

# 00 NIGHTSCOUT INTRO



**NIGHTSCOUT**  
**#WeAreNotWaiting**

# BEWEST GIT WRANGLER



# NIGHTSCOUT LOGO MEDIUM



# A DEXCOM INSERTER

Any advice you have would be helpful. I accidentally dry fired this applicator and rendered it completely useless. Does Dexcom provide any type of replacements for errors such as this?



[Like](#) · [Comment](#)

# DEXCOM MISFIRE COMMENTS

 View 21 more comments

 I My son has been using his DEX for 4 years and I just have to ask- what is a dry fired??  
3 hrs · Like

 Well I have no idea but I know that I pushed and pulled at the same time so it didn't insert.  
3 hrs · Like

 Any, I accidentally plunged the applicator when it wasn't in place. The best way I can describe dry fire is to pull the trigger on a gun when there is no bullet in the chamber. Maybe a poor choice of words on my part.  
3 hrs · Like

 Just File an issue/report/complaint. I wish companies made some "toy"/no-op versions of everything so I could play with them and get used to the process. Maintaining a site where something is external is inserted into your body is a big deal. I wish they all paid more attention to this.

Please do let Dexcom know this happened.  
Just now · Like

# DEXCOM TRIBULATIONS



**[REDACTED] k**

Yesterday at 7:54am · California Heights, CA

My confession, my T1D daughter is away at diabetes camp and to set up this system I had to wear her cgm. It's my first time with the site and honestly it's a little uncomfortable. I'm glad I can take it off and not worry about it, unfortunately for her not so much. I will be more understanding in the future if she wants to take a break from her cgm. This was a good lesson for me.

# IS IT THE STRINGS

 Cameron  
7 hrs · Edited

Hello! Need a little help.. everything appears to have been set up and looks great. Except the website. No graph or data. I have the time and the alert settings.

Uploader looks good, Mongolab has what it needs, and Azure is good on usage.

Ideas?

[Like](#) · [Comment](#)

 [View 39 more comments](#)

 [Kennyworth](#) what is your site url? Can you pm me?  
5 hrs · Like ·  1

 [Cameron](#) I'm up and running!!! Thanks, everyone! 😊  
4 hrs · Like ·  2

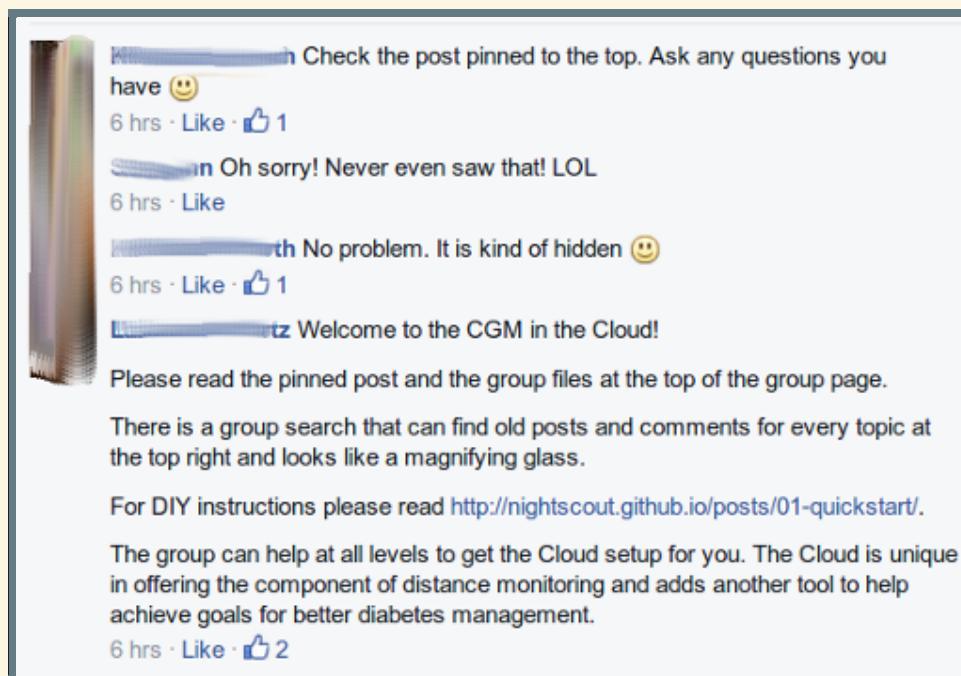
 [Kennyworth](#) Touchdown dance time!  
3 hrs · Like ·  2

# NIGHTSCOUT CGM CLOUD JOINING 01

Hi! I am so excited to have found this group! I almost cried when I saw that this is possible, after saying for years it would be awesome to send my 8 year olds info from the cgm to my phone! My only problem now is WHERE do I start? We have a dexcom and I have an iPhone. I know I need a droid...what else do I need? Any help would be greatly appreciated! 😊

Like · Comment

# NIGHTSCOUT CGM CLOUD JOINING 02



A screenshot of a Facebook group conversation. The first post from a user named 'm' says: "Check the post pinned to the top. Ask any questions you have 😊". It has 1 like and was posted 6 hours ago. A user 'n' replies: "Oh sorry! Never even saw that! LOL". They also have 1 like and it was posted 6 hours ago. A user 'th' replies: "No problem. It is kind of hidden 😊". They have 1 like and it was posted 6 hours ago. A user 'tz' replies: "Welcome to the CGM in the Cloud! Please read the pinned post and the group files at the top of the group page. There is a group search that can find old posts and comments for every topic at the top right and looks like a magnifying glass. For DIY instructions please read <http://nightscout.github.io/posts/01-quickstart/>. The group can help at all levels to get the Cloud setup for you. The Cloud is unique in offering the component of distance monitoring and adds another tool to help achieve goals for better diabetes management." This post has 2 likes and was posted 6 hours ago.

# NIGHTSCOUT SUPPORT

## 00 2

A screenshot of a Facebook group post and its replies. The post is from a user who is excited to have found the group and is asking for help with setting up Nightscout on their Dexcom and iPhone. The post has been liked by 5 people. Several users reply, providing instructions and welcome messages. One user asks about pinned posts, another replies with a link to a quickstart guide, and another welcomes them to the group.

Hi! I am so excited to have found this group! I almost cried when I saw that this is possible, after saying for years it would be awesome to send my 8 year olds info from the cgm to my phone! My only problem now is WHERE do I start? We have a dexcom and I have an iPhone. I know I need a droid...what else do I need? Any help would be greatly appreciated! 😊

Like · Comment

5 people like this.

Check the post pinned to the top. Ask any questions you have 😊

6 hrs · Like · 1

Oh sorry! Never even saw that! LOL

6 hrs · Like

No problem. It is kind of hidden 😊

6 hrs · Like · 1

Welcome to the CGM in the Cloud!

