

Making the diagnostic testing of urine accurate with digital and analogue innovation for global markets.

Peezy Midstream | Peezy First Stream | Peezy@home



The Peezy Specimen Collection









Reliable, hygienic, dignified urine collection for antenatal and urinary tract infection (UTI) screening for women. Selling in the USA with high reimbursement code; new target export territories Europe, Middle East and Asia. Key partners in the USA are Thermo Fisher Scientific and Owen Mumford Inc.

First orders received from the US Department for Defense.



Pure 8-10ml of first-void urine for Sexually Transmitted Infections (STI), some early stage cancer diagnoses and a home menopause management system. Under license with Owen Mumford Limited, shareholder and industry partner with ready customer base.

The triage to treatment home test, ensuring all positive dipped specimens are lab cultured, with digitally transferred results to a prescribing GP or pharmacy so that targeted antibiotics can reach the patent at home, *if needed*.

Peezy@home will reduce Primary Care appointments, generating healthcare cost savings, patient dignity and convenience.

Urine is a vital diagnostic

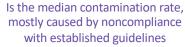




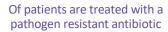








Of the global rise of Antimicrobial Resistance (AMR) has a urinary source











Of blood infections leading to Sepsis have a urinary source

Of UTI related hospital admissions had prolonged inpatient stays

Of outpatients returned for visit

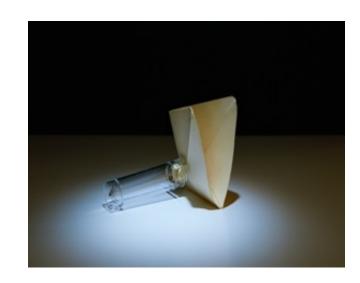
Were treated for a non-existent infection

2001 conception



- Dr Vincent Forte, NHS GP & medical author
- Notices unresolved UTI in female patients
- Considers urine collection methods
- Listens to complaints about collection
- Hit-and-miss collection leads to unreliable analysis, diagnosis & treatment
- Costly repeat appointments and tests
- Invents the Female Freedom Funnel



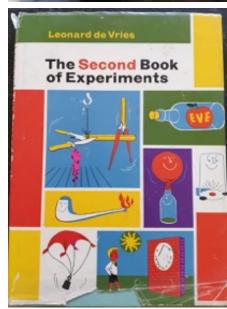


2002-2005 preparing for market



- Dr Vincent Forte makes proof of concept prototypes, inspired by childhood experiments
- Wins inaugural Medical Futures Innovation Award
- Vincent asks sister Giovanna to assist
- Write first business plan
- Approached but rejected by UK urology businesses: "We have our own ideas"
- Commence design development with own money
- Conduct home-spun usability trial through 30 friends and friends of friends: provide water, use Peezy, followed by champagne and canapes

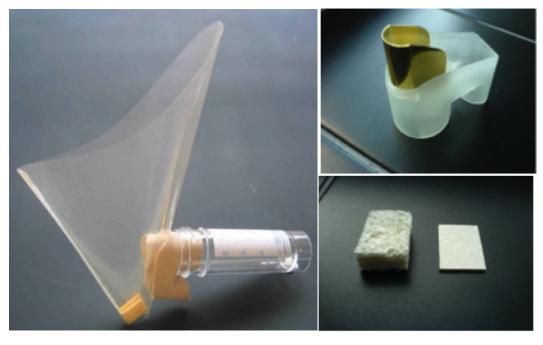




2006-2007 Peezy Mark I



- Achieve seed funds through London Development Agency & matched Angel investment
- Build team + sales database
- Complete design (Maddison)
- Establish manufacturing relationship and processes
 - Ultrasonic welding
 - Assembly
 - Packaging



Original "flushable" corn starch polymer Peezy Midstream used for early evaluations with hospitals (a disaster!)

