analog output of the low pass filter/variable gain amplifier (120) and converts it to a digital format for use by the processor subsystem.

**[0033]** The antenna (123) is used to couple energy to and from the environment to the transmitter and receiver circuitry. There are a large number of UWB antenna designs appropriate for this sort of application. A small microstrip bowtie was selected for this embodiment because of its balance between performance and small form factor. Other antenna designs, including separate transmit and receive antennas, could also be employed. While the description above is provided relative to an UWB radar system, other electro-magnetic spectrum frequencies may also be used. For example, a narrow band radar frequency system may be useful for certain applications.

**[0034]** In the embodiment shown in Fig. 2, there are eight transceivers organized in the linear array (107). The number of transceivers was chosen as a balance between the desire for increased resolution and the desire to minimize the space required to house the array for handheld applications. More transceivers (106) may be employed if either the size restrictions were relaxed or a smaller transceiver circuit and antenna size was used. Additionally, the array could be organized in a two dimensional matrix - for example, an 8x8 matrix, to eliminate the need to move the device across the surgical site. This alternative larger and heavier system may be used in less portable applications. Finally, the number of elements in the array has a significant impact on the processor requirements, with an increase in elements resulting in an exponential increase in the required processing capabilities.

**[0035]** The user interface (UI) as shown in Figures 4A and 4B includes user controls and information indicators for activating the device and performing the search for foreign objects. It may also allow the user to configure and calibrate the device. In this embodiment, the foreign object detector has an on/off switch (124) so that it does not consume power when not in use. Once powered on, the device will not transmit or receive UWB energy until the transmit button (125) is activated. This conserves battery power (when batteries are used, in contrast to a tethered embodiment) and eliminates unnecessary UWB transmissions in the operating environment. Additional UI buttons (126) can be used in conjunction with the LCD screen (127) to configure the device and perform maintenance operations.

**[0036]** The UI may have a variety of indicators – such as audible and visual, which can assist the user in the correct operation of the device, and/or for indicating the detection and location of any foreign object. For example, if the power-on self-test completed successfully, a user-visible indicator (128), such as a green LED, will be illuminated. At that point, the operator knows that the device is ready to be used. On the other hand, if the power-on test is unsuccessful, a user-visible indicator (129), such as a red LED, will be illuminated and a speaker (130) will emit an audible tone. Additionally, an error message indicating the cause of the failure can be written to the LCD screen (127) and stored in non-volatile memory for later analysis. The same fault indicator system can also be used during normal operation to indicate a system fault; for example, to alert the operator that the device is being swept across the patient too quickly.

**[0037]** To assist the operator in positioning the device correctly, the foreign object detector system (100) may have two or more targeting lights (131), such as a series of red LEDs, aligned with the array that beam down from the underside of the device onto the patient. The lights illuminate the patient skin area covering the physical region subject to active radar interrogation, providing a visual indicator to the operator that the device is correctly positioned over the surgical site.

**[0038]** The UI shown in Figures 4A and 4B also typically includes audible and/or visual indicators that alert the operator when the device has detected a foreign object and assists the operator in pinpointing the object's location. For example, when an object is detected, the system (100) illuminates a user-visible indicator (132), such as a red LED, display a graphic or text message on the LCD screen (127), and emits an audible tone from the speaker (130). The same indicators are used to locate the position of the object. For example, as the operator moves the device away from the location where the object was detected, the LED may begin to blink slowly, and the LCD may display an arrow pointing in the direction of the object. Simultaneously, the audible alarm can also become less frequent and fainter. In this way, once an object is detected, the operator can begin to reduce the search area and pinpoint the location by maximizing audible tone and visual indicators.

**[0039]** The individual transmitters and receivers (106) in the array are sequenced in an order that is dependent on the signal-processing algorithm. In this embodiment, where SAR techniques are combined with a matched filter/correlator, each transmitter and receiver pair in a single transceiver is operated in tandem, with the transmitter sending out a series of pulses and the paired receiver collecting the reflections from those pulses across the full range of depths. The next transmitter and receiver pair in the array is then activated and the process repeated until all pairs have been sequenced and the associated data collected. For each position of the device, a two-dimensional matrix of data is collected where each row contains the data as a function of range or depth into the patient's body for a single transceiver and each column contains the data corresponding to a constant range or depth for all transceivers. As the device is moved across the surgical site and the transceiver array collects more data, additional two-dimensional matrices are created. All of the two-dimensional matrices are concatenated to create a three dimensional array of data containing the reflections from the entire surgical site.

**[0040]** The object detection algorithm has five principal steps as shown in Figure 5. First, the clutter rejection algorithm (133) attenuates the large reflection caused by the air/skin interface. Second a data alignment algorithm (134) adjusted the sampled data from the reflections to compensate for variations in height above the patient as the device is scanned over the surgical site. Third, a SAR algorithm (135) coherently adds the data from the multiple transceivers in the array to enhance the resolution. Fourth, a search algorithm (136) correlates the resultant data with a variety of matched filters from the database (137). Finally the correlator output is fed to a threshold detector (138) to determine if a foreign object is present.

**[0041]** The first step in the object detection algorithm is removing any clutter in the received reflections arising from the air/skin boundary. Due to the large difference in dielectric properties between air and skin, there will be a large reflection at the air/skin boundary. This clutter needs to be removed; otherwise it will dominate the reflections and potentially prevent the algorithm from detecting any foreign objects in the patient's body. In this embodiment where the medium and potential targets are predominantly stationary, the clutter can be effectively removed using temporal filters.

**[0042]** As shown in Figure 6, the clutter rejection algorithm (133) attenuates the air/skin clutter by approximating the clutter arrival time in the swept returns and then applies a temporal filter to the swept returns at a point in the return that corresponds to the expected clutter. There are a variety of temporal filter functions applicable, ranging from simple notch filters to more complex models based on the actual received clutter signal. The choice of the temporal filter is driven by the availability of processor resources to handle the necessary computations and the expected proximity of the foreign objects to the skin surface. In this embodiment, a simple temporal notch filter was found to be effective.

**[0043]** The approximation of the clutter arrival time is obtained by passing the swept return through a low pass filter (139) and peak detector (140), where the detected peak corresponds to the center of the clutter. The temporal filter (142) is applied to a delayed version of the swept return created by a scan delay buffer (141) at the point corresponding to the detected peak, effectively attenuating the air/skin clutter.

**[0044]** Once the air/skin clutter has been removed, the sampled data from the reflections must be modified to compensate for variations in the device height above the patient. In embodiments where a human operator manually scans the device over the surgical site, it is expected that the device will not remain within a single plane above the patient's body. Deviations from the plane will introduce errors in the SAR calculations and could prevent the device from detecting a foreign object. The results of the clutter arrival time calculations are used to determine the relative height of the device over the patient. This data is correlated with data from the accelerometer to accurately track the height variations. This information is used to time shift the swept return data using Equation 2 where $t_{CA}(n)$ is the clutter arrival time from sweep(n) and $t_S$ is the sample interval in the swept return data.

Equation (2): $$Datashift = \frac{\left(t_{CA}(n) - t_{CA}(n-1)\right)}{t_S}$$

**[0045]** With the data aligned by compensating for variations in device height, it can be further enhanced by coherent addition using SAR techniques. A synthetic aperture radar (SAR) approximates the capabilities of an ideal long antenna to dramatically increase the resolution of the system. It collects reflections from multiple transceiver positions over time to increase the effective resolution of the radar. In general, the transceiver position is varied sequentially across one or more axes resulting in an improvement in resolution along each axis. In this embodiment, the device has an array of transceivers arranged along one axis (the X axis in Figure 1) and is moved along a second orthogonal axis (the Y axis in Figure 1), yielding an improvement in resolution for both the X and Y axes. Increased resolution improves discrimination between objects and clutter, resulting in a higher probability of detection for the desired target or object.

