



Over 100,000 PIE* Therapy Procedures have been performed with no reports of injury!

Dear Medical Professionals:

We are pleased to provide you with this package of information that should help you with the following:

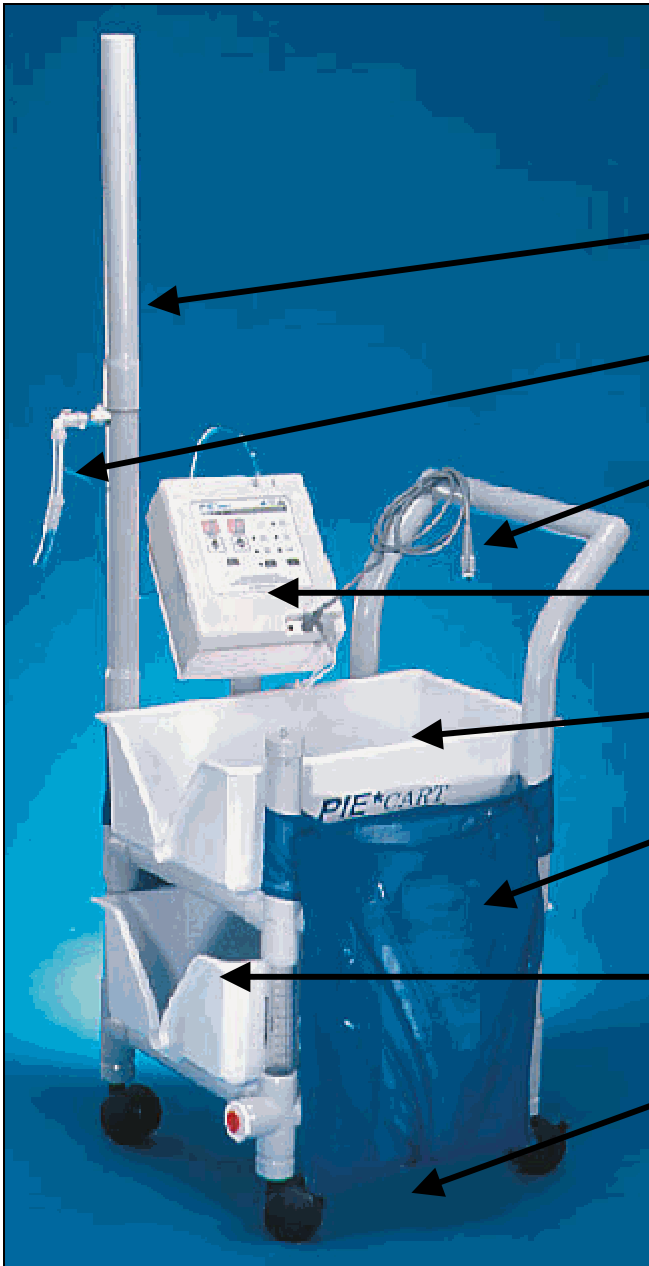
1. Feeling secure in writing an order for a Patient who needs the PIE* Therapy long-term, rehabilitative bowel failure, colonoscopy prep, megacolon reduction, fecal impaction removal or general chronic conditions. (Brief clinical study summaries enclosed.)
2. To know that the PIE* Therapy has been fully clinically published as to its safety.
3. Discover from the "Testimonials" that PIE* Therapy has changed the working conditions, improved patient compliance and provide the ability for patient's early discharge from Institutional Care.
4. The PIE* Therapy is a billable under DRG Codes, (564.0) Constipation, (560.39) Fecal Impaction and (560.39) Other --Neurogenic Bowel ICD9 564.81 -- and has a CPT Code 91123.
5. That efficiency studies have indicated the use of the PIE* Therapy in Institutions has resulted in reducing nursing time.

We are also including CMN forms and our current price list.