Forte Medical

2008-2009 regulatory obligations & awards

- MHRA Registration & FDA Listing
- Experiment with corn and potato start polymers
- Complete design development & prototypes
- Bio-polymers too novel, switch to polypropylene
- Complete QA and regulatory requirements
 - Ship testing, Age testing, Bioburden testing
- Develop instructions for use (IFU)
- Win NHS Health & Social Care Innovation Award
- Win Design Week Awards
 - Best Industrial Product
 - Best of Show





The unofficial tumble test





- Rethink manufacture to reduce cost
- Commission single injection mould tool
- Test, trial and validate

PEEZY MARK II V3 REAL USE FLOW CHART						20 11 2012
PEEZY MARK II			VERSION 3			
Time	Bladder	Flow rate	Collection	Overfill	Drainage	Sponge dilation
1055	half full	medium	15ml	none	8 seconds	Full
1207	very full	very fast	20ml	none	12 seconds	Full
1229	not full	slow	8ml	none	4 seconds	Full
1333	half full	medium	10ml	none	8 seconds	Small central hole
1424	half full	fast	20 ml	none	11 seconds	Full
1557	very full	very fast	8ml	none	15 seconds	Small central hole





2016 Peezy Mark III



Amend design in response to patient trials: easier handling / body-conscious ergonomic improvements / create innovation to remove spillage risk with full tube / add "hood" over entry to tube to reduce first-void contamination from male patients / develop dual attachment for both 30ml and 10ml tube option.



Accurate midstream urine specimen: dry hands, dry bottle, dry floor.

2016 improvements, launch and sales lies



- Boddingtons Plastics complete tooling and packaging machinery
- Launch Peezy Mark III
- LESSON LEARNED: Signed sales and distribution contract with international healthcare sales and distribution business based on highly trained six-strong sales team. Team quietly disbanded without notice, sales strategy reduced to e-mail campaign. Existing customer orders not met and no new sales in six months. Fingers burned ... always conduct due diligence on prospective partners! Trust no-one!
- Join ABHI: industry introductions & export trade missions leading to USA launch
- Develop Budget Impact Model to show short and long-term savings
- Successful ABHI Trade Missions lead to US industry insights, leads and policy, plus establishment of valuable HCPCS (reimbursement) code







2017-2020 structure and sales



- Approach Champions and Advocates
- Generate real-world evidence
- Start Public Health Wales 3-strand study
- UK sales start to rise
- Active PR campaign: talks, events, social media
- US sales and distribution negotiations
- Loyola Stritch School of Medicine published evidence
- Owen Mumford Inc sign non-exclusive sales and distribution partnership
- Thermo Fisher Scientific approach for US sales interest





2010-20 academic clinical trial lessons



Naivety over lax academic clinical trial controls

- Royal Free: not all Peezy Midstream samples were sent to lab if dipstick negative, resulting in all positive evidence (literally) flushed away. Protocol not met.
- Oxford Nuffield: patient full bladder instruction not ensured prior to use, leading to "25% product failure" ... yet detailed MSU instructions given to patients in "normal" cohort. The abstract notes that results could have been different without detailed MSU instructions, which are not usually provided in real-word settings. Lack of parity over patient instructions setting the scene for negative trial outcome.

Universal urine collection kit (30 ml)
PE 40 Standard

This pack contains:

- Genital wipe
- 2. Bottle (30 ml)
- Peezy

Peezy works best with a full bladder

Please read before use



2009-2020 real world evidence



"The best outcomes for patients in the quickest and safest manner".

Health setting / healthcare provider	Contaminatio n rate	Peezy Midstream rate	Patient number	
Barts Health NHS Foundation Trust Urology	23%	1.5%	66	
Pennine Acute Hospitals NHS Foundation Trust Urology	23%	5.0%	104	
Royal Surrey County Hospital Antenatal	9%	2.5%	26	
Watford General Hospital Antenatal	70% reduction of false-positive antenatal specimens: adoption implemented			
North Devon NHS Trust Urology & Antenatal	25%	1.0%	100	
Cardiff and Vale University Health Board Primary Care	8.5%	0%	5 month study	
NHS National Institute for Health Research		Usal	oility Study	
Instructions clearly explained		100%		
Peezy collects midstream easily		94%		
Patients confident using Peezy		94%		

NHS: little impetus to change from the top



Dame Sally Davies, when CMO: go and talk to nurses

50% of the global rise of AMR has a urinary source. UTI guidelines recommend immediate 3-day broad spectrum antibiotics prescribing without investigative culture. Targeted medicine is given only if infection persists and patient must return for further testing. AMR Guidelines recommend no prescribing until problem bacteria are identified and targeted medicine given. We asked "AMR Champion" Dame Sally if a urine collection protocol may be considered to help stem the rise of AMR, particularly amongst women. She then had the power to consider exploring this preventative approach potentially giving pharma companies a longer runway to innovate new medicines,; she chose instead to ignore the opportunity. Case dismissed.