**[0046]** In practice, at each position along the translation axis, the radar generates a series of pulses and the resultant reflections are collected and stored. This process is repeated until data is collected at all positions. Taking the simpler case of a SAR operating across a single translation axis (143) with an associated range axis (144) as shown in Figures 7A and 7B, the initial SAR dataset (145) is a two-dimensional array where one dimension of the array represents the position coordinate (146) and the other dimension represents the range coordinate (147). An individual element in the array, designated as the reference element (148) for a specific position and range, contains the reflections resulting from a single radar position and fixed range or distance from the radar to a target region of interest (149). In the example illustrated in Figure 7, element "$I_{5,4}$" in the initial SAR dataset is the reference element corresponding to the radar at position 4 and collecting the reflections from the target region of interest at range 5.

**[0047]** The initial SAR dataset is processed to create a second dataset, designated as the enhanced SAR dataset, by coherently combining the data from each reference element for a specific target region of interest with the data from all other elements that contain reflections from the same target region of interest. The mathematical operation takes into account the differences in the round trip radial distance and the associated phase shift between the radar position corresponding to the reference element and the radar position for the other elements to coherently add the data. This is illustrated in detail in Figure 8 for the case where the radar (150) is moved from position (i) to position (i+1) with a separation of $D_S$ (151) between the two positions. The round trip distance from the radar at position (i) to the target region of interest (144) is designated $D_i$ (152) while the round trip distance from the radar at position (i+1) to the same target region of interest is designated $D_{i+1}$ (153). From basic geometry, the value for $D_{i+1}$ can be calculated as a function of $D_i$ and $D_S$ as shown in Equation 3. Also, since $D_i$ is a function of the speed of light, the dielectric constant of the medium, and the round trip transit time, $D_{i+1}$ can be expressed as a function of these values.

$$\text{Equation (3):}\quad D_{i+1} = \left(D_i^2 + D_s^2\right)^{1/2} = \left[\left(\frac{ct_i}{\sqrt{\varepsilon_r}}\right)^2 + D_s^2\right]^{1/2}$$

**[0048]** For those cases where Ds<<D(i), this can be further simplified per Equation 4, using a Taylor series approximation, where the round trip distance from the radar at position (i+1) is an algebraic sum of the round trip distance from the radar at position (i) to the target region of interest and a factor, designated the separation factor, that is proportional to the radar separation distance and inversely proportional to the round trip transit time. This equation eliminates the need to calculate two squares and a square root, reducing the computational load on the processor.

$$\text{Equation (4):}\quad D_{i+1} \cong \frac{ct_i}{\sqrt{\varepsilon_r}} + \frac{Ds\sqrt{\varepsilon_r}}{2ct_i} = D_i + \Delta D$$

**[0049]** There will be instances where it will be necessary to use the exact solution to fully optimize the data but in many cases, the approximate solution will provide adequate results. For example, when $D_i$ is equal to $5(D_S)$, the error between the values calculated for $D_{i+1}$ using the exact solution versus the approximation method is less than 1%. Additionally, if the range bin resolution is selected to be equal to the minimum separation factor $\Delta D$, the quantization error will be reduced.

**[0050]** This process is repeated to calculate the radial distance from all positions to the target region of interest. The radial distances are used as indices into the initial SAR data set to extract those elements from the data set containing reflections from the same target region of interest. Each element in the resultant vector is then modified by a term accounting for the relative phase shift of the center frequency of the transmitted spectrum due to the increased round trip distance. The terms are summed and the summation is placed in the enhanced SAR matrix. This operation is described by Equation 5 for an N row by M column matrix, where "I" is an element in the initial SAR data set, "E" is an element in the enhanced SAR data set, "$f_o$" is the center frequency of the UWB spectrum, and "R" is the range bin resolution.

Equation (5): $$E_{a,b} = \sum_{d=1}^{M} I_{a+r,d}\, e^{-j2\pi f_o (b-d)\frac{c\Delta D}{\sqrt{\varepsilon_r}}} \text{ ; for } r \le N-i$$

where:

$$r = \frac{|j-d|\Delta D}{R}$$

**[0051]** The previous process can easily be extended to operate upon a three-dimensional initial SAR data set to generate a three-dimensional enhanced SAR data set.

**[0052]** The final step involves searching the enhanced SAR data for foreign objects. In one embodiment as shown in Figure 9, the search is accomplished by correlating the enhanced SAR data with a series of matched filters (154). The matched filters are empirically generated by scanning individual surgical objects with a foreign object detector system (100) in a controlled environment. The resultant matched filters are stored in a database (137) internal to the device. The database can include filters corresponding to only those objects actually used in a specific procedure, items used in a variety of procedures, and/or objects know to already exist in the patient (e.g. a stent).

**[0053]** The algorithm performs a time domain correlation (155) of the enhanced reflection data with the matched filters using Equation 6, where x represents the incoming signal sequence, y is the matched filter kernel, and $R_{xy}$ is the cross-correlation of the two sequences. If the filter kernel length exceeds 40 to 50 elements, it is usually more computational efficient to calculate the correlation in the frequency domain after transforming the input data and filter kernel with a Fast Fourier Transform (FFT).

Equation (6): $R_{xy}(p)=\sum_{m=-\infty}^{m=+\infty} x(m)\,y(p+m)$

**[0054]** The correlations can be performed sequentially or in parallel, depending on the number of filters and the capabilities of the processing subsystem. The output of each correlation operation is a series of correlation coefficients. The correlation coefficients are passed to a threshold detector (156). If the coefficient exceeds the threshold, indicating a strong match, an object of the class corresponding to the filter has been detected and the device signals the operator.

**Example:** A prototype foreign object detector system as described above was constructed and tested in a laboratory environment. The prototype system used a single UWB transceiver element, a linear motion table, and a personal computer (PC). The test subject was composed of two tissue bags containing a mixture of beef products (meat, fat, and bones) with the test object placed between the two bags.

The UWB transceiver element was mounted at the end of a boom extending from the linear motion table. The motorized system composed of a single UWB transceiver and the linear motion table was used to simulate an actual multi-element UWB array. The output of the UWB transceiver along with the associated timing signal for data synchronization was fed to the audio inputs of the PC for digitization.

Under computer control, the boom was swept across the test subject while the UWB transceiver was actively collecting radar reflection from the test subject. At the end of the pass over the test subject, the resultant data file was processed using a MATLAB script that implemented the described signal processing algorithm. The algorithm was tested against a variety of objects common to the surgical environment. Figures 10 through 14 illustrate the results obtained for a test subject composed of a set of hemostats placed between the two tissue bags. In all five figures, the X-axis corresponds to the direction of motion for the UWB transceiver sweep while the Y-axis represents the range or depth into the test subject.

Figure 10, labeled “Raw Data” is a plot of the original 2-dimensional initial SAR dataset after collection and digitization of the reflections. Although Figure 10 is shown here in black and white, in the original Figure, color was used to represent the amplitude of the reflections obtained at a specific depth and transceiver position. Figure 11, labeled “Reconstructed Image”, is a plot of the 2-dimensional enhanced SAR dataset obtained by coherently adding the reflections from all transceiver positions and depths with respect to each reference cell in the dataset. Figure 12, labeled “Match Filter Image”, is a plot that illustrates the best match against all of the models in the data base of known objects as obtained by correlating the matched filters with the enhanced SAR dataset. In the original Figure 12, color was used in this Figure to show the degree of match between the enhanced SAR dataset and the matched filter reference file. Of course, other display techniques, not using color, could have also been used. Figures 13 and 14, labeled "Metal Instruments" and "Plastic Instruments" respectively, are plots of the results of the correlation operation for two representative matched filter files and illustrates the results of the threshold operation. In this instance, when the enhanced SAR dataset was correlated with the file representing a metal instrument, it produced larger correlation coefficients that those obtained by the plastic matched filter, indicating a stronger match to the metal instruments. Similar positive results were obtained for variety of test objects including several additional metal objects, a number of plastic objects, and a lap sponge with conductive thread.

