UTAH MEDICAL PRODUCTS INC Form 10-K/A July 19, 2005

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 10-K/A

(Amendment No. 1) Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2004

Commission File No.<u>0-11178</u>

#### **UTAH MEDICAL PRODUCTS, INC.**

(Exact name of registrant as specified in its charter)

**Utah** 

87-0342734

(State or other jurisdiction of

(I.R.S. Employer Identification No.)

incorporation or organization)

7043 South 300 West Midvale, UT 84047

(Address of principal executive offices)

Registrant's telephone number, including area code: (801) 566-1200

Securities registered pursuant to Section 12(b) of the Act:

**None** 

Securities registered pursuant to Section 12(g) of the Act:

Title of each Class Common Stock, \$.01 par value

Preferred Stock Purchase Rights

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.

#### YesXNo

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (229.405 of this chapter) 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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

#### YesXNo

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. As of June 30, 2004, the aggregate market value of the voting and nonvoting common equity held by nonaffiliates of the registrant was \$86,897,000.

Indicate the number of shares outstanding of each of the registrant's classes of common stock as of the latest practicable date. As of March 4, 2005, common shares outstanding were 4,090,061.

## DOCUMENTS INCORPORATED BY REFERENCE

List herein the documents incorporated by reference: The Company's definitive proxy statement for the Annual Meeting of Shareholders is incorporated by reference into Part III, Items 10, 11, 12, and 13 of this Form 10-K.

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#### **PART I**

#### **ITEM 1 - BUSINESS**

Utah Medical Products, Inc. ("UTMD" or "the Company") is in the business of producing high quality cost-effective healthcare industry devices that are predominantly proprietary, disposable and for hospital use. Success depends on 1) recognizing needs of clinicians and patients, 2) rapidly designing or acquiring economical solutions that gain regulatory approval, 3) reliably producing products that meet those clinical needs, and then 4) selling through a) UTMD's own direct channels into markets where the Company enjoys an established reputation and has a critical mass of sales and support resources, or

b) establishing relationships with other medical companies that have the proper resources to effectively introduce and support the Company's products.

UTMD's success in providing reliable solutions comes from its proven ability to integrate a number of engineering and technical disciplines in electronics, software, mechanical packaging, instrumentation, plastics processing and materials. The resulting proprietary products represent significant incremental improvements over preexisting clinical tools. UTMD's experience is that, in the case of labor-saving devices, the improvement in cost-effectiveness of clinical procedures also leads to an improvement in overall healthcare including lower risk of complications. UTMD markets a broad range of medical devices used in critical care areas, especially the neonatal intensive care unit (NICU) and the labor and delivery (L&D) department in hospitals, as well as products sold to outpatient clinics and physician's offices.

The opportunity to apply solutions to recognized needs results from an excellent core of practicing clinicians who introduce ideas to the Company, and key employees who are both clinical applications savvy and development engineering adept.

UTMD's products are sold directly to end users in the U.S. domestic market by the Company's own direct sales representatives and independent manufacturers' representatives. In addition, some of UTMD's products are sold through specialty distributors, national hospital distribution companies and other medical device manufacturers. Internationally, products are sold through other medical device companies and through independent medical products distributors. UTMD has representation in all major developed countries with approximately 100 international distributors.

Negative factors that may adversely impact future performance include managed care reforms or hospital group buying agreements that may limit physicians' ability to choose certain products or procedures, new products introduced by other companies that displace UTMD's products, new product regulatory approval delays, changes in the Company's relationships with distribution partners, and loss of key personnel.

UTMD was formed as a Utah corporation in 1978. UTMD publicly raised equity capital one time in 1982. In 1995, Utah Medical Products Ltd., a wholly-owned subsidiary located in Ireland, was formed to establish an international manufacturing capability. In 1997, UTMD purchased Columbia Medical, Inc. (CMI), a Redmond, Oregon company specializing in silicone injection molding, assembly and marketing vacuum-assisted obstetrical delivery systems. In July, 1998 UTMD acquired the neonatal product line of Gesco International, a subsidiary of Bard Access Systems and C.R. Bard, Inc. On March 8, 2000, UTMD returned to the Nasdaq Stock Market after trading on the New York Stock Exchange for about 3 years. The Company was previously listed on Nasdaq for 14 years. The Company's corporate offices are located at 7043 South 300 West, Midvale, Utah 84047 USA. The corporate telephone number is (801) 566-1200. European operations are located at Athlone Business and Technology Park, Athlone, County Westmeath, Ireland. The telephone number in Ireland is (90) 647-3932. CMI's mailing address is 1830 S.E. 1st, Redmond, Oregon

97756. The phone number in Oregon is (541) 548-7738.

#### **PRODUCTS**

## Labor and Delivery/ Obstetrics:

Fetal Monitoring Accessories.

About 60% of births are considered "higher risk" due to lack of prenatal care, among other factors. In many of these births, labor may become complicated and does not progress normally. The obstetrician must assess progression of labor to be able to intervene with drug therapy, infuse a solution to augment amniotic fluid, or ultimately if necessary, perform a Cesarean Section procedure, and be prepared for complications following childbirth.

To assist the physician in assessing fetal well-being, changes in fetal heart rate (FHR) in conjunction with trends in intrauterine pressure are often electronically monitored. UTMD's intrauterine pressure (IUP) catheter product line provides for clinician choices from a traditional fluid-filled system to INTRAN® PLUS, the most widely accepted transducer-tipped system. In addition, adjunct FHR electrodes, leg plates, belly bands and chart paper are offered by UTMD to complete a package of fetal monitoring supplies. UTMD's IUP catheters include:

- IUP-075 and UTMD's other custom fluid-filled catheter kits utilize a saline-filled catheter that is placed within the uterine cavity, connected to a separate external reusable or disposable transducer. This product package, utilizing double lumen catheters, was the traditional mode of intrauterine monitoring prior to the introduction of INTRAN. An intrauterine pressure change is transmitted through the fluid column to the external pressure transducer.
- · Introduced in 1987, INTRAN was the first disposable intrauterine pressure catheter that placed the pressure transducer at the pressure source within the uterine cavity. This design eliminated the complicated setup of fluid-filled systems and provided more accurate pressure waveforms. INTRAN I was discontinued in 1995 in favor of the more widely preferred INTRAN PLUS, also covered by UTMD's original INTRAN patent.
- · INTRAN PLUS was introduced in 1991. The INTRAN PLUS catheter combines the transducer tip concept of INTRAN I with a refined tip design, a zero switch that allows the clinician to verify the reference of the monitor, and a dedicated amnio lumen which provides immediate access to the amniotic fluid environment which may be helpful in the diagnosis and intervention of certain fetal conditions. In 1996, a viewport enhancement which allows physicians to observe amniotic fluid in a closed system was added to INTRAN PLUS. In 1997, UTMD introduced several variations to address user preferences in tip size and zero switch location.

UTMD markets disposable electrodes, catheters and accessories as outlined above, but does not currently market monitors, the electronic capital equipment that process the electrical signals. In addition to products currently offered, UTMD intends to continue to investigate and introduce tools that enhance fetal monitoring techniques, a core area of product development focus.

Vacuum-Assisted Delivery Systems (VAD).

UTMD's VAD Systems include CMI® patented soft silicone bell-shaped birthing cups and patented hand-held vacuum pumps which UTMD believes are the safest products available for use in vacuum-assisted operative deliveries. UTMD's patented soft silicone cup is a bell-shaped cup design should be preferred for fetal well-being in low or outlet fetal stations with occiput anterior presentations, which represent more than 90% of the cases where VAD is indicated. Operative vaginal deliveries using forceps or vacuum-assisted delivery systems provide knowledgeable physicians with an alternative to C-section intervention. Although there are risks associated with operative vaginal deliveries which represent about 15% of all U.S. hospital births, the procedures are generally regarded as safer for the mother, and at least as safe for the fetus, as abdominal (Cesarean) delivery in comparable clinical situations. UTMD estimates that the VAD operative approach is used for about 8-10% of all U.S. births, with forceps continuing to lose ground as the alternative. UTMD's patented bell-shaped soft silicone TENDER TOUCH® cups enjoy a low reported complication rate compared to other vacuum cup designs, as evidenced by the FDA Medical Device Reporting System

which reports specific names of products used in hospitals.

#### Other Obstetrical Tools.

AROM-COT<sup>TM</sup> is a finger cover with a patented prong design to rupture maternal membranes with less patient pain and anxiety. MUC-X is an aspiration device used immediately after birth to clear neonatal respiratory passages and reduce exposure to potential infections. CORDGUARD® is a patented product which unifies the multiple steps of clamping the neonate's cord close to the umbilicus, severing the cord without splattering blood, drawing a clean cord blood sample, and assisting in the removal of the placenta. CORDGUARD's sharpless, closed system reduces the risk of exposure to potentially infected blood, and consequently reduces the high cost of exposure treatment under OSHA and CDC guidelines. In addition, CORDGUARD facilitates obtaining neonatal blood that is otherwise hard to obtain safely and cleanly. Abcorp belts and straps for fetal monitoring by an external tocodynamometer are provided in latex free form in several configurations.

## Neonatal Intensive Care:

#### DISPOSA-HOODTM

The DISPOSA-HOOD is an infant respiratory hood that is used in the NICU to administer oxygen to neonates and flush CO2 (carbon dioxide) while maintaining a neutral thermal environment critical to proper physiologic responses. The DISPOSA-HOOD, placed over the infant's head, incorporates a round diffusor connection specifically designed to disperse the incoming gases along the inner surfaces of the hood, rather than allowing them to blow directly on the infant's head. The design allows more precise FIO2 (fractional inspired oxygen) control, minimizes convective heat loss from the head and provides optimum flows for elimination of CO2 by ventilation. Because it is a disposable product, it allows for excellent visualization of the underdeveloped infant and prevents cross-contamination.

## **DELTRAN® PLUS**

UTMD's DELTRAN blood pressure monitoring system has been adapted specifically for use in the NICU. The streamlined version eliminates needles used for blood sampling, avoids the loss of scarce neonatal blood volume and provides a closed system that reduces the risk of infection. The system features excellent visualization of clearing volume and one-handed use.

### **GESCO®**

In the third quarter of 1998, UTMD acquired the neonatal product line of Gesco International, a subsidiary of Bard Access Systems and C.R. Bard, Inc. GESCO, best known for innovative silicone catheters, gained an early distinctive reputation for its focus on the special developmental needs of tiny critically-ill babies.

A class of catheters called umbilical vessel catheters (UVC's) are specially designed for administering vital medications and fluids immediately following birth through the infant's umbilical vessel into the inferior vena cava. Because of the neonate's small size and lack of vascular development, there is no better access to vital organs. The catheters are also called umbilical artery catheters (UAC's) when placed in one of the umbilical arteries to measure blood pressure or monitor metabolic processes through blood analysis. In developing its UMBILI-CATH<sup>TM</sup> product line, Gesco pioneered the use of soft, biocompatible silicone catheters, helping to reduce the number of insertions required as well as other complications associated with invasive applications. UTMD has expanded the UVC product line to include catheters made from a patented thermosensitive polyurethane (Tecoflex®) that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion. In addition, GESCO provides a convenient catheterization procedure tray of implements and supplies necessary to place UVC catheters, as well as perform other similar procedures.

The primary distinction of GESCO products is that they were developed with the special needs of the neonate in mind, not just cut-down or smaller versions of adult devices. For example, in the case of invasive catheters, the introducer, the soft rounded distal tip, mode of securing to the patient after insertion to avoid migration, luer locking hub with minimal dead space, number of lumens, catheter radiopaque striping for visualization, variations in catheter lengths and diameters and special packaging are all features specially designed for neonates. UTMD continues to

modify product features to incorporate current neonatal nurse practitioner preferences.

The soft, biocompatible silicone catheter concept had important advantages in other applications including peripherally inserted central venous catheters (PICC lines), enteral feeding tubes, urinary drainage catheters, and chest drainage tubes. GESCO developed and marketed initial versions of all of these neonatal products. In order to keep pace with the trend of caring for smaller babies, UTMD has added smaller diameter versions of its URI-CATH® and NUTRI-CATH® products. In 2000, UTMD gained FDA premarketing clearance of a new PICC family of products specifically designed to minimize trauma to the critically ill neonate, named PICC-NATE®. The PICC-NATE product line was designed with the input of experienced neonatal nurse practitioners for use as a long-term indwelling catheter system for single-use, therapeutic central venous infusion of drug solutions, blood products or other fluids and for blood sampling. The soft, strong silicone PICC-Nate comes in two diameter sizes, two types of venipuncture introducers, and two hub configurations. In early 2003, UTMD added a Tecoflex polyurethane version that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion.

Other GESCO specialty products include a disposable peritoneal dialysis set that is a pre-assembled, sterile, closed system, called DIALY-NATE®; a patented silicone oral protection device used to prevent palatal soft tissue injury by orotracheal tubes, called PALA-NATE®; and a lumbar sampling kit with a tiny, specially-beveled needle for obtaining cerebral spinal fluid samples, called MYELO-NATE®.

GESCO's first patented product, HEMO-NATE®, is a disposable filter designed to remove microaggregates from stored blood prior to transfusion into a neonate where any deficiency can have an overwhelmingly negative impact on a neonate's chances for survival, given an under-developed vasculature and small total blood volume. In 2001, UTMD introduced a new filter and an improved blood bag spike for Hemo-Nate, and a needleless version.

In 2005, UTMD will continue to improve and expand its neonatal product line, seeking to reinforce a reputation as having the most developmentally-friendly NICU specialty products in the medical device industry. In addition to products already offered and being developed internally, UTMD will look to expand sales through distribution arrangements with other manufacturers, or through selective acquisitions.

## Gynecology /Urology /Electrosurgery:

LETZ® System

The LETZ System is used to excise cervical intraepithelial neoplasia (CIN) and other lower genital tract lesions related to human papilloma virus (HPV) infections. The electrosurgery procedure with hemostasis has become the standard of care for HPV cervical infection treatment, replacing cold knife scalpel, laser and cryotherapy procedural approaches because it is economical, safe, effective, quick and easy to perform, has fewer potential side effects, and requires little physician training. Most importantly, in contrast to laser (tissue ablation) and cryotherapy (freezing of tissue), LETZ provides a fine tissue specimen for pathological assessment. Therefore, LETZ is effective both as a diagnostic and therapeutic procedure. The LETZ procedure may be performed using local anesthetic in a physician's office, eliminating the time and expense of hospital or surgical center admittance.

UTMD's LETZ System includes patented disposable electrodes, the patented FINESSE® electrosurgical generator, and other miscellaneous components. A disposable loop electrode used to excise the tissue specimen is a pencil-like tube with a thin tungsten wire loop attached. The loop is available in varying sizes and includes a Safe-T-Gauge® that can be positioned so the physician can accurately colposcopically monitor the amount of tissue being excised. UTMD continues to augment its specialty electrodes. For example, the Company introduced a patented conization electrode for deep endocervical disease called C-LETZ®, designed to limit the removal of healthy tissue margins that might compromise adequate cervical function. UTMD also will continue to provide adapters and other components which allow its market-leading specialty electrodes to be used with other manufacturers' electrosurgical generators. The FINESSE electrosurgical generator is the only generator on the market that contains an integral smoke evacuator, required to filter smoke and vapors that contain potentially hazardous particulate material produced during

electrosurgery.