Sincerely

Roy Abell, President
PIE* Medical International, Inc.
888-878-8222
royabell@piemed.com e-mail

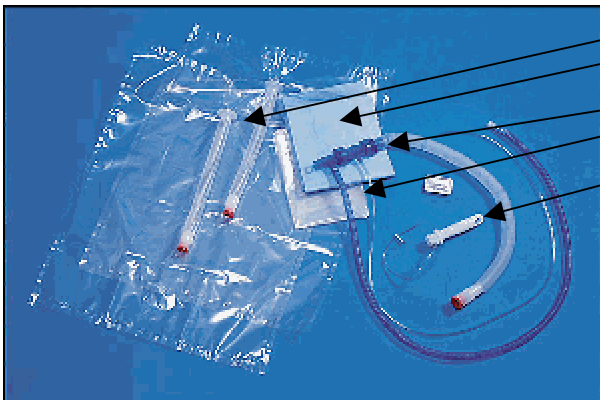
Michael Hardy, RN, Executive VP of Medical Coordination
Bowel Therapy Systems, Inc.
800-359-4405 Mobile
mhardy@piemed.com



PIE* System Model 2005

- Safety pressure relief tower keeping water pressure below 2.5 PSI.
- Patented valve that creates the gentle pulsing activity of the inflow water.
- Remote control button for caregiver or patient to control the inflow and
- PIE* Computer Control that automatically manages the pulsing
- Top tray for holding waste and wastewater disposable bag.
- Storage bag for disposable components. Bag on other side holds additional parts.
- Lower tray for holding fresh water bag.
- 18" X 18" square base. Rolls easily and can be stored in a closet.

Photo of 1 Disposable PiePak used for each Procedure. (15 to a Case)



- 30 - Water bags for waste and freshwater.
- 15 - Bed Protective Pads
- 15 - Valve Assembly with Hoses.
- 15 - Total containment bags
- 15 - Speculums with inflation retention cuffs.

Over 100,000 PIE* Procedures have been performed with no reports of injury!

Certificate of Medical Necessity

For Pulsed Irrigation Therapy* of the Colon

I Certify the Medical Necessity and Urgency of Pulsed Irrigation Therapy (PIE*)
as the Required Therapy for my Patient.

PIE* Therapy is required for this patient due to inadequate results from all other Bowel Therapy
options. PIE* Therapy is being prescribed to treat this patient's diagnosed condition
and is not for the patient's convenience or preference.

Patient's Name _____ S.S.# _____ Birth Date _____

Address _____

Lives at home? Y N If No, where does patient live? _____

Spouse and/or Parent's Name _____ Telephone _____

Medicaid No. _____ Insurance ID # _____

Insurance Co: _____ Contact _____ Tel. # _____

Primary Diagnosis _____

Secondary Diagnoses _____

Neurogenic Bowel (ICD 9 code 564.81) Yes No

HCFA Codes: E0350 and E0352. PIE* Products are FDA Certified as a Class II Medical Devices.

Due to the patient's permanent condition and since other therapies are no longer providing
acceptable results, there is sufficient clinical and case evidence that the PIE* Therapy has
produced repeated successful results with other patients; I prescribe the PIE* Therapy to be
performed as follows:

1 procedure every 2 days for ___ months.

1 procedure every 2 days from this day forward for life.

I prescribe the home therapy system (1) PIE* Therapy Control Unit (E0350) and (15) monthly
PIE* Therapy disposable kits (E0352) to perform the necessary therapy.

Physician Name (Print) _____ Attending Primary Consulting

Address _____ City _____ State _____ Zip _____

Phone _____ UPIN# _____ Fed. ID# _____

Physician's Signature _____ M.D. Date _____

For patient's history and additional information please see CMN Attachment "A".

(For more information on the PIE* Therapy, please go to <http://www.boweltherapy.com>)

Certificate of Medical Necessity - Attachment "A"

Bowel Care Summary for: _____ **Date** _____

S.S.# _____ **Birth Date** _____

Bowel Treatments Implemented: Results:

- Fluids, Fiber, Softeners _____
- Digital Stimulation _____
- Suppositories, Oral Cathartics _____
- Enemas _____
- Bowel Training _____
- Manual Removal _____

Current Treatment Options to Meet Bowel Evacuation Requirements:

Additional Comments:

Additional health complication(s) relating to patient's bowel dysfunction (Check all that applies):

- Decubitus ulcer(s) Recurrent UTI Electrolyte imbalance Dehydration Hemorrhoids mega colon Autonomic dysreflexia Frequent ER/office visits Other _____

As a result of improper bowel elimination, the patient's health is:

Physician's Signature

PIE* Bowel Therapy Clinical Study Abstracts:

Long Term Safety of Pulsed Irrigation Evacuation (PIE) Use with Chronic Bowel Conditions. Digestive Diseases and Sciences, August 1998. Gramlich and Puet.

