Written Testimony on "Smart Health: Empowering the Future of Mobile Applications"

Committee on Science, Space and Technology, Subcommittee on Research and Technology, U.S. House of Representatives

Howard Look, President and CEO, Tidepool
March 2, 2016

Key points:

- Empowered Patients, Citizen Science and Patient-led Innovation is real. We need to embrace it and encourage it. People empowered to do their own research and development fosters patient-led innovation, which leads to safer, more effective care. NOT embracing this is a greater risk to safety and effectiveness because it slows down the the pace of innovation. Examples of patient-led innovation:
    - Nightscout: Access to Dexcom CGM data led to thousands (if not tens of thousands) of people with diabetes, as well as their parents and loved ones, having the peace of mind that they are safe. The community that formed around Nightscout, CGM in the Cloud, provides additional support to engaged patients and their families.
    - Bigfoot Biomedical: A commercial venture building a closed loop "artificial pancreas". Early prototype development prior to forming the company was based on access to Dexcom CGM data and the ability to control Medtronic insulin pumps.
    - OpenAPS: An open source implementation of a closed loop system based on the same access to Dexcom CGM data and control of Medtronic insulin pumps. Even in early form, it clearly leads to safer and more effective treatment than the usual standard of care. There are currently dozens of users and active contributors of the project, and growing quickly.
    - Tidepool: A non-profit organization that has built an open platform enabling access to diabetes data from devices and an ecosystem of applications to emerge to cloud data.
- The White House, Congress and the FDA should not limit the ability of citizens to develop and use their own medical devices as they see fit.
- The White House, Congress and the FDA should ENCOURAGE Citizen Science and Patient-Led Innovation by compelling device makers and software to openly publish their device communication protocols and data access APIs.

    - To overcome concern of liability, law/regulation can make it clear that as long as data and control protocols are correct, accurate, and timely, that what the end-user does with it causes no liability back to the device originator.
    - Law/regulation can also make it clear that data and protocol specifications is a labeling requirement.
- Patients should always have access their own health data, including real-time data generated by devices connected to them (e.g. a CGM or insulin pump) or implanted in them (e.g. an ICD). Patient access to data from devices or clouds should not be limited.

Cloud data providers should:

- Use REST APIs or other well-known APIs mechanisms to expose real-time access to data (any mechanism is fine, but in 2016 we encourage REST APIs; better mechanisms may emerge in the future). Electronic/software access to data key to innovation. It's not good enough to say "you can download a PDF or CSV."
- Use OAuth or similar well-known authentication methods to allow patient-driven access to data.
- Using mechanisms like OAuth and REST APIs will encourage an interoperability an ecosystem of devices and applications to emerge. This will lead to innovation in areas that we can only imagine.

Device Makers:

- SHOULD use well-understood authentication and communication protocols that are based on tried-and-true cryptographic techniques. Don't invent something new.
- SHOULD NOT depend on "security through obscurity" to keep your device safe. Firmware will be reverse engineered, and communication protocols will be sniffed.
- SHOULD permit users to be able to get data off of their device. Do not use "security" as an excuse for not making it possible for data to be extracted from your device by the end user. You can have secure access by end users while still publishing your protocols.
- SHOULD publish control protocols for your device.
    - Doing so does not change its intended use; you can (and should) make it clear which interfaces support intended use and which interfaces are presented for research and development purposes only. This fosters patient-led innovation and better care. It is the responsibility of the third

party using the interfaces to make sure that it does not adversely affect the intended use of the device.
    - You SHOULD NOT limit access to device data because you are "worried about how people will use the data."
    - You SHOULD use well-known authentication and encryption mechanisms as well as data transport protocols. Use standards where possible.
    - You SHOULD NOT limit access to a device by its user using cryptographic techniques.

Also, devices makers COULD do these non-intuitive things that will also spark patient-centered innovation:

- You COULD allow your device to be flashed with new firmware, by the end user, in the field. This will encourage further innovation.
- You COULD publish your source code. This leads to greater inspection and safety.
    - You can still protect your intellectual property if you do this, though it would be nice if you gave your IP away.
    - [1][2] … free and open code gives users the ability to independently assess the system and its risks. Bugs would be patched more easily and quickly, and it would remove the dependence on a single party.

Regulators SHOULD:

- Seek ways to encourage Citizen Science and Patient-led innovation.
- Allow device makers to publish the data protocol and device specification of their devices without that changing the intended use of the device. Liability to the device maker ends with documenting the protocols and ensuring that the data and protocols are accurate. Once the device maker shows that the data is correct, accurate, and timely, it becomes the responsibility of others who use the data and control protocols to ensure safety and efficacy.
- Place no restrictions on "N of 1" studies - empowered patients who design and implement their own studies are a wealth of knowledge and research.
- Allow employees of device companies to opt-in to small-scale trials.
- Make it clear that documenting a Do It Yourself project is not the same as distributing a medical device.

Impediments. These are the impediments that have have prevented efforts from doing more:

- Device companies not being willing to openly publish their device data protocols, or only making them available under terms of confidentiality or limitations on use.

- Companies being concerned that "we don't know what people will do with their data." By contrast, companies should wonder "I wonder what wonderful things will do if we DO give them access to their data!" Some examples:
    - They will invent software that enables them to track their child's blood sugar while at school or on a sleepover, reducing the risk of nocturnal hypoglycemia and increasing quality of life.
    - They will invent devices and systems that do a better job of maintain blood sugar that the usual standard of care, and reducing the risks of hypo- and hyperglycemia.
- Companies being concerned that by making data available, that their competitors will take that data out of context or make inappropriate claims, e.g. "Your insulin pump causes more episodes of hypoglycemia in children than mine does."
- Companies feeling like they "own" the data, and not being willing to let patients use it as they see fit. Or companies not wanting to make the health data that they store available without being paid.