FINESSE® Generator; Specialty Loop, Ball, and Needle Electrodes; FILTRESSE® Evacuator; Other Specialty Electrodes; Other Supplies and Gynecologic Tools.

UTMD has FDA clearance to market its electrosurgical system and tools for use in general surgery applications, including dermatology, plastic surgery and otolaryngology. In 2002, UTMD introduced a product line of ultra-fine tipped microdissection needles, called OptiMicro™ Needles. These electrosurgical needles are particularly useful in plastic and reconstructive surgery applications. FILTRESSE is a stand-alone surgical smoke filtration system that combines high filtration efficiency, low cost and convenient use in a surgical office setting. Other electrosurgery tools and accessories include disposable electrosurgical pens, dispersive pads, footswitches, filter packs, speculums, retractors, forceps, tenacula and hooks. UTMD acquired the distribution rights to a unique reusable four-way expander system which facilitates access to, and visualization of, the cervix, eliminating the need for less effective specula and lateral retractors.

#### **EPITOME®**

EPITOME is a patented electrosurgical scalpel which delivers precise performance in incision and excision with hemostasis while minimizing thermal side effects. Where rapid yet precise dissection of dense tissue is necessary, such as in mammaplasty or abdominoplasty, EPITOME has no peer. An independent study concludes that the EPITOME scalpel provides a significant improvement over older devices in wound healing and patient comfort. EPITOME allows a rapid incision without countertraction, yielding limited morbidity, less post-surgical pain and cosmetically superior results. EPITOME is useful where minimization of thermal tissue injury is important but control of bleeding needed. A patented bendable version of EPITOME with a smaller active electrode was introduced in 1998. Designed to significantly reduce the chance of tissue burns due to inadvertent electrode contact and where a smaller, bent scalpel tip is needed, the bendable EPITOME is of particular value, e.g., to thoracic surgeons in harvesting the internal mammary artery during coronary artery bypass surgery, as well as to otolaryngologists for tonsillectomies.

#### LIBERTY® System

LIBERTY is a device for the conservative treatment and effective control of urinary incontinence in women. UTMD believes that LIBERTY is the easiest-to-use, most cost effective incontinence treatment available that yields a therapeutic effect, not just a cover-up. LIBERTY consists of a battery operated electrical stimulation unit and an intravaginal electrode probe. This physiotherapy technique, which can be done in the privacy of the home, involves passive strengthening of the periurethral muscles. Pulsed, low voltage, high frequency current is applied primarily to the pudendal neuromuscular tissue causing the pelvic area muscles to contract, leading to better muscle tone. Because electrical stimulation has no known adverse side effects, LIBERTY provides women suffering from mild to moderate incontinence an effective, lower cost and lower risk alternative to more traumatic treatments such as surgery and drug therapy.

#### PATHFINDER PLUS<sup>TM</sup>

PATHFINDER PLUS is a proprietary endoscopic irrigation device that allows a uro/gyn surgeon to precisely irrigate with the same hand that controls the endoscope, eliminating the need for a separate assistant to irrigate without visualization.

#### **ENDOCURETTETM**

In cooperation with Mayo Clinic, UTMD developed an advanced curette for uterine endometrial tissue sampling in the doctor's office. The sampling procedure is intended primarily to rule out precancer or cancerous change of the uterus in premenopausal women with abnormal uterine bleeding, or women with postmenopausal bleeding. The device is part of a class of catheters designed to be used without dilitation of the cervix and without general anesthetic. The inherent weakness of this type of device, which is related to its small size, is that it may not remove enough tissue of the endometrium for an accurate histologic assessment. The patented tip of the ENDOCURETTE was designed to obtain a more thorough tissue specimen without the need for dilitation, and without an increase in patient discomfort.

#### **LUMIN®**

LUMIN® is a patented tool developed by UTMD for reliably and safely manipulating the uterus in gynecological laparoscopic procedures. LUMIN combines the strength, range of motion and versatility of the higher end reusable instruments with the lower cost and cleanliness of the inexpensive less functional disposable instruments presently on the market, while at the same time reducing the number of tools needed to move and secure the uterus.

#### **Blood Pressure Monitoring:**

DELTRAN® Disposable Pressure Transducer (DPT)

In pressure monitoring, a transducer is used to convert physiological (mechanical) pressure into an electrical signal that is displayed on electronic monitoring equipment. UTMD developed, patented and is now distributing its disposable transducer as a stand-alone product, and as a component in sterile blood pressure monitoring kits through direct representatives and other medical companies in the U.S., as well as independent distributors and other medical device companies internationally.

The Company believes that the DELTRAN DPT which it designed nearly twenty years ago, and currently manufactures, remains the standard in terms of accuracy, reliability and ease of use. UTMD has an automated assembly line which allows the Company to effectively compete with larger suppliers on the basis of consistent quality and low manufacturing costs. Introduced in 1998, the DELTRAN PLUS provides a closed system for blood sampling, without the use of needles, reducing the risk of an unwanted infection for both the patient and the practitioner.

Pressure Monitoring Accessories, Components and Other Molded Parts.

Components included in blood pressure monitoring kit configurations include flush devices, stopcocks, fluid administration sets, caps, pressure tubing, interface cables and organizers. The Company sells similar components designed for other medical device company applications which incorporate UTMD's technologies and designs. DELTA-CAL<sup>TM</sup> is a calibration device used to check proper functioning of an arterial pressure system. In addition, UTMD sells plastic molded parts on a subcontract basis to a number of medical and non-medical device companies. UTMD believes that this practice helps better utilize its investment in fixed plant and equipment.

#### **MARKETING**

UTMD competes on the basis of its value-added technologies and cost effective clinical solutions. UTMD believes that a number of its products are strong brands because they are recognized as clinically different. The Company's primary marketing challenge is to keep its customers focused on those differences and their important clinical benefits. Access to the clinical decision-makers, together with the active involvement of clinicians in medical device purchasing decisions, is critical to the Company's success.

UTMD's specialty focus, innovation and extensive experience in its specialties are important marketing attributes which help assure its ability to successfully compete and survive in a consolidating marketplace where many suppliers are trying to degrade product differences.

For U.S. hospitals, which represent about 60% of UTMD's device sales, marketing efforts are complicated and fragmented. Although UTMD's focus is with clinicians who take responsibility for obtaining optimal patient care outcomes, other people are generally administratively responsible for hospital purchasing decisions.

#### DISTRIBUTION

An important success factor in the current healthcare industry is access to customers. Although the U.S. hospital supplier environment has been consolidating as a result of group purchasing organizations (GPOs), or their equivalent,

establishing long term contracts with large medical device suppliers with diverse product lines in recent years, the financial relationships and true benefits for hospitals has come under increased scrutiny, both by hospitals' managements themselves and by the government. As a potential positive factor to UTMD's future performance, the increased scrutiny may lead to an understanding consistent with UTMD's belief that hospitals are not currently saving money under many of the GPO contracts. In addition, the longer term overall cost of care will be substantially higher, with quality of care lower, as innovative suppliers are excluded from participating in the marketplace.

The length of time and number of administrative steps required in evaluating new products for use in hospitals has grown substantially in recent years. As a potential negative factor to future performance, as UTMD introduces new products it believes are safer and more effective, it may find itself excluded from certain customers because of the existence of long term supply agreements for existing products. UTMD may also be unable to establish viable relationships with other medical device companies that do have access to users but lack an interest in the Company's approach.

In the United States, UTMD sells its products through its own directly employed sales force and through selective independent manufacturer representatives. The direct representatives concentrate on applications for UTMD products where customer training and support are important. As of March 2005, the direct sales force is comprised of both outside territory representatives operating remotely geographically, and inside representatives who operate by telephone from corporate offices. Direct representatives are trained to understand the medical procedures being performed within UTMD's clinical focus. Through the use of its one-on-one contacts with physicians and other clinicians directly involved in patient care, the direct sales force positions UTMD to gain market leadership with solutions to clinical problems. In addition to its direct representatives, UTMD utilizes third party consulting clinical specialists to augment its customer training programs.

When hospital customers request it, UTMD provides its products through national distribution companies, also known as Med/Surg distributors. Sales to Med/Surg distributors currently comprise less than 10% of total domestic sales. In contrast, eight years ago, national distributors and independent stocking distributors in the U.S. represented more than 65% of UTMD's direct domestic Ob/Gyn business.

In addition to the above traditional sales approaches, UTMD encourages customers to take advantage of fast and easy direct online ordering at <a href="www.order.utahmed.com">www.order.utahmed.com</a>. UTMD's website provides all the convenience of e-commerce demonstrated on other sites. UTMD's experience to date with third party Internet-based exchanges suggests that they do not warrant a significant investment of UTMD resources until customers show more interest in their use.

Additionally, UTMD sells component parts to medical companies for use with their product lines. This OEM distribution channel effort is simply maximizing utilization of manufacturing resources that are otherwise needed for UTMD's primary business, and does not compete with or dilute UTMD's direct distribution and marketing programs.

Internationally, the Company sells its products through about 80 regional distributors and through about 20 OEMs (other medical device manufacturers). The international business is driven by the initiative and resourcefulness of these distributors. UTMD's Internet website **www.utahmed.com** is a frequent conduit for international customer inquiries.

#### NEW PRODUCT DEVELOPMENT

New product development is a key to UTMD's market identity as an innovator. Product development takes three interrelated forms: 1) improvements, enhancements and extensions of current product lines in response to clinical needs or clinician requests, 2) invention of devices that allow significantly different methods of performing medical procedures, representing a quantum improvement in safety, efficacy and/or cost of care, and 3) acquisitions of products or technology from others.

Because of UTMD's reputation as a successful innovator, its financial strength and its established clinician user base, it enjoys a substantial inflow of new product ideas. Internal development, joint development, product acquisitions and licensing arrangements are all included as viable options in the investigation of opportunities. Only a small percentage of ideas survive feasibility screening. For internal development purposes, projects are assigned to a project manager who assembles an interdisciplinary, cross-functional development team. The team's objective is to have a clinically proven, manufacturable and FDA released product ready for marketing by a specific date. Approximately ten projects on the average, depending on the level of resources required, are underway at UTMD at any given time. More than 50% of assigned projects do not succeed in attaining a product that meets all of the Company's criteria. In particular, this includes a product that is highly reliable, easy to use, cost-effective, safe, useful and differentiated from the competition. Once a product is developed, tooled, fully tested and cleared for marketing by the FDA, there remains a reasonable probability it cannot be successfully marketed for any number of reasons, not the least of which is being beaten to the market by a competitor with a better solution, or not having access to users because of limitations in marketing and distribution resources or exclusionary contracts of GPOs.

UTMD's current product development projects are in three areas of focus: 1) obstetrics/ fetal monitoring, 2) neonatal intensive care, and 3) specialized procedures for the assessment and treatment of cervical/uterine disease. UTMD has had 7 patents issued in the last five years. Internal product development expenses are expected to be in the range of 1-2% of sales in 2005. In 2004, UTMD spent \$292 (in thousands) on internal product development activities, or 1.1% of sales. In addition, the Company invested \$10 in new technology rights which have not resulted in a marketable product yet. In 2003 and 2002, internal new product development expenses were \$288 (1.1% of sales) and \$285 (1.0% of sales), respectively.

#### **EMPLOYEES**

At December 31, 2004, the Company had 206 employees. The average tenure of all of UTMD's employees is over eight years. The Company's continued success will depend to a large extent upon its ability to retain skilled employees. No assurances can be given that the Company will be able to retain or attract such employees in the future, although management is committed to providing an attractive environment in which creative and high achieving people wish to work.

To the best of the Company's knowledge, none of the Company's officers or directors is bound by restrictive covenants from prior employers that limit their ability to contribute to UTMD's programs. All professional employees sign a code of conduct and a confidentiality and non-compete agreement, as a condition of employment, and as consideration for receipt of stock option awards and participation in the management bonus program. All employees participate in performance-based bonus programs. None of the Company's employees is represented by labor unions or other collective bargaining groups.

# PATENTS AND TECHNOLOGY LICENSES

The Company owns or exclusively licenses thirty-one unexpired patents, and is the licensee of certain other technology. There can be no assurance, however, that patents will be issued with respect to any pending applications, that marketable products will result from the patents or that issued patents can be successfully defended in a patent infringement situation.

The ability of the Company to achieve critical mass in the marketplace depends in large part on the protection afforded by its patents. In cases where competitors introduce products that may infringe on UTMD's technology, the Company has an obligation to its shareholders to defend its intangible property to the extent that it can afford to do so.

In January 2002, a jury in the U.S. Federal District Court for the District of Utah rendered a verdict in favor of UTMD that the Tyco/Kendall•LTP Softrans 4000 Intrauterine Pressure Catheter literally infringes UTMD's Patent No. 4,785,822 for inventions relating to a "Disposable Intracompartmental Pressure Transducer." UTMD markets the Intran® Plus which practices this patent. The patent infringement lawsuit had been filed in early 1997. In September 2002, the US Federal District Court issued a formal judgment awarding UTMD approximately \$23 million in damages and accrued interest. Additional damages for infringing product sold by Tyco after the January verdict were to be determined by the Court at a later date. In addition, the Court issued a permanent injunction against Tyco prohibiting the manufacturing, marketing, selling and/or otherwise distributing of the 4000 Softrans IUPC for the duration of UTMD's patent. Tyco/Kendall filed an appeal to the decision. In December 2003, the United States Court of Appeals for the Federal Circuit upheld in entirety the District Court's judgment. In January 2004, UTMD received \$31 million from Tyco/Kendall, including post judgment augmented damages and interest.

As a matter of policy, UTMD has acquired and will continue to acquire the use of technology from third parties that can be synergistically combined with UTMD proprietary product ideas. During 2004, ongoing royalties included in cost of goods sold were \$3 (in thousands). Other royalties have been previously paid as a lump sum, or are incorporated into the cost of supplied components which practice certain patents of third parties. Also as a matter of policy, UTMD licenses its proprietary technology to others in circumstances where licensing does not directly compete with UTMD's own marketing initiatives. During 2004, the Company received \$450 in royalty income, the same as in 2003 and 2002. Non-operating income remains a significant portion of UTMD's earnings. UTMD's future financial performance also depends on the marketing ability of other companies that license UTMD's technology.

# **GOVERNMENT REGULATION**

UTMD's products are subject to regulation by the U.S. Food & Drug Administration ("FDA"), as well as other regulatory bodies globally. The FDA has authority to regulate the marketing, manufacturing, labeling, packaging and distribution of medical devices in the U.S. In addition, requirements exist under other federal laws and under state, local and foreign statutes that may apply to the manufacturing and marketing of the Company's products.

