Restoring Continence for Women

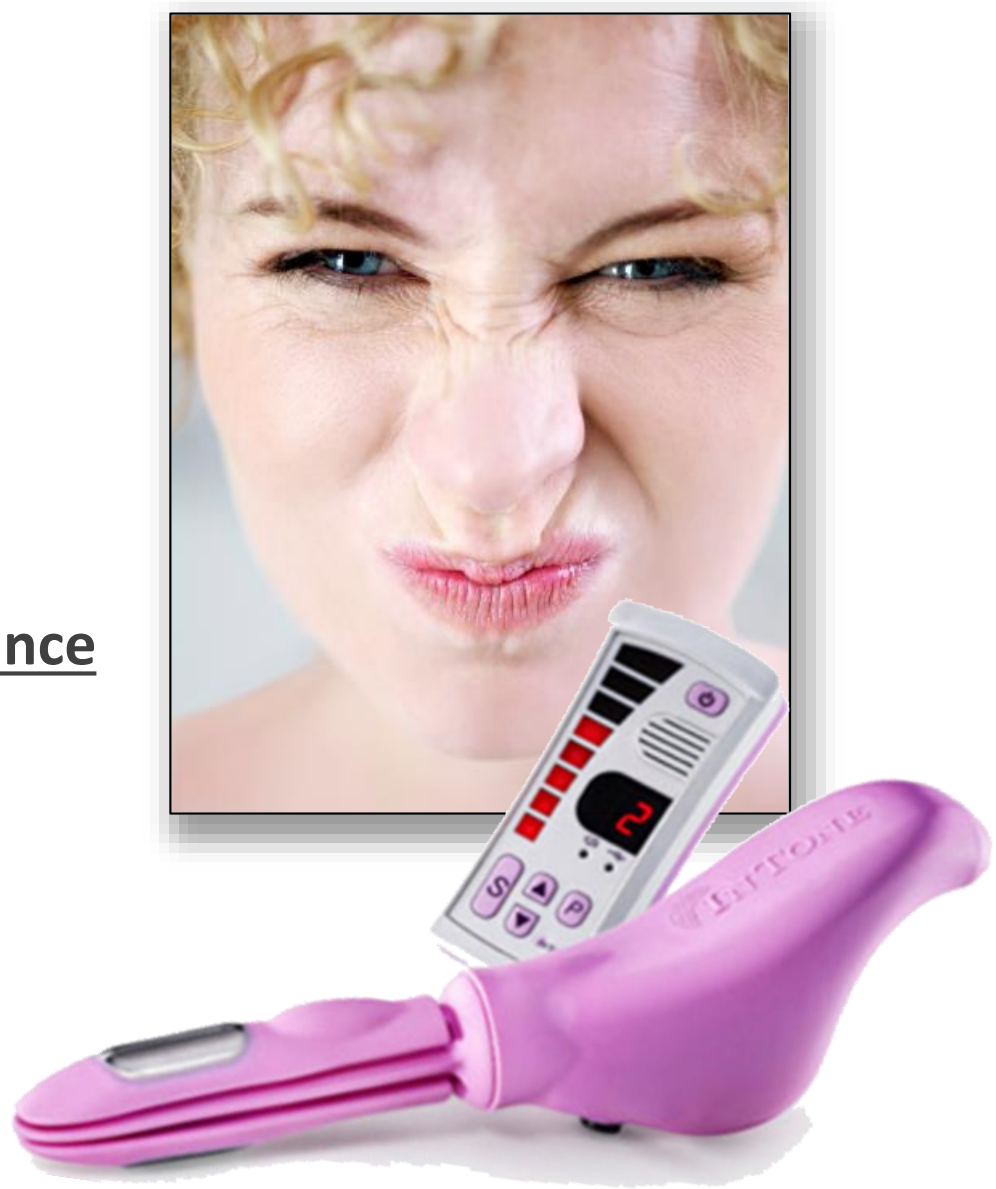
Non-surgical Wearable Device

Gloria Kolb, CEO

- Weakened pelvic floor muscles
- 1 in 3 women
- Leading cause of admission to nursing homes
- $20B US (CDC, 2014)
- Affects quality of life, day to day activities

