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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/835,075	08/01/2024	David Ziring	065472-000887USPX	2843

106303 7590 08/19/2026

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EXAMINER	
JANG, CHRISTIAN Y	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
08/19/2026	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 18/835,075	Applicant(s) Ziring et al.	
	Examiner CHRISTIAN JANG	Art Unit 3791	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 8/6/25.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-2,4-5,7-8,11-12,15,18-19,23-24,26,30,32-33,36,38,40,43,49-50,58 and 61 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-2,4-5,7-8,11-12,15,18-19,23-24,26,30,32-33,36,38,40,43,49-50,58 and 61 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: "wherein at least one the wearable" in line 14 should be "wherein at least one **of** the wearable". Appropriate correction is required.

Claim 43 is objected to because of the following informalities: "the tag is worn at an upper portion of the thigh" in line 2 should be "the tag is adapted to be worn at an upper portion of the thigh". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-5, 7-8, 11-12, 18, 19, 26, and 36 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

As to claim 1, the claim recites that "at least one [of] the wearable device or the smart device" performs all the recited functions, including executing the application to process the stool frequency. However, the application is recited as a component of the smart device earlier

in the claim, and it is unclear how the wearable device, if selected, could execute an application residing on a separate device.

Claim 26 recites the limitation "the transmitter" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 36 recites the limitation "the transmitter" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 1, 12, 18-19, 23, 24, 26, 30, 36, 38, 40, 43, 49, and 58 is/are rejected under 35 U.S.C. 103 as being unpatentable over Eun et al. ("Personalized Urination Activity Management Based on an Intelligent System Using a Wearable Device") in view of Kelly (US 2009/0010390), Dickinson (US 2013/0119255), Arizti (US 2019/0336353), and Karlin (US 2020/0395124).

As to claim 1, Eun teaches a system for monitoring toileting habits of a subject comprising a wearable device worn by the subject (p229 – "urinary management system was established to collect and analyze urinary time and interval data detected through patient-worn smart bands") and a remote system configured to communicate with the wearable device wirelessly and to execute an application to process the captured event frequency data (p229 –

"through a web-based visualization to enable monitoring and appropriate feedback for urological patients"). Eun further teaches "detect when the subject is in a toilet sitting position … based on changes detected by the accelerometer" as it detects a toileting event from the wear's body orientation (p232 – use of an accelerometer and gyro sensor; p229 – device can recognize urination time and spacing based on patient-specific posture and posture changes). Eun also teaches capturing of frequency data of the toileting events so recognized (p231 – comparing a user-completed urination log with the smart band and; p229 – finding an accuracy of 95.8%). Eun fails to expressly teach "a wearable device comprising a tag adapted to be worn by the subject, wherein the tag is attachable to a thigh of the subject such that an orientation of the tag is changed in response to change of the subject's position from a standing position to a sitting position"; "an input unit or a button configured to receive an input from the subject"; and "a transmitter configured to communicate with the user device", as Eun teaches a wrist-worn smart band. In addition, Eun does teach communications between the smart-band and the management system (Fig. 1 – "connection").

Kelly teaches each of these. Kelly teaches an attitude indicator device (Abstract) used to monitor the orientation of a human subject ([0022]) using an attitude indication device (10) that comprises an orientation sensor within an attitude transmitter unit that is worn as an adhesive patch on an individual's thigh ([0073];[0089]). The orientation sensor is responsive to the angle of the thigh and distinguishes a substantially horizontal thigh (e.g. seated) from a downwardly inclined thigh characteristic of standing ([0075], [0084], Fig. 3). Kelly teaches an accelerometer configured to detect changes in positions of the subject ([0025] – acceleration sensor capable of detecting attitude/tilt and positional rate of change), an input unit or a

button configured to receive an input from the subject (momentary switch 96), and a transmitter configured to communicate with the smart device ([0103] – RF transmitter circuit 86 with antenna 88; [0143] – external communications connection 244).

It would have been obvious to modify Eun with Kelly to enable the use of a device that can be discretely worn on a location that yields the greater differentiation between standing and sitting and increase the accuracy of the device. The above combination does not expressly teach "a light sensor configured to detect changes in intensities of light" and detection of the sitting position "with the subject's lower body undressed … undressing detected by the light sensor in response to exposure of the tag attached to the thigh".