All manufacturers of medical devices must register with the FDA and list all medical devices produced by them. The listing must be updated annually. In addition, prior to commercial distribution of some devices for human use, a manufacturer must file a notice with the FDA, setting forth certain information regarding the safety and effectiveness of the device that is acceptable in content to the FDA.

Devices which are classified in Class I are subject only to the general controls concerning adulteration, misbranding, good manufacturing practices, record keeping and reporting requirements. Devices classified in Class II must, in addition, comply with special controls or performance standards promulgated by the FDA.

The Company believes all of its present products are Class I or Class II devices and that the Company is in compliance with all applicable material performance standards as well as FDA cGMP (current good manufacturing practice) quality standards, record keeping and reporting.

In 2003 the FDA began withholding export certificates from UTMD, which action was part of an unresolved disagreement regarding the issuance of a Warning Letter by FDA to UTMD in September 2001. Export certificates are nonbinding letters assuring other countries that a company is in compliance with FDA regulations. The export certificates have now been withheld for many months while UTMD distributes its products in the U.S. without any FDA restriction, or any FDA claim that UTMD's products are unsafe or ineffective. The Company strongly believes that there is no reasonable basis for this denial.

On August 10, 2004, the FDA issued a press release announcing it would seek an injunction against UTMD until it had corrected alleged "deviations" from the Quality System Regulation, 21 CFR Part 820 (QSR). The FDA did not seek a preliminary injunction. UTMD responded with several press releases shortly following the FDA's announcement, and with periodic public updates since then. The FDA press release and filing of the action in the U.S. District Court for the District of Utah caused significant disruption to UTMD's business, in part because of inappropriate activities of UTMD competitors incorrectly telling customers that the Company has been, or was about to be, shut down. As a matter of fact, through the date of this report: 1) UTMD continues to manufacture and distribute all of its products worldwide without any regulatory restriction, 2) There has been no mandated recall or any other regulatory enforcement action that restricts customers from using UTMD's products, 3) There has not been, and is not now, any allegation by the FDA that UTMD's products are not safe or effective, 4) There is no FDA claim of defective products or products not conforming to specifications, and 5) The proven extremely low product liability risk using UTMD's products has not changed. On November 16, 2004 UTMD announced that an FDA enforcement official, officially designated as the knowledgeable FDA representative, testified under oath that the FDA is not claiming in the lawsuit

that UTMD's devices are either unsafe or ineffective. Discovery in the lawsuit is ongoing at the date of this report, with a pre-trial conference scheduled for June 20, 2005. As part of its expert witness testimony in the lawsuit, the Company has provided independent QSR expert certification that UTMD is in substantial compliance with the QSR. (See also Item 3. - Legal Proceedings.)

In 1994, UTMD received certification of its quality system under the ISO 9001/EN 46001 standards ("ISO" stands for "International Organization of Standardization") which it maintained until December 2003. In October 2003, UTMD's Utah facility was initially certified under the more stringent ISO 13485 standard for medical devices, which it currently maintains. UTMD's Ireland facility is certified under the concomitant ISO 13488 standard. The U.S. FDA QSR was developed in harmony with the ISO standards. UTMD remains on a continuous periodic audit schedule by its independent notified body in order to stay current with international regulatory standards, and retain its certification. The most recent audit was conducted in November 2004. UTMD has received formal product certifications allowing the use of the CE Mark (demonstrates proof of compliance with the European Community's ISO standards) for essentially all of its products.

#### SOURCES AND AVAILABILITY OF RAW MATERIALS

Most of the components which the Company purchases from various vendors are readily available from a number of sources. Alternate sourcing of various components is continually underway. Vendors are qualified by Corporate Quality Assurance. The Company has a vendor quality monitoring program that routinely checks all incoming material for conformance to specifications.

#### **EXPORTS**

Revenues from customers outside the U.S. in 2004 were (in thousands) \$6,029 (23% of total sales), as compared to \$5,872 (22% of total sales) in 2003, and \$5,735 (21% of total sales) in 2002. Blood pressure monitoring products represented 67% of international sales in both 2004 and 2003, compared to 70% in 2002. International Ob/Gyn and neonatal product sales were \$2,019 in 2004, compared to \$1,930 in 2003 and \$1,743 in 2002. For financial information by geographical area, please see Notes 1, 4 and 9 to the Consolidated Financial Statements.

UTMD regards the international marketplace as one of the important elements of its growth strategy. UTMD is keenly aware that not only are international markets different from the U.S. market, but also that each country has its own set of driving influences that affects the dynamics of the nature of care given and medical devices used. In 1996 UTMD completed construction of a manufacturing facility in Athlone, County Westmeath, Ireland. The facility offers a number of advantages: 1) from a marketing point of view, faster response to European Union customers, including a better understanding of customized needs, less costly distribution and duty-free access to over 350 million patients; 2) from a regulatory point of view, faster new product introductions; and 3) from a manufacturing point of view, reduced dependence on one manufacturing site and increased capacity at existing U.S. facilities.

# **BACKLOG**

As a supplier of primarily disposable hospital products, the nature of UTMD's business necessitates being very responsive to customer orders and delivering products quickly. Virtually all direct shipments to end users are accomplished within one week of receipt of customer purchase order. Backlog shippable in less than 60 days was approximately \$0.3 million as of both January 1, 2005 and January 1, 2004.

## **SEASONAL ASPECTS**

The Company's business is generally not affected by seasonal factors.

#### PRODUCT LIABILITY RISK MANAGEMENT

The risk of product liability lawsuits is a negative factor in UTMD's business because UTMD's products are frequently used in inherently life threatening situations to help physicians achieve a more positive outcome than what might otherwise be the case. In any lawsuit against a company where an individual plaintiff suffers a permanent physical injury, a possibility of a large award for damages exists whether or not a causal relationship exists. However, no such damages have been awarded against UTMD in its 26 year history.

UTMD is self-insured for product liability risk and reserves funds against its current performance on an ongoing basis to provide for its defense should any lawsuits be filed. The best defense the Company has is the consistent conformance of its proven safe and effective products to specifications. In the last twelve years, UTMD has been named as a defendant, along with each attending physician and hospital, in four product liability lawsuits. All four were related to operative vaginal deliveries where a VAD product was used. The VADS products did conform to specifications. UTMD was ultimately dismissed as a defendant in the lawsuits, and legal costs were not material to performance. During the same period of time, no other UTMD products were the subject of a product liability lawsuit. There are currently no product liability lawsuits in which UTMD is a defendant.

#### FORWARD LOOKING INFORMATION

This report contains certain forward-looking statements and information relating to the Company that are based on the beliefs of management as well as assumptions made by management based on information currently available. When used in this document, the words "anticipate," "believe," "project," "estimate," "expect," "intend" and similar expressions, as they relate to the Company or its management, are intended to identify forward-looking statements. Such statements reflect the current view of the Company respecting future events and are subject to certain risks, uncertainties and assumptions, including the risks and uncertainties stated throughout the document. Although the Company has attempted to identify important factors that could cause the actual results to differ materially, there may be other factors that cause the forward statement not to come true as anticipated, believed, projected, expected, or intended. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may differ materially from those described herein as anticipated, believed, projected, estimated, expected or intended.

General risk factors that may impact the Company's revenues include: the market acceptance of competitive products; administrative practices of group purchasing organizations; obsolescence caused by new technologies; the possible introduction by competitors of new products that claim to have many of the advantages of UTMD's products at lower prices; the timing and market acceptance of UTMD's own new product introductions; UTMD's ability to efficiently and responsively manufacture its products, including the possible effects of lack of performance of suppliers; success in gaining access to important global distribution channels; budgetary constraints; the timing of regulatory approvals for newly introduced products; regulatory intervention in current operations, including the current action filed by the Justice Department on behalf of the FDA against UTMD in the U.S. District Court for the District of Utah (see Government Regulation, above); and third party reimbursement of health care costs of customers.

Risk factors, in addition to the risks outlined in the previous paragraph and elsewhere in this report that may impact the Company's assets and liabilities, as well as cash flows, include: risks inherent to companies manufacturing products used in healthcare, including claims resulting from the improper use of devices and other product liability claims; defense of the Company's intellectual property; productive use of assets in generating revenues; management of working capital, including inventory levels required to meet delivery commitments at a minimum cost; and timely collection of accounts receivable.

Additional risk factors that may affect non-operating income include: the continuing viability of the Company's technology license agreements; actual cash and investment balances; asset dispositions; and acquisition activities that may require external funding.

#### **ITEM 2 - PROPERTIES**

Office and Manufacturing Facilities.

The Company's current operations are located in an 100,000 square foot facility in Midvale, Utah, a suburb of Salt Lake City, a 20,000 square foot facility in Redmond, Oregon, and a 77,000 square foot facility in Athlone, County Westmeath, Ireland. UTMD owns its property and facilities in Utah and Ireland, with the exception of a long-term lease on one section of its Midvale parking lot. The Oregon facility is leased.

UTMD is a vertically-integrated manufacturing company. Capabilities include silicone and plastics-forming operations including injection molding, insert and over-molding, thermoforming and extrusion; sensor production; manual and automated assembly of mechanical, electrical and electronic components; parts printing; various testing modalities; advanced packaging in clean room conditions; and a machine shop for mold-making and fabrication of assembly tools and fixtures. Capabilities also include an R&D laboratory for both electronic and chemical processes, software development resources, communications and computer systems networked real time internationally, and administrative offices.

#### **ITEM 3 - LEGAL PROCEEDINGS**

The Company may be a party from time to time in routine litigation incidental to its business. Presently, there is no such routine litigation ongoing.

On August 9, 2004, the United States of America filed a lawsuit in The United States District Court, Central District of Utah v. UTMD, Kevin L. Cornwell, Chairman & CEO, and Ben D. Shirley, Vice President, Product Development & Quality Assurance. The presiding judge is Judge Bruce S. Jenkins. The government (FDA) is seeking a permanent injunction from alleged deviations of the Quality System Regulation (QSR). The FDA did not seek a preliminary injunction. The relief being sought is to enjoin the Company from manufacturing and shipping products until it conforms with the QSR in a manner that is acceptable to the FDA.

UTMD was served with the complaint on August 12, 2004. On August 10, the FDA released an announcement on its official website regarding filing the lawsuit which contained a personal quotation from Acting Commissioner Lester Crawford which UTMD believes confused and upset people who use UTMD's devices, and thereby harmed UTMD's commerce and shareholder value. In Federal Court, the FDA will have the burden to prove that UTMD is not in compliance with the QSR. On January 31, 2005, attorneys for UTMD filed a Motion to amend Defendant's Answer to assert a counterclaim for damages for abuse of process. The Court expeditiously reviewed and granted Defendant's Motion for Leave to File Amended Answer to Assert Counterclaim. The relief being sought by UTMD includes dismissing the case, reimbursing UTMD for its expenses and requiring FDA to issue a public apology stating that UTMD has been and is in compliance with the QSR.

In addition to the GOVERNMENT REGULATION section in this document, please review UTMD's MD&A section in this report for further discussion regarding its dispute with the FDA.

#### ITEM 4 - SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of security holders through the solicitation of proxies or otherwise during the fourth quarter of the fiscal year covered by this report.

# **PART II**

# ITEM 5 - MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market Information.

UTMD's common stock began trading on the Nasdaq National Market (symbol:UTMD) in 1983. From December 26, 1996 until March 7, 2000, UTMD traded on the New York Stock Exchange (symbol: UM). Since March 8, 2000, UTMD has again traded on the Nasdaq National Market. The following table sets forth the high and low sales price information as reported by Nasdaq for the periods indicated:

		20			20	03		
	I	High Low			High Low			
1st Quarter	\$	26.45	\$	23.52	\$	19.35	\$	17.41
2nd Quarter		27.19		23.80		20.87		18.10
3rd Quarter		27.00		16.02		24.99		20.05
4th Quarter		23.45		17.50		26.30		21.00

#### Stockholders.

The approximate number of beneficial stockholders of UTMD's common stock as of March 4, 2005 was 3,100.

#### Dividends.

On May 10, 2004, UTMD announced that it would begin paying a quarterly cash dividend. The following sets forth cash dividends declared and paid on UTMD common stock over the past two years:

		Per Share
Record Date	Payable Date	<u>Amount</u>
June 16, 2004	July 5, 2004	\$ 0.15
September 16,		
2004	October 5, 2004	0.15
December 16,		
2004	January 5, 2005	0.15
2004 total paid		\$ 0.30
2003 total paid		None

# Issuer Purchases of Equity Securities.

The following table details purchases by UTMD of its own securities during fourth quarter 2004.

	Total Number of Shares	Average Price Paid	Total Number of Shares Purchased as Part of Publicly Announced Plans	Maximum Number (or Approximate Dollar Value) of Shares that May be Purchased Under
Period	Purchased (1)	per Share	or Programs (1)	the Plans or Programs (1)
10/01/04 - 10/31/04	233,200 \$	17.61	233,200	•
11/01/04 - 11/30/04	6,000	17.96	6,000	
12/01/04 - 12/31/04	15,488	21.92	15,488	

Total 254,688 \$ 17.88 254,688

(1) In fourth quarter 2004 UTMD repurchased an aggregate of 254,688 shares of its common stock at an average cost of \$17.88 per share pursuant to a continued open market repurchase program initially announced in August 1992. Since 1992 through 2004, the Company has repurchased 5,979,792 shares at an average cost of \$10.70 per share including broker commissions and fees in open market transactions. In addition, the Company conducted tender offer transactions in which it purchased an additional 2,775,742 shares at an average cost of \$9.76 per share including fees and administrative costs. In total, UTMD has repurchased over 8.7 million of its shares at an average price of \$10.40 per share since 1992. To complete the picture relating to current shares outstanding, since 1992 the Company's employees and directors have exercised and purchased 1.4 million option shares at an average price of \$6.24 per share. All options were awarded at the market value of the stock on the date of the award.

The frequency of UTMD's open market share repurchases depends on the availability of sellers and the price of the stock. Since the conclusion of its November 2002 tender offer, the Company has repurchased shares on a total of thirty-nine trading days, about 8% of the total trading days available. The board of directors has not established an expiration date or a maximum dollar or share limit for UTMD's continuing and long term pattern of open market share repurchases.

The purpose of UTMD's ongoing share repurchases is to maximize the value of the Company for its continuing shareholders, and maximize its return on shareholder equity by employing excess cash generated by effectively managing its business. UTMD does not intend to repurchase shares that would result in terminating its Nasdaq National Market listing.

#### ITEM 6 - SELECTED FINANCIAL DATA

(in thousands, except per share data)

The following selected consolidated financial data of UTMD and its subsidiaries for the five years ended December 31, 2004, are derived from the audited financial statements and notes of UTMD and its subsidiaries, certain of which are included in this report. The selected consolidated financial data should be read in conjunction with UTMD's Consolidated Financial Statements and the Notes included elsewhere in this report.