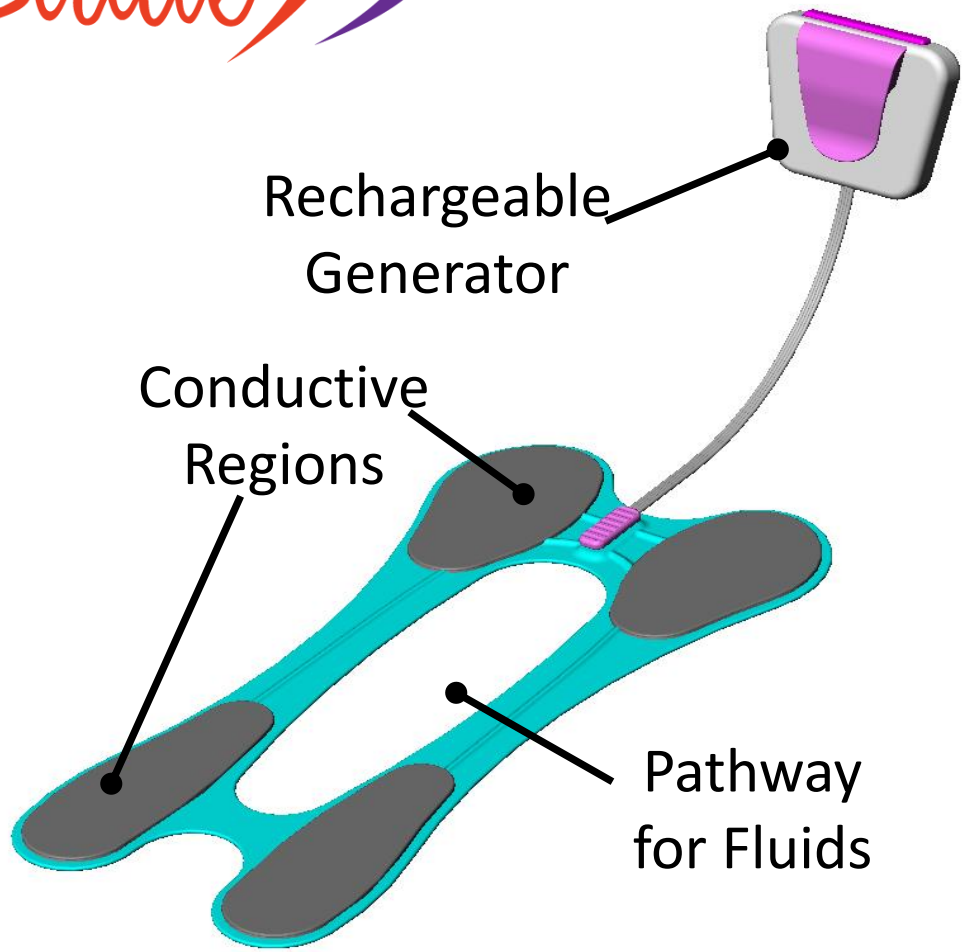
Stress Urinary Incontinence (SUI)

- No medications
- Surgery is last resort
- Pelvic floor muscle strengthening:
  - **EXERCISE:** 3x/day regimen and difficulty in contracting the correct muscles leads to **low compliance**
  - **ELECTRICAL STIMULATION (EMS)**: Vaginal probe requires private space/time, leads to **low adoption**