In order to determine the long-term effects of Pulsed Irrigation Evacuation on the colon, sigmoid/colonoscopy was performed on four patients with spinal cord injuries who have used this procedure an average of 3.5 times weekly, for an average of 6.7 years. No gross or microscopic abnormalities were identified in any of these individuals. Impactions as well as other complaints were markedly diminished or absent following the initiation of PIE* Bowel Therapy. Pulsed Irrigation Evacuation is a safe and effective method for long-term treatment of chronic neurogenic bowel.

Use of Pulsed Irrigation Evacuation in the Management of the Neuropathic Bowel. International Sciences of Paraplegia, 1997. Puet, Jackson and Amy.

Management of the neuropathic bowel is one of the major issues in the treatment of patients with severe spinal cord injury (SCI). Pulsed Irrigation Evacuation (PIE) has been evaluated in several small studies for the clearing of fecal impactions in patients with a neuropathic bowel. Three Hundred, ninety-eight PIE procedures performed on inpatients and outpatients at Hillside Rehabilitation Hospital were evaluated. PIE Bowel Therapy has proven to be both safe and effective in a wide variety of patients with neuropathic bowel, and is a useful addition to traditional methods of bowel management.*

Treatment of Fecal Impaction with Pulsed Irrigation Enhanced Evacuation. Dis Colon Rectum, February 1994. Kokoszka, Nelson, Falconio and Abcarian.

A new method of treating fecal impaction, Pulsed Irrigation Evacuation, is described. Individuals were selected for treatment based on evidence of massive fecal impaction on physical examination or abdominal x-ray and would otherwise have required operative disimpaction. Fourteen individuals were treated for fecal impaction. The patients ranged in age from 13 to 86 years. Only one patient required intravenous sedation, an elderly patient with Alzheimer's disease. The treatment was successful in each case, although repeated treatment was often necessary. No morbidity arose from the treatment. By the midpoint of the study PIE Bowel Therapy was so effective no patient required hospitalization for impaction. These PIE* Procedures demonstrate that Pulsed Irrigation Evacuation, PIE* Bowel Therapy is a simple, quick and effective treatment for severe fecal impaction.*

New Treatment for Rectal Impaction in Children: An Efficacy, Comfort and Safety Trial of the Pulsed Irrigation Enhanced Evacuation Procedure. Journal of Pediatric Gastroenterology and Nutrition, 1994. Gilger, Wagner, Barrish, McCarroll and Healy.

To determine the efficacy, comfort and safety of the pulsed irrigation enhanced evacuation (PIEE) procedure in children, 27 procedures performed on 24 consecutive children were evaluated. Sixteen boys and 8 girls, 4-15 years old (mean 8.7) with chronic constipation, encopresis and rectal impaction made up the test group. Children with known heart, lung or neurological diseases

were excluded. Temperature, pulse, respiratory rate and blood pressure were obtained prior to, during and immediately after the procedure. Abdominal radiographs were obtained before and after the procedure and a single radiologist estimated the degree of disimpaction. Patients graded the discomfort of the procedure at the time of speculum insertion and every 15 minutes. Serum sodium, potassium, chloride and bicarbonate values were obtained before and immediately after and 90 minutes after the procedure and compared by paired Student analysis. In conclusion, the PIE* Bowel Therapy procedure successfully disimpacted all patients either immediately or within hours of completion. Patients accepted the procedure well and no clinically significant electrolyte changes were noted. This new method of rectal disimpaction appears to be safe, effective and acceptable to children.

Pulsed Irrigation Enhanced Evacuation: New Method for Treating Fecal Impaction. Arch Phys Med Rehabil, October 1991. Puet, Phen and Hurst.