Dickinson teaches a wearable electronic device for detecting clothing (Abstract) comprising a light sensor that is configured to detect changes in optical intensity, color, light, or shadow in the near vicinity of the electronic module ([0058]) and states such sensors are useful in determining whether the device is covered by clothing ([0058]). Dickinson additionally teaches that the housing of the electronic module (501) is shaped and can be worn about a leg ([0073]).

It would have been obvious to modify the above combination with Dickinson to additionally detect whether clothing has been removed in determining a toilet sitting event, and rule out any other types of sitting that is unrelated to going to the toilet, to decrease the number of false positives and thereby increase the accuracy of the device. The above combination fails to expressly teach a bowel tracker system, "confirm that the subject is having a bowel movement in response to the input received via the input unit or button, or in

response to a user input received via the smart device" and "capture stool frequency data following the confirmation of the bowel movement by the subject".

Arizti teaches a sensor device (300) that is attachable to the skin via a bio-adhesive material ([0074]), the sensor device comprising a motion sensor in the form of an accelerometer (334), and a consumer-engageable button (346). Arizti teaches that the user can acknowledge a bowel movement via action of said button to allow for tracking timing, frequency, or other aspects of a wearer's bowel movement history ([0078]).

It would have been obvious to modify the above combination with Arizti to enable manual confirmation of a bowel movement event, to allow discrimination between the bowel movement and urination. The above combination fails to expressly teach that the smart device is configured to execute "an application" to process the stool frequency data.

Karlin teaches a mobile device (120) comprising computer-readable code (126) constituting an application for monitoring gastrointestinal function (Fig. 1B). The application receives data such as stool events ([0029] – 238) with time attributes ([0037]) and allows it to derive such classifications as frequency ([0098]).

It would have been obvious to modify the above combination with Karin to allow the execution of stool-frequency processing data in a smartphone application as taught by Karlin, to allow the monitoring to be done on a device that is widely used and assessable to the general population.

As to claim 12, Eun teaches capture of the time and interval of each recognized toileting event and transmission of said data to the management system (p229 – Abstract). Arizti teaches communication of the button acknowledgement for tracking timing, frequency, or

other aspects of a wearer's bowel movement history ([0078]) and displaying any information gathered and processed ([0089]). Karin teaches an assessment screen (280) to obtain user entry of a stool shape based on the Bristol Stool Scale (280a-280g; [0030]). It would have been obvious to further modify the above combination with the above features to allow tracking of stool quality for better diagnostical data, along with increased accuracy over having the patient attempt recall stool quality at a time later than the event.

As to claim 18, the above combination results in the recited limitation as Eun teaches that capturing, transmitting, processing, and displaying of toilet frequency data is performed passively or automatically without requiring the subject's direct or manual input via the wearable device and/or smart device (p231 – automatic) and Karin also teaches that data upload is a process that is triggered automatically upon launching the data collection process ([0056]).

As to claim 19, Arizti teaches the sensor device has a memory device to temporarily store data for when communication between the sensor device and a remote processing module is unavailable ([0086]). Kelly teaches that the transmitter range is approximately fifty feet ([0111]). It would have been obvious to further modify the above combination with Aritzi and Kelly to allow transmission of data when the devices are within communicable distance but store the data for later transmission if they are not within the threshold distance, so that data is not lost whenever they are not within range.

As to claim 23, any of the acts that correspond to the functions mapped for claim 1 are rejected in similar fashion. In addition, Kelly teaches a process flow for registering orientation

measurements, threshold comparisons, and data transmission (Fig. 3), while Eun supplies the teaching of recognizing a toileting event from posture changes (p229).

As to claim 23, Kelly teaches determining the seated position from the thigh tag (Fig. 3). Eun teaches the use of an alternative limb in the wrist (Abstract) which reads on a smartwatch worn by the subject detecting that the subject is seated or the smartwatch being detected to be substantially parallel to the ground. It would have been obvious to implement either or both detection points, as it would be a substitution yielding similar and thus equivalent results.

