

INVIVO CORP
Form 10-K
September 29, 2003

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FORM 10-K

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

- x **Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended JUNE 30, 2003**

OR

- o **[] Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____**

Commission file number 0-15963

INVIVO CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other Jurisdiction
of Incorporation or Organization)

77-0115161
(I.R.S. Employer
Identification No.)

4900 HOPYARD RD., SUITE 210,
PLEASANTON, CALIFORNIA
(Address of principal executive offices)

94588
(Zip Code)

Registrant's telephone number, including area code: (925) 468-7600

Securities to be registered pursuant to Section 12(b) of the Act:
NONE

Securities to be registered pursuant to Section 12(g) of the Act:
COMMON STOCK, \$.01 par value per share

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes o No x

The aggregate market value of registrant's voting Common Stock held by non-affiliates of the registrant as of December 31, 2002 was approximately \$56,397,200.

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There were 3,917,149 shares of the registrant's Common Stock, \$.01 par value per share, outstanding as of September 19, 2003.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's definitive proxy statement to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year June 30, 2003 are incorporated by reference in Part III.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements regarding Invivo Corporation's plans, expectations, estimates and beliefs. These forward-looking statements are only predictions and involve risks and uncertainties, including among other things, statements regarding the Company's anticipated revenue, costs and expenses. Actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. The Company is not obligated to update or revise these forward-looking statements to reflect new events or circumstances. Factors that could cause actual results, events or circumstances to differ from forward-looking statements made in this report include those set forth in the following Risk Factors section. You are also urged to carefully review the risks described in other documents that Invivo Corporation files with or furnishes to the Securities and Exchange Commission from time to time, including quarterly reports on Form 10-Q and current reports on Form 8-K.

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PART I

ITEM 1. BUSINESS

OVERVIEW

Invivo Corporation designs, manufactures and markets monitoring systems that measure and display vital signs of patients in medical settings, for use in both magnetic resonance imaging (MRI) environments and in general patient monitoring applications. The Company s systems simultaneously monitor heart function, respiration, heart rate, blood oxygen levels, invasive and non-invasive blood pressure and exhaled carbon dioxide levels. The Company s Invivo Research, Inc. (Invivo Research) subsidiary developed the first multi-parameter vital sign patient monitoring system for use during MRI.

Invivo Research has established relationships with most of the world s largest MRI equipment manufacturers. It presently maintains distribution agreements or other original equipment manufacturers, or OEM, vendor relationships with Siemens A.G. Medical Engineering Group (Siemens Medical), Philips Medical Systems (Philips Medical), Hitachi Medical Corporation (Hitachi Medical), and GE Medical Systems (GE Medical). GE Medical, Siemens Medical and Philips Medical have approved the use of Invivo Research s monitors for incorporation into their MRI equipment. Invivo Research is currently working with Philips Medical to develop an integrated MRI compatible patient vital signs monitoring system for use with Philips Medical s MRI scanner designed for cardiovascular disease diagnosis.

On April 3, 2003, the Company acquired Medical Data Electronics Inc. (MDE), a wholly-owned subsidiary of SensorMedics Corporation and an indirect subsidiary of VIASYS Healthcare Inc., for \$9.3 million in cash. MDE is a manufacturer of wireless patient monitoring products. MDE s results of operations have been included in the Company s consolidated financial statements since the date of acquisition.

On May 10, 2002, Invivo Corporation sold substantially all of the assets of Sierra Precision, a wholly-owned subsidiary of the Company, to 3D Instruments, LLC. Sierra Precision is a manufacturer of gauges that monitor and control oxygen flow for safety, industrial and governmental markets. Sierra Precision represented approximately 12% of Invivo Corporation s consolidated revenues for the first nine months of fiscal year 2002. On May 30, 2002, Invivo Corporation sold substantially all of the assets and transferred certain liabilities of Lumidor Safety Corporation (Lumidor), a wholly-owned subsidiary of the Company, to Zellweger Analytics, Inc. Lumidor is a manufacturer of portable and fixed gas detection instrumentation for worker safety. Lumidor Safety represented approximately 13% of Invivo Corporation s consolidated revenues for the first nine months of fiscal year 2002.

With the sale of the assets of Sierra Precision and Lumidor, the Company now derives approximately 97% of its total revenue from its medical line of products. In addition, as a result of the sales of these subsidiaries, the Company currently operates in one segment.

The Company s headquarters are located at 4900 Hopyard Road, Suite 210, Pleasanton, California 94588 and the Company s telephone number is (925) 468-7600. The Company s Website is www.invivocorp.com.

INDUSTRY

MEDICAL

MRI

MRI is a non-invasive diagnostic tool that uses magnetic fields and radio frequencies to produce images of internal organs and structures of the body. As a result, MRI scanners are used worldwide, and are located principally in hospitals and stand-alone imaging centers. The Company believes that roughly half of these MRI scanners are located in the United States.

The Company estimates that over 2,300 new MRI units were sold worldwide in calendar year 2002, and believes that the MRI marketplace will continue to grow as new uses for MRI are developed.

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MRI patient monitoring technology enables physicians to track vital signs while the patient is undergoing an MRI procedure. While not every MRI use requires a patient monitor, as uses continue to expand the Company believes patient monitoring during the MRI procedure will continue to become increasingly important. The MRI environment presents unique challenges for patient monitoring. A monitor must not interfere with the MRI in a manner that degrades the image. In addition, the monitor signal must be protected from the MRI's magnetic field and radio frequencies in order to maintain the accurate performance of the monitor. The Company is aware of only three other companies currently manufacturing MRI patient monitors and believes that Invivo Research is the market leader.

The Company expects that growth in the MRI monitoring market will come from new MRI unit placements, outfitting existing MRI equipment not presently equipped with monitoring devices, and replacing existing MRI patient monitors.