Silo budget systems

Manchester Midwives positive business case for Peezy Midstream purchase and use was rejected by Maternity Procurement manager, due to savings landing in lab budget. No joining of dots to improve UTI diagnosis and treatment or whole-life cost savings.

Lack of incentive for labs to change

Labs are paid *per specimen*: reduced retests or false positives will negatively impact revenue. No incentive to improve specimen quality and outcomes.

Short-termism

Pressure for immediate "savings" impressed upon procurement by policy wonks make investment in preventative devices unattractive for short-term reporting structures. NHS Supply Chain Catalogue deny price increase after eight years at 83p. Cost increases mean we can no longer afford to sell to the UK market and improve UTI and prenatal screening.

Investment in prevention is healthier, safer and cheaper than cure.

2020-2022 C19 and company restructure



UK

- Growing sales died overnight, due to Covid-related cessation of point of care testing
- NHSCC refusal to allow price increase: no margin, no market
- Company opted for NHS Supply Chain Catalogue delisting (remained on Framework)

USA

- Covid delays Owen Mumford US market entry launch, re-fired with success in 2022
- Thermo Fisher Scientific 8-month due diligence: signed sales & distribution agreement
- First US trial: "This is a game changer for women"
- Customers project sales over 3m unit within two years

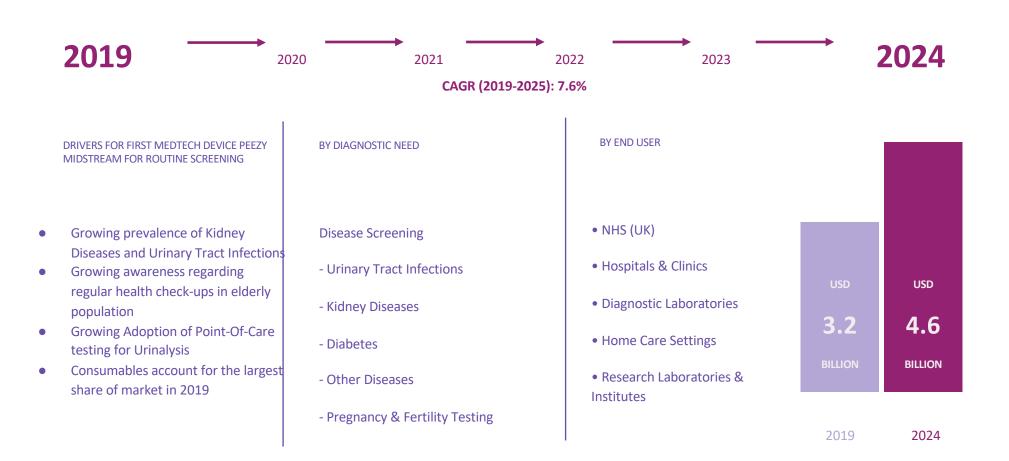
Peezy@home in response to growth of home testing landscape

- Peezy@home conceived for NHS prenatal, online & retail triage to treatment system
- All positive dips sent directly to lab for culture to identify problem bacteria
- Targeted antibiotic delivered to patient at home
- System meets future Antimicrobial Resistance (AMR) policies
- NB: 50% of the global rise of AMR has a urinary source
- NB: 47% of blood infections that lead to Sepsis has a urinary source