**[0055]** Various embodiments have been described. Of course, many changes, substitutions and uses of equivalents can be made, within the spirit and scope of the invention. The invention, therefore, should not be limited, except by the following claims and their equivalents.

WHAT IS CLAIMED IS:

1. A system for detecting a foreign object in a patient's body, comprising:

a detector including a radar transmitter and a radar receiver;

a signal processor linked to the radar receiver, for processing signals transmitted by the radar transmitter, reflected off of the patient's body, and received by the radar receiver; and

an indicator for indicating the presence of a foreign object in the patient's body based on results of signal processing by the signal processor.

2. The system of claim 1 wherein the detector is a hand-held detector and the signal processor is within the handheld detector.

3. The system of claim 1 wherein the signal processor is separate from the handheld detector and is linked to the handheld detector via a wire or wireless connection.

4. The system of claim 1 wherein the radar transmitter comprises an array of ultra wide band radar elements.

5. The system of claim 1 further including an accelerometer in or on the handheld detector.

6. A system for detecting a foreign object within a patient, without physically contacting the patient, comprising:

an ultra wide band radar system, including:

a processor subsystem having one or more digital signal processors; memory and at least one data port;

a linear array of ultra wide band transceivers, each transceiver having an ultra wide band transmitter, an ultra wide band receiver and an ultra wide band antenna; and

a user interface having an audible indicator subsystem, or a visual indicator subsystem, or both.

7. The system of claim 6 with the processor subsystem further including a statistical signal processor having one or more of:

a clutter rejection filter for attenuating reflections from the air skin interface;

a motion compensation algorithm to allow the system to compensate for movement of the device by the operator;

a synthetic aperture radar algorithm to coherently add the reflections received by multiple transceivers to enhance the returns; and a search algorithm to determine if a foreign object exists in the search volume and to aid in locating the foreign object.

8. The system of claim 6 further including an external computer system linked directly or indirectly to the processor subsystem.

9. The system of claim 6 wherein the transceiver elements in the array are sequenced in an order that is dependent on the selected signal-processing algorithm.

10. The system of claim 6 further including:

a pulse repetition frequency generator for controlling transmit pulse timing;

a direct impulse generator for creating pulses transmitted by the radar element.

a pattern generator for creating a ramp waveform;

a sample and hold for sampling the radar reflections based on timing signals synthesized from the pulse repetition frequency generator and the pattern generator;

an integrator for summing multiple returns from a single range to improve the signal to noise ratio;

a low pass filter for limiting the bandwidth of the received signal to minimize aliasing during the analog to digital conversion process;

a variable gain amplifier for providing signal amplification; and

an analog to digital converter responsible for converting the analog output of the radar receiver to a digital format for processing by the digital signal processor.

11. The system of claim 6 further including a visual indicator subsystem having light elements for illuminating the search area on the patient's body during the search process.

12. The system of claim 11 further including a visual screen for displaying text messages or graphics feedback to the operator on the state of the device and the progress towards foreign object detection and location.

13. The system of claim 6 further including a clutter rejection filter including:

a low pass filter for smoothing the incoming reflections by attenuating the higher frequency components;

a peak detector for identifying the depth at which the largest reflection occurs;

a scan buffer for maintaining a copy of the most recent set of reflections; and a temporal filter for attenuating the signals corresponding to the reflections from the air/skin interface.

14. The system of claim 6 further including:

an accelerometer on or in the handheld detector;

an integration algorithm for converting the acceleration data to velocity and displacement data; and

a data alignment algorithm for aligning the data to compensate for any undesired motion of the device.

15. The system of claim 6 further including:

a transmitter and receiver sequencing protocol for improved data collection;

a data set of the initial SAR data of collected reflections from the array after motion compensation;

a radial distance algorithm for calculating the radial distance to the target region; and

a coherent addition algorithm for coherent addition of elements for the initial SAR data set using the relative phase shift as a function of the radial distance based on the center frequency of the transmitted spectrum.

16. The system of claim 6 further including a search algorithm for searching the enhanced synthetic aperture radar data set for known foreign objects, with the search algorithm including:

a database of matched filters corresponding to the reflections from a set of known surgical tools and objects;

a correlation algorithm that calculates the cross correlation of the matched filters and the enhanced SAR data set produced by the synthetic aperture radar algorithm; and

a threshold detector that evaluates the correlation results and determines if an object has been detected.

17. A method for detecting a foreign object in a patient, comprising:

transmitting a radar signal to the patient;

receiving a reflected radar signal from the patient;

processing the reflected radar signal;

comparing the processed reflected radar signal to radar reflection parameters of known foreign objects; and

indicating the presence of a foreign object when the comparison indicates that the processed reflected radar signal sufficiently matches the parameters of a known foreign object.

18. A method for detecting a foreign object in a patient, comprising:

transmitting a radar signal to the patient;

receiving a reflected radar signal from the patient;

processing the reflected radar signal; and

indicating the presence of a foreign object when the comparison indicates that the processed reflected radar signal sufficiently matches the parameters of a known foreign object.

19. The method of claim 18 further including the step of creating and displaying an image of a detected foreign object, based on the processed reflected signal.