GENERAL PATIENT MONITORING

General patient monitoring products measure, display and document vital signs information obtained from sensors attached to the patient. The principal customers of patient monitoring products include hospitals and outpatient surgery centers.

The Company estimates the worldwide market for patient monitoring products that measure multiple vital signs, including MRI and general patient monitoring, was approximately \$2.0 billion in calendar year 2002. This market consists of three sectors identified by their environments. The first sector is the portable monitoring market that includes the emergency room, bedsides, catheter laboratories and neo-natal care units of hospitals. The second sector is the inpatient and outpatient operating room market. The final sector includes intensive and critical care units in hospitals.

INDUSTRIAL INSTRUMENTATION

The Company's industrial instrumentation product line consists of pressure and infrared sensor instrumentation that are utilized in industrial settings. The Company does not expect the industrial instrumentation sector in which it competes to experience growth in the foreseeable future.

PRODUCTS

MRI PATIENT MONITORING

Through its patented technologies and proprietary shielding techniques, the Company is able to monitor a patient's vital signs without disrupting the MRI process. The Company's monitors for use in the MRI environment include:

OMNI-TRAK 3100. In the late 1980s, Invivo Research pioneered the development of vital signs monitoring during magnetic resonance imaging with the introduction of the Omni-Trak 3100. The Omni-Trak 3100 provides continuous monitoring of key aspects of a patient's vitality, including electrocardiograph, respiration, heart rate, blood oxygen levels, invasive and non-invasive blood pressure and expired carbon dioxide levels.

OMNI-TRAK 3150. In April 1998, the Company introduced its next-generation MRI monitor. The Omni-Trak 3150 incorporates all of the features of the Omni-Trak 3100 and is compact, mobile and easy to use. Through state-of-the-art radio transmission, the Omni-Trak 3150 communicates with our Millennia remote display controller, allowing critical data to be viewed by physicians and technicians in both the MRI room and the control room.

MAGNITUDE. In fiscal 2001, the Company introduced its full featured, high-end MRI monitor. The Magnitude provides Digital Signal Processing (DSP) of the electrocardiogram (ECG) signal for enhanced ECG performance and removal of MRI gradient artifact. The Magnitude is battery-operated with a unique design that allows portability and thus does not restrict placement in relation to the MRI system. The Magnitude includes 2.4 GHz wireless communication with a color LCD remote display in the MRI control room and also offers sophisticated parameters such as invasive pressures, end-tidal CO₂, and automatic identification and measurement of anesthetic agents.

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MAGNITUDE AS. In fiscal 2003, the Company introduced an anesthesia delivery system designed and engineered to safely operate in the MRI environment. Manufactured and serviced exclusively for the Company by Draeger Medical Inc., the Magnitude AS features integrated electronic ventilation and airway volume, pressure, and oxygen monitoring.

GENERAL PATIENT MONITORING

BEDSIDE MONITORING

The Company offers a broad range of general patient monitors for bedside monitoring in a variety of areas such as the operating room, neonatal intensive care units (NICU), emergency room and patient recovery rooms. The Company's Millennia series of bedside monitors offer flexible monitoring for a wide range of patient care environments and acuity levels.

M12. Introduced in fiscal 2003, the M12 patient monitor is the next generation in the Company's Millennia series of monitors. The M12 offers a large 12-inch color display with comprehensive vital signs monitoring including anesthetic agent identification and measurement.

M6. In fiscal 2003, the Company introduced the compact M6 patient monitor. The M6 is designed for both transport and bedside monitoring and offers basic parameter monitoring in a monitor weighing less than three pounds with a battery life of five hours.

ESCORT PRISM. The ESCORT Prism series of monitors are an integral component of the product line acquired by the Company through the acquisition of MDE in April 2003. The ESCORT Prism incorporates clinical information system (CIS) connectivity and is optimized for operation on the Company's AutoNet wireless networking system. The flexible color display bedside monitor can be used in a variety of hospital departments and is available in configured (Prism SE) or modular (Prism) models. The Prism can be used for higher-acuity patient needs and is available in up to eleven simultaneous vital sign parameters.

CENTRAL STATION MONITORING AND TELEMETRY

The Company's central station monitoring and ambulatory telemetry system solutions allow a single nurse to monitor many stationary and/or ambulatory patients simultaneously from a convenient central station.

CENTURION 2000. The Company's Centurion 2000 is a PC-based central station monitoring system that combines signals from both wireless and hardwired M12 patient monitors and can be configured to accommodate up to forty patients per system by interconnecting central stations. The Centurion 2000 complies with new Wireless Medical Telemetry Service (FCC-WMTS) frequencies established by the Federal Communications Commission.

ESCORT VISION. The ESCORT Vision central station is capable of providing centralized, real-time patient monitoring, CIS connectivity, alarm surveillance and documentation of up to sixteen telemetry transmitters and/or bedside monitors. The ESCORT Vision central station utilizes MDE's AutoNet wireless spread spectrum technology communication system. The AutoNet's wireless architecture utilizes movable nodes and repeaters to ensure optimal exchange of data between the bedside monitor and the central station and complies with FCC-WMTS frequencies.

ESCORT GUARDIAN. The ESCORT Guardian telemetry unit is a multi-lead ECG and pulse oximetry transmitter with an interactive display. All telemetry data from the Guardian transmitter can also be displayed on both the ESCORT Vision central station and the ESCORT bedside monitors.

ANGEL TELEMETRY SYSTEM. The Angel telemetry system, which was acquired in the MDE acquisition, consists of a lightweight (2.8 oz.) fully-configured single-patient use 5-lead ECG telemetry transmitter (Angel) and a more traditional /multi-patient use transmitter (Angel-MP). Each Angel and Angel-MP transmitter is a self-contained unit with pre-installed components utilizing auto-configuration technology, thereby reducing administrative costs and downtime associated with traditional telemetry units. The single-patient Angel also eliminates cleaning and risk of cross-contamination. The Angel was commercially released in April 2003 and the Angel-MP was released in May 2003.