Fecal impaction is a common problem in patients with neurological impairment. The Pulsed Irrigation Evacuation (PIE) procedure is a new method of clearing fecal impactions using pulses of warm water in controlled amounts to hydrate stool and improve peristalsis. Thirty-seven PIE Bowel Therapy procedures were performed on 28 patients with a variety of neurological problems. The PIE* procedure was observed to be effective and safe. It should be useful adjunct to a proper bowel management program.*

Per-rectal Pulsed Irrigation Versus Per-oral Colonic Lavage for Colonoscopy Preparation: A Randomized, Controlled Trial. Gastrointestinal Endoscopy, 1991. Chang, Erickson, Schandler, Coye, and Moody.

The aim of this study was to compare the efficacy and patient tolerance of a new Pulsed Irrigation Evacuation system to colonic lavage for colonoscopy preparation. Thirty-four prospective patients scheduled for routine colonoscopy were randomized to one of two preparations: a per-rectal Pulsed Irrigation Evacuation, PIE Bowel Therapy device (18 patients) versus per-oral colonic lavage (15 patients). Colonoscopy preparation was assessed on a 0 to 4 plus scale by region and overall. This was done live and by videotape by two independent endoscopists who were blinded to the patient's preparation. There was no significant difference with respect to cleanliness of the colon with Pulsed Irrigation Evacuation patients having an average of overall preparation score of 3.0 ± 0.19 (SEM) versus colonic lavage patients with a score of 3.14 ± 0.19 . There was also no statistically significant difference between the two groups with respect to demographics, time to reach the cecum, time for entire procedure, volume of aspiration or wash or sedation given. The new Pulsed Irrigation Evacuation device, PIE* Bowel Therapy, provides an alternative to the standard per-oral lavage solution for colonoscopy preparation.*

Dissolution of a Barium Impaction Ileus in a Child Using the PIEE Procedure. Journal of Pediatric Gastroenterology and Nutrition, 1995. Gilger, Wagner and Kelley.

Barium contrast examinations, utilizing either barium meal or enema, are still a common choice for visualization of the gastrointestinal tract in children. After completion of these x-ray procedures the contrast material should be thoroughly evacuated from the bowel. Residual barium sulfate remaining in the gastrointestinal tract has the potential to harden, forming true "concretions" that can become impacted. Purgatives or enemas are often given after barium studies to insure complete evacuation of the contrast material. However, once the barium impaction has formed in the colon, routine enema preparations such as Phosphosoda, oil retention, tap water and soapsuds are

frequently ineffective. Recently, the Pulsed Irrigation Evacuation (PIE) (Avatar 2000 Bowel Evacuation System, Aegis Medical, Denver, CO, U.S.A.) procedure was introduced as a simple, effective method for removal of rectal impaction in adults and children. PIE is an automated enema in which controlled pulses of warm water are delivered into the rectum, serving to hydrate feces and promote peristalsis. We report the successful evacuation of a severe barium impaction in a child with total colonic Hirschsprung's disease using the PIE Bowel Therapy Procedure.

For an efficiency study in the Institutional environment, <http://www.piemed.com/avatar.html>

Complete Clinical Studies for PIE* Bowel Therapy are available at: www.boweltherapy.com

Over 100,000 PIE* Procedures have been performed with no reports of injury!

PIE* Testimonials:

Michael Andorsky, M.D...

The Johns Hopkins University School of Medicine,
The John Hopkins Hospital, Department of Pediatrics

"As director of the John Hopkins Pediatric Bowel Management Clinic, I have used the PIE* machine to remove fecal impaction and prevent fecal incontinence in children with spina bifida...this has proved to be a valuable adjunct to their bowel maintenance...the PIE* machine has reduced the need for hospital admissions for bowel evacuation...I have used it both in the outpatient department and in the patients' home."

Mark A. Gilger, M.D.

Texas Children's Hospital

"It is my privilege to write a letter in support of the PIE*...our studies confirmed the PIE* to be safe, acceptably comfortable and most importantly, effective in removing fecal impactions in children...we also have recently confirmed the ability of the PIE* to remove serious barium impactions...we currently use the PIE* on a daily basis at Texas Children's Hospital...it is a simple alternative to expensive manual or surgical disimpaction of the rectum...I vigorously endorse the PIE* device for use in children and welcome any inquiries.

John H. Grimes, MD ...