#### Year Ended December 31

	2004	2003		2002		2001		2000	
Net Sales	\$ 26,485	\$ 27,137	\$	27,361	\$	26,954	\$	27,193	
Net Income	10,220	20,761		7,165		5,934		5,373	
Earnings Per Common Share									
(Diluted)	2.19	4.25		1.36		1.14		.90	
Total Assets	41,262	49,694		23,387		23,572		25,423	
Working Capital	20,194	21,405		5,437		5,400		5,418	
Long-term Debt	0	0		4,956		2,501		10,000	
Cash Dividends Per Common									
Share	0.30	None		None		None		None	

Quarterly	Data for 2004

	First Quarter		Second Quarter		Third Quarter		Fourth Quarter	
Net Sales	\$	6,616	\$	6,827	\$	6,670	\$	6,372
Gross Profit		3,850		3,934		3,779		3,503
Net Income		5,175		1,841		1,807		1,397
Earnings Per Common Share								
(Diluted)		1.07		.38		.39		.32

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	First	Second	Third	Fourth		
	Quarter		Quarter	Quarter		Quarter
Net Sales	\$ 6,877	\$	6,840	\$ 6,761	\$	6,659
Gross Profit	3,977		4,033	3,979		3,902
Net Income	1,788		1,837	1,861		15,274

Earnings Per Common Share (Diluted)

(Diluted) .37 .38 .38 3.10

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

The following comments should be read in conjunction with accompanying financial statements. Dollar amounts are in thousands except per-share amounts and where noted.

Productivity of Assets and Working Capital.

a) Assets. Year-end 2004 total assets were \$41,262, compared to \$49,694 in 2003. Year-end assets in both years were substantially higher than in prior years due to the Tyco patent infringement damages, reflected in cash and investments in year-end 2004 and receivables in year-end 2003. The change in total assets was not related to sales activity. It reflected the difference in the Tyco damages due UTMD at the end of 2003 and the cash and investment balances resulting from the damages at the end of 2004 after income taxes on the income resulting from the infringement damages had been paid. The same statement applies to the net change in current assets. In 2005, total asset turns will depend primarily on UTMD's use of its cash and investment balances.

Although other current asset categories netted out to remain about the same, 2004 ending inventory balances were about \$400 lower and receivables were about \$400 higher. As a result, average inventory turns increased to 3.7 in 2004 from 3.3 in 2003 despite a decline in sales activity. Management expects to sustain 3.7 inventory turns in 2005. Because year-ending 2004 accounts receivable (A/R) balances increased 12%, calculated average days in A/R aging was 51 on December 31, 2004 based on 4Q 2004 shipment activity. Although this is well within management's objective of 55 days, it is less favorable than at the end of 2003. A/R over 90 days from invoice date were about 5% of total A/R at year-end 2004, compared to 4% at year-end 2003. The Company believes these older A/R are collectible or within its reserve balances for uncollectible accounts.

Working capital at year-end 2004 was \$20,194 compared to \$21,405 at year-end 2003. Both amounts far exceed UTMD's working capital needs for normal operations. UTMD's current ratio increased to 5.7 from 2.7, due mainly to the decrease in income taxes due resulting from the patent infringement damages. 2005 working capital balances and current ratio will depend primarily upon the timing and extent of use of cash and investment balances. The non-cash and investment components of working capital are expected to remain within management targets.

Property, plant and equipment (PP&E) assets are comprised of Utah, Oregon and Ireland manufacturing molds, production tooling and equipment, test equipment, computer/ communications equipment and software, and the Utah and Ireland facilities. UTMD leases the Oregon facility, involved in the 1997 CMI acquisition, and a portion of the Midvale parking lot. In 2004, PP&E depreciation of \$739 exceeded new PP&E asset purchases of \$411. Net PP&E assets, however, increased \$53 compared to the end of 2003 because of a \$252 increase in dollar-valued Ireland PP&E assets. In 2004, the U.S. dollar (USD) declined in value relative to the euro by about 8%. Slightly higher consolidated PP&E (in U.S. dollar terms) and lower sales resulted in a slightly lower PP&E turn. In 2005, depreciation of fixed assets is expected to exceed new fixed asset purchases required to sustain current operations, which will improve PP&E asset turns unless the U.S. dollar continues to weaken, further inflating the dollar value of Ireland PP&E.

The current book value of consolidated PP&E is 37% of acquisition cost. Management believes that PP&E is in good working order and capable of supporting increased sales activity.

Intangible assets are comprised of goodwill resulting from acquisitions and the costs of obtaining patents and other technology rights. Goodwill of \$7,191 is the result of three acquisitions in 1997, 1998 and 2004 which were made in cash at conservative valuations. Goodwill increased \$946 in 2004 as a result of the acquisition of Abcorp Medical, UTMD's supplier of fetal monitoring belts. The increase in 2004 goodwill was offset by \$70 amortization of other intangible assets. As of the end of 2004, goodwill on the balance sheet has been reduced by 24% from the goodwill resulting at time of acquisition. The reduction is a result of UTMD using previous GAAP through 2001 for the

purchase method of acquisition accounting. Under current GAAP, the goodwill will not be expensed unless and until the value of the acquired entity becomes impaired. The acquisitions reflected in goodwill continue to be viable parts of UTMD's overall business activities, representing 26% of total sales in 2004.

b) <u>Liabilities</u>. Excluding accrued and deferred income taxes, UTMD's total liabilities at the end of 2004 and 2003, which were \$3,952 and \$3,227, respectively, were both less than 10% of total assets reduced by the total accrued tax liability. At the end of 2004, UTMD's total debt ratio decreased to 12% from 26% at the end of 2003. The decline was due to accrued taxes on the patent infringement damages receivable item on the balance sheet at the end of 2003 which were paid in 2004.

#### Results of Operations.

<u>a)</u> Revenues. Global consolidated sales decreased 2% in 2004 compared to 2003. Foreign (international) sales increased 3% while U.S. (domestic) sales declined 4%. Revenues were negatively affected by an August 10 FDA press release that announced that the FDA filed a lawsuit against UTMD. International revenues continued to be negatively affected by the FDA's refusal, continuing since 2003, to provide Certificates to Foreign Governments (CFGs).

UTMD divides its domestic sales into two primary distribution channels: "direct sales" which are sales to end user customers by UTMD's direct sales force, independent commissioned sales reps, specialty distributors and national hospital distribution companies, and "OEM sales" which are component sales to other companies where products are packaged and resold as part of another company's product offerings. As a percentage of total domestic sales, direct sales were 93% of domestic sales in both 2004 and 2003, and 94% in 2002. The remaining sales were OEM sales, e.g. 7% of domestic sales in 2004 were domestic OEM sales. Domestic direct sales represented 72% of global consolidated sales in 2004 compared to 73% in 2003 and 74% in 2002.

Domestic direct sales which appeared least affected by the FDA announcement were sales where clinicians make the purchase decision. Consequently, the least affected sales were sales to physician offices and clinics. Hospital labor and delivery (L&D) department sales appeared to be the most affected. Hospital NICU sales were less affected than L&D because practitioners still have major discretion in determining what products are purchased. In order to help gain further attention of concerned hospital administrators, UTMD instituted a special "loyalty discount" in late August. Ignoring the effect of the special U.S. hospital customer loyalty discount (the Discount) in effect from August 20 through November 30, 2004, UTMD's sales were down 1% from 2003. The amount of the Discount was \$374.

International sales in 2004 were 23% of global consolidated sales compared to 22% and 21% in years 2003 and 2002, respectively. Of the 2004 international sales, 60% were made in Europe, compared to 58% in both 2003 and 2002. Ireland operations (UTMD Ltd.) shipped 59% of international sales (in USD terms) in 2004 compared to 63% in 2003 and 59% in 2002. UTMD Ltd. 2004 shipments, including intercompany to Midvale, were down 15% in euro terms, and down 5% in USD terms, compared to 2003.

UTMD groups sales into four product-line categories: 1) obstetrics, comprised of labor and delivery management tools for monitoring fetal and maternal well-being, for reducing risk in performing difficult delivery procedures and for improving clinician safety; 2) gynecology/ electrosurgery/ urology, comprised of tools for gynecological procedures associated primarily with cervical/ uterine disease including LETZ, endometrial sampling, diagnostic laparoscopy, and other MIS procedures; specialty excision and incision tools; conservative urinary incontinence therapy devices; and urology tools; 3) neonatal care, comprised of devices that provide developmentally-friendly care to the most critically ill babies including providing vascular access, administering vital fluids, maintaining a neutral thermal environment, providing protection and assisting in specialized applications; and 4) blood pressure monitoring/ accessories/ other, comprised of specialized components and molded parts sold on an OEM basis to other companies. In these four categories, UTMD's primary revenue contributors often enjoy a dominant market share and typically have differentiated product features protected by patents.

## Revenues by product category:

- 1. Worldwide obstetrics product sales were \$10,918 in 2004 compared to \$11,435 in 2003 and \$11,977 in 2002. Without the Discount, 2004 obstetrics sales were \$11,120. Of the \$517 decline in total obstetrics sales, \$154 was from lower sales of vacuum-assisted delivery systems (VADS), an 11% decline, and \$1,136 from lower Intran Plus (IUPC) sales, a 12% decline. Abcorp sales of \$842 helped offset the declines. After August 10, the lower IUPC and VADS sales resulted primarily from concerns of hospital administrators related to the press release from the FDA. Other contributing factors included a trend in obstetrics practice that favors abdominal operative deliveries over vaginal operative deliveries because of medical malpractice litigation risk, and increased competition including effects of product bundling agreements. Cheaper priced, less clinically-effective products represent significant competition where hospital administrators are constrained by GPO contracts or may not take the total cost of care into consideration, including increased risk of complications and utilization rates. International obstetrics sales increased to \$774 in 2004 from \$665 in 2003.
- 2. Consolidated global gynecology/ electrosurgery/ urology product sales were \$5,142 in 2004 compared to \$5,324 in 2003 and \$5,271 in 2002. Without the Discount, 2004 sales were \$5,212. International sales in this category decreased 9%. International sales were negatively affected by not being able to supply requested FDA CFGs to international distributors.
- 3. Consolidated global neonatal product sales were \$4,134 in 2004 compared to \$4,142 in 2003 and \$3,852 in 2002. Without the Discount, 2004 sales were \$4,217. International neonatal product sales increased 39%.
- 4. Worldwide blood pressure monitoring and accessories (BPM) sales were \$6,292 in 2004 compared to \$6,236 in 2003 and \$6,261 in 2002. Without the Discount, 2004 sales were \$6,310. International sales in this category, which includes plastic molded components increased 2%.

Looking forward to 2005, UTMD's improvement in sales depends primarily on the timing of a favorable resolution of the lawsuit with the FDA, receipt of CFGs and restoration of its good reputation for supplying high quality devices. If the FDA lawsuit is resolved by the middle of the year, management believes that it can achieve a 2-3% increase in 2005 sales relative to 2004.

b) <u>Gross Profit</u>. UTMD's average 2004 gross profit margin (GPM), the surplus after costs of manufacturing, inspecting, packaging, sterilizing and shipping products (COGS) are subtracted from net revenues, was 56.9% compared to a Company record 58.6% in 2003 and 57.6% in 2002. As a percentage of sales, the negative effect of the Discount was more pronounced on gross profits than on sales. In 2004, UTMD experienced higher materials costs, particularly for plastics, along with increased labor costs, lower absorption of fixed overhead costs because of lower sales, and an unfavorable shift from higher margin products to lower margin products. The unfavorable cost trends were partially offset by lower depreciation expense on fixed assets and recoveries of previous years' misappropriated funds. With regard to the latter, UTMD recognized a favorable contribution to gross profit of \$181 and \$241 for 4Q 2004 and 2004, respectively, as the result of recovery of misappropriated funds that had reduced gross profit performance in prior years. The Audit Committee of UTMD was fully involved in the investigation and resolution of this matter.

With respect to gross profits in UTMD's sales channels, OEM sales are sales of UTMD components that are marketed by other companies as part of their product offerings. UTMD utilizes OEM sales as a means to help maximize utilization of its capabilities established to satisfy its direct sales business. As a general rule, prices for OEM sales expressed as a multiple of direct variable manufacturing expenses are lower than for direct sales because, in the OEM and international channels, UTMD's business partners incur significant expenses of sales and marketing. Because of UTMD's small size and period-to-period fluctuations in OEM business activity, allocations of fixed manufacturing overheads cannot be meaningfully allocated between direct and OEM sales. Therefore, UTMD does not report GPM

by sales channels.

UTMD targets an average GPM greater than or equal to 55%, which it believes is necessary to successfully support the significant operating expenses required in a highly complex and competitive medical device marketplace. Management expects to achieve this GPM target again in 2005. Expected favorable influences include growth in sales volume without a similar increase in manufacturing overhead expenses, a larger percentage of total sales from higher margin products and a continued emphasis on reengineering products and processes to reduce costs. Expected unfavorable influences are continued increases in material costs, competitive pressure on pricing and higher wage rates.