In summary:

- We need to shift the thinking from "We are worried about what people will do with this data" to "We wonder what incredible and wonderful things will do if we DO give them access to their data!"
- Patients should not be required to "outsmart" the very companies whose devices and services they depend on in order to receive life-saving therapy by reverse engineering the devices.
- Instead of seeking ways to limit what an engaged patient can do, we should seek ways to empower them. Along the way, we will also inspire and engage other patients who might have otherwise thought that the usual standard of care was as good as it gets.
- The avalanche of patient-led innovation and citizen science has begun. We need to do everything we can to foster and catalyze this revolution.

References:

[1] https://opensource.com/life/10/8/how-open-source-community-could-save-your-life
[2] http://www.softwarefreedom.org/resources/2010/transparent-medical-devices.pdf

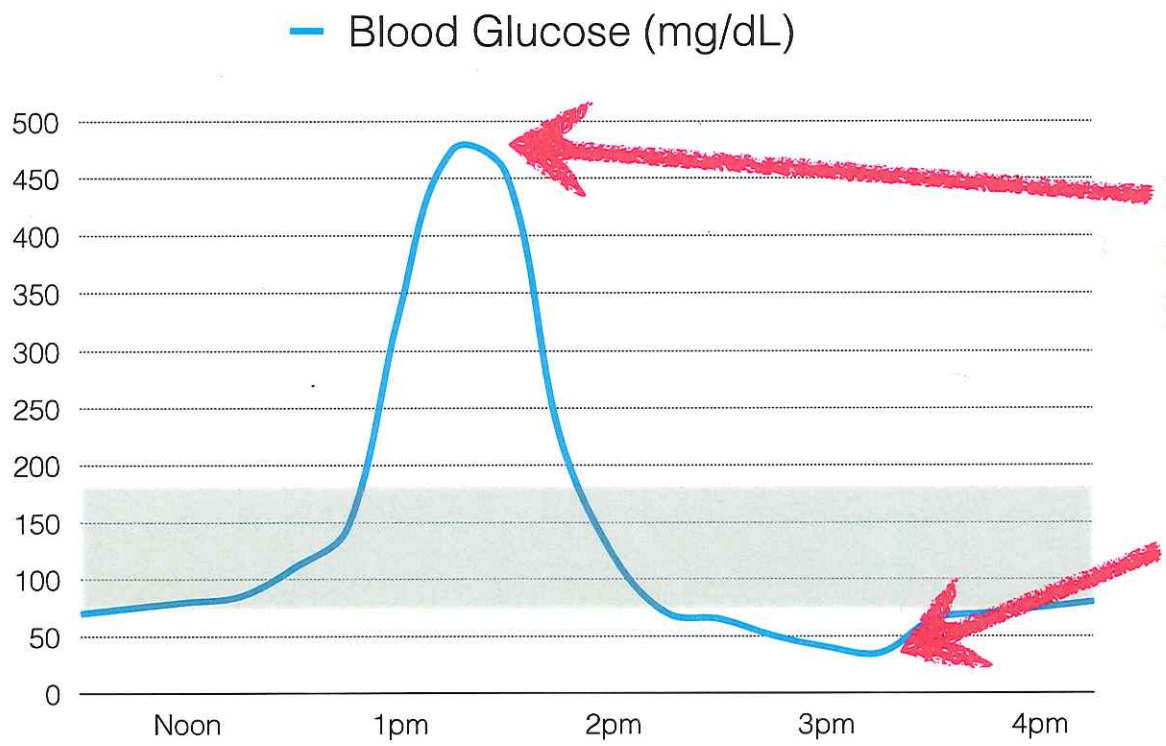
TIDEPOOL

Howard Look
President and CEO, Founder

Testimony before:
Committee on Science, Space and Technology
Subcommittee on Research and Technology
U.S. House of Representatives

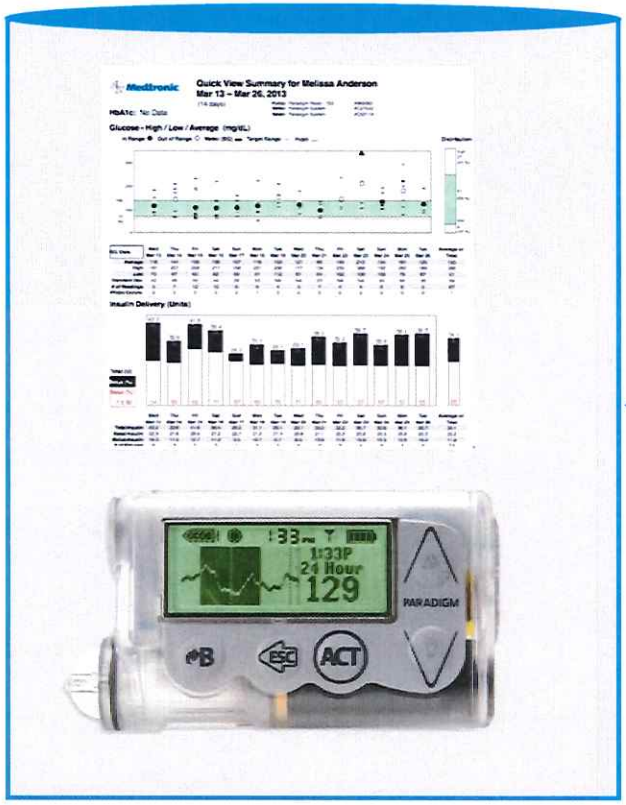
March 2, 2016

Katie Look
First Day of 6th Grade, 2011
(5 days before diagnosis)