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SINGLE PARAMETER MONITORING

OMEGA 1400. The Omega 1400 is a non-invasive blood pressure monitor that uses digital signal processing for fast and consistent measurements.

SCOUT. The Scout is a low-cost, hand-held blood oxygen level monitoring unit.

INDUSTRIAL INSTRUMENTATION

The Company's industrial sensor and instrumentation products consist of pressure sensors and infrared non-contact temperature measuring devices.

The infrared non-contact temperature measuring products are used in a wide variety of industrial instrumentation situations. These include the fabrication of semiconductors, the manufacturing of metals and glass, and miscellaneous automotive, plant maintenance, construction and food preparation applications. The Company's quickTemp is a hand-held, pocket-sized, infrared non-contact thermometer.

The Company sells its pressure sensing devices primarily to plastic extrusion equipment manufacturers who use these devices in their production processes. Manufacturers in the food, beverage, synthetic fiber and pharmaceutical industries also use these devices to measure the pressure of processing ingredients.

SALES AND MARKETING

The Company sells its patient monitoring products in the United States through a direct sales force. Effective July 2003, MDE's sales force was integrated into the Invivo Research sales force thereby utilizing one sales force for all monitoring products. The domestic sales force includes 38 salespersons organized into six regions in the United States. Distributors, assisted by the Company's eight international sales personnel located in Europe and in the Far East, handle sales throughout the rest of the world.

The Company sells its patient monitoring products primarily to hospitals and, to a lesser degree, to stand-alone imaging centers, outpatient surgery centers and OEM customers. The Company has OEM or worldwide distribution agreements with Siemens Medical, Philips Medical, Hitachi Medical and GE Medical for its MRI monitoring equipment. These relationships facilitate the sale of monitors with the MRI equipment manufactured by these companies. Sales to GE Medical accounted for 10.3% and 13.4% of the Company's revenues in fiscal 2003 and fiscal 2002, respectively.

The Company has also established relationships with hospital group purchasing organizations such as HealthTrust, Premier Inc., AmeriNet, Inc., Broadlane, Inc., Novation, LLC, HealthSouth Corporation and MedAssets HSCA, Inc.

The Company markets its industrial instrumentation products mostly through distributors and its own sales personnel. The Company sells the products primarily to various industrial users.

Foreign sales represented 20%, 26% and 27% of the Company's total sales in fiscal 2003, 2002 and 2001. The Company is actively trying to expand its international sales. See Note 16 of the Notes to Consolidated Financial Statements for additional information regarding foreign sales.

The Company's backlog of unfilled purchase orders for all its products was approximately \$12.1 million as of June 30, 2003. The Company's backlog of unfilled purchase orders for all its products was approximately \$7.9 million as of June 30, 2002 and approximately \$11.3 million, including those of its discontinued operations, as of June 30, 2001. Within the next 12 months, the Company expects to ship all of its current backlog. Because of customer changes in delivery schedules and the possible cancellation of orders, backlog as of any particular date may not be representative of the Company's actual sales for any succeeding fiscal period. Historically, order cancellations have not been significant. The Company's businesses are not inherently seasonal, although orders and shipments in the first and second fiscal quarters have been historically lower than the third and fourth quarters.

MANUFACTURING AND ASSEMBLY

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Other companies manufacture components and subassemblies to the Company's specifications. The Company then assembles its products at its facilities in Florida and California. The Invivo Research facility in Florida and the MDE facility in California are ISO 9001 certified. The Company generally obtains the materials and supplies that it uses to produce its products from a wide variety of suppliers. The Company has not experienced any significant shortages. Although certain materials that the Company uses in the manufacture of medical devices are available from only a few suppliers, the Company does not anticipate any significant difficulties in obtaining any of these materials in the foreseeable future.

COMPETITION

The medical markets in which the Company competes include MRI and general patient monitoring. The Company is aware of three current competitors in the worldwide MRI monitoring market. The Company believes that it is the market leader in the MRI monitoring market. The general patient monitoring market is highly competitive and includes companies that are much larger than the Company with significantly greater financial resources. The Company estimates there are approximately 15 to 20 competitors in the general patient monitoring market.

In the medical device business, price is an important factor in hospital purchasing patterns as a result of cost containment pressures on the health care industry. To the extent that healthcare reform measures negatively affect the financial condition of hospitals and thereby reduce their capital purchases, the Company expects price to continue to be a very important competitive factor. The Company also competes on the basis of product reliability, quality, technical features, performance and service. The Company's products are priced competitively with others in the market and the Company is comparable on quality, technical features, performance and service, the other important competitive factors in this market.

The markets for the Company's non-medical products are, in general, characterized by a relatively limited number of competitors; however, these markets are highly competitive. The Company estimates there are five to ten competitors in each of these markets. The Company competes on price, product reliability, quality, technical features, performance and service in these markets.

GOVERNMENTAL REGULATION

The patient monitoring devices the Company manufactures and markets are subject to regulation by the FDA and, in some instances, corresponding state and foreign governmental agencies.

The Company's existing medical devices were cleared for marketing in the United States through the FDA's section 510(k) premarket notification process. The 510(k) premarket notification process is available where the new product being submitted to the FDA can be compared to a pre-existing commercially available product that performs functions the FDA considers to be substantially equivalent. If a product does not meet the eligibility requirements for the 510(k) process, then its application must be submitted, instead, under the more time consuming and costly premarket approval procedure.

The Company's manufacturing facilities and the manufacture of its products are subject to FDA regulations regarding registration of manufacturing facilities, compliance with FDA good manufacturing practices and the reporting of adverse events. The FDA's good manufacturing practices, titled "Quality System Regulation", require preproduction design controls and implementation of a full quality assurance system along with standards for manufacturing processes and facilities and record keeping for device failure and complaint investigations. The Company is subject to periodic on-site inspection for compliance with such regulations. The FDA may also conduct investigations and evaluations of the Company's products at its own initiative or in response to customer complaints or reports of malfunctions. If the FDA believes that its regulations have been violated, it has extensive enforcement authority including the power to seize, embargo or restrain entry of products from the market and to prohibit the operation of manufacturing facilities until the noted deficiencies are corrected to their satisfaction.