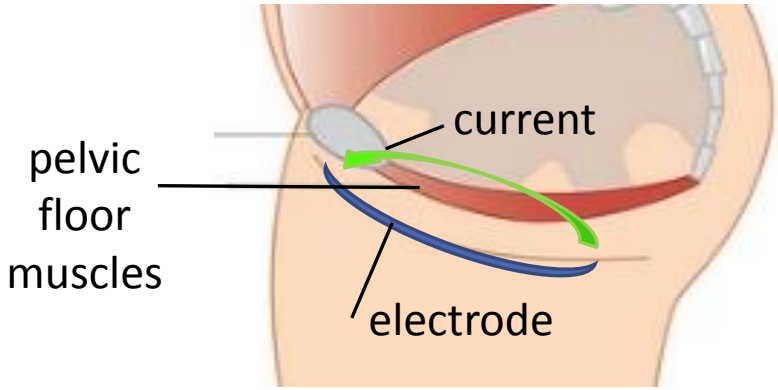


2/3 of affected women forego treatment and suffer quietly

Current Treatment



- ✓ Easy to use correctly
- ✓ Easy to remember to do
- ✓ Use anytime
- ✓ Discreet
- ✓ Comfortable
- ✓ Non-surgical and drug-free
- ✓ Effective



Etude™ - The Solution

The Etude helps to restore normalcy and reduce embarrassing situations.

Value Proposition

Surface electrical stimulation improves urinary leakage, strength and pressure of contractions and quality of life

- **HHS 900+ article meta analysis** – "Benefits of EMS on treating incontinence are large"
  (Agency for Healthcare Research, HHS 2012)

- **Recent Publications** - "Effects of surface and intravaginal electrical stimulation results similar" (Correia 2013)

- **Elidah's prototype** – Successful initial user tests
  - International Continence Society ICS

How do you know it will work?

- **Gloria Kolb, CEO**
  - Engineering (MIT, Stanford U), MBA (Babson)
  - Entrepreneur / MIT's TR35 / Boston's 40 under 40
  - First startup- we received 4 FDA approvals on $2M. *Fortune Small Business'* 14 Hot Startups
  - Successfully commercialized devices!
- **Eric Kolb, CTO**
  - Engineering (RPI, Case Western)
  - 18 years medical device R&D / 25 US patents
  - Wearable medical technology experience
  - Successfully commercialized devices!
- **Dr. Leslie Rickey** and **Cherrilyn Richmond**
  - Pelvic Floor Disorders and Rehabilitation
- **Dr. Ellen May** and **Dr. Kenneth Blau**
  - ObGyns each with 35+ years experience
- **Dr. Tim Watson-** Physiologist Expert on EStim
- **Chris Hufnagel-** prior Marketing/Bus Dev for competitor

Women's Health Connecticut

Yale-New Haven Hospital

Danbury Hospital

Experienced Medical Device Team

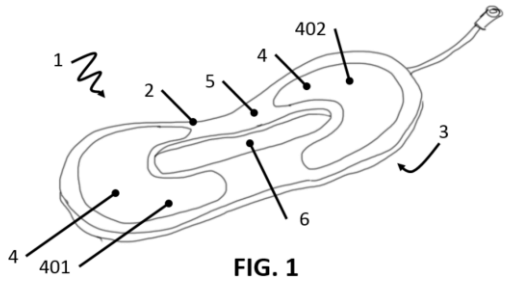


FIG. 1

- Non-Provisional Patent Application Filed (4/2014)
- International PCT PCT/US2015/025500 (4/2015)
- Independent Patent Search (Foresight Tech, 3/2014)

- Class 2 Device: 90-day 510(k)
- Predicates are EMS electrodes (code: IPF) and incontinence EMS devices (code: KPI)
- Classified as “Low risk device”

- Reimbursement codes already exist (CPT codes: 64550, 97014, 97032 and HCPCS code: E0740 and G0283)
- Medicare reimbursement for competitive product is $58/month rental (InTone, InControl Medical)

IP / Regulatory / Reimbursement

Vaginal EMS
(InTone and others)

- Vaginal! $800
- $35M in 3 years

Sacral Nerve
(Urge Incontinence-Medtronic)

- Long-term implant
- $15K for the device

Thigh Garments
(Neurotech Vital - Europe)