- c) Operating Profit. Operating profit, or income from operations, is the surplus after operating expenses are subtracted from gross profits. Operating expenses include sales and marketing (S&M) expenses, research and development (R&D) expenses and general and administrative (G&A) expenses. Litigation expenses are included as part of G&A expenses. Operating expenses in 2004 were lower by \$1,571 than in 2003. This was due to litigation expenses and bonuses in 2003 related to the conclusion of the Tyco litigation of \$2,208 which were not present in 2004, offset by FDA litigation expenses in 2004 not present in 2003. 2004 operating profit increased \$745 to \$9,259 from \$8,514 in 2003. 2002 operating profits were \$10,542. UTMD's operating profit margin (operating profits divided by total sales) was 35.0% in 2004, compared to 31.4% in 2003 and 38.5% in 2002. Operating expenses as a percentage of sales were 21.9% in 2004, compared to 27.2% in 2003 and 19.1% in 2002. The higher expenses as a percentage of sales in 2004 and 2003 compared to 2002 were due primarily to litigation. Looking forward to 2005, UTMD expects to control operating expenses excluding litigation expenses below 19% of sales. Based on the date set by the Federal Court for the pretrial conference, UTMD has accrued in 2004 an estimate for litigation expenses for resolution of the FDA lawsuit. However, UTMD cannot estimate with certainty the length of time required to resolve the lawsuit. A delay would be a double negative by continuing to retard sales activity while at the same time increasing time-related litigation costs as an addition to 2005 operating expenses.
- i) S&M expenses: S&M expenses are the costs of communicating UTMD's differences and product advantages, providing training and other customer service in support of the use of UTMD's solutions, processing orders and funding GPO fees. Because UTMD sells internationally through third party distributors, its S&M expenses are predominantly employed for U.S. business activity where it sells directly to clinical users. The largest component of S&M expenses is the cost of directly employing representatives that provide coverage across the U.S. Year 2004 S&M expenses decreased to \$2,253 from \$2,364 in 2003 and \$2,472 in 2002, as UTMD continued to focus on the productivity of its direct sales force. As a percent of total sales, S&M operating expenses were 8.5% in 2004, 8.7% in 2003 and 9.0% in 2002. Looking forward, UTMD plans higher S&M expenses during 2005 due to Group Purchasing Organization fees, increased advertising expenses and new marketing initiatives, but intends to manage S&M expenses to remain less than 9% of total sales.
- ii) R&D expenses: R&D expenses include the costs of investigating clinical needs, developing innovative concepts, testing concepts for viability, validating methods of manufacture, completing regulatory documentation and other activities required for design control, responding to customer requests for product enhancements, and assisting manufacturing engineering on an ongoing basis in developing new processes or improving existing processes. Internal R&D expenses were \$292 in 2004, \$288 in 2003 and \$285 in 2002. As a percent of sales, 2004 and 2003 R&D expenses were 1.1% compared to 1.0% in 2002. In addition to new products still being developed, a number of existing products were enhanced or updated in 2004. In 2005, UTMD will opportunistically employ R&D resources to invest where management anticipates it can get a significant return with future new product sales. 2005 R&D expenses are again likely to be in the range of 1% of sales.
- iii) G&A expenses: G&A expenses include the "front office" functional costs of executive management, finance and accounting, corporate information systems, human resources, shareholder relations, risk management, protection of intellectual property, and legal costs. In addition to employing the personnel required to coordinate or manage the preceding functions, G&A expenses include outside director costs, outside legal counsel and litigation experts, independent accounting audit fees, 401(k) administration, NASDAQ exchange fees, write-offs of uncollectible receivables, business insurance costs and corporate contributions to charitable organizations. G&A expenses were \$3,262 in 2004, \$4,726 in 2003 and \$2,464 in 2002. As a percent of sales, G&A expenses were 12.3% in 2004, 17.4% in 2003 and 9.0% in 2002. All three years included litigation expenses relating to the patent infringement lawsuit with Tyco/Kendall•LTP or lawsuits with the FDA. In addition, all three years include increasing G&A expenses to comply with required governance activities mandated by The Sarbanes Oxley Act of 2002. It is management's objective to hold G&A expenses to about 9% of sales in 2005, exclusive of litigation expenses.

d) Non-operating Income, Non-operating Expense and EBT. Non-operating income, or other income, includes the Tyco patent infringement damages, royalties from licensing UTMD's technology to other companies, rent from leasing underutilized property to others, income earned from investing the Company's excess cash and gains or losses from the sale of assets, offset by non-operating expenses which include interest expenses and bank fees. Non-operating income was \$6,858 in 2004, \$25,338 in 2003 and \$454 in 2002. Tyco patent infringement damages comprised \$6,060 of non-operating income in 2004, and \$24,884 in 2003. The increase in other 2004 non-operating income resulted from investment income on much higher average cash and investment balances, higher rental income and no interest expense. Royalties received were \$450 in all three years. Future royalties may vary depending on the success of other companies in selling products licensed by UTMD, and the remaining life of the applicable patents. In 2004, UTMD had no interest expense because it did not utilize its bank line-of-credit. In 2003 and 2002, respectively, interest expense was \$47 and \$36. UTMD expects non-operating income in 2005 to be between \$500 and \$800. No patent infringement damages are expected in 2005 since the patent infringement case against Tyco has been concluded, and there is presently no open patent litigation. Although UTMD has claimed damages as part of its counterclaim against the FDA, no FDA damages were included in the above 2005 estimate for non-operating income. The actual amount of 2005 non-operating income received will depend on many factors including: the timing of utilization of cash balances for share repurchases, dividends or acquisitions; the market performance of UTMD's liquid investments; the need for capital to support litigation; and cash flow from normal operating performance; in addition to the outcome of UTMD's counterclaim against the FDA.

Earnings before income taxes (EBT) result from adding UTMD's non-operating income to its operating profits. EBT were \$16,117 in 2004, \$33,852 in 2003 and \$10,996 in 2002. The Tyco patent infringement damages contributed to EBT in 2004 and 2003. Given the 2005 projections previously noted, management is targeting 2005 EBT of about \$11,000, minus costs related to the FDA lawsuit which cannot be estimated now.

e) Net Income, EPS and ROE. Net income is EBT minus income taxes. Net income in 2004 decreased to \$10,220 from \$20,761 in 2003. 2002 net income was \$7,165. The Tyco patent infringement damages contributed to Net Income, EPS and ROE in 2004 and 2003. The effective income tax rate in 2004 was 36.6% compared to 38.7% in 2003 and 34.8% in 2002. Year to year fluctuations in the tax rate have resulted from: 1) differences in distribution of state income taxes; 2) variations in profits of the Ireland subsidiary which is taxed at a 10% rate on exported manufactured products; 3) extraterritorial income exclusions; 4) higher marginal tax rates for EBT above \$10 million; and 5) other factors such as R&D tax credits. Management expects that UTMD's consolidated income tax rate will be lower in 2005 compared to 2004, but this is difficult to predict.

UTMD's net income expressed as a percentage of sales ranks in the top performance tier of all U.S. publicly-traded companies at 38.6%, 76.5% and 26.2% for years 2004, 2003 and 2002, respectively. This profitability performance factor is the primary driver for UTMD's return on shareholders' equity (ROE).

Earnings per share (EPS) is net income divided by the number of shares of stock outstanding (diluted to take into consideration stock option awards which are "in the money," i.e., have exercise prices below the current period's weighted average market value). Diluted 2004 EPS were \$2.19, compared to \$4.25 in 2003 and \$1.36 in 2002. The end of 2004 weighted average number of diluted common shares (the number used to calculate diluted EPS) were 4,675 (in thousands) compared to 4,885 shares in 2003 and 5,263 shares in 2002. Dilution for "in the money" unexercised options for the year 2004 was 276 (in thousands) shares compared to 359 in 2003 and 350 in 2002. The total number of options outstanding at year-end was about the same in 2004 as 2003, following a 23% decline in the prior year. Dilution decreased in 2004 from 2003 because the average number of options outstanding decreased substantially, partially offset by a higher average share price in the stock market. Actual outstanding common shares as of December 31, 2004 were 4,105,000.

Return on shareholders' equity (ROE) is the portion of net income retained by UTMD (after payment of dividends) to internally finance its growth, divided by the average accumulated shareholders' equity during the applicable time period. ROE includes balance sheet measures as well as income statement measures. ROE in 2004 was 23% (28% before dividends), compared to 79% in 2003 and 42% in 2002. This ratio determines how fast the Company can afford to grow without adding external financing that would dilute shareholder interests. For example, a 20% ROE will financially support 20% growth in revenues without issuing more stock. The lower ROE in 2004, despite a continued excellent net profit margin, was due to payment of dividends to shareholders which reduced retained profits, much higher average cash and investment balances which reduced total asset turns, and no long-term debt which reduced financial leverage compared to prior years. Looking forward, 2005 ROE is projected to be lower than 2004 if cash and investment balances are maintained at current levels, shareholder dividends are continued and no non-operating income from litigation damages is received. In UTMD's opinion, achieving growth in revenues and EPS without diluting shareholder interests maximizes shareholder value. UTMD's ROE has averaged 34% per year over the last 18 years.

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Liquidity and Capital Resources.

Cash Flows. Cash (and investment) balances were \$16,928 at the end of 2004, compared to \$1,484 at the end of 2003.

Net cash provided by operating activities, including adjustments for depreciation and other non-cash operating expenses, along with changes in working capital, totaled \$27,459 in 2004 compared to \$8,335 in 2003 and \$8,656 in 2002. Major changes in operating assets and liabilities in both 2004 and 2003 were related to the accrual and receipt of about \$31 million from Tyco International for patent infringement, and taxes on that income. Cash provided by operating activities in 2004 includes continued excellent net income performance, aided by a \$446 tax benefit attributable to exercise of employee options, compared to the same tax benefit in 2003 of \$1,108 and \$354 in 2002.

The Company's use of cash for investing activities was primarily as a result of purchases of short-term investments, in an effort to make prudent use of excess cash. UTMD expended \$22,103 in 2004 on such purchases, compared to \$737 in 2003 and none in 2002. In 2004, UTMD received \$8,202 from selling short-term investments. UTMD invested \$1,012 in second quarter 2004 to acquire Abcorp, Inc., its vendor for fetal monitoring belts. Please see the table under Supplemental Disclosure of Cash Flow Information for detail of the Abcorp assets purchased.

In 2004, UTMD received \$1,111 and issued 117,482 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 122,908 option shares in 2004, with 5,426 shares immediately being retired as a result of the individuals trading the shares in payment of the exercise price of the options. UTMD paid \$6 to meet tax withholding requirements on options exercised. UTMD repurchased 555,765 shares of stock in the open market at a cost of \$10,692 during 2004. Option exercises in 2004 were at an average price of \$10.05 per share. Share repurchases in the open market were at an average cost of \$19.24 per share, including commissions and fees. In 2003, the Company received \$882 from issuing 197,432 shares of stock on the exercise of employee and director stock options, including 101,420 shares retired upon an employee trading those shares in payment of the stock option exercise price and related tax withholding requirements.

During 2004, UTMD did not utilize its bank line of credit. In 2003, UTMD made repayments of \$4,956 on its note payable, which eliminated the line of credit balance remaining at the end of 2002, while receiving \$0 in proceeds from the line of credit. In 2002, UTMD made loan repayments of \$2,501 and received \$4,956 in proceeds from the line of credit to finance the November 2002 tender offer for UTMD share repurchases.

Management believes that future income from operations and effective management of working capital will provide the liquidity needed to finance growth plans. Planned 2005 capital expenditures are expected to be approximately \$600 to keep facilities, equipment and tooling in good working order. In addition to capital expenditures, UTMD plans to use cash in 2005 for selective infusions of technological, marketing or product manufacturing rights to broaden the Company's product offerings; for continued share repurchases if the price of the stock remains undervalued; and if available for a reasonable price, acquisitions that may strategically fit UTMD's business and are accretive to performance. Management believes that the Company has sufficient cash to finance costs of the FDA litigation without effecting other normal operations. The revolving line of credit will continue to be available for liquidity when the timing of acquisitions or repurchases of stock require a large amount of cash in a short period of time not otherwise available from existing cash and investment balances.

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In summary, management plans to utilize cash not needed to support normal operations in one or a combination of the following: 1) to make investments in new technology; 2) to acquire a product line that will help spur revenue growth and better utilize UTMD=s infrastructure; and/or 3) to buy back UTMD shares in the open marketplace.

Contractual Obligations and Contingent Liabilities and Commitments

The following is a summary of UTMD's significant contractual obligations and commitments as of December 31, 2004 (in thousands):

Contractual Obligations and Commitments	Le Total	ss than 1 year	1-3 years	3-5 years	Iore than 5 years
Long-term debt obligations	\$ - \$	- \$	- \$	- \$	-
Operating lease obligations	1,095	108	142	111	734
Purchase obligations (1)	1,788	1,788	-	-	-
Total	\$ 2,883 \$	1,896 \$	142 \$	111 \$	734

(1) The majority of UTMD's purchase obligations constitute raw materials for use in its manufacturing operations. UTMD has the right to make changes in, among other things, purchase quantities, delivery schedules and order acceptance.

### Critical Accounting Policies and Estimates

The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as the reported amounts of revenues and expenses during the reporting period.

Management bases its estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily available from other sources. Management has identified the following as the Company's most critical accounting policies which require significant judgment and estimates. Although management believes its estimates are reasonable, actual results may differ from these estimates under different assumptions or conditions.

- · Allowance for doubtful accounts: The majority of the Company's receivables are with hospitals and medical device distributors. Although the Company has historically not had significant write-offs of bad-debt, the possibility exists, particularly with foreign customers where collection efforts can be difficult or in the event of widespread U.S. hospital bankruptcies.
- · Inventory valuation reserves: The Company strives to maintain a good balance of inventory to (1) meets its customer's needs while (2) not tying-up an unnecessary amount of the Company's resources increasing the possibility of, among other things, obsolescence. The Company believes its method of reviewing actual and projected demand for its existing inventory allows it to arrive at a fair inventory valuation reserve. While the Company has historically not had significant inventory write-offs, the possibility exists that one or more of its products may become unexpectedly obsolete for which a reserve has not previously been created. The Company's historical write-offs have not been materially different from its estimates.

Management's Outlook.

In summary, in 2005 UTMD plans to

- 1) clear up its unresolved QSR status with the U.S. FDA that has hindered international sales, slowed new product development, stymied business development, clouded UTMD's previously excellent reputation for quality products and consumed an inordinate amount of human and financial capital since 2001;
- 2) continue outstanding operating performance;
- 3) actively look for new acquisitions to facilitate sales growth; and
- 4) utilize current cash balances in shareholders' best long-term interest.

Item 3 of this report describes the legal proceedings regarding UTMD's dispute with the FDA. The U.S. Court will determine if UTMD is violating any provisions of the QSR. The FDA has the burden to prove its allegations. UTMD and its highly reputable independent experts maintain that UTMD has been and is in substantial compliance with all applicable government regulations.

Because the FDA is not claiming that the Company's devices are unsafe or ineffective, or do not meet predetermined specifications, UTMD and its lawyers believe that an injunction to cease manufacturing and shipping products is not a realistic possibility, even if the Court agrees with FDA allegations. If the Court agrees with any of the FDA allegations, the Company's responsibility would be to implement procedures that satisfy the Court's determination. Because of this and because UTMD does not understand the factual basis for FDA's allegations, the Company has not spent resources analyzing the potential financial impact of the relief being sought by the FDA. Management further believes that the primary negative financial impact was suffered by UTMD when the FDA chose to release a public announcement on August 10, 2004 regarding the lawsuit which UTMD believes contains defamatory statements.

There is not and never has been an imminent public health risk relating to use of UTMD's products. The FDA has a variety of remedies to address device risks without any resort to the courts. None of those remedies has ever been applied to any UTMD device, because none has been justified. The FDA Denver District Office shut off communication with UTMD after 2001 while it performed inspection after inspection in an attempt to build a case. The case that was finally filed involves alleged QSR violations that the agency has been unable to substantiate, despite an effort coordinated by the CDRH including four comprehensive inspections, some involving "national expert" FDA inspectors. An independent expert, a nearly thirty year FDA compliance veteran and former District Director retained by UTMD, has alleged misconduct within FDA, which will be adjudicated by the Court as part of the present lawsuit.

There continue to be no FDA restrictions on UTMD's production and distribution of its products, the clinical acceptance and differentiation of which have been clearly demonstrated by continued customer demand through 2004.

UTMD will continue to focus on differentiating itself, especially from commodity-oriented competitors. UTMD is small, but its employees are experienced and diligent in their work. Our passion is in providing innovative clinical solutions that will help reduce health risks for women and their babies. The Company has a defined focus and does not seek to become big as a primary motivation. We just want to do an excellent job in meeting our customers' needs and provide our shareholders with excellent returns.

The reliability and performance of UTMD's products is high and represents significant clinical benefits while providing minimum total cost of care. Physicians do care about the well-being of their patients, but their time is limited to evaluate choices, and they have hospital administrators to deal with who often look at the initial price of a product, without understanding the total cost of care picture which includes complications and unnecessary utilization.