The Company seeks, where appropriate, to comply with the certification and safety standards of organizations such as Underwriters Laboratories and the various safety and test regulations of the European Community.

The manufacture and testing of the Company's medical devices requires it to handle and store small quantities of a wide variety of chemicals, some of which are highly toxic. Certain of these chemicals pose a serious threat to workers and others who may come in contact with them if improperly used or handled. Most municipalities, including those in which the Company is presently located, now require that the proposed storage and use of dangerous chemicals receive local approval. State air quality boards, or similar agencies,

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must also approve the venting, and certain other aspects of handling, of these types of chemicals. These municipal and state agencies may, as a condition to the granting of approvals and permits, impose certain procedural limitations on the Company's storage and handling of these chemicals and structural requirements on the facilities where these chemicals are stored and used. They also impose record keeping and reporting requirements on the users of these chemicals.

Compliance with these requirements has not, to date, had a material effect on the Company's capital expenditures, earnings or competitive position. Nonetheless, environmental regulation at the local, state and national levels continues to evolve, and the possibility exists that more stringent limitations and requirements may become applicable to the Company.

RESEARCH AND EXPERIMENTAL

During fiscal years 2003, 2002, and 2001 the Company's research and experimental expenses were approximately \$3.3 million, \$3.0 million, and \$2.6 million, respectively. These expenditures are for the development of new vital sign monitoring products and the enhancement of existing ones.

INTELLECTUAL PROPERTY

The Company's success and competitive position depends, among other things, on its continued ability to develop new proprietary technology while protecting the Company's existing intellectual property. As of June 30, 2003, the Company held twelve US patents expiring at different times between 2004 and 2020.

There is no assurance that any of the Company's current or future patent applications will result in patents, and the Company's existing or future patents may be circumvented, declared invalid or challenged as to scope or ownership. For these and other reasons, the Company may not realize any competitive advantage from the Company's existing patents and any patents that the Company may be granted in the future. Furthermore, others may develop technologies that are similar or superior to the Company's proprietary technologies or design around any patents that the Company may hold. In addition, the Company has not secured patent protection in foreign countries and the Company cannot be certain that the steps the Company takes to prevent misappropriation of its intellectual property abroad will be effective, or that the application of foreign laws to technology developed abroad will not adversely effect the validity or enforceability of the Company's U.S. patents.

EMPLOYEES

As of June 30, 2003 the Company had 302 employees. The Company is not a party to any collective bargaining agreement and has not experienced a strike or work stoppage. The Company considers its overall relations with its employees to be good.

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The following table sets forth information with respect to the real property owned or leased by the Company which it considers material to its business.

LOCATION	GENERAL CHARACTER AND USE OF THE PROPERTY	OWNERSHIP OR DATE OF EXPIRATION OF LEASE
Pleasanton, California	3,200 square-foot headquarters facility	April 2006
Fremont, California	8,000 square-foot building used as the Company's manufacturing and distribution facility for its industrial instrumentation products	July 2006
Arleta, California	36,000 square-foot building used as the manufacturing, distribution and administrative facility for the Company's MDE subsidiary	June 2005
Orlando, Florida	54,000 square-foot building used as the manufacturing, distribution and administrative facility for the Company's Invivo Research subsidiary	Owned

From time to time, the Company leases smaller facilities as its needs dictate. The Company considers its facilities to be sufficient for its current operations.

ITEM 3. LEGAL PROCEEDINGS

The Company's medical device subsidiary, Invivo Research, was one of two third-party defendants named in a lawsuit in June of 1994 by Southern Nevada Surgical Center and Surgex Southern Nevada, Inc. in Nevada State District Court. The underlying action in this matter stemmed from an incident involving a surgical patient undergoing a procedure at the Southern Nevada Surgical Center. The patient suffered a serious permanent brain injury. A lawsuit was filed on behalf of the patient against the surgical center and the anesthesiologist who monitored the patient. The defendants in that action made a substantial settlement to the patient. Southern Nevada Surgical Center (SNSC) and Surgex were seeking indemnity and contribution in the aggregate of approximately \$14 million from the manufacturer of the anesthetic gas machine and Invivo Research, which manufactured the vital signs monitor used in this procedure. SNSC and Surgex alleged that both the anesthetic gas machine and the vital signs monitor were defective. The Company believes that the vital signs monitor operated properly and was properly designed for its intended function.

On August 18, 1999, the Nevada District Court granted the Company's Motion to Dismiss for Failure to Prosecute. The Order granted dismissal of the SNSC and Surgex contribution claims, without prejudice, based upon Nevada law that provides that an action must be brought to trial within five years of the date of the filing of the original action. The dismissal was appealed.

In April of 1997, the plaintiff's insurer, CNA, filed an action with identical causes in the same Nevada State Court. This second action was removed by the Company to U.S. District Court. The action by CNA was dismissed by the District Court on January 19, 2000 as the District Court found CNA did not have standing as the real party of interest. CNA appealed the decision to the Ninth Circuit Court of Appeals. A three-member panel of the Ninth Circuit reversed the dismissal and remanded the case back to Federal District Court on July 30, 2001. The Company appealed this decision and requested a decision from the full panel of the Ninth Circuit. The Ninth Circuit, without issuing an opinion, unanimously voted to deny the Petition for Rehearing in this matter. The action was remanded to the U.S. District Court for further proceedings.

In August of 2003, all parties to the U.S. District Court and Nevada District Court actions reached a global settlement as a result of which the claims against the Company were dismissed with prejudice. The claims against the Company were settled within the

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Company's insurance coverage policy limits and no contribution was made by the Company as a result of the settlement. In addition, the parties are in the process of executing a release in favor of the Company from any past or future claims that may arise out of the matters litigated.