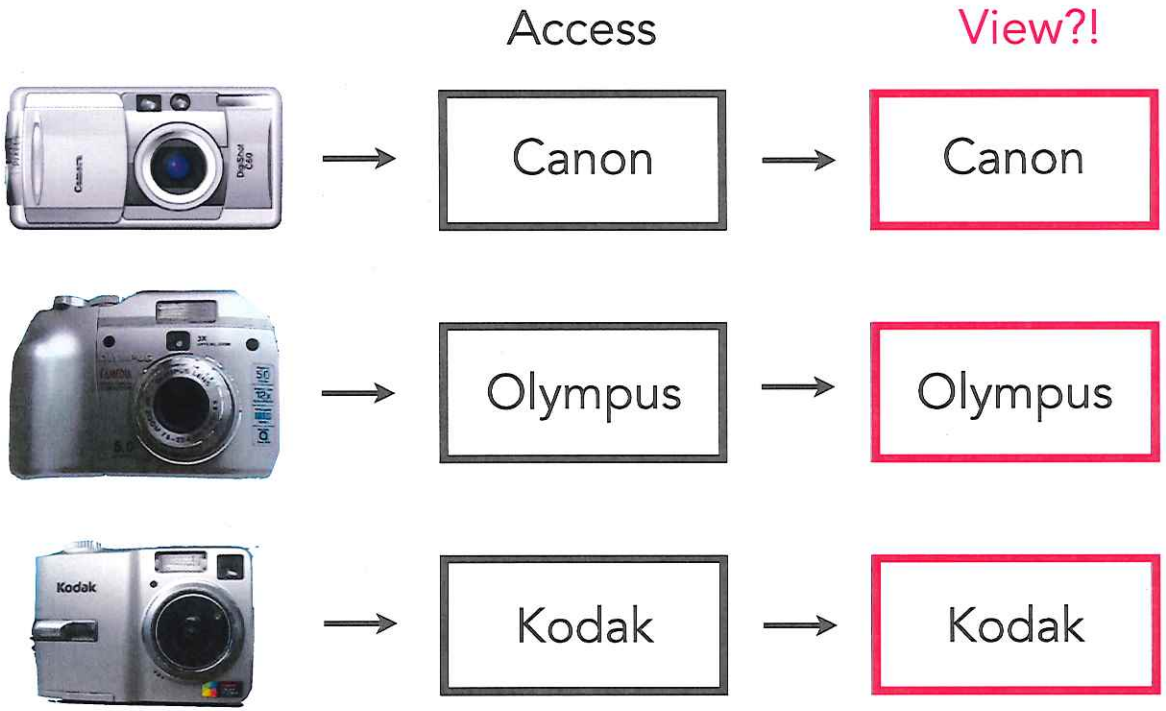


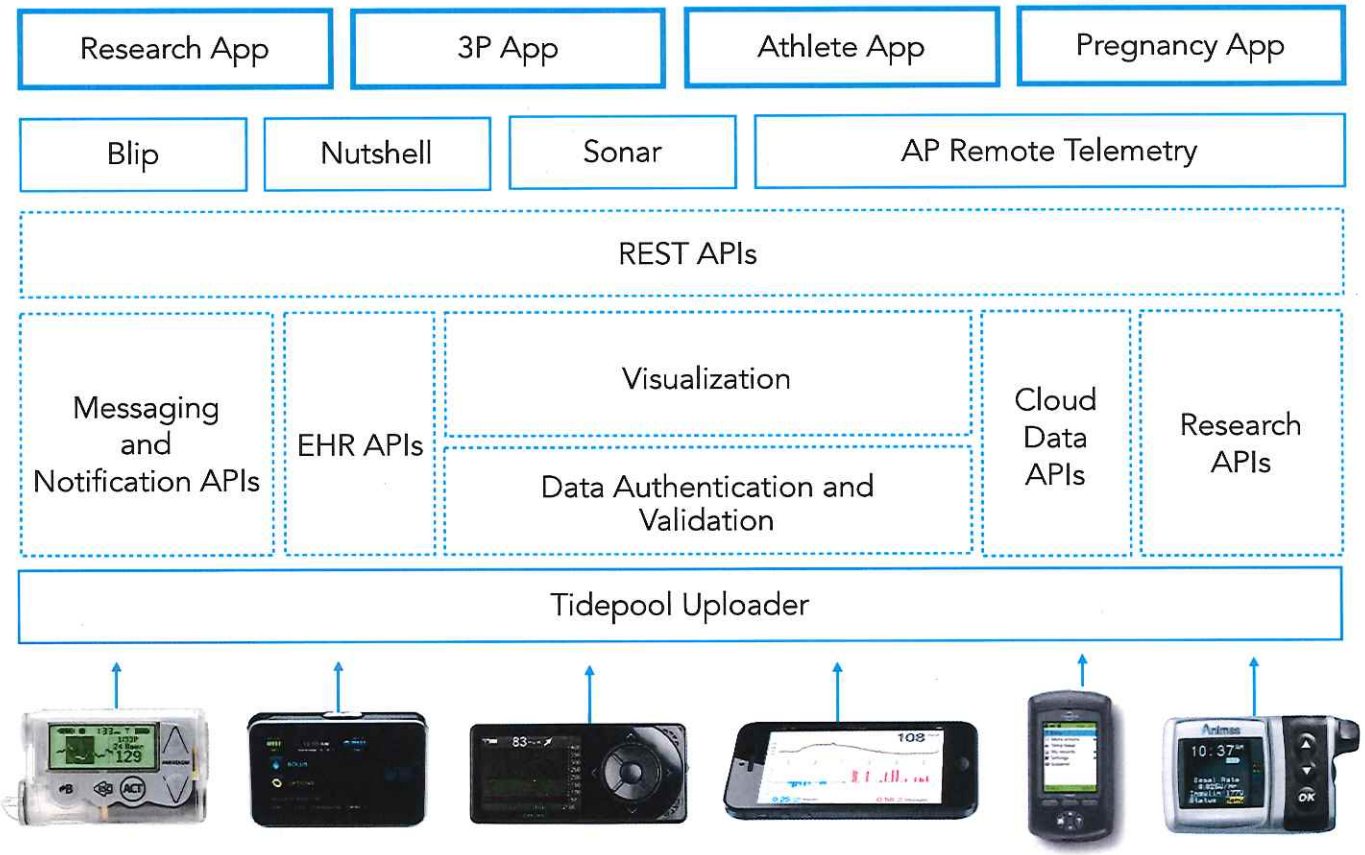
Long term complications:
nerve damage, kidney failure, blindness, amputation