In the U.S., UTMD will continue (FDA willing) to leverage its reputation as an innovator which will responsively take on challenges to work with physicians who use its products in specialty hospital areas, or outside the hospital in their office practices. Internationally, where UTMD must depend on the knowledge, focus, relationships and energy of

independent distributors, management will continue to closely monitor performance and recruit needed business partners.

Looking back five years to the end of 1999, UTMD's EPS have more than doubled, and its year-ending share price has more than tripled. In comparison, the NASDAQ Composite, S&P 500 Index and DJIA were down 46%, down 17% and down 6%, respectively, over that same five year time span.

In 2004, UTMD again demonstrated a high positive cash flow, managing working capital effectively and keeping new capital expenditures below its rate of depreciation of existing assets. UTMD's balance sheet is strong enough to finance an acquisition in 2005 without issuing stock. In considering acquisitions, UTMD looks to acquire successful companies that will enhance its specialist focus. When UTMD acquires a company, it probably will be for cash and with the idea that it will be able to retain key resources that helped make the acquired entity successful.

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### Accounting Policy Changes.

None.

In December 2004, the FASB issued SFAS 123 (revised 2004), "Accounting for Stock Based Compensation." This statement supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." This revised statement establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods and services, including the grant of stock options to employees and directors. The Statement is effective for periods beginning after June 15, 2005, and will require the Company to recognize compensation cost based on the grant date fair value of the equity instruments it awards. The Company currently accounts for those instruments under the recognition and measurement principles of APB Opinion 25, including the disclosure-only provisions of the original SFAS 123. Accordingly, no compensation cost from issuing equity instruments has been recognized in the Company's financial statements. The Company estimates that the required adoption of SFAS 123 (R) in third quarter 2005 will have a negative impact on its consolidated financial statements. Please see note 1, starting on page F-12 for an estimate of the impact this Statement would have had on the Company's net income for the periods covered by this report.

### ITEM 7A - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company had manufacturing operations, including related assets, in Ireland denominated in the EURO, and sold products under agreements denominated in various Western European currencies. The EURO and other currencies have been and are subject to exchange rate fluctuations that are beyond the control of UTMD. The exchange rate for the EURO was .7335, .7958 and .9551 per U.S. Dollar as of December 31, 2004, 2003 and 2002, respectively. Please see Note 1, starting on page F-12. UTMD manages its foreign currency risk without separate hedging transactions by converting currencies as transactions occur.

### ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See index to financial statements and financial statement schedule at page F-1.

### ITEM 9 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

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### ITEM 9A - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

UTMD Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in the Securities Exchange Act of 1934 Rule 13a-15(f). UTMD's Board of Directors, operating through its audit committee, provides oversight to its financial reporting process.

UTMD evaluated the effectiveness of the design and operation of its disclosure controls and procedures. Based on that evaluation, UTMD's Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2004, its disclosure controls and procedures are effective.

Management's Report on Internal Control Over Financial Reporting.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, the Company has included, as part of this Form 10-K, a report of management's assessment of the effectiveness of its internal controls as of December 31, 2004. Jones Simkins, P.C., the independent registered public accounting firm of the Company, has audited management's assessment of, and the effectiveness of, the Company's internal control over financial reporting. Management's report, and the report of Jones Simkins, P.C. appear on pages F-2 and F-3 of this Form 10-K under the captions "Management's Report on Internal Control Over Financial Reporting" and "Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting" and are incorporated herein by reference.

Changes in Internal Control Over Financial Reporting.

**ITEM 9B - OTHER INFORMATION** 

There have been no changes in UTMD's internal control over financial reporting that materially affected, or were reasonably likely to materially affect, the Company's internal control over financial reporting during the fourth quarter of the fiscal year ended December 31, 2004, and there were no significant deficiencies or material weaknesses.

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### **PART III**

### ITEM 10 - DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information from the definitive proxy statement of the registrant under the caption, "PROPOSAL NO. 1. ELECTION OF DIRECTORS: General," "Directors and Nominees," "Executive Officers," and "Compliance with Exchange Act Requirements," is incorporated herein by reference, *expressly excluding* the material set forth under the subcaptions "Report of the Compensation and Option Committee" and "Stock Performance Chart."

UTMD adopted a Code of Ethics for its executive officers, including the Chief Executive Officer, and outside directors in October 2003. The Code of Ethics, along with UTMD's Code of Conduct, which covers all exempt employees (including all officers and outside directors) and certain non-exempt employees, is posted on UTMD's web site at <a href="https://www.utahmed.com">www.utahmed.com</a>. UTMD intends to post on its website any waivers of or amendments to its Code of Ethics.

### **ITEM 11 - EXECUTIVE COMPENSATION**

The information from the definitive proxy statement of the registrant under the caption, "PROPOSAL NO. 1. ELECTION OF DIRECTORS: Executive Compensation," "Compensation and Option Committee Interlocks and Insider Participation," "Employment Agreements, Termination of Employment, and Change in Control," and "Director's Compensation" is incorporated herein by reference, *expressly excluding* the material set forth under the subcaptions "Report of the Compensation and Option Committee" and "Stock Performance Chart."

### ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information from the definitive proxy statement of the registrant under the caption, "PROPOSAL NO. 1. ELECTION OF DIRECTORS: Security Ownership of Management and Certain Persons" is incorporated herein by reference.

### ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

None.

### ITEM 14 - PRINCIPAL ACCOUNTING FEES AND SERVICES

The information from the definitive proxy statement for the 2005 annual meeting of stockholders under the caption "Independent Public Accountants" is incorporated herein by reference.

### PART IV

### ITEM 15 - EXHIBITS, FINANCIAL STATEMENT SCHEDULES

- (a) The following documents are filed as part of this report or incorporated herein by reference.
  - 1. Financial Statements.

(See Index to Consolidated Financial Statements at page F-1.)

2. Supplemental Schedule.

Financial Statement Schedules are omitted because they are inapplicable or the required information is otherwise included in the accompanying Financial Statements and the notes thereto.

3. Exhibits.

	SEC		
Exhibit #	Reference #	<u>Title of Document</u>	<u>Location</u>
1	3	Articles of Restatement of the Articles of Incorporation	See Original Filing
2	3	Articles of Correction to the Restated Articles of	See Original Filing
		Incorporation	
3	3	Bylaws	Incorporated by
			Reference (1)
4	4	Rights Agreement dated as of July 30, 2004, between Utah	Incorporated by
		Medical Products, Inc., and Registrar and Transfer Company	Reference (2)
5	4	Designation of Rights, Privileges, and Preferences of Series	Incorporated by
		"A" Preferred Stock	Reference (1)
6	10	Employment Agreement dated December 21, 1992 with	Incorporated by
		Kevin L. Cornwell*	Reference (3)
7	10	Amendment, effective May 15, 1998, to Employment	Incorporated by
		Agreement dated December 21, 1992 with Kevin L.	Reference (3)
		Cornwell*	
8	10	Utah Medical Products, Inc., 2003 Employees' and Directors'	Incorporated by
		Incentive Plan*	Reference (4)
9	10	Loan Agreement, dated 3 July, 2002 between Utah Medical	Incorporated by
		Products, Inc and U.S. Bank National Association	Reference (5)
10	10	Revolving Promissory Note, dated July 3, 2002 by Utah	Incorporated by
		Medical Products, Inc. to U.S. Bank National Association	Reference (5)
11	10	Second Amendment to Loan Agreement, dated 30 August	Incorporated by
		2004 between Utah Medical Products, Inc. and U.S. Bank	Reference (6)
		National Association	
12	10	Summary of Officer and Director Compensation	See Original Filing
13	21	Subsidiaries of Utah Medical Products, Inc.	Incorporated by
			Reference (7)
14	23	Consent of Jones Simkins, P.C., Company's independent	This Filing
		auditors for the years ended December 31, 2004 and	-
		December 31, 2003	

### **SEC**

Exhibit #	Reference #	<u>Title of Document</u>	<b>Location</b>
15	23	Consent of Tanner LC, Company's independent	This Filing
		auditors for the year ended December 31, 2002	
16	31	Certification of CEO pursuant to Rule 13a-14(a) as adopted	This Filing
		pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	
17	31	Certification of Principal Financial Officer pursuant to Rule	This Filing
		13a-14(a) as adopted pursuant to Section 302 of the	
		Sarbanes-Oxley Act of 2002	
18	32	Certification of CEO pursuant to 18 U.S.C. §1350, as	This Filing
		Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act	
		of 2002	
19	32	Certification of Principal Financial Officer pursuant to 18	This Filing
		U.S.C. §1350, as Adopted Pursuant to Section 906 of the	
		Sarbanes-Oxley Act of 2002	

<sup>\*</sup> Management contract of compensatory plan or arrangement required to be filed pursuant to Item 14(c).

- (1) Incorporated by reference from the Company's registration statement on form S-8 filed with the Commission effective February 10, 1995.
- (2) Incorporated by reference from the Company's report on form 8-K filed with the Commission on October 1, 2004.
- (3) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2003.
- (4) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2002.
- (5) Incorporated by reference from the Company's quarterly report on form 10-Q filed with the Commission for the quarter ended June 30, 2002.
- (6) Incorporated by reference from the Company's quarterly report on form 10-Q filed with the Commission for the quarter ended September 30, 2004.
- (7) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 1999.

### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned this 19th day of July, 2005.

### UTAH MEDICAL PRODUCTS, INC.

By: \_/s/ Kevin L. Cornwell Kevin L. Cornwell Chief Executive Officer

By: /s/ Greg
A.
LeClaire
Greg A.
LeClaire
Chief
Financial
Officer

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## UTAH MEDICAL PRODUCTS, INC. CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2004, 2003 and 2002

# UTAH MEDICAL PRODUCTS, INC. Index to Consolidated Financial Statements December 31, 2004, 2003 and 2002

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### MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's internal control over financial reporting includes those policies and procedures that:

- · pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- · provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- · provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As required by Section 404 of the Sarbanes-Oxley Act of 2002, management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*.

Based on our assessment and those criteria, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2004.

The Company's independent registered public accounting firm, Jones Simkins, P.C., has audited management's assessment of the Company's internal control over financial reporting as of December 31, 2004, and their report is shown on the next pages.

By: \_/s/ <u>Kevin L.</u> <u>Cornwell</u> Kevin L. Cornwell Chief Executive Officer

By: <u>/s/ Greg</u>
A.
LeClaire

Greg A.
LeClaire
Chief
Financial
Officer

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have audited management's assessment, included in the accompanying report titled *Management's Report On Internal Control Over Financial Reporting*, that Utah Medical Products, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control-Integrated Framework* issued by the *Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. Utah Medical Products, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Utah Medical Products, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control-Integrated Framework* issued by the *Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. Also in our opinion, Utah Medical Products, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control-Integrated Framework* issued by the *Committee of Sponsoring Organizations of the Treadway Commission (COSO)*.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the December 31, 2004 consolidated financial statements of Utah Medical Products, Inc. and our report dated January 17, 2005 expressed an unqualified opinion.

\_/s/ Jones Simkins, P.C.

JONES SIMKINS, P.C. Logan, Utah January 17, 2005

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders' of Utah Medical Products, Inc.

We have audited the accompanying consolidated balance sheets of Utah Medical Products, Inc. as of December 31, 2004 and 2003 and the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the auditing standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Utah Medical Products, Inc. as of December 31, 2004 and 2003 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Utah Medical Products, Inc. internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)* and our report dated January 17, 2005 expressed an unqualified opinion.

/s/ Jones Simkins, P.C.

JONES SIMKINS, P.C. Logan Utah January 17, 2005

### INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of Utah Medical Products, Inc.

We have audited the consolidated statements of income and other comprehensive income, stockholders' equity, and cash flows of **Utah Medical Products**, **Inc.** for the year ended December 31, 2002. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of **Utah Medical Products, Inc.** for the year ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

/s/ Tanner LC

Salt Lake City, Utah January 21, 2003

### UTAH MEDICAL PRODUCTS, INC. CONSOLIDATED BALANCE SHEET

### December 31, 2004 and 2003

(In thousands)

<u>ASSETS</u>		2004	2003			
Current assets:						
Cash	\$	1,818	\$	762		
Investments, available-for-sale (note 3)		15,110		722		
Accounts receivable, net (note 2)		3,730		3,326		
Inventories (note 2)		2,859		3,268		
Prepaid expenses and other current assets		263		219		
Litigation receivable (note 13)		-		24,884		
Deferred income taxes (note 7)		750		721		
Total current assets		24,530		33,902		
Property and equipment, net (note 4)		9,058		9,005		
Goodwill		7,191		6,245		
Goodwiii		7,191		0,243		
Other intangible assets - net (note 2)		483		542		
Total assets	\$	41,262	\$	49,694		
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts payable	\$	698	\$	368		
Accrued expenses (note 2)	Ψ	3,638	Ψ	12,129		
Total current liabilities		4,336		12,497		
Total Culton nuomico		1,550		12,17		
Deferred income taxes (note 7)		769		665		
Total liabilities		5,105		13,162		
Commitments and contingencies (notes 6 and 10)		-		-		
Stockholders' equity:						
Preferred stock, \$.01 par value; 5,000 shares						
authorized, no shares issued and outstanding		-		-		
Common stock, \$.01 par value; 50,000 shares						
authorized, issued 4,105 shares in 2004 and 4,544						
shares in 2003		41		45		
Accumulated other comprehensive income		226		(260)		
Retained earnings		35,890		36,747		
Total stockholders' equity		36,157		36,532		
Total liabilities and stockholders' equity	\$	41,262	\$	49,694		

See accompanying notes to financial statements.

# UTAH MEDICAL PRODUCTS, INC. CONSOLIDATED STATEMENT OF INCOME AND COMPREHENSIVE INCOME

### Years ended December 31, 2004, 2003 and 2002

(In thousands, except per share amounts)

		2004		2003	2002
Sales, net (notes 9 and 10)	\$	26,485	\$	27,137	\$ 27,361
Cost of goods sold (notes 9 and 10)		11,419		11,245	11,598
Gross margin		15,066		15,892	15,763
Operating expenses:					
Sales and marketing		2,253		2,364	2,472
Research and development		292		288	285
General and administrative		3,262		4,726	2,464
Operating income		9,259		8,514	10,542
Other income (expense):					
Dividend and interest income		238		5	6
Royalty income		450		450	450
Interest expense		-		(47)	(36)
Other, net		6,170		24,930	34
Income before provision for income taxes		16,117		33,852	10,996
Provison for income taxes (note 7)		5,897		13,091	3,831
Net income	\$	10,220	\$	20,761	\$ 7,165
Earnings per common share (basic) (notes					
1 and 2):	\$	2.32	\$	4.59	\$ 1.46
Earnings per common share (diluted)					
(notes 1 and 2):	\$	2.19	\$	4.25	\$ 1.36
Other comprehensive income:					
Foreign currency translation net of taxes					
of \$107, \$288 and \$244	\$	222	\$	548	\$ 457
Unrealized gain on investments net of					
taxes of \$61, \$12 and \$0		157		19	-
Total comprehensive income	\$	10,599	\$	21,328	\$ 7,622
See accom	panying	notes to finance	ial state	ments.	