Please read the pinned post and the group files at the top of the group page.

There is a group search that can find old posts and comments for every topic at the top right and looks like a magnifying glass.

For DIY instructions please read <http://nightscout.github.io/posts/01-quickstart/>.

The group can help at all levels to get the Cloud setup for you. The Cloud is unique in offering the component of distance monitoring and adds another tool to help achieve goals for better diabetes management.

6 hrs · Like · 2

# NIGHTSCOUT TESTIMONIAL 2



# NIGHTSCOUT WELCOME QUESTIONS 01



T [REDACTED]

11 hrs

This site is awesome. It is great to read about so many wonderful things going on technology wise. I was interested in all the posts about using the pebble. I currently have one and use it for everything. My question is; is there an app for use with the g4. I can't find one, also setting it up. Is there an easy process. Thanks for any advise.

[Unlike](#) · [Comment](#)

# NIGHTSCOUT WELCOME QUESTIONS 02

 Welcome to the CGM in the Cloud!

Please read the pinned post and the group files at the top of the group page.

There is a group search that can find old posts and comments for every topic at the top right and looks like a magnifying glass.

For DIY instructions please read <http://nightscout.github.io/posts/01-quickstart/>.

The group can help at all levels to get the Cloud setup for you. The Cloud is unique in offering the component of distance monitoring and adds another tool to help achieve goals for better diabetes management.

10 hrs · Unlike ·  2

 Please also check out the forums here <http://nightscout.info/forum/> if you have any questions please don't hesitate to ask.

10 hrs · Unlike ·  1

# WELCOME TO CLOUD



Natascha I just found this group today too and I've shed quite a few happy tears. We are getting ready to send my T1 to kindergarten in August and to say that this is an answer to prayer is an understatement.

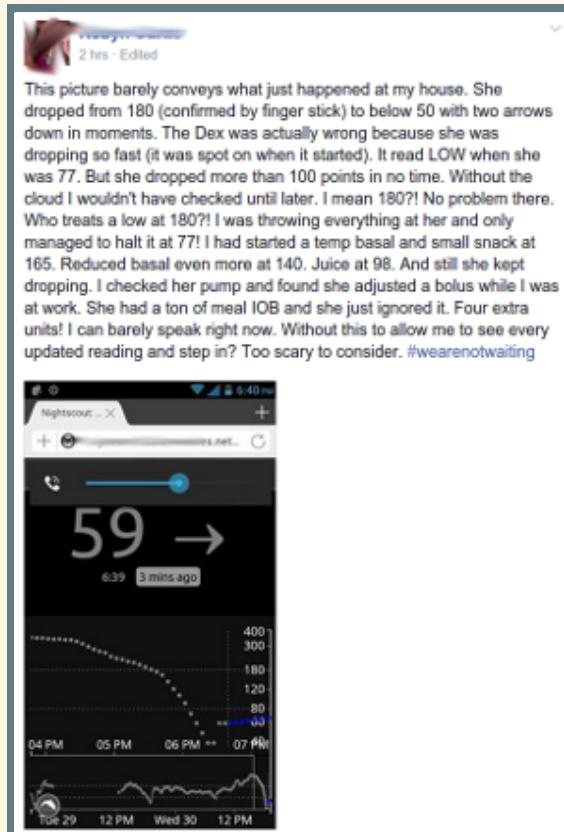
6 hrs · Like ·  7



Linda It is even more than you imagine. The Cloud is a huge leap forward to giving parents extra peace of mind. Welcome!

6 hrs · Like ·  3

# DROP LIKE A ROCK



# NIGHTSCOUT TESTIMONIAL 11

July 20 at 5:49pm

Awesome — with [REDACTED]an.



Like · Comment

1 like · 26 others like this.

[REDACTED]n #bestsummerever!!! Thank you!! can't say it  
enough

July 20 at 5:51pm · Like · 2

# NIGHTSCOUT TESTIMONIAL 34



4 hrs · San Francisco, CA

My sister called at 7am this morning to wake me up. "Dude, you're going low!" Thank you, Nightscout! And thanks to the nightscout devs who made remote monitoring real.

[Unlike](#) · [Comment](#)

 You,  and 47 others like this.

# SAFE AT DANCE CLASS

McKinney, TX · Yesterday at 2:10pm

Another Nightscout win: I look down and see 90 and falling on my watch. I have a dance teacher pull her from class to have a snack. Finger poke: 49. Yep, this is a big deal. Thank you!

[Like](#) · [Comment](#)

and 46 others like this.

This is why I struggle to understand the fda etc reluctance to allow us access to realtime data. Yes, we absolutely should not rely solely on cgm data but if it is available WHY cant we easily get real time access through manufacturers supplied kit. Why has it relied on desperate parents producing a diy system. WHY???

Yesterday at 2:22pm · Edited · [Unlike](#) · 6

AMEN, AMEN! Amen!

Yesterday at 2:19pm · [Like](#) · 1

# WHAT DOES DEX SAY



A screenshot of a Facebook post. The post is from a user whose profile picture is a blue and yellow abstract design, and whose name is blurred. It was posted on June 9. The text of the post is as follows:

Today my 5 year old son is at Lego Camp - in Foreign to us place. With this set up, I can allow him to be a kid! I am not texting him asking for dexcom readings! I can refresh my browser or check the pebble watch to see if I need to alert him to test!

Each one of us in this group knows just how valuable this system is! I am forever in the debt to the creators and people who continue to improve this system.

You all are amazing people! Thank you for this priceless resource!!!!

Below the post, there are links for "Unlike · Comment" and a like count of "You, [REDACTED] and 13 others like this." There is also a "Chat (0)" button.

# WSJ SCARY ANECDOTE

 [REDACTED]er > CGM in the Cloud  
12 mins · 

I went to work this am and looked down at my pebble after a while.. it said 104 and dropping. I called the house but he wouldn't answer... and no answer on the cell. Sisters had left for work already. Then I noticed the reading was 45 min. Ago. I rushed home and my son was 28. Words can not express my gratitude to those people who have put so much into this project. He is back to 119 and talking again. I however now need to pull it together and go back to work.

Like · Comment

6 people like this.