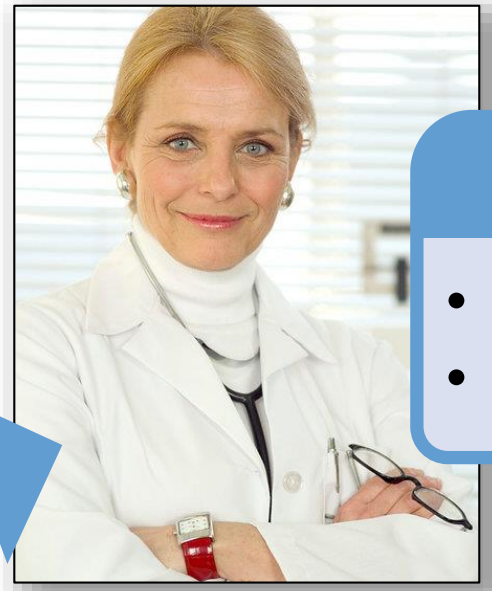
- Requires private time/space
- Eight electrodes
- Lean over table, 30 minutes

Competitive Technologies

Market & Customers (3P's)

Mild to Moderate SUI

25M women ($10B US)



Physician

- Primary care, OB/GYN
- (Eventually will flip Urologist)

Direct to Patient

- Too embarrassed to talk
- Will try EMS without vaginal probe

Payers

- Treatment/ Preventative
- Saves $ on surgery/ care ($20B)

Physician as Customer

Value: A conservative tool, gets patient out of office

- Prescription required for reimbursement
- Needs demonstration of positive outcomes

Patient as Customer

Value: Helps to avoid embarrassment

- Seeks out treatment options independently

- Sales Reps call on physician (direct / indirect models)
- Clinical data
- Trade shows
- Reimbursement assistance

- Sell device(s)
- Rent device (per month)
- Replacement electrodes

- Informational website
- Direct to patient, social marketing (mommy groups)
- Publicity
- Online ordering

