Supplementary Table 1. Inclusion/Exclusion criteria for concept elicitation interviews

Inclusion criteria

Participants must have/have been:

- Provided written informed consent to participate
- At least 18 years of age
- Met Rome III diagnostic criteria for FD,[*] as detailed by the following:
    - Onset of symptoms occurred at least six months prior to diagnosis
    - Presented with one or more of the following symptoms for the last three months:
        - Bothersome postprandial fullness
        - Early satiation
        - Epigastric pain
        - Epigastric burning
    - No evidence of structural disease (including an upper endoscopy)[†] that was likely to explain the symptoms
- Fluent in US English (i.e., able to speak, read, and write)
- Willing and able to participate in a one-hour, face-to-face interview

Exclusion criteria

Participant had at least one of the following:

- Gastroparesis (history of diagnosis of gastroparesis or suspected gastroparesis by the investigator)
- Vomiting (one or more times/week)
- Active IBS[‡]
    - In the last three months and in the absence of antidiarrheal or laxative use:
        - Active IBS-C: Hard or lumpy stools [Bristol Stool Form Scale (BSFS) Type 1-2] >25% of bowel

movements and loose (mushy) or watery stools (>Type 6 on BSFS) <25% of bowel movements

- Active IBS-D: Loose (mushy) or watery stools (>Type 6 on BSFS) >25% of bowel movements and hard or lumpy stools (BSFS Type 1-2) <25% of bowel movements
- Active IBS-M: Hard or lumpy stools (BSFS Type 1-2) >25% of bowel movements and loose (mushy) or watery stools (>Type 6 on BSFS) >25% of bowel movements

  - Upper or lower abdominal symptoms improved with bowel movements

- Active chronic constipation‡
  - Must include *two or more* of the following in the last three months:
    - Straining during at least 25% of defecations
    - Lumpy or hard stools in at least 25% of defecations
    - Sensation of incomplete evacuation for at least 25% of defecations
    - Sensation of anorectal obstruction/blockage for at least 25% of defecations
    - Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
    - Fewer than three defecations per week
  - Loose stools are rarely present without the use of laxatives
- Active GERD‡
  - Defined as more than one day per week with heartburn. Heartburn is considered to be burning and/or pain behind the breastbone (as opposed to epigastric burning and/or pain) and/or regurgitation (fluid or food coming up from the stomach to the mouth or throat)
  - Proton pump inhibitor (PPI) use is acceptable if adequately treating the cardinal symptoms of GERD (e.g., heartburn, regurgitation), but subjects would be excluded with residual GERD symptoms or non-response based on the overall GERD exclusion

- Small intestinal bacterial overgrowth
- Symptomatic gallbladder disease
- Symptomatic pancreatic disease
- Type 1 diabetes or uncontrolled type 2 diabetes at the time of screening
- Used nonsteroidal anti-inflammatory drugs (NSAIDs) two or more days per week (excluding aspirin use of ≤325 mg/day)
- Used chronic opioid therapy
- Known celiac disease
- Abused drugs or alcohol within the past 12 months
- Alarm symptoms (e.g., weight loss, GI bleeding, unexplained anemia, or dysphagia), unless investigated and the cause was not found to fulfill other exclusion criteria
- A history of major abdominal surgery [for example any bowel resection, gastric bypass or resection, esophagectomy, pancreatectomy, etc. (however, this does not include, for example, uncomplicated appendectomy or cholecystectomy, hysterectomy, tubal ligation)]
- Pregnant or breastfeeding
- An acute or chronic condition that, based on the recruiting clinician's assessment, precluded him or her from participating in the study
- A condition or was in a situation which may have put him/her at significant risk, may have confounded the study results, or may have interfered significantly with the subject's participation in the study (e.g., difficulty hearing, cognitive impairment)

*Drossman DA, Corazziari E, Delvaux M, Spiller RC, Talley NJ, Thompson WG, et al. Appendix A: Rome III Diagnostic Criteria for FGIDs. In: Drossman DA, Corazziari E, Delvaux M, Spiller R, Talley NJ, Thompson WG, et al., editors. Rome III The functional Gastrointestinal Disorders. 3rd ed. McLean, Virginia: Degnon Associates, Inc.; 2006. p. 885-97.