 [REDACTED]y I cannot imagine. Glad he is ok!  
4 mins · Like

 [REDACTED]de I started crying reading this.. Geez. I am glad he is alright.  
2 mins · Like



2 mins · Like

 [REDACTED]er Thanks all. Me too. I can't believe I'm going to work. I'm a mess. Deep breathes....  
1 min · Like

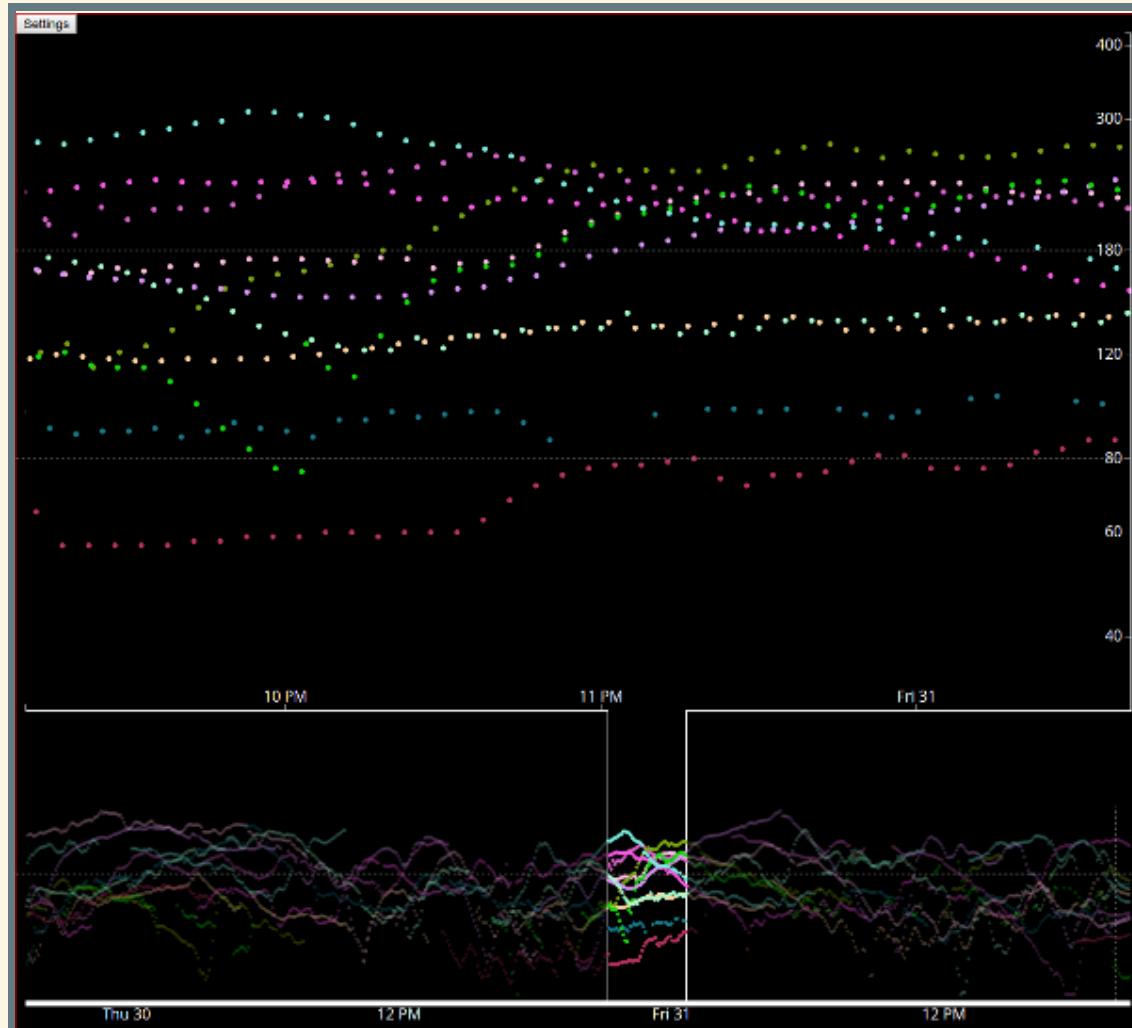
# WSJ SCARY DETAIL



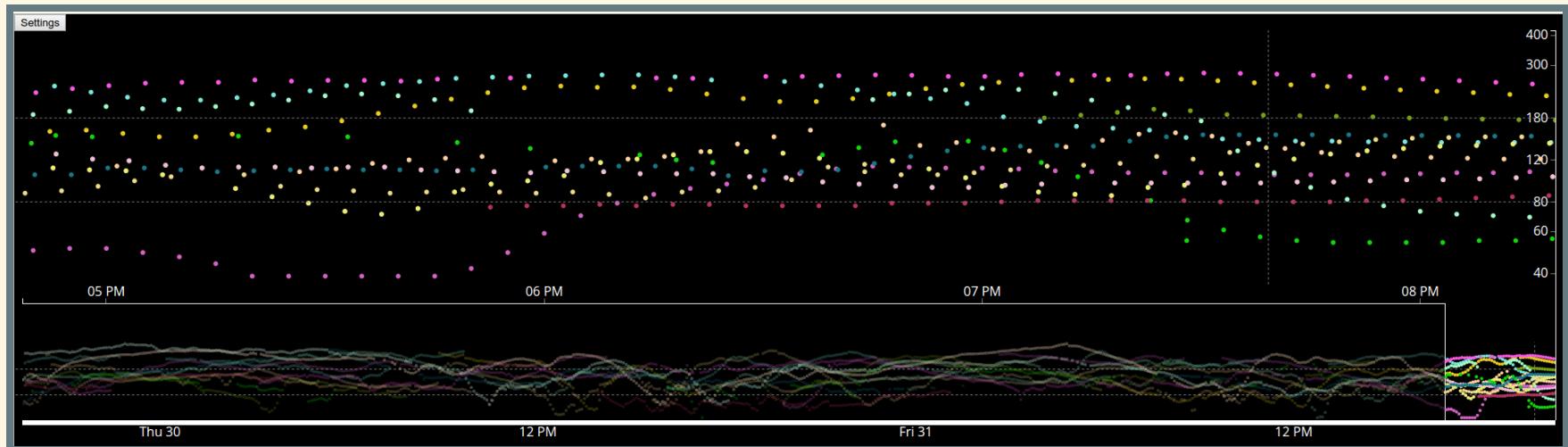
# WSJ SCARY STORIES



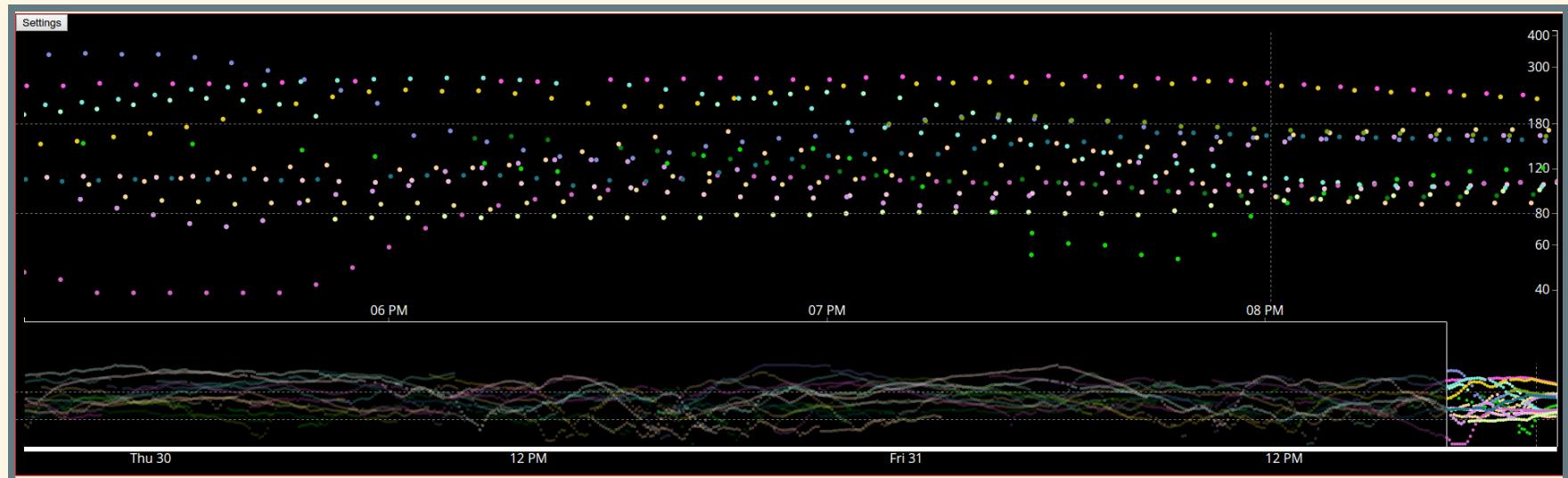
# HALLOWEEN 05



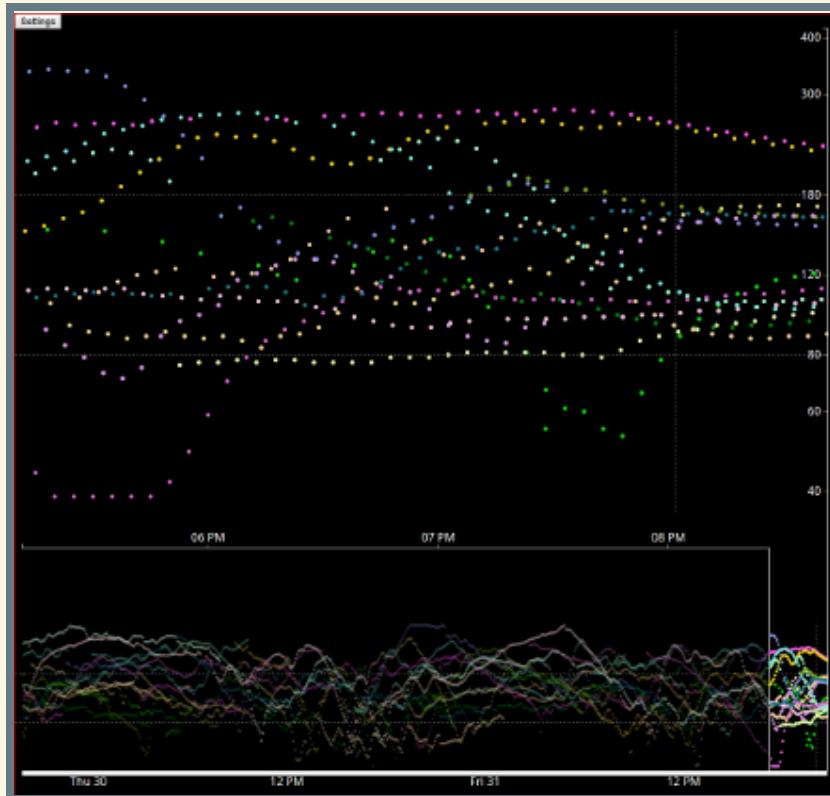
# HALLOWEEN 08



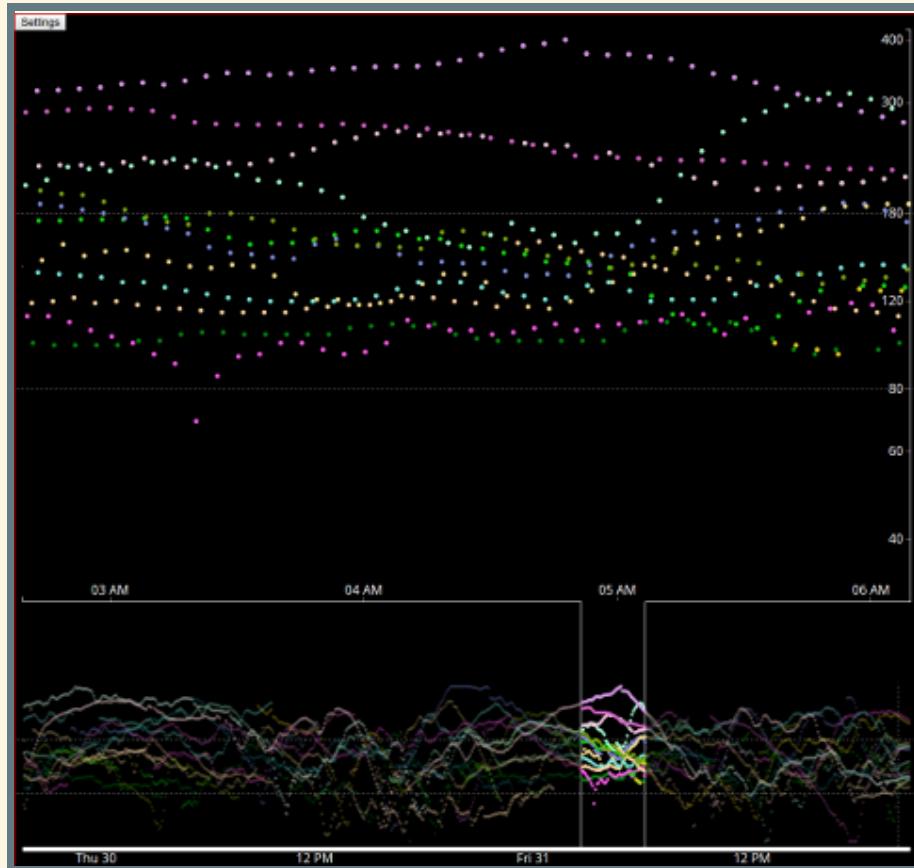
# HALLOWEEN 11



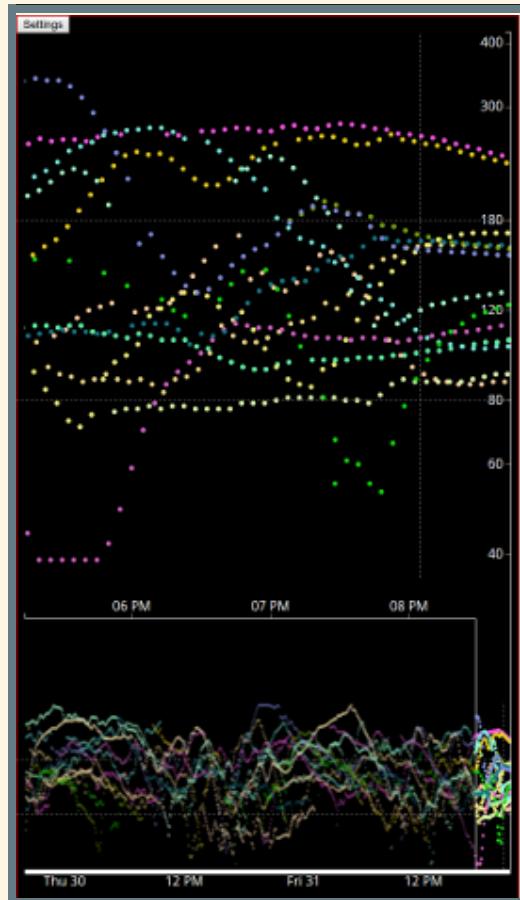