In November, 1999, four individuals previously employed by the Company's Invivo Research subsidiary filed a multi-plaintiff lawsuit against the Company in the Middle District Court of Florida alleging violations of the Age Discrimination in Employment Act. Subsequent to the filing, three additional individuals chose to opt-in to the case, one of the individuals later voluntarily dismissed all claims with prejudice and a second individual filed a voluntary motion for dismissal from the case. The remaining plaintiffs claimed entitlement to back pay and front pay in an aggregate amount of approximately \$2 million. The trial for this matter began in mid-May of 2003. At the conclusion of the trial on May 29, 2003, the jury found for the Company on all counts.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 4(A). EXECUTIVE OFFICERS OF THE COMPANY

The executive officers and directors as of June 30, 2003 are listed below, together with brief accounts of their business experience and certain other information.

<u>NAME</u>	<u>AGE</u>	<u>POSITION</u>
James B. Hawkins	47	President, Chief Executive Officer, Secretary and Director
John F. Glenn	42	Vice President, Finance and Chief Financial Officer
Stuart Baumgarten	49	Vice President, Invivo Corporation; President, Invivo Research, Inc.

James B. Hawkins has been President, Chief Executive Officer and a Director of Invivo Corporation and its predecessor since August 1985. He also has served as Secretary of the Company since July 1986. He earned his undergraduate degree in Business Commerce from Santa Clara University and his MBA from San Francisco State University.

John F. Glenn was appointed Vice President, Finance and Chief Financial Officer of Invivo Corporation in November 1990. Mr. Glenn earned his undergraduate degree in Business Administration from the University of Nevada and his MBA from the University of Santa Clara.

Stuart Baumgarten has been President of the Invivo Research subsidiary since November 1998. From March 1996 to November 1998, Mr. Baumgarten served as Vice President of Sales and Marketing for Invivo Research. Prior to joining the Company, Mr. Baumgarten spent approximately 16 years with the patient monitoring division of Datascope Corporation where he held various sales positions culminating as Vice President of Domestic Sales. He earned his degree in Communication Sciences from the Herbert H. Lehman College, City University of New York.

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The Company's common stock is traded on the Nasdaq National Market under the symbol SAFE. The following table describes, for the quarters indicated, the high and low sale prices for a share of the Company's common stock as reported on the Nasdaq National Market.

	<u>HIGH</u>	<u>LOW</u>
YEAR ENDED JUNE 30, 2003		
First Quarter	\$ 15.20	\$ 12.12
Second Quarter	\$ 15.43	\$ 11.45
Third Quarter	\$ 15.25	\$ 13.15
Fourth Quarter	\$ 18.45	\$ 13.48
YEAR ENDED JUNE 30, 2002		
First Quarter	\$ 12.08	\$ 8.91
Second Quarter	\$ 13.65	\$ 11.00
Third Quarter	\$ 13.50	\$ 11.64
Fourth Quarter	\$ 15.28	\$ 11.00

As of June 30, 2003 the Company had 54 stockholders of record of its common stock and approximately 800 beneficial holders.

DIVIDEND POLICY

The Company intends to retain future earnings to finance the expansion of its business and does not anticipate paying any cash dividends on its common stock in the foreseeable future. If the Company were to declare dividends in the future, such dividends would be paid at the discretion of its board of directors after taking into account various factors, including, among other things, the Company's financial condition, results of operations, cash flows from operations, current and anticipated cash needs and expansion plans, the income tax laws then in effect and the requirements of Delaware law. In addition, the Company's credit facility prohibits the payment of dividends without consent from the lender.

The Company has not declared cash dividends on its common stock in the two most recent fiscal years.

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The operations data set forth below with respect to the fiscal years ended June 30, 2003, 2002 and 2001 and the balance sheet data at June 30, 2003 and 2002 are derived from, and are qualified by, reference to the Company's audited consolidated financial statements included elsewhere herein and should be read in conjunction with those financial statements and the notes thereto. The operations data set forth below with respect to the fiscal years ended June 30, 2000 and 1999 and the balance sheet data at June 30, 2001, 2000 and 1999 are derived from audited consolidated financial statements not included herein. The historical results presented below are not necessarily indicative of the results to be expected for any future fiscal year.

(IN THOUSANDS, EXCEPT PER SHARE DATA)
FISCAL YEAR ENDED JUNE 30,

	2003	2002	2001	2000	1999
CONSOLIDATED STATEMENT OF OPERATIONS DATA:					
Sales	\$53,340	\$42,088	\$38,054	\$36,633	\$34,717
Gross profit	27,260	22,095	20,069	19,056	18,545
Operating expenses					
Selling, general and administrative	19,291	15,910	15,510	13,560	12,722
Research and experimental	3,337	3,026	2,615	2,288	2,371
Other income (expense)	582	183	747	1,088	(153)
Loss on Sale of G.C. Industries			(601)		
Income tax expense	1,724	1,133	695	1,314	974
Income from discontinued operations		3,416	1,658	1,984	1,492
Net income	\$ 3,490	\$ 5,625	\$ 3,054	\$ 4,967	\$ 3,818
Basic net income per common share	\$.82	\$ 1.27	\$.69	\$ 1.15	\$ 1.07
Weighted average common shares outstanding (basic)	4,259	4,427	4,403	4,329	3,552
Diluted net income per common share	\$.77	\$ 1.23	\$.68	\$ 1.10	\$ 1.00
Weighted average common shares outstanding (diluted)	4,504	4,581	4,476	4,497	3,831

	JUNE 30,				
	2003	2002	2001	2000	1999
CONSOLIDATED BALANCE SHEET DATA:					
Working capital	\$26,873	\$38,838	\$31,380	\$26,730	\$22,949
Total assets	59,333	60,758	52,011	49,476	44,641
Long-term debt	1,351	1,464	1,647	1,393	1,375
Stockholders' equity	44,097	49,481	43,709	40,325	35,167