As to claim 26, Kelly teaches a receiver communication channel (244) comprising a Bluetooth device ([0143]). Bluetooth, having an finite range, is inherently configured to enable communication between devices within a specified distance.

As to claim 30, Karin teaches the application of stool classification and monitoring to Crohn's disease, ulcerative colitis, and functional bowel disorders such as irritable bowel disease ([0103]). As noted previously, Eun teaches the detection of height above ground, Kelly the detection of the horizontally situated thigh, Dickinson the light-threshold for detecting removal of clothing. It would have been obvious to modify the above combination to utilize the device to the patient population identified by Karlin to allow the use of the device for the population that could most benefit from its usage.

As to claims 36 and 38, Kelly teaches an audio output ([0143] – audio transducer 254) and a real-time feedback of the wearer's positional attitude ([0031]). Arizti teaches the button (346) input confirming the bowel movement ([0078]) and an audio device comprising a speaker and/or microphone in the data gathering module ([0084]). Karlin teaches an updating setting screen (215) for enabling reminders and push notifications ([0029]), and an assessment screen

(280) for providing a push notification for requesting an ecological momentary assessment ([0029]), and training a classification model (700) employing a machine learning algorithm ([0076]) from the dataset.

As to claims 40, 43, 49, 58, and 61, the wearable-device limitations that correspond to the structure mapped for claim 1 is rejected in the same manner. Arizti teaches that the sensor thickness are between 0.2 and 1.5 cm. In addition, Eun's teaching of deriving the toileting event from the wear's height information relative to the ground (p231) with the inertial signals reads on a decrease in a height position of the user exceeding a second threshold for claim 58. Kelly's discrimination of a horizontal's oriented thigh ([0026]) renders obvious the limitations of claim 61, as it would be capable of determining when the thigh is horizontally situated. Dickinson teaches the use of a timer (1701) as well as light-intensity threshold comparisons ([0058]), which renders obvious the 2/3-second window. The examiner notes that all recited specific percentage thresholds are routine optimization of a variable disclosed in a range in the prior art absent a showing of criticality.

Claim(s) 2, 7, 11, 32, and 50 is/are rejected under 35 U.S.C. 103 as being unpatentable over Eun et al. ("Personalized Urination Activity Management Based on an Intelligent System Using a Wearable Device") in view of Kelly (US 2009/0010390), Dickinson (US 2013/0119255), Arizti (US 2019/0336353), and Karlin (US 2020/0395124), and further in view of Chen ("Bathroom Activity Monitoring Based on Sound") and Herdt (US 2019/0147731).

As to claim 2, Kelly teaches the thigh tag reporting a horizontal orientation in the seated posture (Fig. 3), Dickinson teaches the persistence timer establishing a threshold duration

(1702), and Arizti teaches the device as a smartphone ([0089]) paired with a transmitter ([0028]), and data gathering using a microphone ([0084]). The above combination does not expressly teach the sound of the toilet flush to determining a bowel movement activity. Chen teaches the classification of a flushing sound from others such as washing hands, showering, brushing teeth, etc (p51) whereas Herdt teaches determining the usage of bathroom facilities by sensing the activation (flushing) of a toilet ([0031]). It would have been obvious to modify the above combination with Chen and Herdt to enable the use of a flushing sound as another point of data in verifying that the user has had a bowel movement (as opposed to e.g. sitting down to change their pants).

As to claim 7, Kelly teaches an audio output unit or speaker (264) and the input unit or button (96). Arizti teaches that the data gathering module contains an audio device comprising a speaker and/or microphone ([0084]) and that the sensor device comprises a flash memory component (326) and that it could be used to store data when communications between the sensor device and the remote data processing module is unavailable ([0086]). Karlin teaches the smart device display (125), push notifications (218), and the ecological momentary assessment (280-288). Dickinson teaches acting on a sensed state only after it persists beyond a predetermined interval (1702).