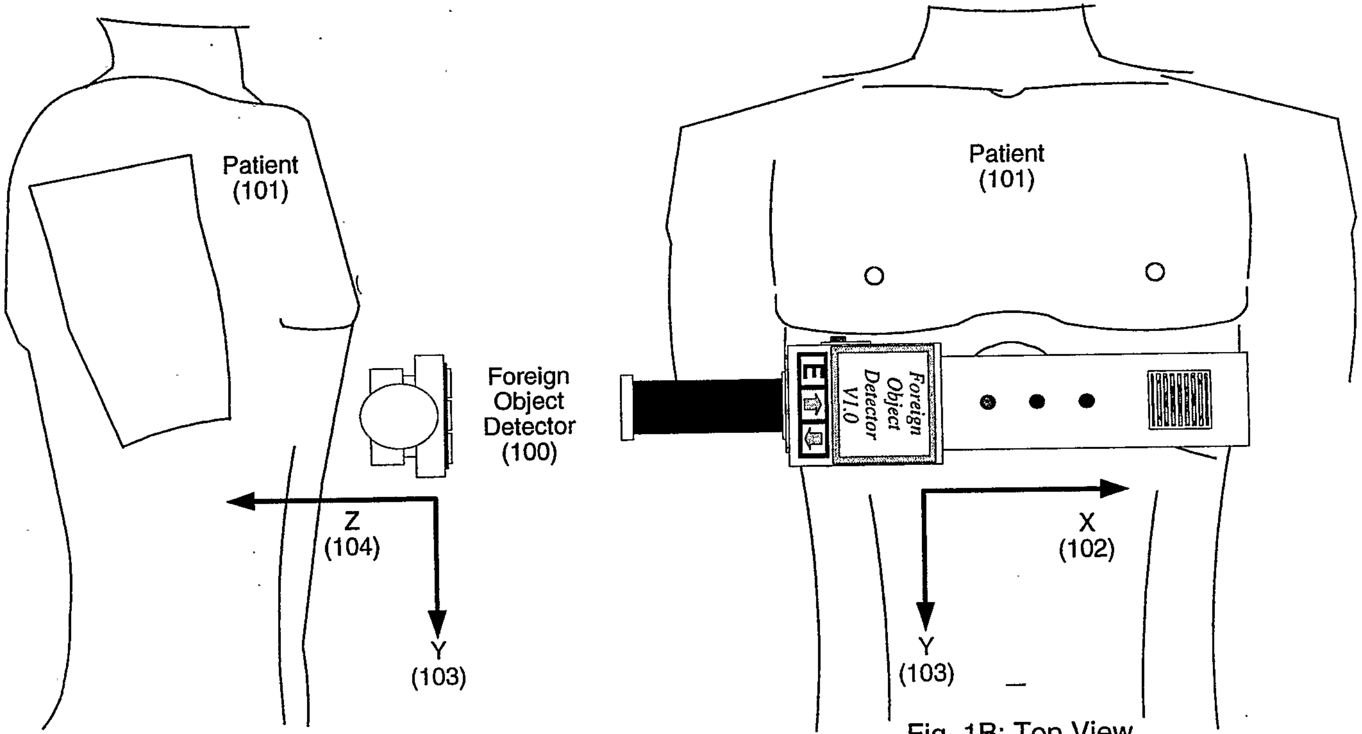


Fig. 1A: Side View

Fig. 1B: Top View

Coordinate System with Patient and Detector

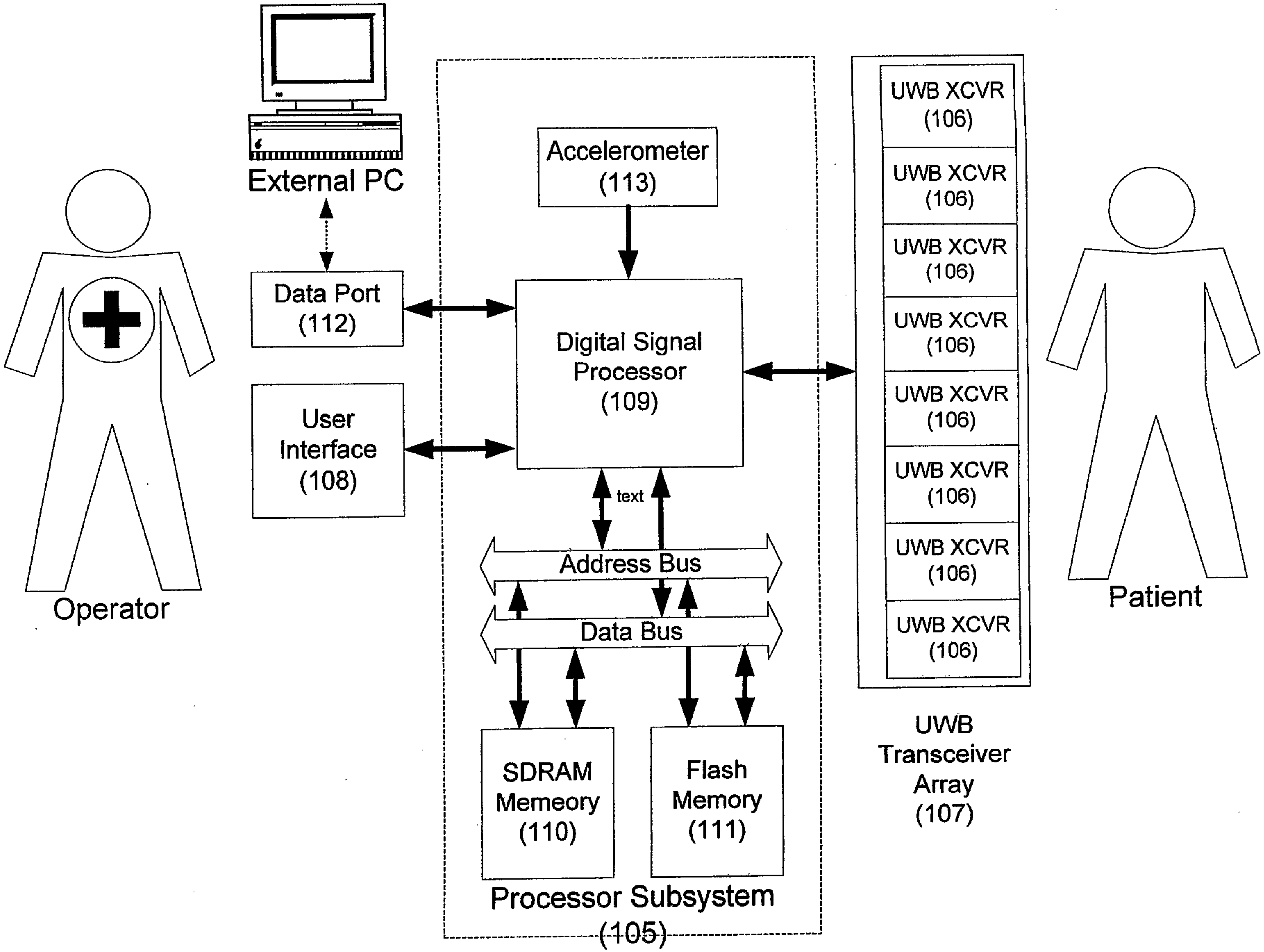


Figure 2: Block Diagram of the System Architecture