### <u>UTAH MEDICAL PRODUCTS, INC.</u> <u>CONSOLIDATED STATEMENT OF CASH FLOW</u>

### Years Ended December 31, 2004, 2003 and 2002

(In thousands)

	2004		2003	2002	
Cash flows from operating activities: Net income	\$	10,220	\$	20,761	\$ 7,165
Adjustments to reconcile net income to	Ф	10,220	Ф	20,701	\$ 7,103
net cash provided by operating activities:					
Depreciation and amortization		809		984	1,172
Gain on investments		(52)		(11)	1,172
Provision for (recovery of) losses on		(32)		(11)	<u>-</u>
accounts receivable		3		(93)	18
Loss on disposal of assets		5		4	-
Deferred income taxes		75		(47)	108
Tax benefit attributable to exercise of		, 3		(17)	100
stock options		446		1,108	354
(Increase) decrease in:				1,100	
Accounts receivable		(226)		36	577
Accrued interest and other receivables		(191)		257	(316)
Inventories		437		174	(168)
Prepaid expenses and other current assets		(43)		(32)	(31)
Litigation receivable		24,884		(24,884)	-
Increase (decrease) in:				, , ,	
Accounts payable		312		(291)	154
Accrued expenses		(9,220)		10,369	(377)
Net cash provided by operating activities		27,459		8,335	8,656
Cash flows from investing activities:					
Capital expenditures for:					
Property and equipment		(411)		(272)	(517)
Intangible assets		(10)		(122)	-
Purchases of investments		(22,103)		(737)	-
Proceeds from the sale of investments		8,202		98	-
Net cash paid in acquisition		(1,012)		-	-
Net cash used in investing activities		(15,334)		(1,033)	(517)
Cash flows from financing activities:					
Proceeds from issuance of common stock					
- options		1,111		882	1,113
Common stock purchased and retired		(10,692)		(2,240)	(11,787)
Common stock purchased and retired -		( - ) /		( , /	(,, -, )
options		(6)		(555)	(31)
Proceeds from note payable		-		-	4,956
Repayments of note payable		-		(4,956)	(2,501)
Dividends paid		(1,331)		-	<u> </u>
Net cash used in financing activities		(10,918)		(6,869)	(8,250)

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Effect of exchange rate changes on cash	(151)	44	26
Net increase (decrease) in cash and cash			
equivalents	1,056	477	(85)
Cash at beginning of year	762	285	370
Cash at end of year	\$ 1,818	\$ 762 \$	285

See accompanying notes to financial statements.

### UTAH MEDICAL PRODUCTS, INC. CONSOLIDATED STATEMENT OF CASH FLOW

### Years Ended December 31, 2004, 2003 and 2002

### (In thousands)

Continued

### SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

	2004	2003	2002
Cash paid during the year for:			
Income taxes	\$ 14,294	\$ 2,628	\$ 3,568
Interest	\$ -	\$ 47	\$ 25

During 2004, the Company purchased all of the oustanding stock of Abcorp Medical, Inc. The Company paid cash and recorded net assets from the acquisition as follows:

Cash	\$ 11
Accounts receivable	127
Inventory	25
Prepaid insurance	19
Equipment, net	16
Accounts payable	(96)
Accrued expenses	(25)
Goodwill	946
Total cash paid	1,023
Less cash received	(11)
Net cash investment	\$ 1,012

See accompanying notes to financial statements.

### UTAH MEDICAL PRODUCTS, INC. CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

### Years Ended December 31, 2004, 2003 and 2002

(In thousands)

	Common Shares	on Stock Amount		Additional Paid-in Capital		Accumulated Other Comprehensive Income			Retained Earnings		Total Stockholders' Equity	
Balance at January 1, 2002	5,029	\$	50	\$	_	\$	(1,816)	\$	19,973	\$	18,207	
Shares issued upon	3,027	Ψ	30	Ψ	_	Ψ	(1,010)	Ψ	17,773	Ψ	10,207	
exercise of employee												
stock options for cash	137		1		1,112		-		-		1,113	
Shares received and												
retired upon exercise	(2)				(2.1)						(21)	
of stock options	(2)		-		(31)		-		-		(31)	
Tax benefit attributable												
to appreciation of stock options	_		_		354						354	
Common stock	_		-		334		-		-		334	
purchased and retired	(721)		(7)		(1,435)		_		(10,345)		(11,787)	
Foreign currency	(121)		(,)		(1,100)				(10,5 15)		(11,707)	
translation adjustment	_		_		_		701		_		701	
Net income	-		-		-		-		7,165		7,165	
Balance at December												
31, 2002	4,443	\$	44	\$	-	\$	(1,115)	\$	16,793	\$	15,722	
Shares issued upon												
exercise of employee												
stock options for cash	299		3		2,465		-		-		2,468	
Shares received and												
retired upon exercise	(4.0.4)											
of stock options	(101)		(1)		(2,141)		-		-		(2,142)	
Tax benefit attributable												
to appreciation					1 100						1 100	
of stock options	-		-		1,108		-		-		1,108	
Common stock purchased and retired	(07)		(1)		(1.422)				(907)		(2.240)	
Foreign currency	(97)		(1)		(1,432)		-		(807)		(2,240)	
translation adjustment	_		_				836				836	
Unrealized holding gain	_		_		_		030		_		650	
from investments,												
available-for-sale, net of												
taxes	_		_		_		19		_		19	
Net income	-		-		-		-		20,761		20,761	
Balance at December												
31, 2003	4,544	\$	45	\$	_	\$	(260)	\$	36,747	\$	36,532	
	123		1		1,234		-		-		1,235	

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Shares issued upon							
_							
exercise of employee							
stock options for cash							
Shares received and							
retired upon exercise							
of stock options	(5)	(0)	(124)	_	-		(124)
Tax benefit attributable							
to appreciation							
of stock options	_	_	446	-	_		446
Common stock							
purchased and retired	(557)	(5)	(1,556)	-	(9,130	)	(10,691)
Foreign currency							
translation adjustment	-	-	-	329	-		329
Unrealized holding gain							
from investments,							
available-for-sale, net of							
taxes	-	_	_	157	-		157
Common stock							
dividends	-	-	-	-	(1,947	)	(1,947)
Net income	-	_	_	_	10,220		10,220
Balance at December					, -		
31, 2004	4,105	\$ 41	\$ -	\$ 226	\$ 35,890	\$	36,157
,	.,	,	т	20	+ 22,070	Ψ	20,12.

See accompanying notes to financial statements.

### Note 1 - Summary of Significant Accounting Policies

### **Organization**

Utah Medical Products, Inc. and its wholly owned subsidiaries, principally Utah Medical Products Ltd., which operates a manufacturing facility in Ireland, and Columbia Medical, Inc., (the Company) are in the business of producing specialized devices for the healthcare industry. The Company's broad range of products includes those used in critical care areas and the labor and delivery departments of hospitals, as well as outpatient clinics and physicians' offices. Products are sold in both domestic U.S. and international markets.

### Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although actual results could differ from those estimates, management believes it has considered and disclosed all relevant information in making its estimates that materially affect reported performance and current values.

### **Principles of Consolidation**

The consolidated financial statements include those of the Company and its subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

#### Cash and Cash Equivalents

For purposes of the consolidated statement of cash flows, the Company considers cash on deposit and short-term investments with original maturities of three months or less to be cash and cash equivalents.

#### Investments

The Company classifies its investments as "available for sale." Securities classified as "available for sale" are carried in the financial statements at fair value. Realized gains and losses, determined using the specific identification method, are included in operations; unrealized holding gains and losses are reported as a separate component of accumulated other comprehensive income. Declines in fair value below cost that are other than temporary are included in operations.

### Concentration of Credit Risk

The primary concentration of credit risk consists of trade receivables. In the normal course of business, the Company provides credit terms to its customers. Accordingly, the Company performs ongoing credit evaluations of its customers and maintains allowances for possible losses which, when realized, have been within the range of management's expectations as reflected by its reserves.

The Company's customer base consists primarily of hospitals, medical product distributors, physician practices and others directly related to healthcare providers. Although the Company is affected by the well-being of the global healthcare industry, management does not believe significant trade receivable credit risk exists at December 31, 2004.

The Company maintains its cash in bank deposit accounts, which at times, may exceed federally insured limits in addition to Fidelity Investments accounts. The Company has not experienced any losses in such accounts and believes it is not exposed to a significant credit risk on cash and cash equivalent balances.

### Note 1 - Summary of Significant Accounting Policies (continued)

### **Inventories**

Finished products, work-in-process, raw materials and supplies inventories are stated at the lower of cost (computed on a first-in, first-out method) or market (see Note 2).

### **Property and Equipment**

Property and equipment are stated at cost. Depreciation and amortization are computed using the straight-line and units-of-production methods over estimated useful lives as follows:

Building and improvements 30-40

years

Furniture, equipment and tooling 3-10

years

### **Long-Lived Assets**

The Company evaluates its long-lived assets in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, "Accounting for the Impairment of Long-Lived Assets." Long-lived assets held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, the Company compares the projected undiscounted future cash flows associated with the related asset or group of assets over their estimated useful lives against their respective carrying amounts. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets and is recorded in the period in which the determination was made.

### **Intangible Assets**

Costs associated with the acquisition of patents, trademarks, license rights and non-compete agreements are capitalized and are being amortized using the straight-line method over periods ranging from 5 to 17 years. UTMD's goodwill is tested for impairment annually, in the fourth quarter of each year, using a fair value measurement test, in accordance with SFAS 142. UTMD would also perform an impairment test, between annual tests, if circumstances changed that would more than likely reduce the fair value of goodwill below its net book value. If UTMD determined its goodwill were impaired, a second step would be completed to measure the amount of the impairment loss. UTMD does not expect its goodwill to become impaired in the foreseeable future.

### **Loans to Related Parties**

The Company has not made loans to related entities including employees, directors, shareholders, suppliers or customers, nor does it guarantee the debt of related entities.

### Revenue Recognition

The Company believes that revenue should be recognized at the time of shipment as title generally passes to the customer at the time of shipment. Revenue recognized by UTMD is based upon documented arrangements and fixed contracts in which the selling price is fixed prior to completion of an order. Revenue from product and service sales is generally recognized at the time the product is shipped or service completed and invoiced, and collectibility is reasonably assured. There are circumstances under which revenue may be recognized when product is not shipped, all of which meet the criteria of SAB 104:

1) The Company provides engineering services, for example, design and production of manufacturing tooling that may be used in subsequent UTMD manufacturing of custom components for other companies. This revenue is recognized when UTMD's service has been completed according to a fixed contractual agreement.

### Note 1 - Summary of Significant Accounting Policies (continued)

- 2) The Company manufactures products for other companies (OEM customers) according to fixed longer term supply contracts which are not cancelable or changeable. Occasionally, an OEM customer will request the Company to bill completed products according to the contract, but hold shipment for some business purpose of the customer (e.g. awaiting some mating component from another supplier).
- 3) The Company manufactures products for foreign companies according to fixed contracts which are not cancelable or changeable. Occasionally, a foreign customer under a prepay obligation will request the Company to bill completed products according to the contract, but hold shipment until payment will be made.

### **Income Taxes**

The Company accounts for income taxes under SFAS No. 109, "Accounting for Income Taxes," whereby deferred taxes are computed under the asset and liability method.

### **Legal Costs**

The Company has been involved in lawsuits which are an expected consequence of its operations and in the ordinary course of business. The Company is currently involved in litigation with the FDA which it does not consider an expected consequence of its operations, or in the ordinary course of its business. The Company maintains a reserve for legal costs consistent with its previous experience and anticipated costs. The reserve for legal costs at December 31, 2004 and 2003 was (in thousands) \$1,260 and \$1,050, respectively (see Note 2).

### Earnings per Share

The computation of basic earnings per common share is based on the weighted average number of shares outstanding during each year.

The computation of earnings per common share assuming dilution is based on the weighted average number of shares outstanding during the year plus the weighted average common stock equivalents which would arise from the exercise of stock options outstanding using the treasury stock method and the average market price per share during the year.

The shares (in thousands) used in the computation of the Company's basic and diluted earnings per share are reconciled as follows:

	2004	2003	2002
Weighted average number of shares outstanding - basic	4,399	4,526	4,913
Dilutive effect of stock options	276	359	350
Weighted average number of shares outstanding,			
assuming dilution	4,675	4,885	5,263

### Note 1 - Summary of Significant Accounting Policies (continued)

### **Stock-Based Compensation**

At December 31, 2004, the Company has stock-based employee compensation plans, which are described more fully in Note 8. The Company accounts for those plans under the recognition and measurement principles of APB Opinion 25, "Accounting for Stock Issued to Employees," and related Interpretations, and has adopted the disclosure-only provisions of SFAS 123, "Accounting for Stock-Based Compensation." Accordingly, no compensation cost has been recognized in the financial statements, as all options granted under those plans had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant.

Starting July 1, 2005, in accordance with SFAS 123 (revised 2004), the Company will be required to begin recognizing compensation cost related to its stock option plans. Please see note 14, below.

Had compensation cost for the Company's stock option plans been determined based on the fair value at the grant date for awards starting in 1995 consistent with the provisions of SFAS 123, the Company's net earnings and earnings per share would have been reduced to the pro forma amounts indicated below (in thousands, except per share amounts):

	Years ended December 31,					
	2004		2003		2002	
Net income as reported	\$	10,220	\$	20,761	\$	7,165
Deduct:						
Total stock-based employee compensation expense						
determined under fair value based method for all						
awards, net of related tax effects		(388)		(178)		(175)
Net income pro forma	\$	9,832	\$	20,583	\$	6,990
Earnings per share:						
Basic - as reported	\$	2.32	\$	4.59	\$	1.46
Basic - pro forma	\$	2.24	\$	4.55	\$	1.42
Diluted - as reported	\$	2.19	\$	4.25	\$	1.36
Diluted - pro forma	\$	2.10	\$	4.21	\$	1.33

### Translation of Foreign Currencies

Assets and liabilities of the Company's foreign subsidiary are translated into U.S. dollars at the applicable exchange rates at year-end. Net gains or losses resulting from the translation of the Company's assets and liabilities are reflected as a separate component of stockholders' equity. A negative translation impact on stockholders' equity reflects a current relative U.S. Dollar value higher than at the point in time that assets were actually acquired in a foreign currency. A positive translation impact would result from a U.S. dollar weaker in value than at the point in time foreign assets were acquired.

Income and expense items are translated at the weighted average rate of exchange (based on when transactions actually occurred) during the year.