"My patient, J.R.B., has been a paraplegic for many years...has had increasing difficulty emptying bowels and constipation of bowel impactions has frequently been a major problem for him...all standard therapies, including stool softeners, laxatives, enemas and manual disimpaction have proven ineffective...because of this, we have prescribed use of the PIE for him, and it has already proven to make a marked difference in his care."

Margaret Falconio-West, RN, BSN, CGRN, CETN

Highland Park Hospital

"I can attest to the wonderful results of patient comfort, effective bowel evacuation, and the avoidance of surgery...these surgeries, alone, can cost up to \$10,000...another beauty of the PIE* is that we were able to keep patients out of the hospital altogether, even with repeat procedures, they were treated on an outpatient basis...it is a wonderful machine...thank you for bringing it to the people that need it!"

L.H. (Parkinson's Plus)...

"I was hospitalized for 7 weeks because of an impaction and the doctor not being able to regulate my bowels...the doctor recommended the PIE...since using the PIE, I have been able to regulate

my bowel movements so that I don't have accidents, which was a common occurrence, nor have I had an impaction...without the PIE, both of these happened...doctors have tried everything with me, enemas, suppositories, laxatives, etc., but nothing ever really worked for me like the PIE. Without the use of the PIE, chances are I would have to be placed in a nursing home."

James F. Frisbie, MD

Veteran's Administration

"The PIE* proved to be a great success...positive improvement regarding vital signs...not only eliminated impaction problems...one patient after 3 weeks experienced natural peristaltic action...in past year 3 KUBs to evaluate previous distended upper colon...noticed a definite contraction and toning of the colon...in my opinion the PIE* has prevented surgery...advised continued use of the PIE* to avoid and prevent many future medical problems."

David H. Doan, MD...

"My patient, I.N., who has long standing paraplegia secondary to a previous spinal cord meningioma...has been using the PIE for the past few years...the patient's pattern of recurrent hospital admission and emergency room evaluation have essentially disappeared...the PIE has been extremely effective for this patient...effective not only on her medical care but also medical costs, and has dramatically improved her quality of life..."

Virginia Storey, R.N.

The University of Illinois Hospital at Chicago

"Since becoming acquainted with the PIE* technique, I find it viable, easily accomplished, and well tolerated by patients...therefore, I have recommended its use to physicians and nurse colleagues at other hospitals and institutions...the PIE* procedure has been used successfully on numerous patients here at our facility on an out-patient basis, thus preventing a costly, usually avoidable in-patient hospitalization."

Alexis D. Butler, RN

Director of Nursing

East Alabama Medical Center

"this is an excellent opportunity to "sing the praises" of PIE*...since we purchased the PIE*, we have used it for virtually every application it was meant to be used for: impaction removal; both inpatient and outpatient (75%), bowel prep for colectomy, colonoscopy, and radiology procedures (20%) and home health visits for impacted home bound patients (10%)...in many instances the PIE* has prevented hospitalization and/or reduced LOS thereby reducing costs."

David H. Doan, MD...

"My patient, I.N., who has long standing paraplegia secondary to a previous spinal cord meningioma...has been using the PIE for the past few years...the patient's pattern of recurrent hospital admission and emergency room evaluation have essentially disappeared...the PIE has been extremely effective for this patient...effective not only on her medical care but also medical costs, and has dramatically improved her quality of life..."

A.B., RN ...

"In many instances, PIE has prevented hospitalization and/or reduced LOS thereby reducing costs."

Wafaa A.Foad, MD ...

"My brother had autonomic hyperreflexia in 1993 (the blood pressure was elevated with distension of bowel, rectum and bladder). This attack of sudden elevation in his blood pressure led to a

stroke - bilateral cerebral hemorrhage. He recovered from the coma after two weeks to lose his speech. I wish he had the PIE* earlier. Maybe this all would have never happened. Since we have been using the PIE, our life has been much easier. He has one bowel movement every other day...regular, no bleeding, no mess, no hemorrhoids, no fissures, less time."

C.H., RN ... "meant shortening the length of a patient's stay in the hospital...less nursing time...PIE system used to remove impactions...again shortening patients' length of stay...requiring less nursing time..."