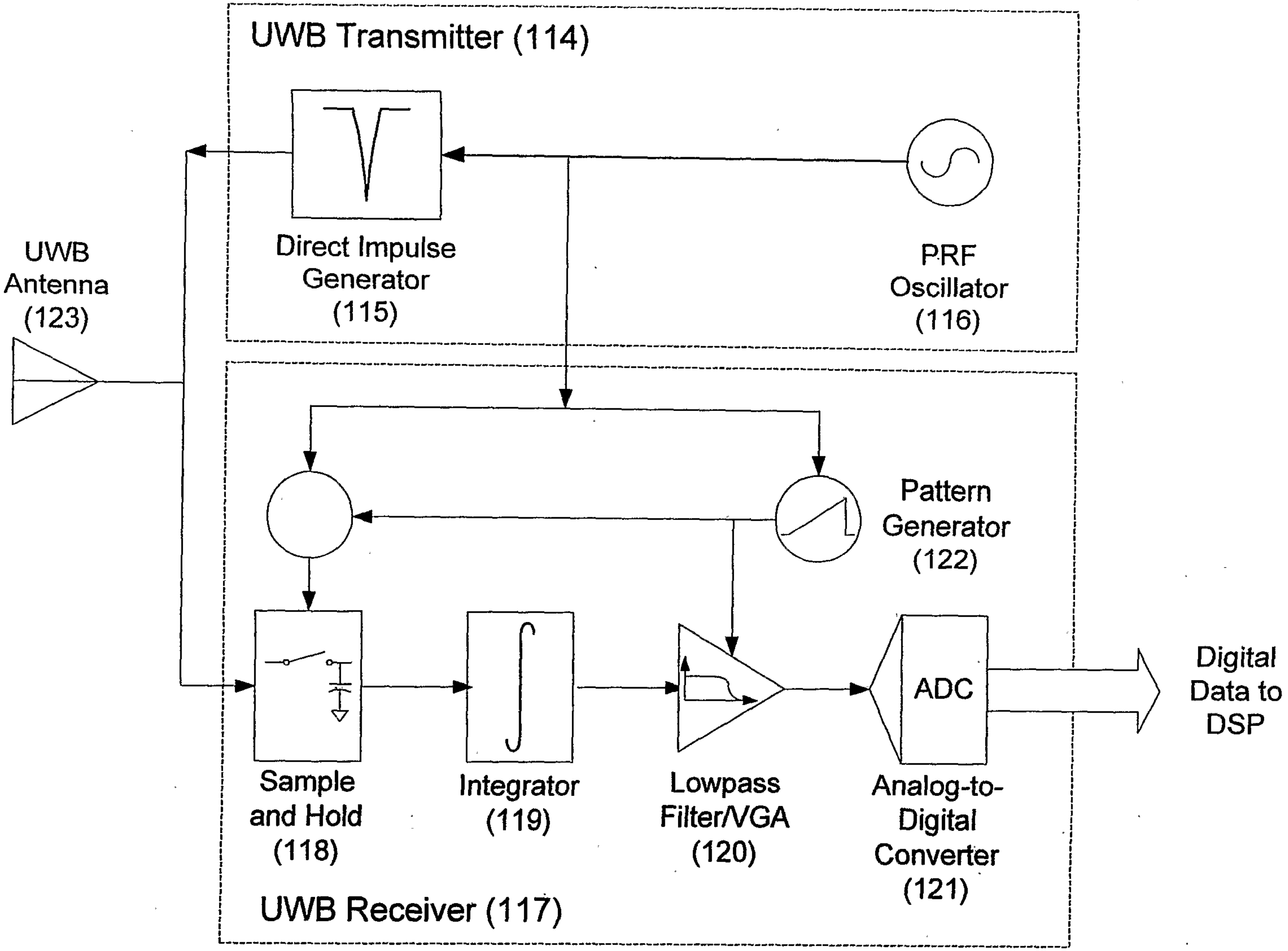


Figure 3: Block Diagram of the UWB Transceiver

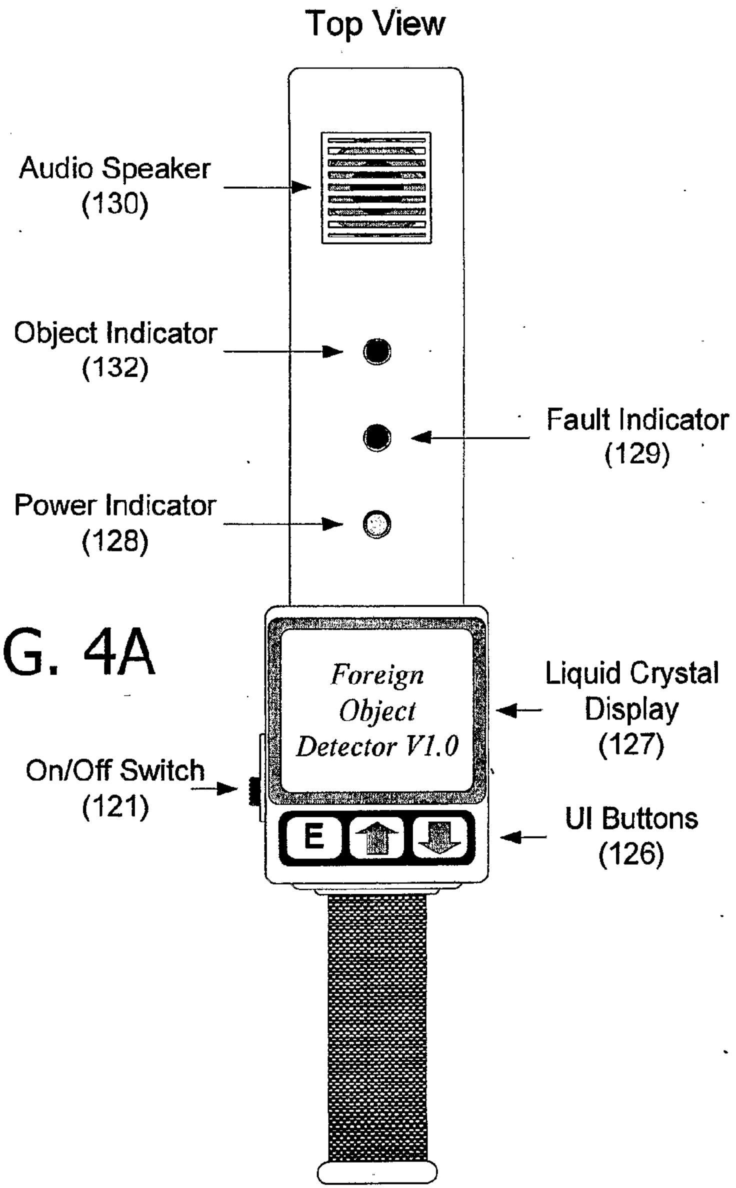


FIG. 4A

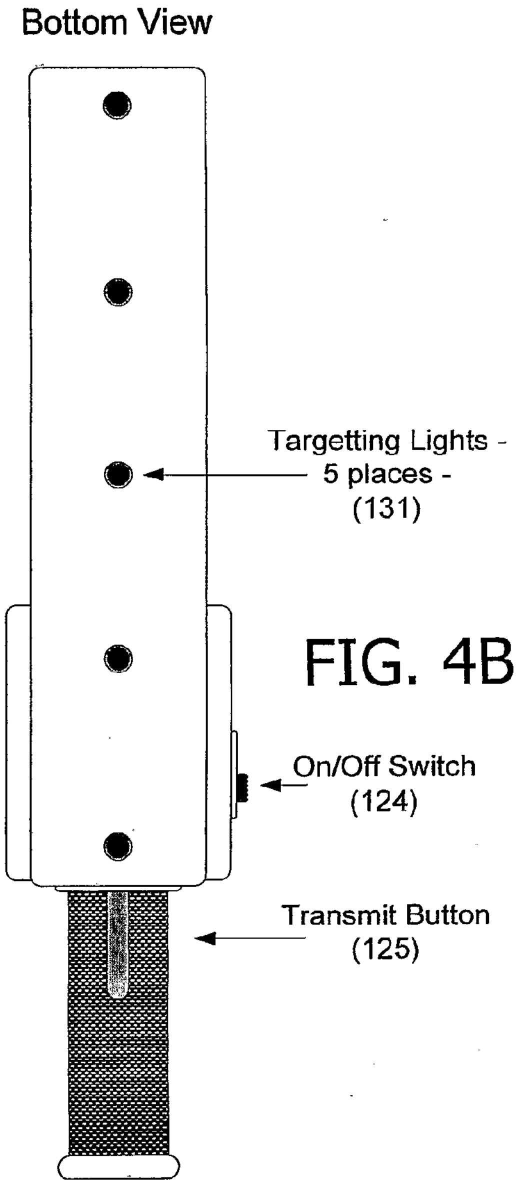
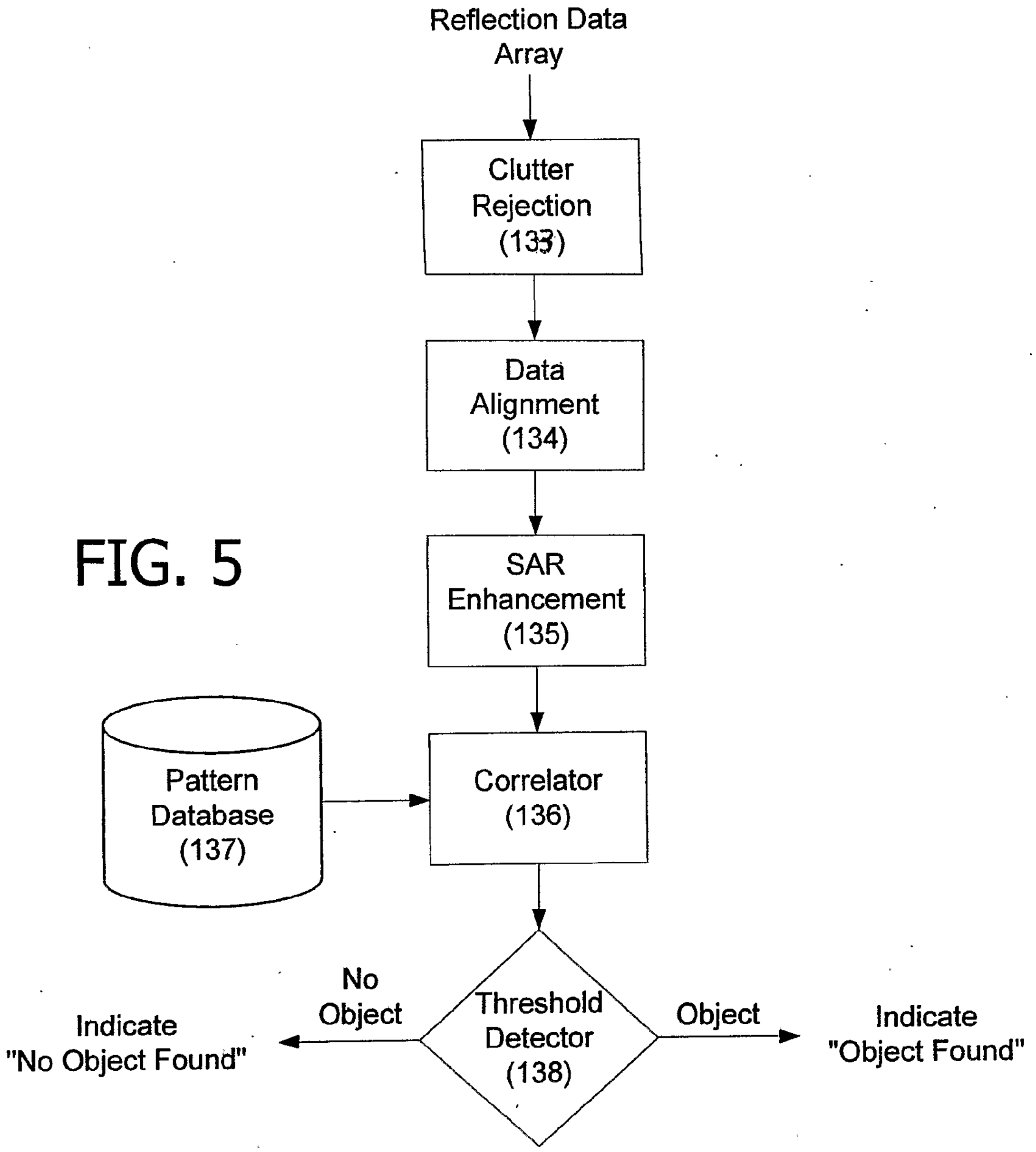