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

RESULTS OF OPERATIONS

YEAR ENDED JUNE 30, 2003 COMPARED TO YEAR ENDED JUNE 30, 2002

Sales

Sales for fiscal 2003 increased 26.7% to \$53,339,800 compared to sales of \$42,088,300 for fiscal 2002. The increase was primarily due to growth in sales of general patient monitoring products along with growth in sales of the Company's magnetic resonance imaging, or MRI, vital signs monitors and the new Magnitude AS anesthesia delivery system for the MRI introduced in the second quarter of fiscal 2003. The increase in sales of general patient monitoring products was primarily due to sales of two new products, the M12 bedside monitor introduced in the first quarter of fiscal 2003 and the Centurion 2000 central station monitoring system introduced in the fourth quarter of fiscal 2002. The Company's sales also increased by approximately \$3,670,000 as a result of the acquisition of MDE in April 2003.

Gross Profit

The gross profit margin for fiscal 2003 decreased to 51.1% from 52.5% in fiscal 2002. The decrease in the gross profit margin was primarily attributable to the increase in sales of the Magnitude AS anesthesia delivery system for the MRI and general patient monitoring products, including those of MDE, which have lower gross profit margins than MRI monitors. The Magnitude AS is sold under an exclusive distributor agreement with Draeger Medical, Inc. providing for lower gross profit margins than the other vital signs monitors sold by the Company. The Company's gross profit margin on the MRI vital signs monitor did not change materially for fiscal 2003.

Operating Expenses

Selling, general and administrative expenses for fiscal 2003 increased 21.2% or \$3,380,800 from the previous fiscal period. Selling, general and administrative expenses were 36.2% of sales for fiscal 2003 compared with 37.8% in fiscal 2002. The increase in these expenditures was due to higher administrative expenses in support of the increase in sales as well as higher insurance costs, increased legal and professional expenses, an increase in the provision for bad debt and expenditures on behalf of MDE. The increase for these periods were also attributable to increased selling expenses primarily as a result of higher wages and commissions on the higher sales volume along with increased promotional activities.

Research and experimental expenses for fiscal 2003 increased 10.3% or \$310,500 as compared to fiscal 2002. The increase was primarily attributable to research and development expenses on behalf of MDE. Research and experimental expenses were 6.3% of sales for fiscal 2003 compared to 7.2% in fiscal 2002. The Company plans to continue its efforts in developing new products and enhancing its existing ones and expects research and experimental expenditures as a percentage of sales to be in the 6.5% to 7.0% range in fiscal 2004.

Other Income and Expense

Interest income was \$567,100 for fiscal 2003 as compared to \$290,500 for fiscal 2002. The increase was due to the larger cash and short-term investment balances that the Company held throughout most of fiscal 2003 until the use of approximately \$9.9 million to finance a repurchase of its common stock in February 2003 and approximately \$9.3 million for the purchase of MDE in April 2003.

Provision for Income Taxes

The effective tax rate for fiscal 2003 was 33.0% as compared to 33.9% for fiscal 2002. The decrease in the effective rate was primarily due to the effect of federal tax-exempt interest income from short-term investments and the benefit of the Extraterritorial Income Exclusion (EIE) and other credits.

YEAR ENDED JUNE 30, 2002 COMPARED TO YEAR ENDED JUNE 30, 2001

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Sales

Sales for fiscal 2002 increased 10.6% to \$42,088,300 compared to sales of \$38,053,600 for fiscal 2001. Sales at the Company's medical business increased 13.7% for fiscal 2002, and was primarily the result of the continued growth in sales volume of the Company's MRI vital signs monitor due to increased acceptance and usage of MRI procedures in hospital settings. Millennia sales for fiscal 2002 increased slightly as the patient monitoring market continues to experience flat to slow growth. The Company's industrial instrumentation products experienced a sales decline of \$821,100 or 32.2% for fiscal 2002.

Gross Profit

The gross profit margin remained stable at 52.5% as the gross profit margin at the medical device business remained strong at 54.0% with the continued sales growth in MRI vital signs monitors. The gross profit margin for fiscal 2002 was impacted by the write-off of slow moving and obsolete inventory of approximately \$175,000 at the Company's non-contact infrared thermometer business in the third quarter of fiscal 2002 as that business continued to experience a prolonged sales decline. Throughout fiscal 2002, gross margins of the industrial instrumentation product lines declined due primarily to the impact of the decreased sales relative to fixed cost of sale components.

Operating Expenses

Selling, general and administrative expenses for fiscal 2002 increased 2.6% or \$400,500 from the previous fiscal period. Selling, general and administrative expenses were 37.8% of sales for fiscal 2002 compared with 40.8% for fiscal 2001 as the growth in sales for fiscal 2002 more than offset the increase in selling, general and administrative expenses. The increase in these expenditures in aggregate for fiscal 2002 was primarily due to higher selling expenses on the higher sales volume at the medical device business along with higher facility leasing and depreciation expenses at the industrial instrumentation product line and corporate facilities. These increases offset a decrease in selling expenses on the lower sales volume at the industrial instrumentation business along with the effect of the Company's adoption of SFAS No. 142, Goodwill and Other Intangible Assets, effective July 1, 2001 as a result of which the Company stopped amortizing its goodwill. Amortization of goodwill in fiscal 2001 was \$254,400.

Research and experimental expenses for fiscal 2002 increased 15.7% or \$411,400 from the previous fiscal period. Research and experimental expenses were 7.2% of sales for fiscal 2002 compared to 6.9% in fiscal 2001. The increase in fiscal 2002 was due to increased expenditures of the medical device business on its next generation vital signs monitors which offset a decline in research and experimental expenditures at the industrial instrumentation product lines.

