

TABLE 1. Device Overview

Device name (FDA approval; commercially available ^a)	Proposed commercial use	Proposed study use	Device use, frequency, and duration	Proposed mechanisms and benefits	Results of published trials or cost	Round(s)
leva Pelvic Health System ²⁰ (Y;Y)	UI, mixed UI, stress UI, urge (OAB), PFMT	Monitoring (OAB) and/or treatment (PFMT)	1 to 2 days/week for 5 mins each time	Intravaginal accelerometer-based PFMT	Pilot trials are promising ^{21,b}	1
eCoin ^{22,23} (IT;N)	Remote neuromodulation; implantable PTNS	Urge UI, refractory OAB	-	Subcutaneous implantable device, stimulating tibial nerve fibers causing inhibition of the micturition pathway in SC and pelvic/pudendal nerve to inhibit OAB	Pilot trial resulted in reduction in leaks; trial ongoing, 3 month intervention, 9 month follow-up	1
BlueWind RENOVA ²² (IT;N)						
Uromonitor (P;N)	Catheter-free wireless cystometry	Monitoring of UI (OAB)	Device, app, 12-month subscription	Intravesical pressure sensor for remote bladder monitoring	Preliminary results promising	1
PeriCoach (Y;Y, but not in US) ^c	UI, stress UI, PFMT	Treatment (TR-assisted PFMT)	Once daily for 5 min for 8 weeks	Uses 3 visual biofeedback sensors for real-time remote results via app	\$299 (device, app, 12m subscription)	1
Elvie (P;Y) ^c	UI, mixed UI, stress UI, PFMT	Treatment (TR-assisted PFMT)	5 min/day for 3 days/week	Kegel exercises, app with 1 internal and 1 external sensor	\$199	1
Carin Pro (P;Y) ^c	Stress UI, PFMT	Treatment (TR-assisted PFMT)	Once daily for 10 mins, for 8 weeks	Sensor to track leaks, leakproof underwear, app for daily PFMT	\$332.16 (app only, \$33.43)	1, 2
Innovo (Y;Y)	Stress UI, PFMT	Treatment (TR-assisted PFMT)	Once daily for 30 min; 5 days/week for 4 to 12 weeks	NMES to perform 180 Kegels via wearable shorts with 8 sensors	\$499	1, 2
DFree (P;Y) ^c	Urgency UI (OAB); notify user when to void	Monitoring (OAB, IE) and/or treatment (urge UI)	None specified; use as needed	Uses ultrasound to sense how much urine is in the bladder; real-time objective measure uploaded onto app	\$100/month or \$399	1, 2, 3, 4
Perifit (Y;Y) ^c	UI, mixed UI, stress UI, prolapse, sexual pain, PFMT	Treatment (TR-assisted PFMT)	Once weekly or 5 min/day for 30 min total/week	Kegel exercises, app, and video game using internal sensors for biofeedback	\$139	1, 2, 3, 4

app, application; FDA, Food and Drug Administration; IE, incomplete emptying; IT, in trials; N, no; NMES, neuromuscular electrical stimulation; OAB, overactive bladder; P, pending at the time of the study; PFMT, pelvic floor muscle training; PTNS, posterior tibial nerve stimulation; SC, spinal cord; TR, telerehabilitation; UI, urinary incontinence; Y, yes.

Note: Devices for men: kGoal added the Boost external training device. Carin now offers an option for men, WiL, with a sensor and underwear to track leaks. Both appeared online after the stakeholder meetings were completed.

^aAs of date of study, March 2021.

^bAlso being tested for fecal incontinence (ClinicalTrials.gov NCT04027335). In the last 10 years, since neuromodulation (sacral nerve stimulation and percutaneous tibial nerve stimulation) was approved by the FDA, no progress has been made in this space. BlueWind RENOVA and eCoin are the only modified devices in neuromodulation recently developed (< 5 years), which may grow the field.

^cRequires an application downloaded onto a smartphone device.