FIG. 4B

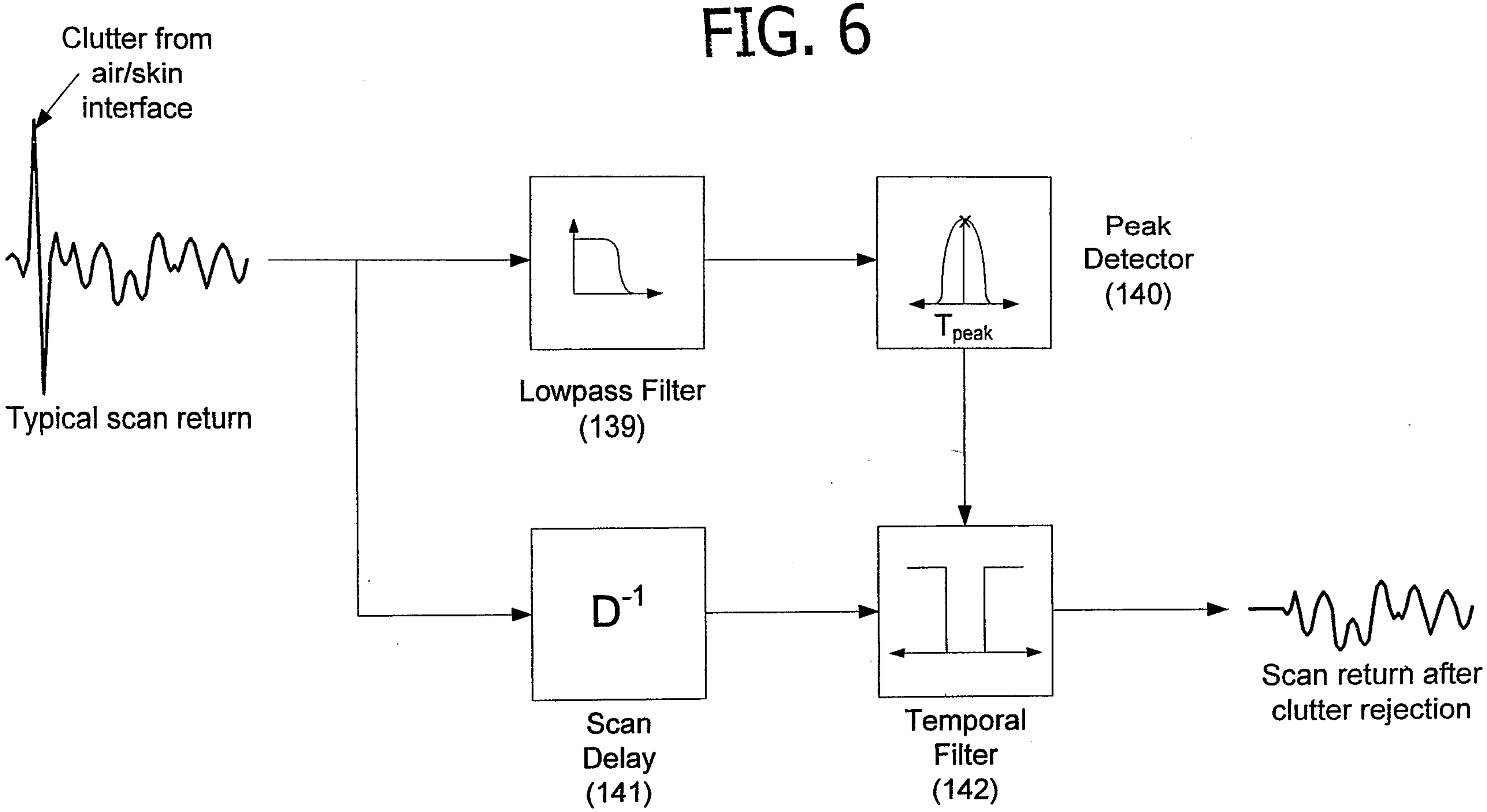
Illustration of the User Interface (UI)