Note 2 - Detail of Certain Balance Sheet Accounts

	December 31,				
	2004		2003		
Account receivable (in thousands):					
Receivables	\$ 3,636	\$	3,373		
Accrued interest and other	171		27		
Less allowance for doubtful accounts	(77)		(74)		
	\$ 3,730	\$	3,326		
Inventories (in thousands):					
Finished products	\$ 932	\$	1,495		
Work-in-process	640		631		
Raw materials	1,287		1,142		
	\$ 2,859	\$	3,268		
Other intangible assets (in thousands):					
Patents	2,025		2,015		
License rights	293		293		
Trademarks	224		224		
Non-compete agreements	175		175		
	2,717		2,707		
Accumulated amortization	(2,234)		(2,165)		
	\$ 483	\$	542		
Accrued expenses (in thousands):					
Income taxes payable	\$ 384	\$	9,270		
Payroll and payroll taxes	963		1,479		
Reserve for litigation costs	1,260		1,050		
Dividends payable	616		-		
Other	415		330		
	\$ 3,638	\$	12,129		

# Note 3 - Investments

The Company's investments, classified as available-for-sale consist of the following (in thousands):

	December 31,						
		2004		2003			
Investments, at cost	\$	14,822	\$		691		
Equity Securities:							
-Unrealized holding gains		295			31		
-Unrealized holding (losses)		(7)			0		
Investments, at fair value	\$	15,110	\$		722		

# Note 3 - Investments (continued)

Changes in the unrealized holding gain on investment securities available-for-sale and reported as a separate component of accumulated other comprehensive income are as follows (in thousands):

	December 31,						
		2004		2003			
Balance, beginning of year	\$	19	\$		-		
Gross unrealized holding gains, net of (losses),							
in equity securities		257			31		
Deferred income taxes on unrealized holding							
gain		(100)			(12)		
Balance, end of year	\$	176	\$		19		

UTMD held available-for-sale investments in municipal debt securities with the following maturities and amounts:

December 31

	Beccineer 51,						
	2004		2003				
Maturity less than 1 year	\$ 9,081	\$		_			
Maturity greater than 10 years	1,475			-			

During 2004 and 2003 UTMD had proceeds from sales of available-for-sale securities of \$8,202 and \$98, respectively and associated realized gains of \$52 and \$11, respectively. UTMD uses the specific identification method to calculate its realized gains. UTMD did not have sales of available-for-sale securities in 2002.

# Note 4 - Property and Equipment

Property and equipment consists of the following (in thousands):

	2004	2003
Land	\$ 1,089 \$	1,052
Buildings and improvements	9,283	8,738
Furniture, equipment and tooling	13,763	13,966
Construction-in-progress	41	111
	24,176	23,867
Accumulated depreciation and amortization	(15,118)	(14,862)
	\$ 9,058 \$	9,005

Included in the Company's consolidated balance sheet are the assets of its manufacturing facilities in Utah, Oregon and Ireland. Property and equipment, by location, are as follows (in thousands):

	December 31, 2004										
	Ţ	Utah		Utah		Oregon		Ireland		Total	
Land	\$	621	\$	-	\$	468	\$	1,089			
Building and											
improvements		4,234		32		5,017		9,283			
Furniture, equipment											
and tooling		11,627		1,245		891		13,763			

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Construction-in-progress	41	_	-	41
Total	16,523	1,277	6,376	24,176
Accumulated				
depreciation and				
amortization	(12,224)	(1,271)	(1,623)	(15,118)
Property and equipment,				
net	\$ 4,299	\$ 6	\$ 4,753	\$ 9,058

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Note 4 - Property and Equipment (continued)

	Utah	December Oregon	: 31,	2003 Ireland	d Total		
Land	\$ 621	\$ -	\$	431	\$	1,052	
Building and							
improvements	4,082	32		4,624		8,738	
Furniture, equipment							
and tooling	11,901	1,245		820		13,966	
Construction-in-progress	111	-		-		111	
Total	16,715	1,277		5,875		23,867	
Accumulated depreciation and							
amortization Property and equipment,	(12,221)	(1,267)		(1,374)		(14,862)	
net	\$ 4,494	\$ 10	\$	4,501	\$	9,005	

#### Note 5 - Note Payable

The Company has an unsecured bank line-of-credit agreement which allows the Company to borrow up to a fixed maximum amount (in thousands) of \$5,000 at an interest rate equal to either the bank's LIBOR rate plus 1.25%, the bank's prime rate less 1.00%, or a daily rate based on LIBOR plus 1.35%. The line-of-credit-balance matures on May 31, 2006 and had an outstanding balance of \$0 at both December 31, 2004 and 2003. The principal financial loan covenants are a restriction on the total amount available for borrowing to 1.25 times the last twelve months' EBITDA, which as of December 31, 2004 and 2003 was equal to (in thousands) \$21,158 and \$43,506, respectively, and a requirement to maintain a net worth in excess of \$10 million, which at the end of 2004 and 2003 was (in thousands) \$36,157 and \$36,532, respectively.

#### Note 6 - Commitments and Contingencies

#### **Operating Leases**

The Company has a lease agreement for land adjoining its Utah facility for a term of forty years commencing on September 1, 1991. On September 1, 2001 and subsequent to each fifth lease year, the basic rental was and will be adjusted for published changes in a price index. The Company also leases its CMI building in Oregon under a two-year non-cancelable operating lease. Rent expense charged to operations under these operating lease agreements was approximately (in thousands) \$107, \$105 and \$104 for the years ended December 31, 2004, 2003 and 2002, respectively.

Future minimum lease payments under its lease obligations as of December 31, 2004 were as follows (in thousands):

Years ending December 31:	An	nount
2005	\$	107
2006		66

2007	37
2008	37
2009	37
Thereafter	808

Total future minimum lease payments \$ 1,092

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# Note 6 - Commitments and Contingencies (continued)

#### **Product Liability**

The Company is self-insured for product liability risk. "Product liability" is an insurance industry term for the cost of legal defense and possible eventual damages awarded as a result of use of a company's product during a procedure that results in an injury of a patient. The Company maintains a reserve for product liability litigation and damages consistent with its previous long-term experience. Actual product liability litigation costs and damages during the last three reporting years have been immaterial which is consistent with the Company's overall history.

The Company absorbs the costs of clinical training and trouble-shooting in its on-going operating expenses.

## Warranty Reserve

UTMD maintains a warranty reserve to provide for estimated costs which are likely to occur. The amount of this reserve is adjusted, as required, to reflect its historical experience. The following table summarizes changes to UTMD's warranty reserve during 2004 (in thousands):

Beginning Balance, January 1, 2004	\$ 30
Changes in Warranty Reserve during 2004:	
Aggregate reductions for warranty repairs	(7)
Aggregate changes for warranties issued during reporting	
period	13
Aggregate changes in reserve related to preexisting	
warranties	24
Ending Balance, December 31, 2004	\$ 60

### Litigation

The Company has been involved in lawsuits which are an expected consequence of its operations and in the ordinary course of business. There are no such lawsuits currently pending. With respect to the FDA's August 2004 lawsuit against UTMD, seeking to enjoin the Company from manufacturing and shipping products until it conforms with the QSR in a manner acceptable to the FDA, the Company has applied its accounting policy to accrue legal costs that can be reasonably estimated. Accordingly UTMD created a litigation cost reserve included in current liabilities that reflects its estimate of an additional approximately \$1,000 (in thousands) in litigation costs that will be incurred through June 2005, at which time the Company expects the lawsuit to be resolved. The Company has always strongly maintained that it is in substantial compliance with all government regulations. If the U.S. Court disagrees with the Company or if the adjudication of the matter extends beyond June 2005, the Company is unable to estimate its possible costs and there may be a materially adverse effect on the Company's financial condition or results of operations. Alternatively, if the U.S. Court agrees with it and dismisses the FDA claims, the Company may have the opportunity to seek restitution of its litigation costs and damages.

### Irish Development Agency

In order to satisfy requirements of the Irish Development Agency in assisting the start-up of its Ireland subsidiary, the Company agreed to invest certain amounts and maintain a certain capital structure in its Ireland subsidiary. The effect of these financial relationships and commitments are reflected in the consolidated financial statements and do not represent any significant credit risk that would affect future liquidity.

#### Note 7 - Income Taxes

Deferred tax assets (liabilities) consist of the following temporary differences (in thousands):

	December 31,								
	20	004		2003					
	Current		Long-term		Current		Long-term		
Inventory write-downs and differences									
due to UNICAP	\$ 73	\$	-	\$	169	\$	-		
Allowance for doubtful accounts	30		-		29		-		
Accrued liabilities and reserves	641		23		523		12		
Other	6		(42)		-		22		
Depreciation and amortization	-		161		-		164		
Earnings from subsidiary	-		(911)		-		(863)		
Deferred income taxes, net	\$ 750	\$	(769)	\$	721	\$	(665)		

The components of income tax expense are as follows (in thousands):

	Years ended December 31,					
	2004		2003		2002	
Current	\$ 5,822	\$	13,138	\$	3,715	
Deferred	75		(47)		116	
Total	\$ 5,897	\$	13,091	\$	3,831	

Income tax expense differed from amounts computed by applying the statutory federal rate to pretax income as follows (in thousands):

	Years ended December 31,					
		2004	2003		2002	
Federal income tax expense at the statutory rate	\$	5,480	\$	11,510	\$	3,738
State income taxes		806		1,693		482
ETI, foreign sales corporation and tax credits		(164)		(68)		(182)
Other		(225)		(44)		(207)
Total	\$	5,897	\$	13,091	\$	3,831

#### Note 8 - Options

The Company has stock option plans which authorize the grant of stock options to eligible employees, directors and other individuals to purchase up to an aggregate of 1,014,226 shares of common stock, of which 755,526 are outstanding as of December 31, 2004. All options granted under the plans are granted at current market value at date of grant, and may be exercised between six months and ten years following the date of grant. The plans are intended to advance the interest of the Company by attracting and ensuring retention of competent directors, employees and executive personnel, and to provide incentives to those individuals to devote their utmost efforts to the advancement of the Company. Changes in stock options were as follows:

## Note 8 - Options (continued)

2004	<u>Shares</u>	Price Range Per Share
Granted	164,100	\$18.00\$25.59 -
Expired or canceled	44,767	6.75 25.59
Exercised	122,908	6.50 17.71
Total outstanding at December 31	755,526	6.50 25.59
Total exercisable at December 31	554,727	6.50 24.02
2003		
Granted	82,200	\$17.71 \$24.02 -
Expired or canceled	12,562	6.75 17.71
Exercised	298,852	6.50 15.01
Total outstanding at December 31	759,101	6.50 24.02
Total exercisable at December 31	625,859	6.50 14.60
2002		
Granted	74,100	\$14.60\$15.01 -
Expired or canceled	31,574	6.50 15.01
Exercised	137,089	6.50 14.25
Total outstanding at December 31	988,315	6.50 15.01
Total exercisable at December 31	870,414	6.50 14.25

For the years ended December 31, 2004, 2003 and 2002, the Company reduced current income taxes payable and increased additional paid-in capital by (in thousands) \$446, \$1,109 and \$354, respectively, for the income tax benefit attributable to sale by optionees of common stock received upon the exercise of stock options.

# **Stock-Based Compensation**

The Company has adopted the disclosure-only provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," as described in Note 1.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Years ended December 31,				
	2004	2002			
Expected dividend yield	0.7%	-	-		
Expected stock price volatility	39.0%	40.5%	41.7%		
Risk-free interest rate					
(weighted average)	3.7%	3.5%	4.3%		
Expected life of options	6.2 years	5.9 years	5.2 years		

The per-share weighted average fair value of options granted during 2004, 2003 and 2002 is \$10.07, \$8.89 and \$6.52, respectively.

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## Note 8 - Options (continued)

## Stock-Based Compensation (continued)

The following table summarizes information about stock options outstanding at December 31, 2004:

	(	Options Outstanding Weighted Average Remaining Weighted				xerci	sable Weighted
Range of Contractual Average Average						•	
Exercise	Number	Life	Life Exercise Number Ex			Exercise	
Prices	Outstanding	(Years)		Price	Exercisable		Price
\$ 6.50 - 7.25	276,052	3.71	\$	6.83	276,052	\$	6.83
9.125 - 15.01	280,068	2.97		12.81	260,510		12.72
17.71 - 25.59	199,406	9.03		22.72	18,165		20.32
\$ 6.50 - 25.59	755,526	4.84	\$	13.24	554,727	\$	10.04

## Note 9 - Geographic Sales Information

The Company had sales in the following geographic areas (in thousands):

	Unite	ed States	Europe	Other		
2004	\$	20,452 \$	3,639 \$	2,394		
2003		21,266	3,376	2,495		
2002		21,626	3,337	2,398		

### Note 10 - Revenues by Product Category

The Company had revenues in the following product categories (in thousands):

Product Category	2004	2003	2002
Obstetrics	\$ 10,917	\$ 11,435	\$ 11,977
Gynecology/Electrosurgery/Urology	5,142	5,324	5,271
Neonatal	4,134	4,142	3,852
Blood Pressure Monitoring and			
accessories	6,292	6,236	6,261

## Note 11 - Product Sale and Purchase Commitments

The Company has license agreements for the rights to develop and market certain products or technologies owned by unrelated parties. The confidential terms of such agreements are unique and varied, depending on many factors relating to the value and stage of development of the technology licensed. Royalties on future product sales are a normal component of such agreements and are included in the Company's cost of goods sold on an ongoing basis.

The Company has in the past received and continues to receive royalties as a result of license agreements with unrelated companies that allow exclusive or nonexclusive rights to the Company's technology.

#### Note 12 - Employee Benefit Plan

The Company has a contributory 401(k) savings plan for employees, who are at least 21 years of age, work 30 hours or more each week, and have a minimum of one year of service with the Company. The Company's contribution is determined annually by the board of directors. Company contributions were approximately (in thousands) \$92, \$95 and \$94 for the years ended December 31, 2004, 2003 and 2002, respectively.

#### Note 13 - Fair Value Financial Instruments

None of the Company's financial instruments, which are current assets and liabilities that could be readily traded, are held for trading purposes, except investments. Detail on investments is provided in note 3, above. The Company estimates that the fair value of all financial instruments at December 31, 2004, does not differ materially from the aggregate carrying value of its financial instruments recorded in the accompanying consolidated balance sheet.

## Note 14 - Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 123 (revised 2004), "Accounting for Stock Based Compensation." This statement supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." This revised statement establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods and services, including the grant of stock options to employees and directors. The statement is effective for periods beginning after June 15, 2005, and will require the Company to recognize compensation cost based on the grant date fair value of the equity instruments it awards. The Company currently accounts for those instruments under the recognition and measurement principles of APB Opinion 25, including the disclosure-only provisions of the original SFAS 123. Accordingly, no compensation cost from issuing equity instruments has been recognized in the Company's financial statements. The Company estimates that the required adoption of SFAS 123 (R) in third quarter 2005 will have a negative impact on its consolidated financial statements. Please see note 1 for an estimate of the impact this statement would have had on the Company's net income for the periods covered by this report.