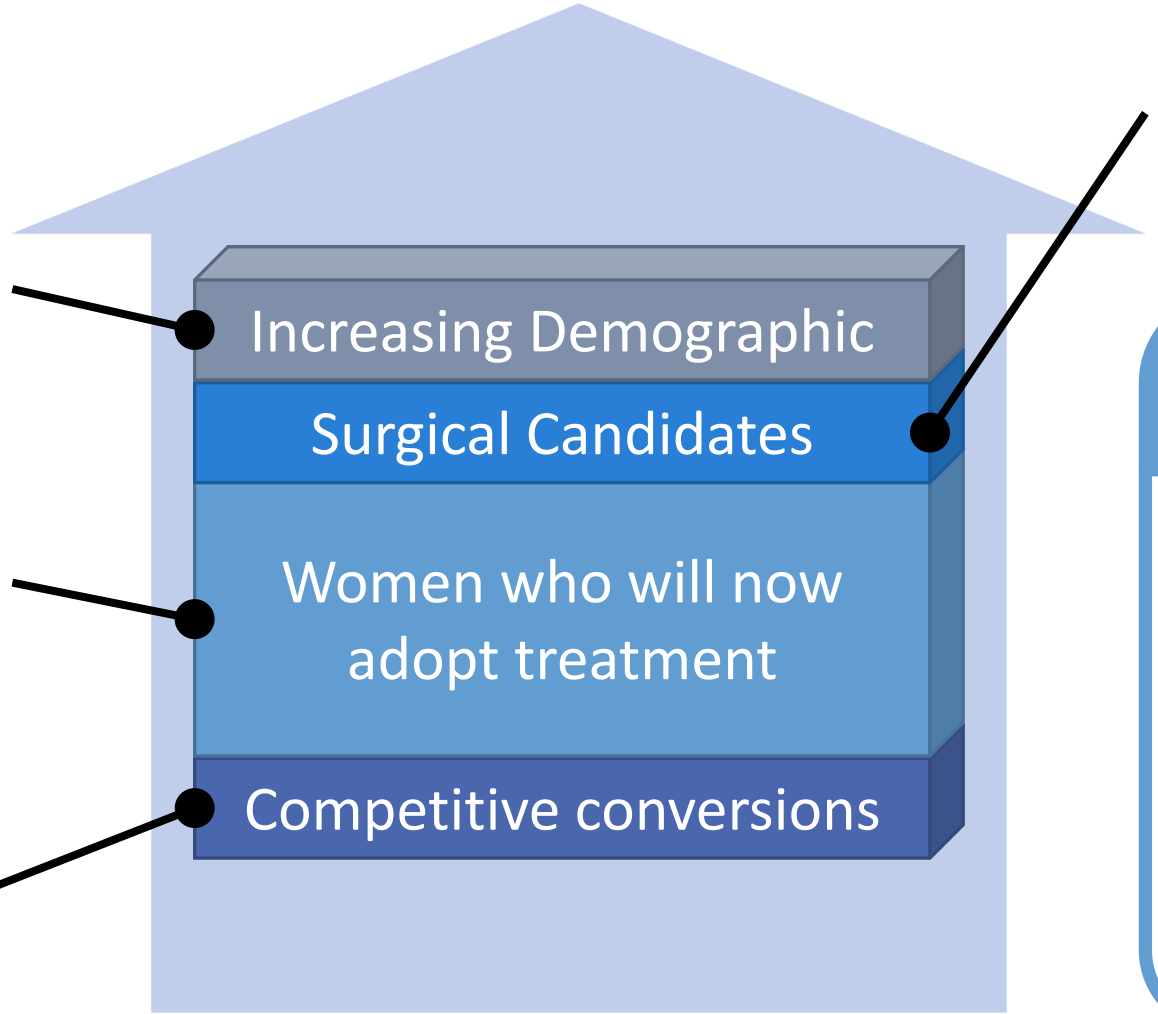
Channels

Global urinary incontinence treatment market – $1.6B (2011) / $3B in 2022

Affected population expected to double in next 40 years

2/3 of symptomatic women currently forego treatment

$304M in US therapeutic products (2007)



Alternative to surgery

Future Markets Same Technology

1. Urge, Mixed Incontinence (EMS known to work)
2. Vulvodynia, pelvic pain
3. Male Incontinence (50% incidence after prostate surgery)

Growing Market Opportunity

Profitability

Sell or Rent System:
- $500 ASP
- Cost: $50-80 (80+% profit)

Sell Disposable electrodes:
- $8 each
- Cost: $3-5 (50% profit)

Sales

- Sales in 2016
- Profitable in 2017
- Breakeven in 2018
- 0.1% marketshare by 2020 (conservative 30K units)

	5-Yr Financials with US Sales ($000)				
	2015	2016	2017	2018	2019
Total Net Sales		**500**	**2,300**	**5,600**	**10,700**
COGs		170	680	1,700	3,230
Gross Profit		**330**	**1,620**	**3,900**	**7,470**
Op Expenses					
Sales & Mktg		200	800	1,000	800
R&D/Quality	260	400	400	300	300
G&A	40	150	150	200	200
Total Op Expens	300	750	1,350	1,500	1,300
EBITDA	**(300)**	**(420)**	**270**	**2,400**	**6,170**
Taxes	0	0	0	780	2,468
NET EARNINGS	**(300)**	**(420)**	**270**	**1,620**	**3,702**

Electrode sales

System sales

Projections

Date	Raised	Source- (ALL NON-DILUTIVE)	Use of
April 2014	$10,000	Kolb Consultants	Research & Early development
Feb 2015	$18,000	CCAT	Rapid prototyping
June 2015	$150,000 *(+$30,000 pending)*	NSF SBIR Phase I	Electrode development Quality systems
June 2015	$10,000	CT Next- EIA	Start of generator design
Sep 2015	$60,000	CT Innovations- SBIR Supplement	Clinical Pilot study
Oct 2015	$25,000	CT Innovations- Talent Bridge	Engineering and marketing interns