†For PRO measure development purposes, it was not a practical option to request a new upper endoscopy be performed for enrollment into the study. Therefore, if a subject had an upper endoscopy in the past, was diagnosed by a physician as having

FD, and there had not been any worsening of signs or symptoms since the diagnosis, the subject was considered for enrollment if all other inclusion and exclusion were met.

‡For these conditions, active was defined as experiencing cardinal symptoms of that condition with or without treatment

Supplementary Table 2. Usability questionnaire results

Item	N=49*	
	Range	Average
1. On a scale from "0" (not at all difficult) to "10" (extremely difficult), how difficult was it to turn on the device?	0–4	0.39
2. On a scale from "0" (not at all difficult) to "10" (extremely difficult), how difficult was it to read the questions on the screen of the device?	0–3	0.16
3. On a scale from "0" (not at all difficult) to "10" (extremely difficult), how difficult was it to select answers to the questions with the device?	0–5[†]	0.18
4. On a scale from "0" (not at all difficult) to "10" (extremely difficult), how difficult was it to move between screens on the device?	0–2	0.06
5. On a scale from "0" (not at all difficult) to "10" (extremely difficult), how difficult was it to turn off the device?	0–8[‡]	0.49

*Participants who completed the electronic format of the *FDSD* (n=49) were asked five questions regarding the usability of the handheld device

†Only one participant (2.0%, n=1/49) selected a "5" when responding to the difficulty of selecting answers to the questions with the device, and reported the difficulty was "because of [her] nails"

‡Participants who reported difficulty turning off the device without prior training reported the difficulty was due to it not being immediately apparent what mechanism turned off the device

Supplementary Table 3. Item distribution: descriptive analysis on the *Functional Dyspepsia Symptom Diary* items (N=57)

***FDSD* Item**	**Response Selected, n (%)** **0=No [concept]; 10=Worst imaginable [concept]**										
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
1. Stomach pain.	3 (5.3%)	5 (8.8%)	3 (5.3%)	7 (12.3%)	4 (7.0%)	10 (17.5%)	12 (21.1%)	3 (5.3%)	5 (8.8%)	2 (3.5%)	3 (5.3%)
2. Burning in the stomach.	7 (12.3%)	1 (1.8%)	6 (10.5%)	6 (10.5%)	6 (10.5%)	6 (10.5%)	11 (19.3%)	8 (14.0%)	2 (3.5%)	3 (5.3%)	1 (1.8%)
3. Nausea	13 (22.8%)	5 (8.8%)	1 (1.8%)	7 (12.3%)	7 (12.3%)	7 (12.3%)	3 (5.3%)	4 (7.0%)	5 (8.8%)	3 (5.3%)	2 (3.5%)
4. Bloating	5 (8.8%)	4 (7.0%)	1 (1.8%)	2 (3.5%)	9 (15.8%)	7 (12.3%)	8 (14.0%)	5 (8.8%)	6 (10.5%)	4 (7.0%)	6 (10.5%)
5. Stomach fullness	3 (5.3%)	5 (8.8%)	1 (1.8%)	1 (1.8%)	3 (5.3%)	13 (22.8%)	5 (8.8%)	7 (12.3%)	8 (14.0%)	7 (12.3%)	4 (7.0%)
6. Early satiety	8 (14.0%)	4 (7.0%)	2 (3.5%)	4 (7.0%)	4 (7.0%)	7 (12.3%)	4 (7.0%)	9 (15.8%)	5 (8.8%)	7 (12.3%)	3 (5.3%)
7. Burping/belching rating	4 (7.0%)	6 (10.5%)	3 (5.3%)	8 (14.0%)	4 (7.0%)	11 (19.3%)	5 (8.8%)	7 (12.3%)	3 (5.3%)	2 (3.5%)	4 (7.0%)
8. Burping/belching bother	15 (26.3%)	2 (3.5%)	2 (3.5%)	4 (7.0%)	5 (8.8%)	13 (22.8%)	0 (0.0%)	6 (10.5%)	2 (3.5%)	5 (8.8%)	3 (5.3%)