L.H. (Parkinson's Plus)... "I was hospitalized for 7 weeks because of an impaction and the doctor not being able to regulate my bowels...the doctor recommended the PIE...since using the PIE, I have been able to regulate my bowel movements so that I don't have accidents, which was a common occurrence, nor have I had an impaction...without the PIE, both of these happened...doctors have tried everything with me, enemas, suppositories, laxatives, etc., but nothing ever really worked for me like the PIE. Without the use of the PIE, chances are I would have to be placed in a nursing home."

S.B. ... "My son suffered a spinal cord injury...from day one, his biggest problem has been bowel control...impactions resulted in hemorrhoid surgery...without the PIE, his bowel problems kept him unemployed and his only income was Social Security Disability...after receiving the PIE, his life changed dramatically...enabled him to attend school...earns in excess of \$30,000 annually...now has employer paid health insurance...the PIE was the most cost effective purchase we ever made..."

G.J.L. (C-6 Quad)... "Has given me the freedom to enjoy an active social life, finish college, and more importantly, to return to work."

L.L.M. (Spinal Injury)... "I have become more independent in my bowel program...use less attendant care...fewer bladder infections...no emergency room visits...helped me psychologically...more in control of my life."

C.C.M. (Spinal Injury)... "I was left with a non-reflex bowel...treated by 8 different specialists...hospitalized twice...for 4 years the PIE procedure has helped me the most. I did not have any success with suppositories or enemas...daily laxatives gave relief, but also bowel accidents kept me from leaving home."

D.B. (C4/C5 Quad)... "In the past I had many problems with my rectum from the rigorous bowel program that was needed...bleeding and in great pain from digital stimulation...eventually developed fissure in the anus and was admitted to the hospital for surgery...doctors helped me find the PIE to stop this cycle...doctors and I are sure the PIE has kept me from another surgery..."

W.J. ... "My son was born with spina bifida. He has had bowel and bladder problems since birth...tried many different methods of bowel control with no success...while in hospital for kidney infection due to bowels not being empty, his doctor tried the PIE...very impressed and doctor decided it was the method Richard needed...have been using the machine since 1988 and has only been hospitalized for one infection...keeps us out of the hospital for 3 to 4 days because of kidney infections...we used to average 2 hospital stays per year...PIE paid for itself in the first 6 months by keeping us out of the hospital..."

D.B. (M.S.) ... "I now have control of my own bowels...before the PIE*, embarrassing bowel movements would cause me not to go anywhere for months...now I can go places and do things."

T.R. (M.S.) ... "I don't know what I would do without the PIE*...has helped avoid hospitalization because digital stimulation, enemas, and laxatives just do not work...had a bleeding ulcer, and thanks to the PIE, I didn't have to take laxatives and irritate the ulcer even more."

K.W. (Quad) ... "Has eliminated the problem of severe autonomic hyper-reflexia that accompanies other methods of bowel evacuation."

M.M. (Autistic Son) ... "For many years my son with autism has had bowel impaction problems and largely because of this problem he ended up in an institution...the PIE is everything I could ask for...my son can even go swimming and live in the community...we are working on supported employment...I feel the PIE might actually have saved his life."

B.W. (T-12 Spinal Injury) ... "I was injured on October 30, 1987...for the next several years I could not have a regular bowel system... enemas were never a success...suppositories worked part time but many times did not...my rectum became very inflamed and painful from the suppositories...the PIE gives me much better control of my bowels...I am able to get out and go places now...the painful inflammation has cleared up...my life is much better because of the PIE."

PIE* Third Party Coverage:

The following are some of the reimbursement resources that have covered the PIE* products. Your reimbursement source to be different and one to add to this list:

Administrative Service Consultants, Div. of Employee Benefit Claims of Wisconsin, Inc.

Aetna Life & Casualty

Aetna US Healthcare

American Automobile Association

Amerisure Companies

Alliance (APWU)

Blue Cross Blue Shield of Arizona

Blue Cross Blue Shield of California

BlueCross BlueShield of Illinois

Blue Cross and Blue Shield (Anthem) of Indiana

BlueCross BlueShield of Kansas

BlueCross BlueShield of Massachusetts

Blue Cross Blue Shield of Maryland

Blue Cross Blue Shield of Michigan

BlueCross BlueShield of New Jersey

Blue Cross and Blue Shield of N.C.