Other Income and Expense

Interest income was \$290,500 for fiscal 2002 as compared to \$435,200 for fiscal 2001. The decrease was due to the lower interest rates earned on the Company's short-term investments.

Provision for Income Taxes

The effective tax rate for fiscal 2002 was 33.9% compared to 33.2% for the prior year. The slight increase was due to the effects of state income taxes and settlement of state income tax examinations. The effective rate differs from the statutory rate due principally to the benefit of a foreign sales corporation and other credits.

Discontinued Operations

On May 10, 2002, the Company completed the sale of Sierra Precision, a wholly-owned subsidiary of the Company, for approximately \$4.9 million. On May 30, 2002, the Company sold Lumidor Safety Corporation, a wholly-owned subsidiary of the Company, for approximately \$12.0 million. In conjunction with the discontinuance of these operations, the Company recorded a gain on the disposal of the subsidiaries of \$3,250,300 (net of income tax of \$2,142,800). Revenue from discontinued operations for fiscal 2002 was \$12,175,400. Revenue from discontinued operations for fiscal 2001 was \$16,225,500. Income from discontinued operations for fiscal 2002 was \$3,416,300. Income from discontinued operations for fiscal 2001 was \$1,657,700.

LIQUIDITY AND CAPITAL RESOURCES

Working capital at June 30, 2003 decreased to \$26,872,700 from \$38,837,900 at June 30, 2002. This decrease was primarily the result of the Company's tender offer for 650,000 shares of its common stock at a purchase price of \$15.00 per share in February of 2003 and the acquisition of MDE in April 2003. The aggregate purchase price including expenses for payment for the shares tendered in the stock repurchase was

approximately \$9.9 million, which the Company funded from available cash and short-term investments.

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The purchase price for MDE was approximately \$9.3 million and was funded from the Company's existing balances of cash and short-term investments.

Net cash used in operating activities was \$308,500 for fiscal 2003 compared with \$5,825,300 and \$1,710,600 provided by operating activities for fiscal 2002 and fiscal 2001, respectively. This increase in net cash used in operating activities was largely the result of changes in operating assets and liabilities, particularly accounts receivable, inventories, accrued expenses and deferred income taxes.

Capital expenditures were \$1,562,200 for fiscal 2003 compared to \$2,013,200 for fiscal 2002 and \$762,300 for fiscal 2001. Capital expenditures in fiscal 2003 were primarily related to sales demonstration equipment for the medical business sales force. Cash used in financing activities for fiscal 2003 consisted primarily of the stock repurchase described above.

The Company believes that its remaining cash and short-term investments, along with its borrowing capacity, will be sufficient to support its working capital and capital expenditure requirements throughout fiscal 2004.

The Company renewed its \$1,000,000 revolving bank line of credit on January 1, 2003. The line of credit is unsecured. At June 30, 2003, \$1,000,000 was available under the line of credit.

A summary of future minimum lease payments required under noncancelable leases with terms in excess of one year as of June 30, 2003 follows:

	Operating leases
Fiscal year ending June 30:	
2004	\$ 944,600
2005	956,900
2006	551,500
2007	269,600
2008	250,500
Thereafter	732,100
	<hr/> \$3,705,200 <hr/>

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and judgments that affect its reported amounts of assets and liabilities, revenues and expenses and related disclosures of contingent assets and liabilities. On an ongoing basis the Company evaluates its estimates, including those related to allowance for doubtful accounts, inventory reserves, warranty obligations, intangible assets and contingencies and litigation. The estimates are based on the information that is currently available to the Company and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could vary from those estimates.

The Company believes that the following critical accounting policies involve the more significant judgments and estimates used in the preparation of its financial statements:

Revenue Recognition

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred and title has transferred, the price is fixed and determinable, and collectibility is reasonably assured. The Company accrues for estimated sales returns and other allowances at the time of recognition of revenue, which is typically upon shipment, based on historical experience. If different assumptions were employed in making these estimates, the amount of reported revenue could be affected.

Allowance for Doubtful Accounts

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The Company maintains an allowance for doubtful accounts for estimated losses resulting from the failure of its customers to make required payments. On an on-going basis, the Company evaluates the collectibility of accounts receivable based on a combination of factors. In circumstances in which it is aware of a specific customer's inability to meet its financial obligation, it records a specific reserve of the bad debt against amounts due. In addition, the Company also makes judgments and estimates of the collectibility of accounts receivable based on historical bad debt experience, customers' creditworthiness, current economic trends, recent changes in customer payment trends, and deterioration in the customers' operating results or financial position. If circumstances change adversely, additional allowances may be required.

Inventory

Inventories are stated at lower of cost or market with cost determined by the first-in, first-out method. The Company reviews the components of inventory on a regular basis for excess, obsolete and impaired inventory based on estimated future usage and sales. The Company may be required to write-down inventory it is carrying at higher value due to changes in competitive conditions, new product introductions by the Company or its competitors, or rapid changes in customer demand, in which event the Company's gross margins would be adversely affected.

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Goodwill

The Company uses assumptions in establishing the carrying value of its goodwill. The criteria used for these evaluations include management's estimate of the asset's continuing ability to generate positive income from operations and positive cash flow in future periods compared to the carrying value of the asset. If assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Factors that would influence the likelihood of a material change in goodwill include significant changes in the asset's ability to generate positive cash flow, a significant decline in the economic and competitive environment on which the asset depends and significant changes in the Company's strategic business objectives.

Warranty

The Company provides for the estimated cost of product warranties at the time the related revenue is recognized. The amount of this provision is determined by using historical experience and estimated future costs associated with the Company's different products. Should actual product failure rates or estimated costs to repair those product failures differ from the Company's estimates, revisions to the estimated warranty provision would be required and gross margins would be adversely affected.

Income Taxes

The Company bases its estimate of deferred tax assets and liabilities on current tax laws and rates. The Company's accounting for deferred tax consequences represents management's best estimate of future events that can be appropriately reflected in the accounting estimates.