Acute, short term dangers:
cognitive impairment, seizure, coma, death

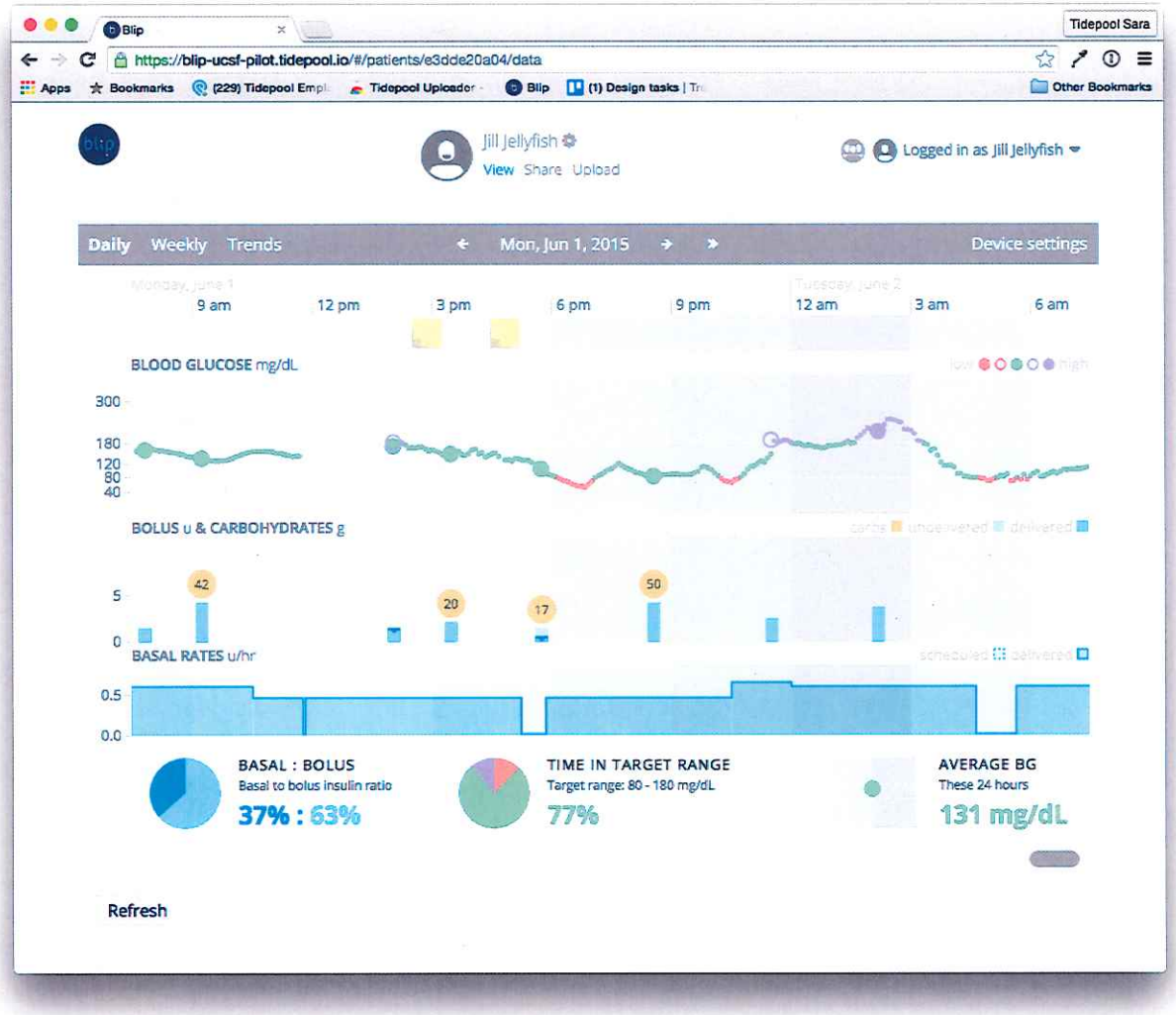

Medtronic
Quick View Summary for Melissa Anderson
Mar 13 – Mar 26, 2013
HbA1c: No Data
Glucose - High / Low / Average (mg/dL)
Insulin Delivery (Units)
133
1:33P
24 Hour
129
PARADIGM
ESC
ACT