Licensing . Partnerships . White label

The urinalysis market is growing



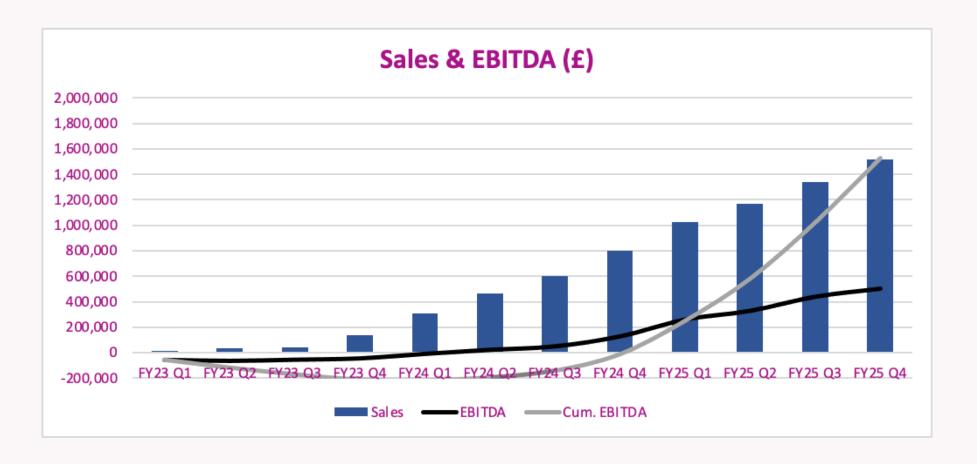


Gross profit margin growth



Notes

- Licensing / royalty business model has reduced significantly the company's ongoing working capital required
- 12 month funding requirement, during which time US ordering pattern will be established
- Further investment if needed, may be sought at a higher valuation or by way of alternative funding methods



Customer forecast and product status









Routine female health and antenatal / inmarket: generating revenues in the USA with orders from Thermo Fisher Scientific and a US Government agency through Owen Mumford

Company forecasts take account only of customer's own projections

License agreement signed with Owen Mumford Limited. First-void urine required to screeni for Sexually Transmitted Infections (STI), cancers & menopause management.

Prudent assessment has been agreed between Owen Mumford Limited and Forte Medical Digital "triage to treatment" home test: licensed planned from 2023/2024.

US market home test development underway.

Forecasts will be established during commercialisation process; market reports indicate growing global appetite for home UTI testing growing to US\$billions annually.

622k units @ £1.25

over next 12 months

35k units @ £1.25

over next 12 months

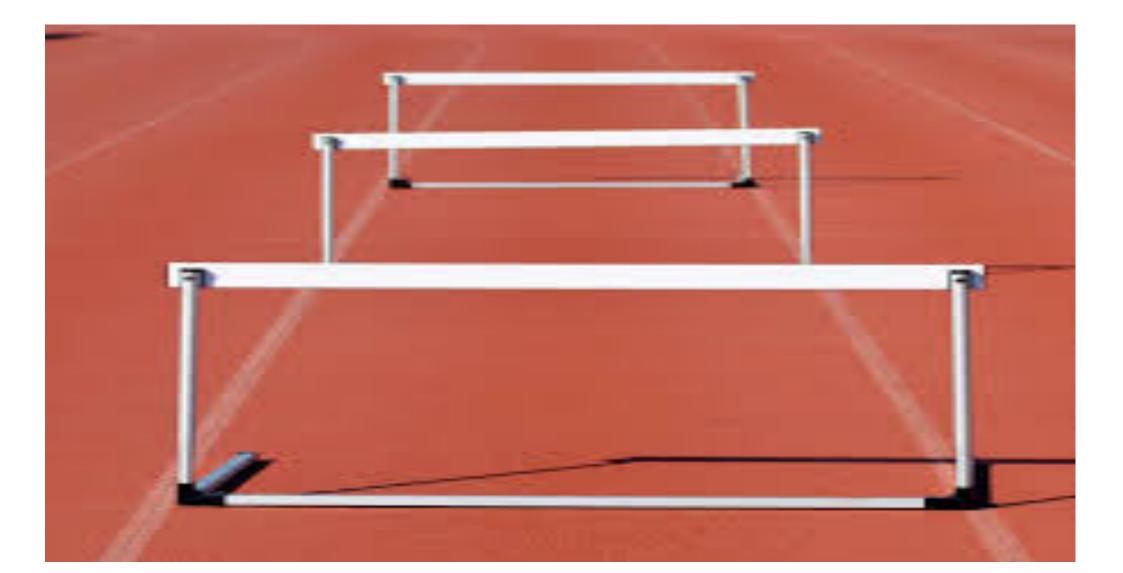
New specimen collection devices are in the pipeline to be commercialised once our existing portfolio scales

The pandemic has transformed the face of diagnostics, bringing testing into the home in a way many public health officials never imagined possible.

Financial Times, 9th June 2021

What about the hurdles?
Dive under, over or around them ...
Exploit the pause they create to rethink strategy







The evolution





Thank you.

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