BlueCross BlueShield of Oklahoma

Blue Cross Blue Shield of Pennsylvania

Blue Care of Tennessee

Blue Shield of Tennessee

Blue Shield of Pennsylvania

Regence Blue Shield of Idaho

Blue Cross Blue Shield of South Carolina

CIGNA Insurance Company

Department of Health and Human Services (Medicaid), California

California Children Services

Department of Health and Human Services (Medicaid), Missoula, MT

Connecticut Medicaid

Missouri Medicaid

Minnesota Medicaid
Montana Medicaid
Vermont Medicaid
Dade County Dept of Health & Social Services, Dade County, WI
Dept of Social Services Of Louisiana
Farm Bureau Insurance Company of Michigan
GEHA - Government Employees Health Association
Healthsource-Provident
Houston General Insurance Co.
John Alden Insurance Company
John Hancock Insurance
Mail Handlers Benefit Plan (MHBP)
Mass Mutual
Mississippi Municipal Service Co.
Nationwide Insurance
National Telephone Cooperative
North American Health Plans
Old Republic Insurance Companies
Principal Group
Provident Life & Accident
Prudential HealthCare HMO
Secure Horizons/ PacifiCare, TX
State Farm Mutual Auto Insurance Co.
State of Washington Uniform Medical Plan
SAIF Corporation- Workman's Compensation
United Healthcare of North Carolina, Inc.
USF&G Co.
Vertihealth of California
Department of VA Spina Bifida Healthcare Benefits, Denver VA
Biloxi V.A., Biloxi, Mississippi
Birmingham V.A., Birmingham, Alabama
Cleveland VA, Cleveland, OH
Denver V.A., Denver, CO
Durham V.A., Durham, NC
Grand Junction V.A., Grand Junction, CO
Gainesville VA, Gainesville, FL
Houston V.A., Houston, TX
Hines V.A., Hines, IL
Miami V.A., Miami, FL
Murfreesboro V.A., Murfreesboro, TN
Nashville V.A., Nashville, TN
Richmond V.A., Richmond, VA
Palo Alto V. A., Palo Alto, CA
San Diego V.A., San Diego, CA
San Juan V.A., San Juan, PR
Tampa V.A., Tampa, FL
Washington V.A., Washington, DC



Price List Effective September 6, 2002

Item #	PIE* Equipment	List price
P1	PIE* 2005 System (Control, Cart and all Equipment Components)	\$6864.00
Monthly Disposable Supplies		
P2	Case of PIE*paks (15 @ every other day use) All items being fully disposable.	\$683.00 Per Case
PIE* Required Initial Training		
PT	Training Outside Atlanta	\$1200.00
PIE* Replacement/Optional Equipment		
P4	PIE* 2005 Control	\$5,995.00
P5	PIE* Cart	\$869.00
PIE* Disposable Components		
P7	Water Containment Bags (15)	\$187.00
P8	Water Containment Bags (4)	\$51.00
P9	Speculums (15)	\$187.00
P10	B-Valve Assembly (2)	\$104.00
PIE* Equipment Replacement Components		
P11	PIE* Battery Pack Complete	\$125.00
P12	A-Valve Assembly (2)	\$102.00
P13	PIE* Manual Fill System	\$75.00
P15	PIE* Cart Replacement Pump	\$121.00
P17	PIE* Battery Charger	\$87.00
P18	PIE*Cuff Inflation Bulb	\$11.00
P19	PIE* Remote Control Assembly	\$136.00
P20	PIE* Pressure Regulating Tower	\$175.00
P21	PIE* Battery	\$55.00
PIE* Equipment Rental/Financing Programs		
P23	2 Month Trial Rental based upon success then purchase. (After 10 years, all trials were converted to purchase.)	\$649.00 mo

All purchases are subject to UPS Freight Charges.

With 2- month trial rental, purchase will receive credit of all rental payments.

WARRANTY: All Equipment with the exception of Battery 1 year.

Battery -- six months.

PIE* Medical International, Inc. | 4809 Riverview Way | Duluth, Georgia 30097
888-878-8222 | Fax: 770-446-3830