83
400
350
300
250
200
150
100
50
dexcom

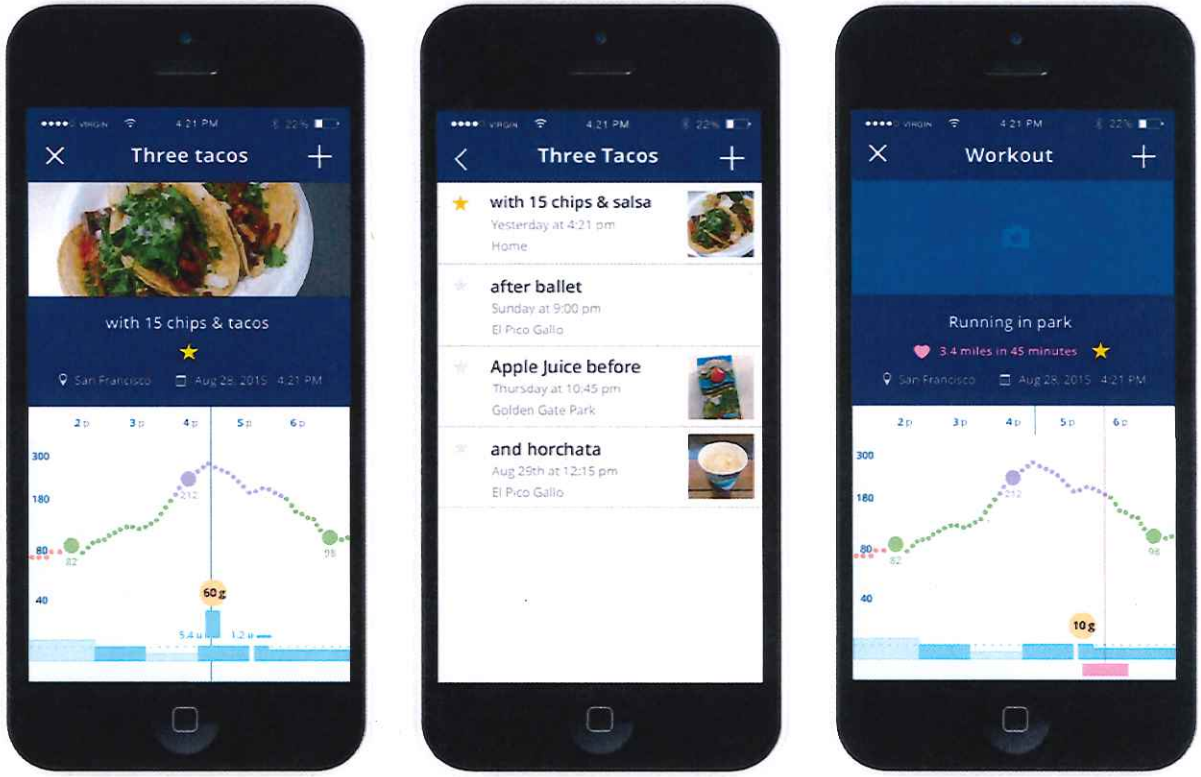

Access
View?!
Canon
Canon
Olympus
Olympus
Kodak
Kodak

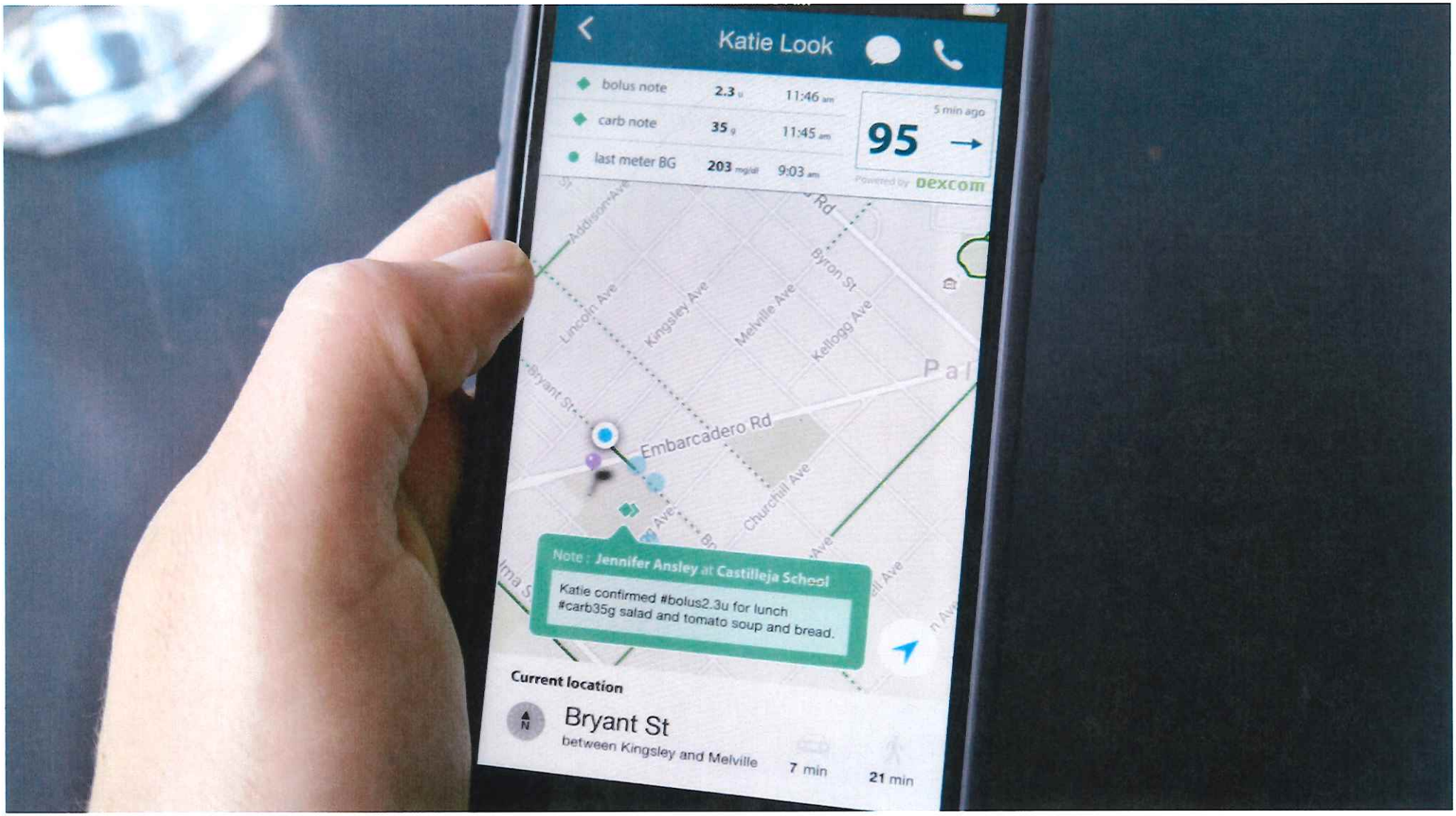

Research App
3P App
Athlete App
Pregnancy App
Blip
Nutshell
Sonar
AP Remote Telemetry
REST APIs
Messaging and Notification APIs
EHR APIs
Visualization
Data Authentication and Validation
Cloud Data APIs
Research APIs
Tidepool Uploader

Blip

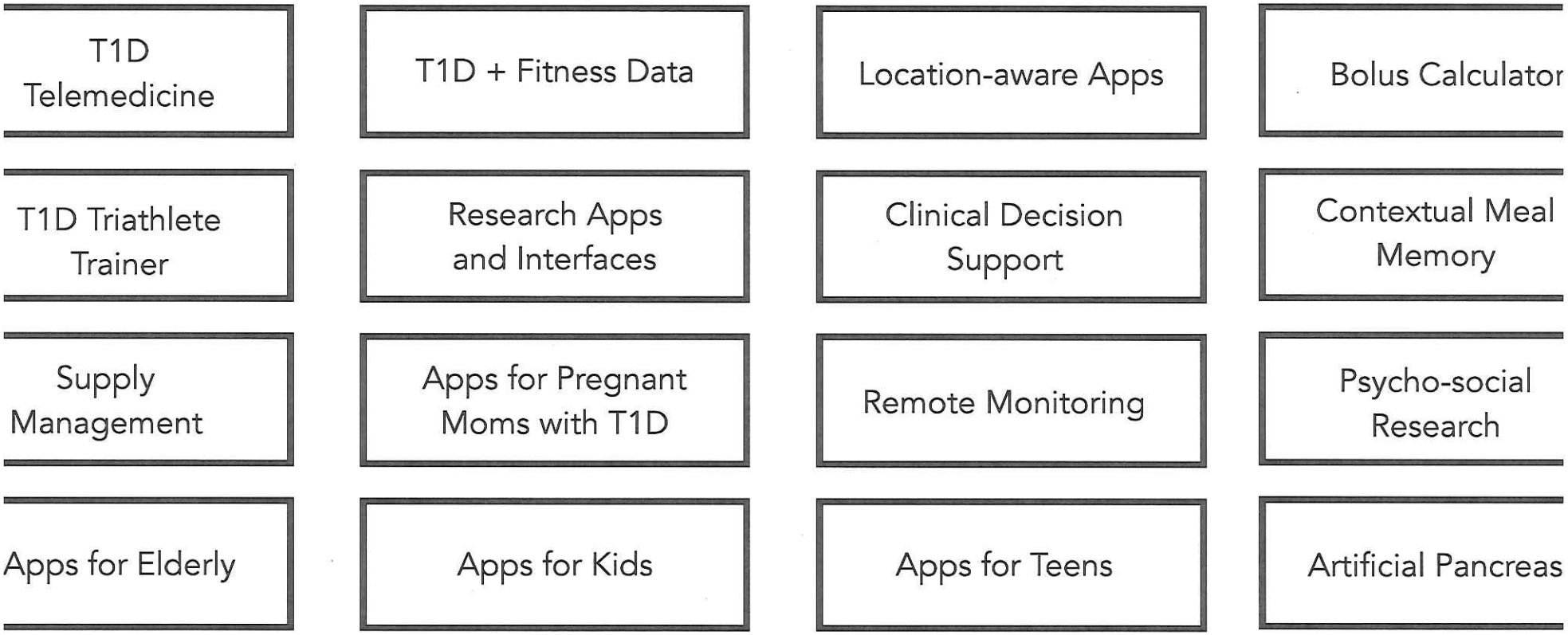

Blip
Tidepool Sara
https://blip-ucsf-pilot.tidepool.io/#/patients/e3dde20a04/data
Apps
Bookmarks
(229) Tidepool Empl
Tidepool Uploader
Blip
(1) Design tasks | Tr
Other Bookmarks
Jill Jellyfish
View Share Upload
Logged in as Jill Jellyfish
Daily Weekly Trends
Mon, Jun 1, 2015
Device settings
9 am
12 pm
3 pm
6 pm
9 pm
12 am
3 am
6 am
BLOOD GLUCOSE mg/dL
300
180
120
80
40
BOLUS u & CARBOHYDRATES g
5
0
42
20
17
50
BASAL RATES u/hr
0.5
0.0
BASAL : BOLUS
Basal to bolus insulin ratio
37% : 63%
TIME IN TARGET RANGE
Target range: 80 - 180 mg/dL
77%
AVERAGE BG
These 24 hours
131 mg/dL
Refresh