- LLC with single member ownership by Kolb Consultants (founders)
- Electrode manufactured – working to get cost down
- Deliverable- Electrode FDA cleared

Funds Raised and Development Status

Raising:

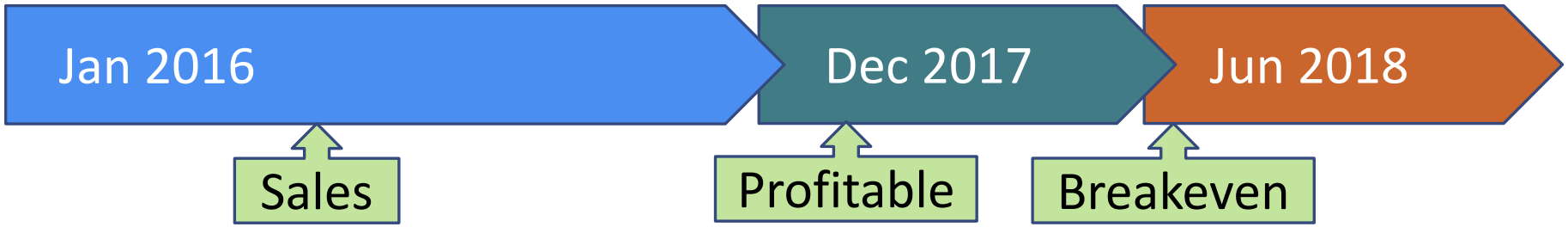
$250,000-750,000 $1,000,000

$2M gets us to Breakeven

For:

- Generator design and prototyping
- System refinement
- IEC testing
- IRB marketing/ efficacy study (n=30)
- FDA **510(k) System**

- Manufacturing build up
- Marketing – large scale awareness



Potential Sources:

- $500,000 CT Bioscience Fund (Dec)
- $750,000 NSF Phase II (June 2016)

$1M @ $3.5M valuation
$50M exit in 5 years = 14x multiple
= 70% IRR

Wearable Treatment for Incontinence

- ✓ **Technology:** Demonstrated efficacy
- ✓ **Market:** 1/3 of women & fills a gap
- ✓ **Team:** Experienced device team
- ✓ **Timeline:** Quick 510(k) regulatory pathway
- ✓ **Revenue:** Two paths, recurring disposable

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Support Slides

- Phased approach to front load risk
- Developing electrode component first
- Utilize “off-the-shelf” generator
- Conduct clinical study to confirm efficacy of electrode prior to development of full system

Women's Health Connecticut

- FDA cleared low risk device so no IDE required, only hospital IRB required.

Fully functional prototype complete

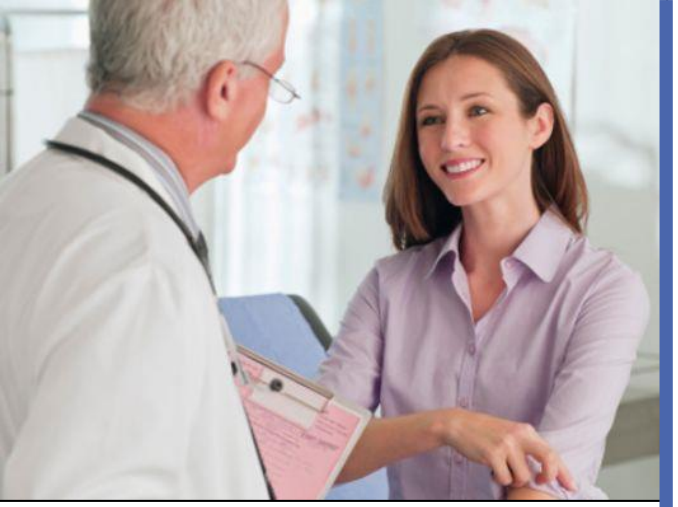
Ongoing assessment of multiple candidate stimulators