# HALLOWEEN 12



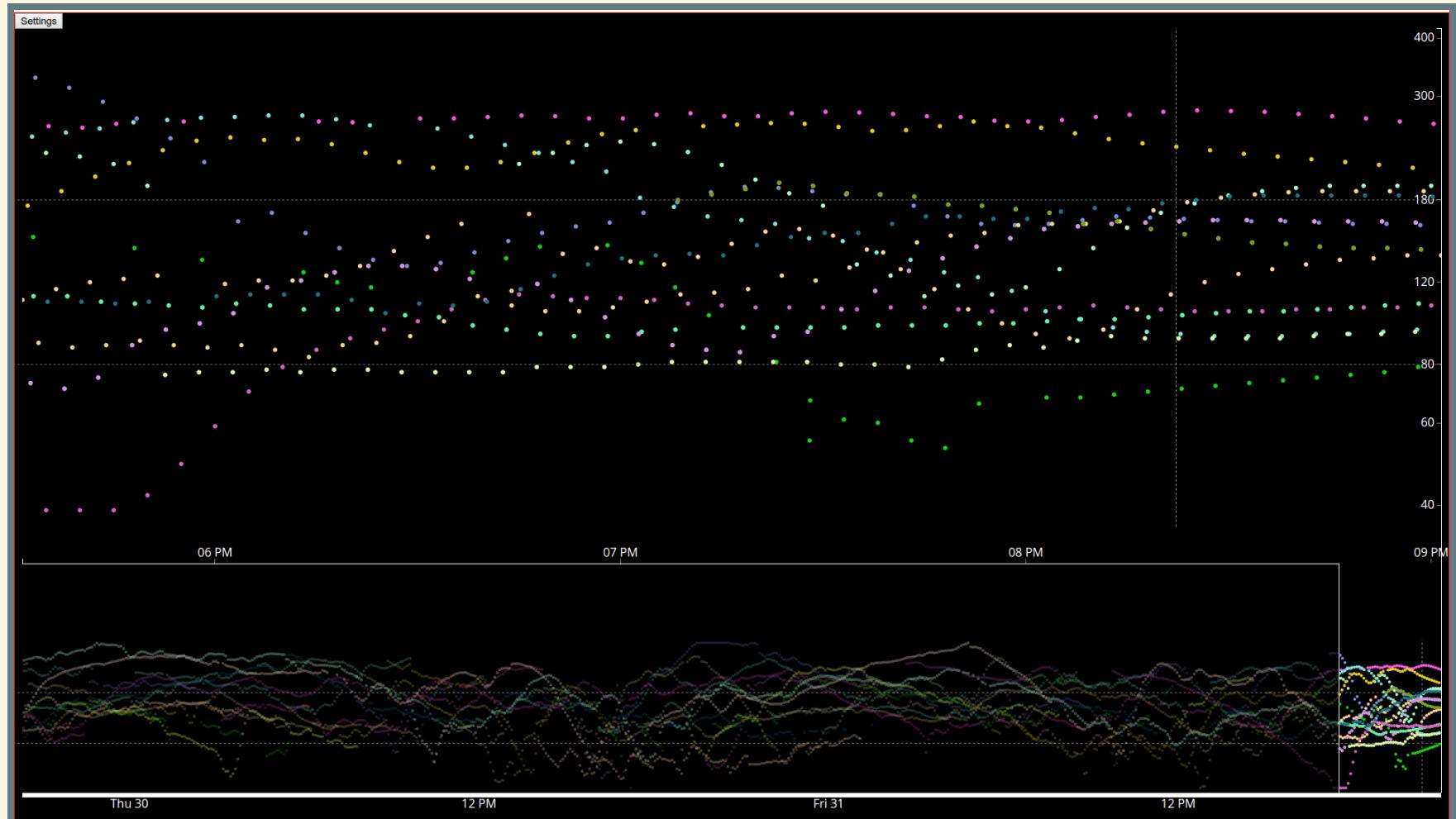
# HALLOWEEN 13



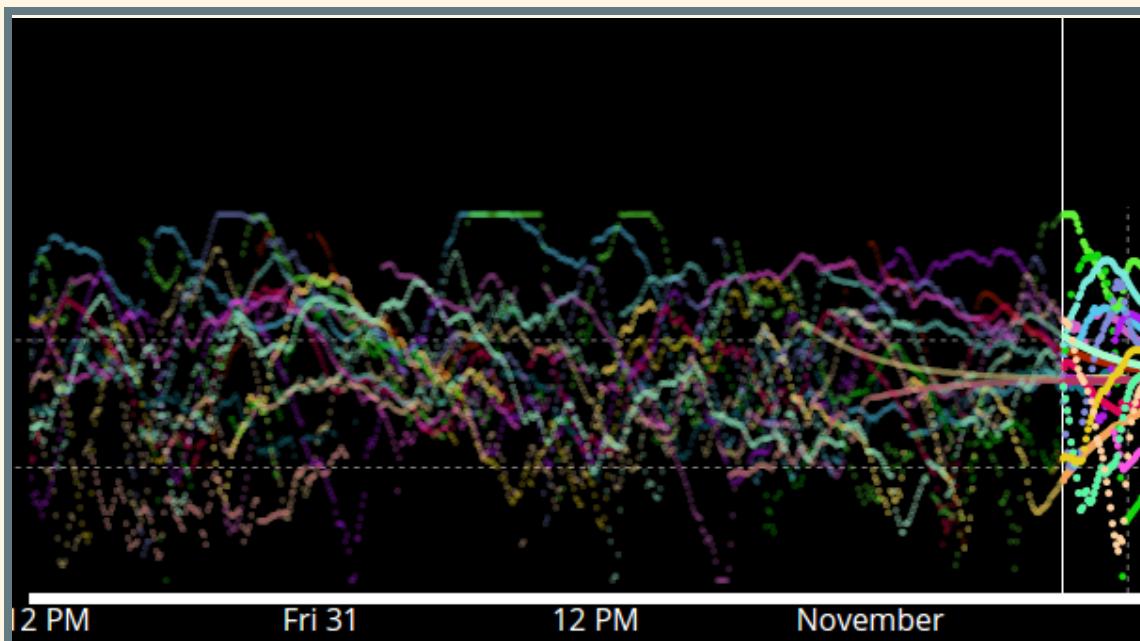
# HALLOWEEN 15



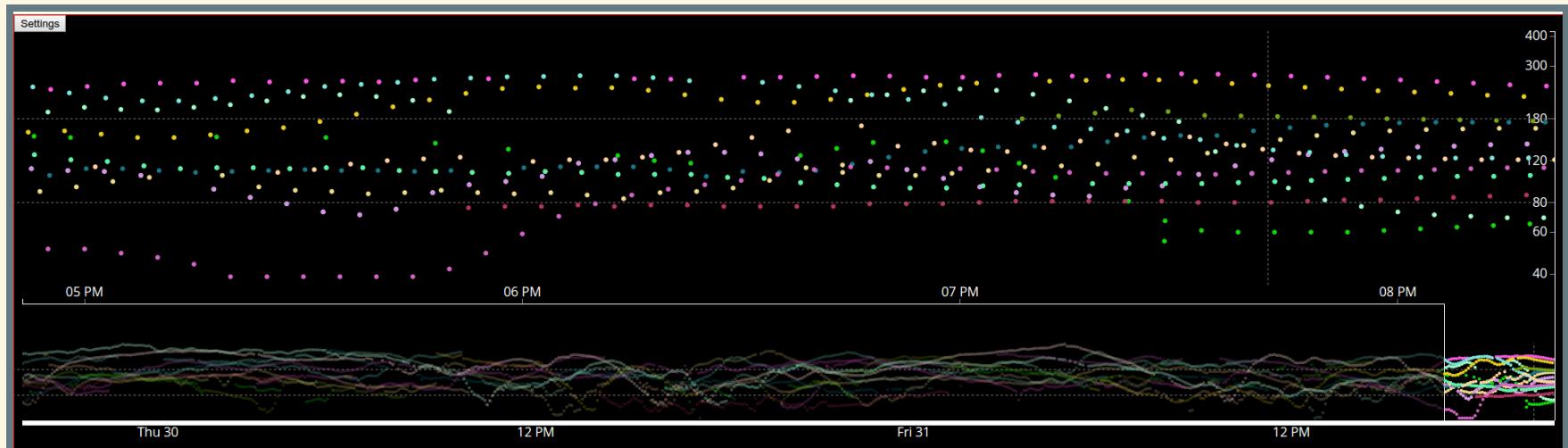
# HALLOWEEN 20



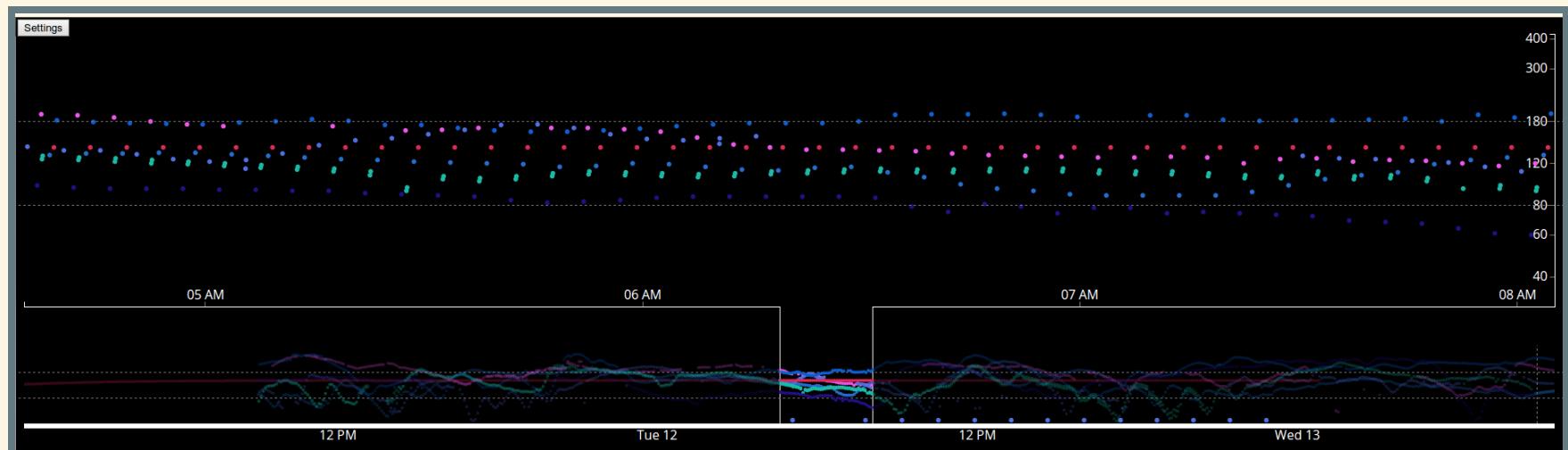
# HALLOWEEN 28



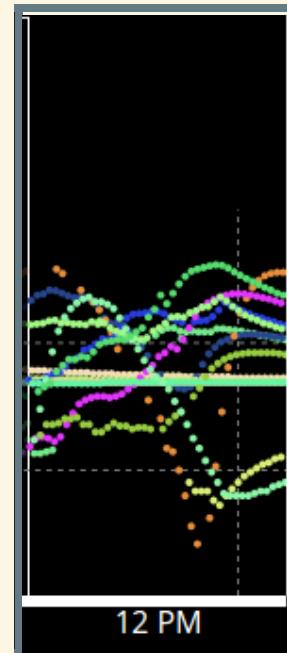
# NIGHTSCOUT 09



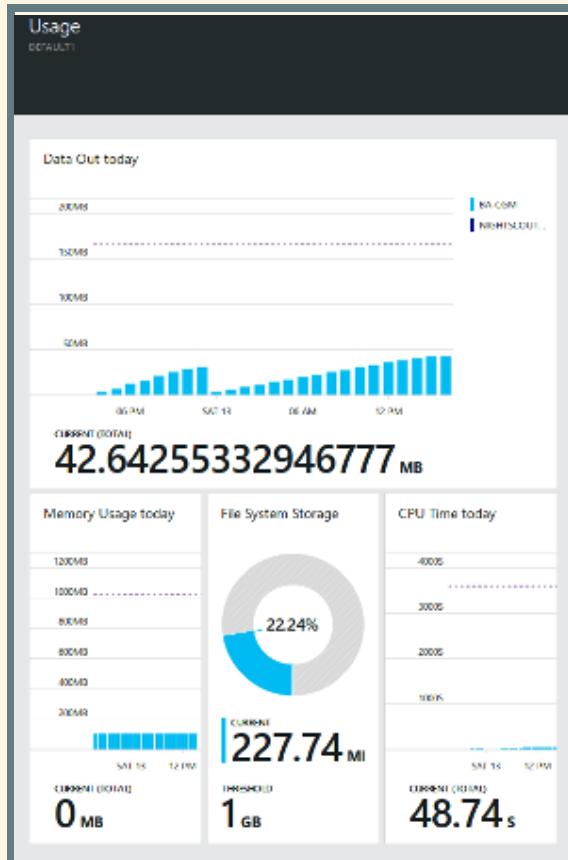
# NIGHTSCOUT AGGREGATOR 2



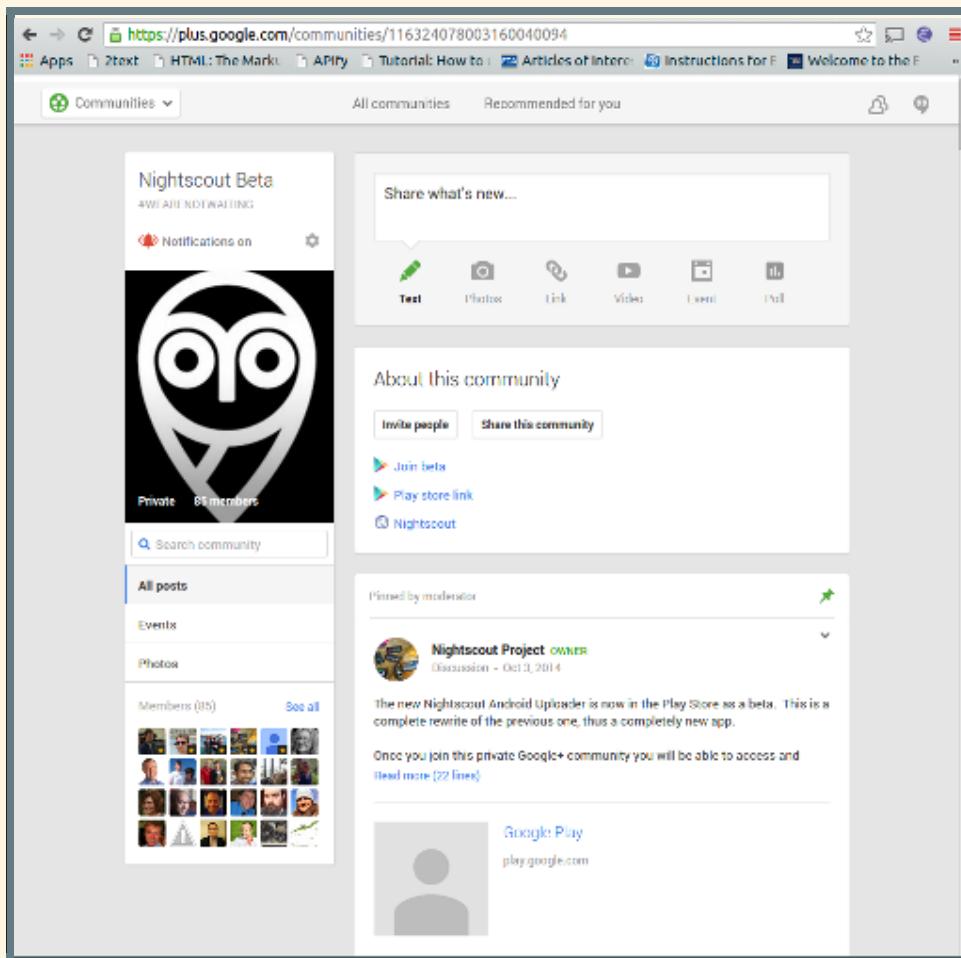
# NIGHTSCOUT NOON 04



# AZURE DATA OUT



# PLUS BETA GROUP



# ACTION SOFTBALL

[REDACTED] **julycurtis** My daughter has been at camp and trying to check in with her is giving me even more grey