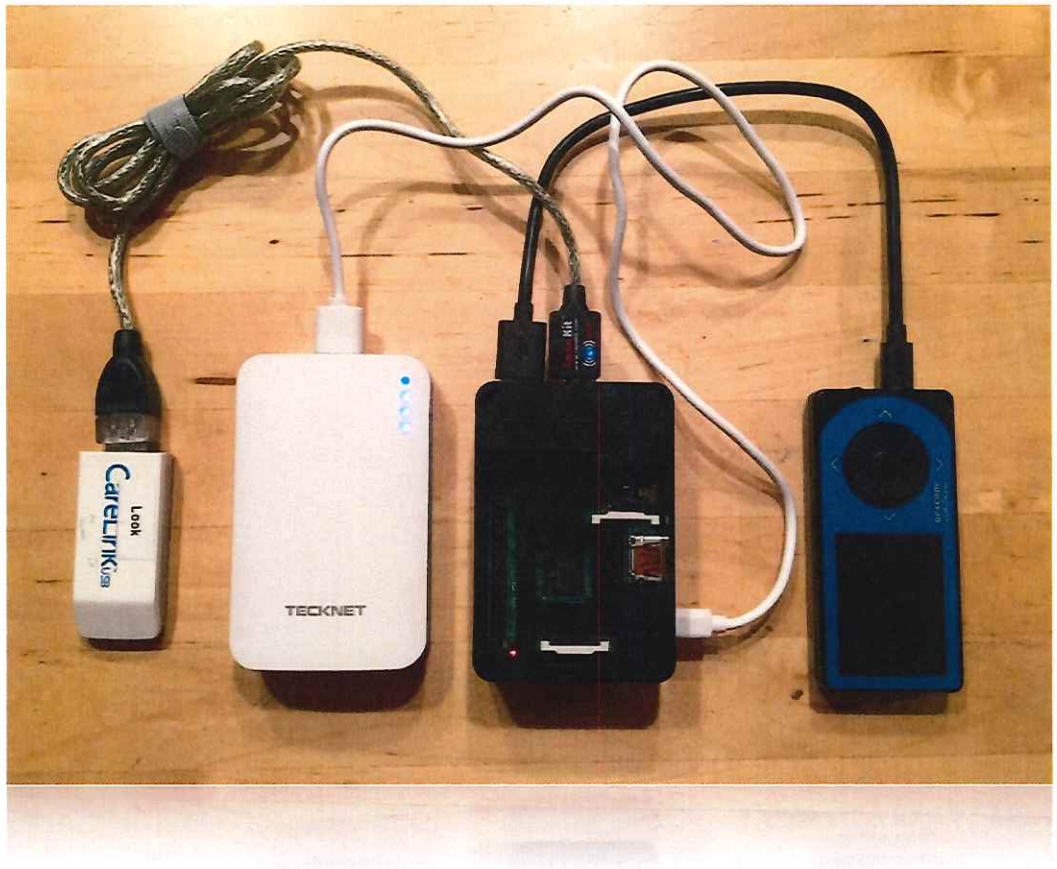
Nutshell

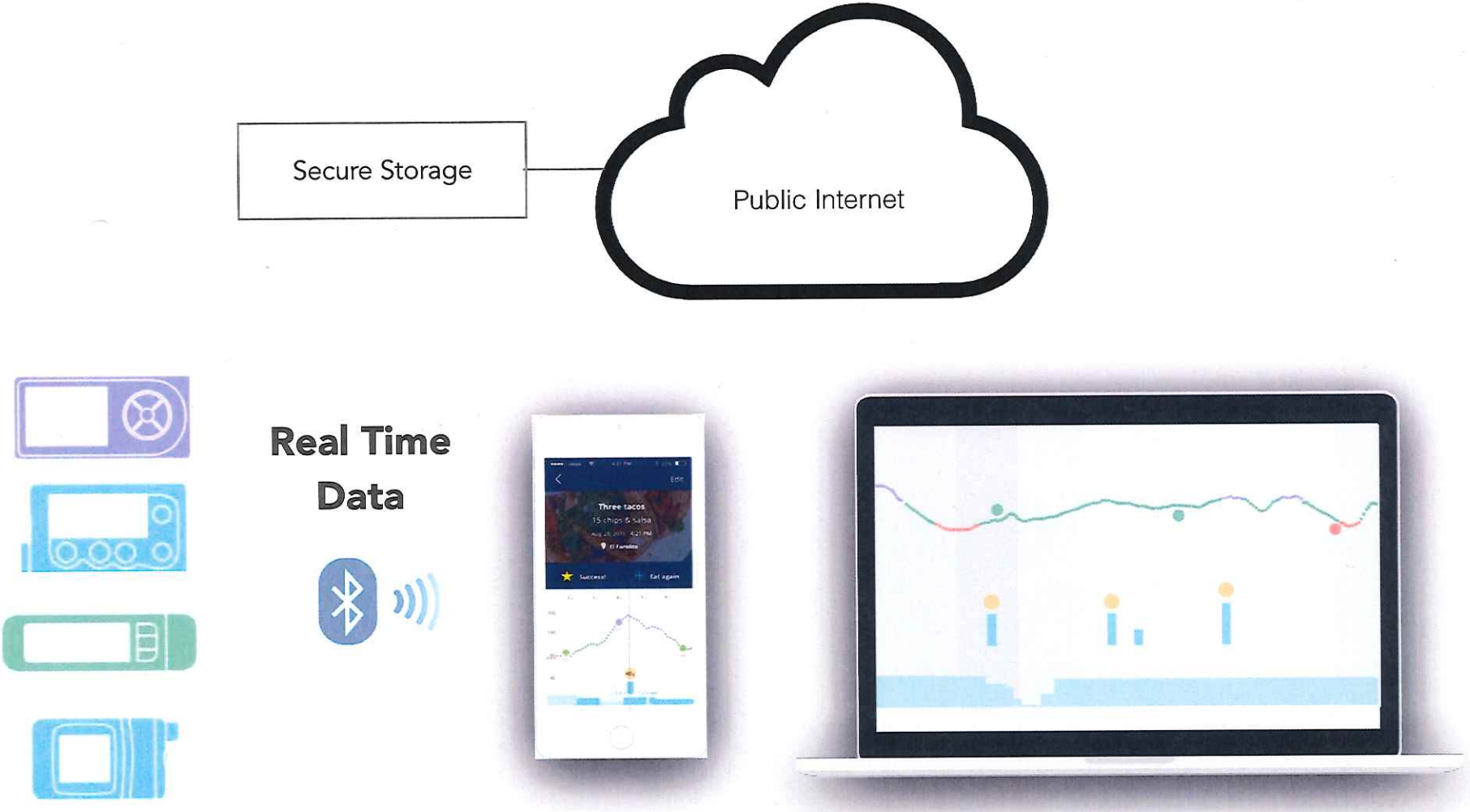

Three tacos
with 15 chips & tacos
Three Tacos
with 15 chips & salsa
Yesterday at 4:21 pm
Home
after ballet
Sunday at 9:00 pm
El Pico Gallo
Apple Juice before
Thursday at 10:45 pm
Golden Gate Park
and horchata
Aug 29th at 12:15 pm
El Pico Gallo
Workout
Running in park
3.4 miles in 45 minutes


Katie Look
bolus note 2.3 u 11:46 am
carb note 35 g 11:45 am
last meter BG 203 mg/dl 9:03 am
5 min ago
95
Powered by dexcom
Embarcadero Rd
Kingsley Ave
Melville Ave
Kellogg Ave
Churchill Ave
Byron St
Lincoln Ave
Bryant St
Note : Jennifer Ansley at Castilleja School
Katie confirmed #bolus2.3u for lunch #carb35g salad and tomato soup and bread.
Current location
Bryant St
between Kingsley and Melville
7 min
21 min

A Type 1 Diabetes Application Ecosystem




Look
CareLink USB
TECKNET


Secure Storage
Public Internet
Real Time Data
Three tacos
15 chips & salsa

TIDEPOOL

Howard Look
@howardlook
@Tidepool_org
howard@tidepool.org

Biography for Howard Look, President and CEO, Founder, Tidepool

Howard Look is the President, CEO and Founder of Tidepool, a Silicon Valley non-profit startup with the mission of liberating data from diabetes devices and catalyzing an ecosystem of applications that help reduce the burden of managing Type 1 Diabetes.

In June, 2015, Howard received the "White House Champions of Change Award for Precision Medicine" on behalf of Tidepool's work. In February, 2016, he shared the stage with President Barack Obama during a panel discussion at the Precision Medicine Initiative summit.