FIG. 5

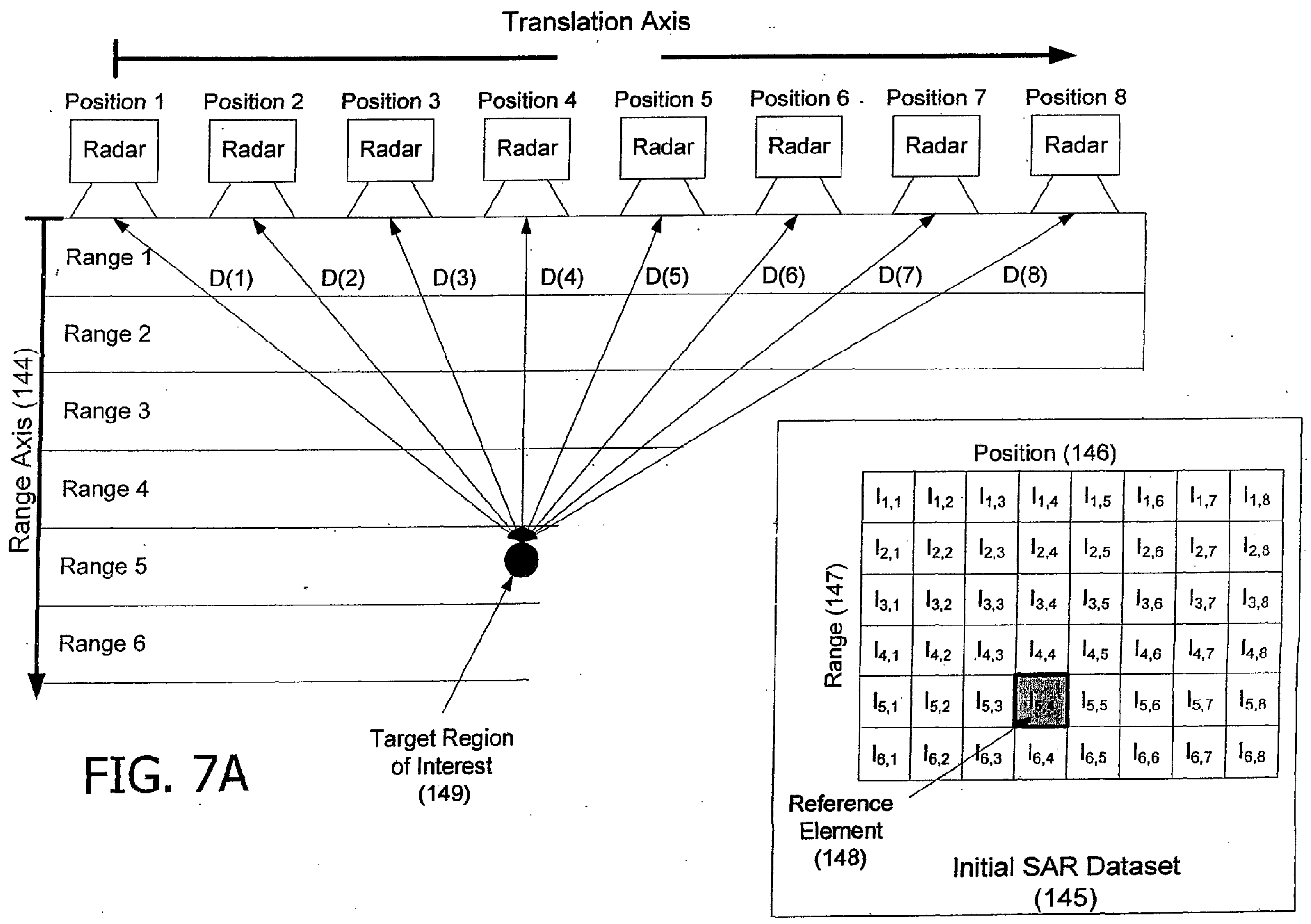


Block Diagram of the Signal Processing Algorithm

FIG. 6



Block Diagram of the Clutter Rejection Filter



|  |  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|---|
| $I_{1,1}$ | $I_{1,2}$ | $I_{1,3}$ | $I_{1,4}$ | $I_{1,5}$ | $I_{1,6}$ | $I_{1,7}$ | $I_{1,8}$ |
| $I_{2,1}$ | $I_{2,2}$ | $I_{2,3}$ | $I_{2,4}$ | $I_{2,5}$ | $I_{2,6}$ | $I_{2,7}$ | $I_{2,8}$ |
| $I_{3,1}$ | $I_{3,2}$ | $I_{3,3}$ | $I_{3,4}$ | $I_{3,5}$ | $I_{3,6}$ | $I_{3,7}$ | $I_{3,8}$ |
| $I_{4,1}$ | $I_{4,2}$ | $I_{4,3}$ | $I_{4,4}$ | $I_{4,5}$ | $I_{4,6}$ | $I_{4,7}$ | $I_{4,8}$ |
| $I_{5,1}$ | $I_{5,2}$ | $I_{5,3}$ | $I_{5,4}$ | $I_{5,5}$ | $I_{5,6}$ | $I_{5,7}$ | $I_{5,8}$ |
| $I_{6,1}$ | $I_{6,2}$ | $I_{6,3}$ | $I_{6,4}$ | $I_{6,5}$ | $I_{6,6}$ | $I_{6,7}$ | $I_{6,8}$ |

FIG. 7A

Illustration of the SAR Geometry

FIG. 7B

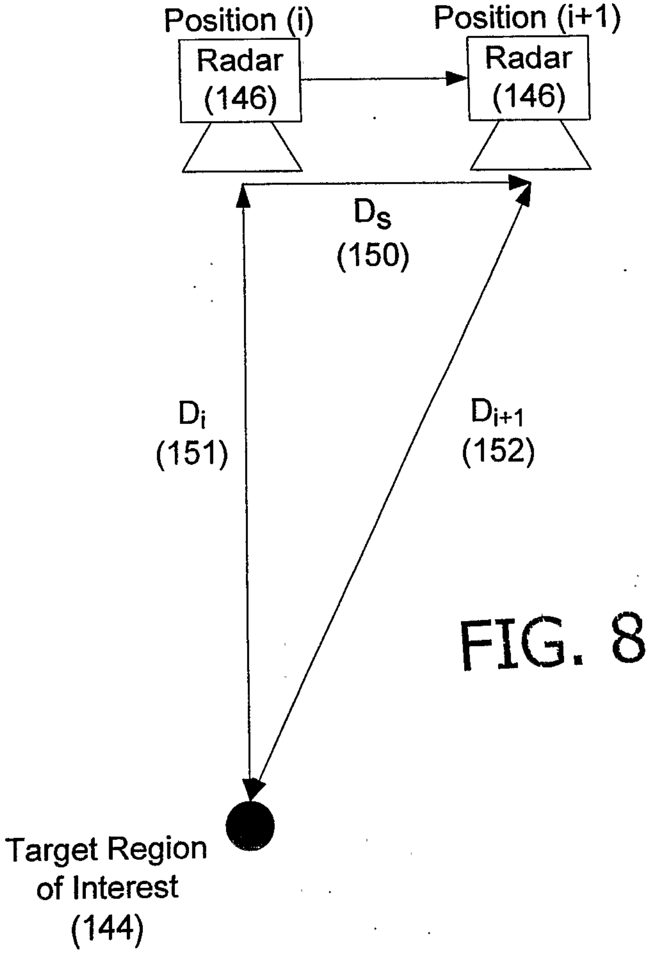
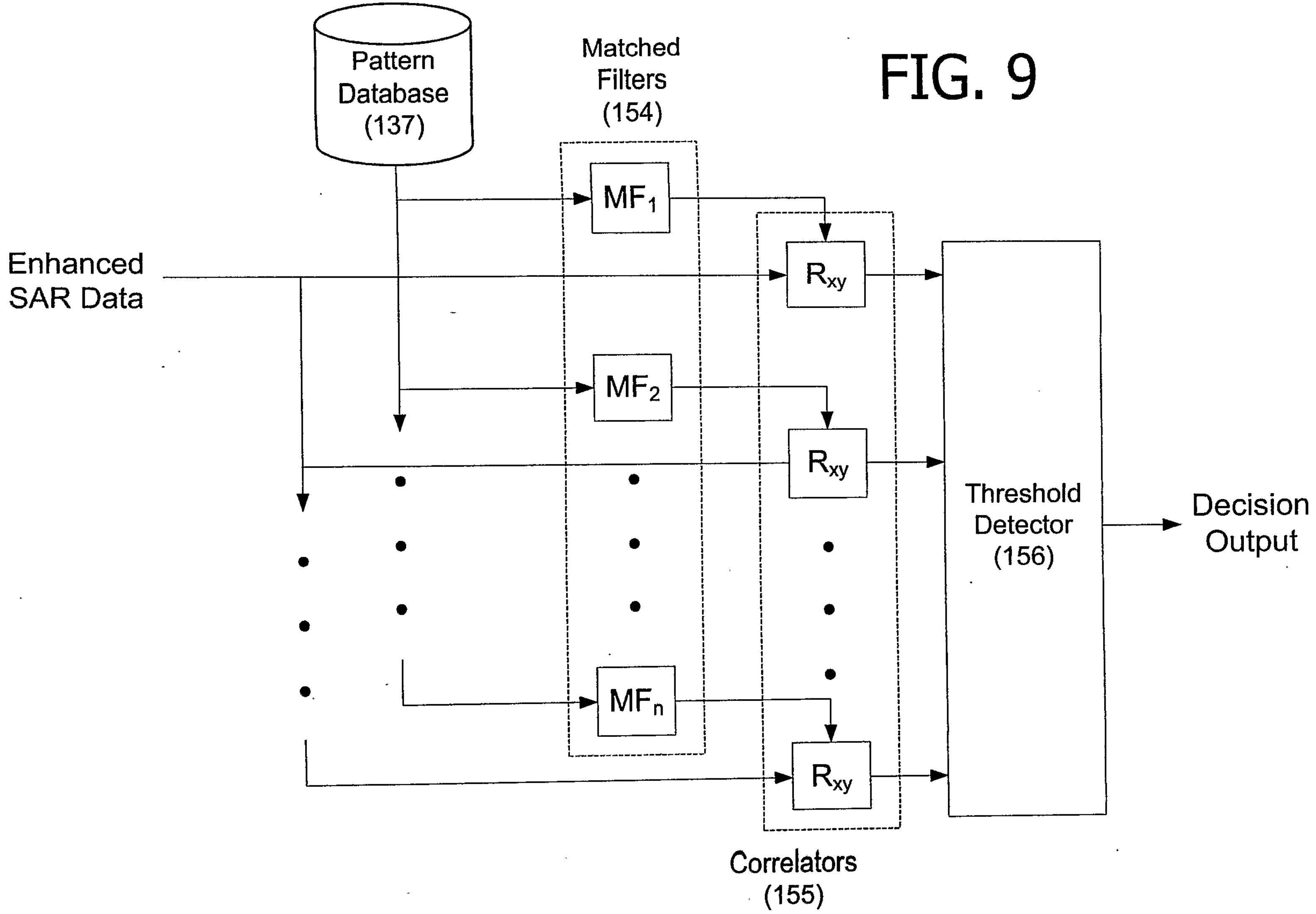