The above combination fails to expressly teach “receive acoustic data sensed by the microphone and/or acoustic data sensed by a microphone of the smart device; and determine whether the subject is seating on in the toilet sitting position based on the received acoustic data”. Chen teaches the classification of a flushing sound from others such as washing hands, showering, brushing teeth, etc (p51) whereas Herdt teaches determining the usage of

bathroom facilities by sensing the activation (flushing) of a toilet ([0031]). It would have been obvious to modify the above combination with Chen and Herdt to enable the use of a flushing sound as another point of data in verifying that the user has had a bowel movement (as opposed to e.g. sitting down to change their pants).

As to claim 11, Eun teaches determining the seated position by applying an LSTM based recurrent neural network (p230) "based on changes in patients' posture (p231) that's implemented at the patient management system and not the band (Fig. 3; "Methods"). Karlin teaches a classification model (700) for machine learning using a convolutional neural network (CNN) ([0067]). It would have been obvious to train the demarcation algorithm on the subject's button confirmations as it's a form of confirmation of whether the event has occurred and would result in accurate training.

As to claim 32, the method corresponds to the functions mapped for claim 7 and are rejected on the same combination for the same reasons.

As to claim 50, Chen teaches determining that a bathroom voiding activity has occurred from the acoustic data alone (p56). Therefore Chen teaches determining that the user is having a voiding event "regardless the changes detected by at least the light sensor indicate that the user is sitting on the toilet". It would have been obvious to further modify the above combination with Chen, and use acoustic sound over the light sensor data, as the user is less likely to be avoid making the noise associated with the voiding event while it is far easier to avoid light by doing said voiding event in darkness. As noted previously, both Eun and Karlin teaches the neural network model.

Claim(s) 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Eun et al. ("Personalized Urination Activity Management Based on an Intelligent System Using a Wearable Device") in view of Kelly (US 2009/0010390), Dickinson (US 2013/0119255), Arizti (US 2019/0336353), and Karlin (US 2020/0395124), and further in view of Borke et al. (US 2012/0112906).

As to claim 4, Borke teaches radio-signal reader devices positioned at fixed points of interest, which work in conjunction with an ID tag worn by the user to determine if they have visited the area ([0071]) and allows for the identification of a zone based on the devices coming within a communication distance ([0081]). It would have been obvious to further modify the above combination with Borke and utilize a tag, which can then be affixed to a toilet, and utilize the system in determining a toilet sitting of the subject, as yet another way of building redundancy into the system.

Claim(s) 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Eun et al. ("Personalized Urination Activity Management Based on an Intelligent System Using a Wearable Device") in view of Kelly (US 2009/0010390), Dickinson (US 2013/0119255), Arizti (US 2019/0336353), Karlin (US 2020/0395124), and Borke et al. (US 2012/0112906), and further in view of Lee et al. (US 2012/0112906).

As to claim 5, Lee teaches various types of RFID tags, including a high frequency transponder with a read range of about up to a meter ([0060]). It would have been obvious to modify the above combination with Lee to utilize a tag with an operational distance of less than

1 meter as to differentiate between going to the bathroom to sit on a toilet versus another event, such as washing hands.

Claim(s) 8 and 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Eun et al. ("Personalized Urination Activity Management Based on an Intelligent System Using a Wearable Device") in view of Kelly (US 2009/0010390), Dickinson (US 2013/0119255), Arizti (US 2019/0336353), Karlin (US 2020/0395124), Chen ("Bathroom Activity Monitoring Based on Sound") and Herdt (US 2019/0147731), and further in view of Hershey et al. ("CNN Architectures for Large-Scale Audio Classification")

The above combination does not expressly teach that the acoustic data are robustly identified using a neural network model tuned for acoustic classification running on the smart device; and a neural network model utilizes transfer learning to first pre-train a convolutional neural network (CNN) with a large corpus of labeled acoustics data.

Hershey teaches the application of a convolutional neural network to classify the soundtracks of a large corpus of labeled acoustics data using a dataset comprising 70 million training videos of 5.24 million hours (Abstract). It would have been obvious to modify the above combination with Hershey to use a CNN trained model to identify acoustic data to increase the accuracy of the device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any nonprovisional extension fee (37 CFR 1.17(a)) pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached Monday-Friday (7-3:30 EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Chen can be reached at 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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