hair. I can't wait until I can monitor her in my office while she's at camp or school. It will be such an incredible relief!

June 26 at 1:45pm · Like ·  3

[REDACTED] **amy** We have [REDACTED] in testing every 90 minutes and texting me with his numbers. He has a vibrating multi-alarm watch that reminds him. He's been more responsible than any 9 year old should have to be.

June 26 at 2:02pm · Like ·  2

[REDACTED] **th** We use ours for our daughters softball games. Seems to work really well unless she is in the outfield but as soon as she comes in it updates. Last night she didn't have to test once because she stayed level the whole game and I was able to reassure her that it was just nerves and not low bg!!!

June 26 at 2:42pm · Unlike ·  5

[REDACTED] #whywearenotwaiting

 Chat (7)

# LIBERTY CAMP



# MUST SEE TV



# 100 CLUB 01

A close-up photograph of a yellow CGM (Continuous Glucose Monitor) device. The screen displays a large '100' with a right-pointing arrow, followed by the text 'CHECK CGM'. Below this, there's a circular icon with '1h' and a small 'OK' button. At the bottom of the screen, the time '1:35' is shown above the text 'Fri 16'. The word 'EVE' is visible at the very bottom. A person's thumb is partially visible, pointing towards the device.

My Sweet Pea joined the  
Cookie Monster 100 Club  
(Upgrading this weekend? Maybe \_\_\_\_\_? )

Like · Comment · Get Notifications · Share

10 others like this.

January 16 at 8:04pm · Like



A screenshot of a Facebook post from a page called 'CGM in the Cloud'. The post features a cartoon illustration of a smiling yellow star with a red outline. The number '100' is written in the top right corner of the star, and the text 'Great job!' is written in the center. The post includes a timestamp of 'January 16 at 10:38pm' and a 'Like' button. There is also a comment section below the image.