Initial human test successful. Reduced leakage at 1.5 month

Developing protocol with clinical advisors/ investigators

Risk Mitigating Development Strategy

Sales	2015	2016	2017	2018	2019	2020
Consumer Unit Sales		1,000	3,000	8,000	15,000	23,000
		0.004%	0.01%	0.03%	0.06%	0.09%
Consumer Sales		$ 500,000	$ 1,500,000	$ 4,000,000	$ 7,500,000	$ 11,500,000
Distributor (Rx) Unit Sales		0	1000	2000	4000	8000
Distributor Sales			$ 800,000	$ 1,600,000	$ 3,200,000	$ 6,400,000
Growth rate (n+1)/n			360%	143%	91%	67%
	5-Yr Financials with US Sales ($000)					
	2015	2016	2017	2018	2019	2020
Total Net Sales		**500**	**2,300**	**5,600**	**10,700**	**17,900**
COGs		170	680	1,700	3,230	5,270
Gross Profit		**330**	**1,620**	**3,900**	**7,470**	**12,630**
Op Expenses						
Sales & Mktg		200	800	1,000	800	600
R&D/Quality	260	400	400	300	300	300
G&A	40	150	150	200	200	200
Total Op Expens	300	750	1,350	1,500	1,300	1,100
EBITDA	**(300)**	**(420)**	**270**	**2,400**	**6,170**	**11,530**
Taxes	0	0	0	780	2,468	4,612
NET EARNINGS	**(300)**	**(420)**	**270**	**1,620**	**3,702**	**6,918**
(cumulative NE)	(300)	(720)	(450)	1,950	6,170	11,530



SurveyMonkey

connecticut innovation summit

FORESIGHT

- **High Interest with Physicians**
  - 15+ Interviews- Primary care and OB/Gyns want conservative
- **Patients Interested**
  - 60+ SUI Patient Interview & Surveys
  - 84% never heard of EMS or refuse to use vaginal probes
  - 68% more likely to try EMS if no vaginal probe
- **Winner:**
  - CT Angel Investor Forum favorite among 22 Life Science companies (Innovation Summit)
- **Favorable** – Foresight 3rd Party Assessment

Recent Customer Validation

- Management? (70% wears pad, 27% not yet)
- Treatment? (77% Kegels, only 3% EMS, only 23% talked to doctor)
- EMS? (3% worked well, 3% didn't stick with it,
  - whopping 86% never heard of it, or refuse to use intravaginal EMS
- Biggest problem with other non-surgical treatment is: hard to find time or remember to do Kegels, close 2nd- didn't see much improvement
- Compared to Vaginal Probe, 66% would be more likely to use, 31% same
- 13% had surgery, and all still wear pads, and would pursue more treatment if it had faster results, didn't require surgery, and were less painful
- 23% talked about it with their doctor and only 1/7 of those had surgery
- Regarding Most important features of Surface EMS: "Hands-free, go about normal tasks", "small and discreet", and then "body-contacting surface disposable"

Survey Results – 35 SUI Patients

"Nonsurgical Treatments for Urinary Incontinence... Comparative Effectiveness“

- April 2012, Agency for Healthcare Research
- Reviewed 905 references, 148 Random Controlled trials for non-pharma, non-surgical
- 9 studies with vaginal EStim, different freq and length: UI was improved and benefit was consistent across the studies. QOL improved with majority.
- Continence achieved in 1/3 PF muscle training (exercises), 1/6 PF and bladder training, 1/6 vaginal EStim
- "Benefits from pelvic floor muscle training, bladder training, and electrical stimulation are large, and adverse effects are uncommon. Benefits from drugs are small. Drugs for urgency UI have comparable effectiveness."
- Other methods to increase adherence to PFMT was insufficient (audiotapes, personal reminders, etc.) even after 1000 women.