FIG. 8

Detailed Illustration of the SAR Geometry

# FIG. 9



Block Diagram of the Matched Filter/Correlator

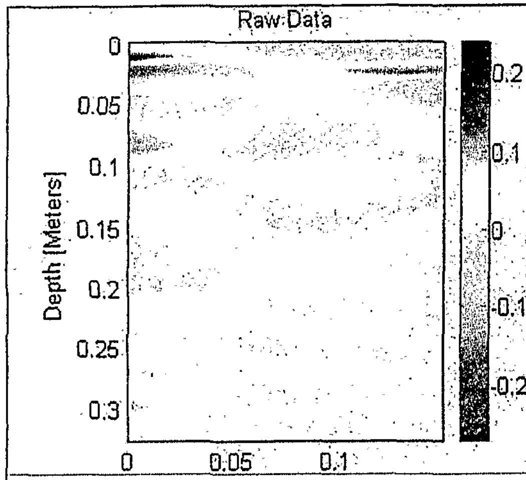


FIG. 10

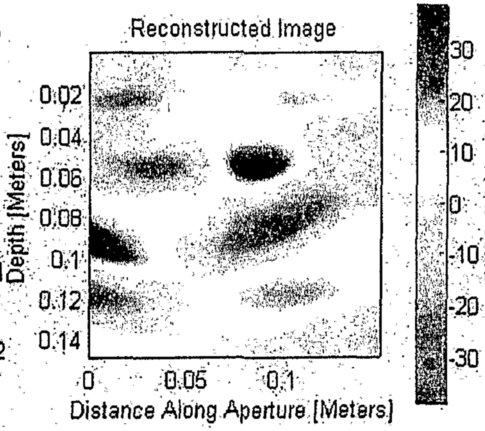


FIG. 11

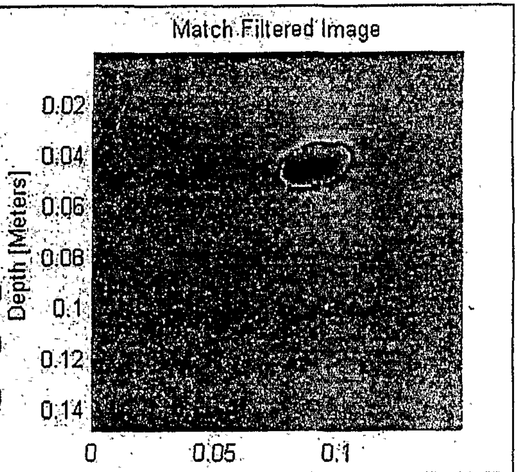


FIG. 12

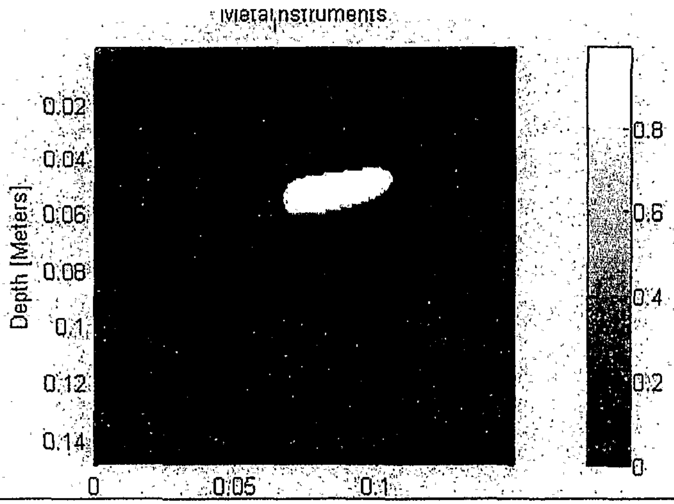


FIG. 13

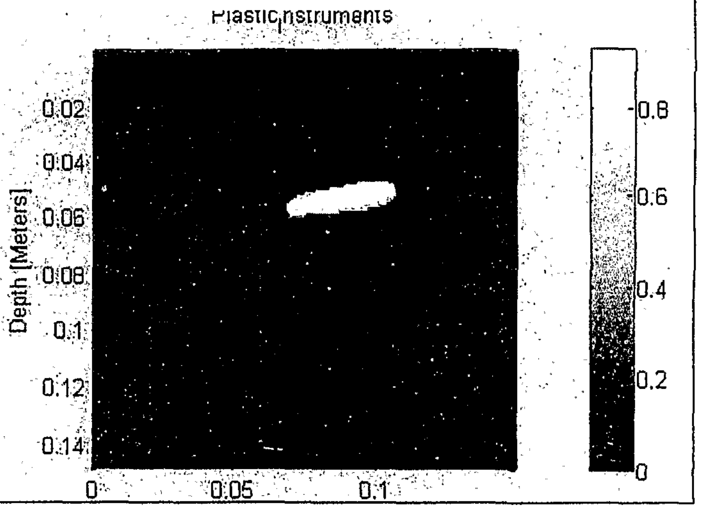


FIG. 14