RECENT ACCOUNTING PRONOUNCEMENTS

In August 2001, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 144. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and provides new rules on asset impairment and a single accounting model for long-lived assets to be disposed of. Although retaining many of the fundamental recognition and measurement provisions of SFAS No. 121, the new rules significantly change the criteria that would have to be met to classify an asset as held-for-sale. The new rules also supersede the provisions of Accounting Principles Board Opinion No. 30, *Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*, with regard to reporting the effects of a disposal of a segment of a business and require operating losses from discontinued operations to be displayed in discontinued operations in the period(s) in which the losses are incurred. SFAS No. 144 was effective in fiscal 2003, and did not have a material impact on the Company's consolidated financial statements.

In April 2002, the FASB issued SFAS No. 145, *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement 13, and Technical Corrections* (SFAS 145). SFAS No. 145 revises the criteria for classifying the extinguishments of debt as extraordinary and the accounting treatment of certain lease modifications. SFAS No. 145 was effective in fiscal 2003, and did not have a material impact on the Company's consolidated financial statements.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 establishes accounting guidelines for the recognition and measurement of a liability for the cost associated with an exit or disposal activity initially at its fair value in the period in which the liability is incurred, rather than at the date of a commitment to an exit or disposal plan. This standard was effective January 1, 2003 for all exit or disposal activities initiated after that date and did not have a material impact on the Company's consolidated financial statements.

In November 2002, the FASB issued Interpretation (FIN) No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN No. 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees and requires that they be recorded at fair value. The initial recognition and measurement provisions of FIN No. 45 are to be applied only on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of this interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The Company does not have any material indirect guarantees of indebtedness of others as of June 30, 2003.

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In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* an amendment of FASB Statement No. 123. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. The Company does not intend to expense stock options; therefore the adoption of this statement will not have any impact on the Company's consolidated financial position or results of operations. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements. The Company adopted the disclosure provision of SFAS No. 148 as of December 31, 2002.

In January 2003, the FASB issued FIN No. 46 *Consolidations of Variable Interest Entities*. This interpretation requires a company to consolidate variable interest entities (VIE) if the enterprise is a primary beneficiary (holds a majority of the variable interest) of the VIE and the VIE possesses specific characteristics. It also requires additional disclosure for parties involved with VIEs. The provisions of FIN No. 46 are effective for fiscal 2003. Since the Company does not have any unconsolidated VIEs, the adoption of FIN No. 46 did not have an impact on its financial position or results of operations.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, to amend and clarify financial accounting and reporting for derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. SFAS No. 149 requires that contracts with comparable characteristics be accounted for similarly and clarifies under what circumstances a contract with an initial net investment meets the characteristics of a derivative as discussed in SFAS No. 133. In addition, it clarifies when a derivative contains a financing component that warrants special reporting in the statement of cash flows. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The Company believes that the adoption of SFAS No. 149 will not have an impact on its financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). The provisions of SFAS No. 150 are effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The Company believes that the adoption of SFAS No. 150 will not have an impact on its financial position or results of operations.

RISK FACTORS

THE COMPANY IS DEPENDENT ON A CONCENTRATED LINE OF PRODUCTS

The Company's future financial performance is dependent on its patient monitor product lines, which include a limited number of products. The growth of the market for the Company's MRI monitors is heavily dependent on the further acceptance of MRI technology as a diagnostic tool. In the general patient monitoring market, future growth of the Company's bedside monitors is dependent on the Company's ability to further penetrate an already competitive market. By virtue of its acquisition of MDE in April 2003, the Company acquired additional patient monitor products and therefore continues to be subject to the risk of concentration in this industry.

In addition, the recent consolidation in the medical care provider market has resulted in a number of very large purchasers of medical devices. These large purchasers typically prefer to establish relationships with medical device manufacturers that have broad and diverse product lines, and therefore, may seek relationships with companies that are larger than the Company.

The failure of the Company's products to continue to gain market acceptance, the market's transition away from any existing line of products or a continued consolidation of the medical care provider market could have a material adverse effect on the Company's business and results of operations.

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THE COMPANY FACES SUBSTANTIAL LEVELS OF COMPETITION

The Company has encountered and will continue to encounter significant competition in the sale of its products. The Company's general patient monitoring competitors include a number of large multinational corporations. Some of these competitors may be able to adapt more quickly to new or emerging technologies and changes in customer requirements, or to devote greater resources to the development, promotion and sale of their products than the Company can. In the MRI patient monitoring market, the Company has enjoyed a significant first-to-market advantage over its competitors. However, competitors have introduced products that compete with the Company's MRI vital signs monitoring products. In addition, as the market for MRI vital signs monitoring products expands it may attract competitors with greater resources.

Additionally, competition may increase if new companies enter the Company's markets or if existing competitors expand their product lines or intensify efforts within existing product lines. The introduction of competitive products may result in a decrease in the Company's market share and in a decrease in the prices at which the Company is able to sell its products. The Company's market share could also be adversely affected by increasing concentration in the medical care provider market. Any decrease in the Company's market share or decrease in the prices at which the Company is able to sell its products could have a material adverse effect on its business and results of operations.

THE COMPANY'S FINANCIAL RESULTS MAY FLUCTUATE

The Company's financial results may fluctuate significantly from period to period because of a variety of factors, many of which are beyond its control. These factors include:

- increased competition, including possible future competition in the MRI monitor market
- changes in the Company's pricing policies and those of its competitors
- changes in the Company's operating expenses or capital expenditures
- timing and market acceptance of new and upgraded product introductions by the Company and its competitors
- introduction of alternative technologies by the Company and its competitors
- effect of potential acquisitions
- other general economic factors

Fluctuations caused by these and other factors could have a material adverse effect on the Company's business and results of operations, and correspondingly, on the trading prices of the Compa