Prior to working on healthcare challenges at Tidepool, Howard held technology leadership positions in the 3D and consumer electronics space:

> Howard was VP of Software at Amazon (Seattle, WA) and Amazon's consumer electronics subsidiary, Lab126 (Cupertino, CA), where he led a secret software project to develop devices that leverage cloud services.
>
> Prior to Amazon, Howard worked at Linden Lab, where he led the team that delivered the open-sourced Second Life Viewer 2.0 project. "Second Life" is a collaborative, online, 3D, virtual reality experience.
>
> Howard was VP of Software at Pixar Animation Studios, where he led the software development and user experience teams that built Pixar's proprietary 3D animation film-making system. If you wait long enough, you can see Howard's name scroll by in the credits for *Cars*, *Ratatouille* and *WALL-E*.
>
> Prior to Pixar, Howard was on the founding team at TiVo where, as VP of Software and User Experience, he led the efforts that made TiVo as easy to use as it was disruptive.
>
> Howard started his career at Silicon Graphics Computer Systems, also known as SGI. There he worked on numerous projects, including "Inventor", a 3D graphics toolkit, and the O2 Out of Box Experience.

Howard holds a Bachelor of Science in Computer Engineering from Carnegie Mellon University in Pittsburgh, PA. He grew up in Litchfield, Connecticut and now lives in Palo Alto, California with his wife, Melissa Anderson and their three children. His teenaged daughter has T1D.

Learn more about Tidepool at Tidepool.org
Follow Howard on Twitter: @howardlook
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