# 100 CLUB 02

 ► CGM in the Cloud  
January 3 at 7:28pm · AA

First night our daughter is sleeping over her grandparents and she hit the [100 club!](#) Thanks to you guys I can see it.

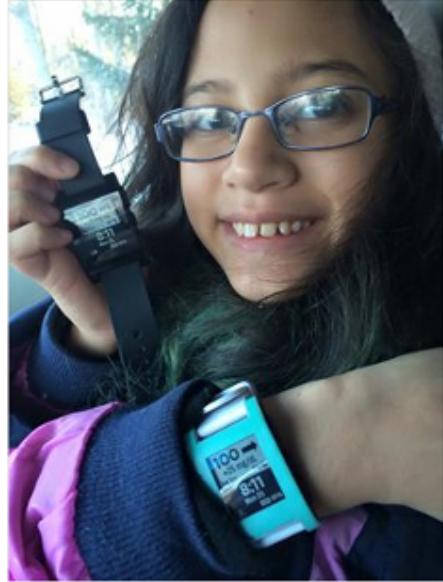


Like · Comment ·  14  1

# 100 CLUB 03

 [Lori Boos](#) > CGM in the Cloud  
January 5 at 6:14am · [16](#)

Is it crazy that I had to pull over to the side of the road to take this picture on the first day back to school? Are you getting tired of my "100" posts yet?  
— at [\[REDACTED\] Middle School](#).



Like · Comment · [73](#) [16](#)

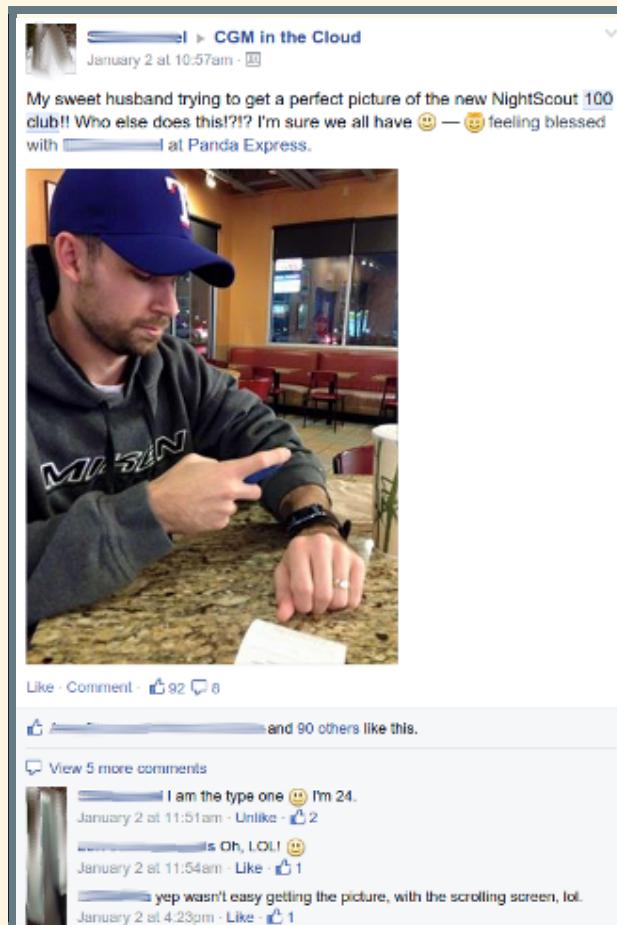
[and 70 others like this.](#)

[View previous comments](#) 1 of 16

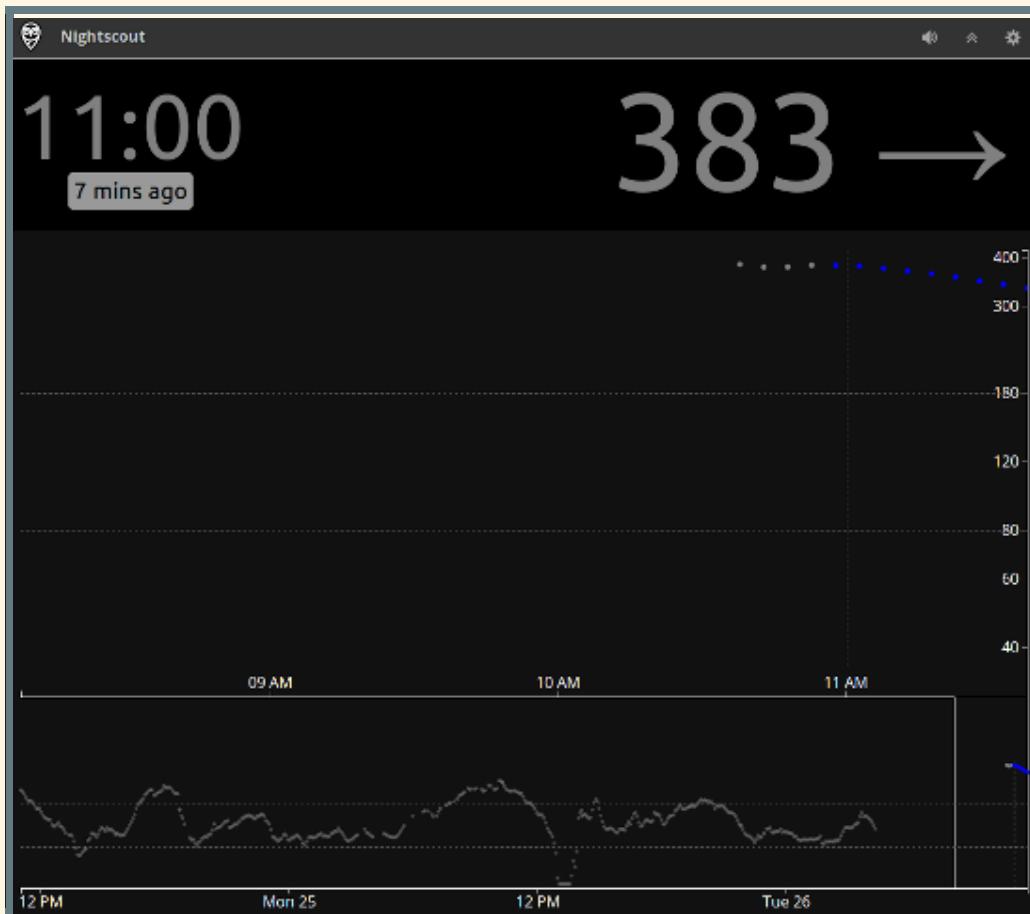
 [Lori #100club](#)     
January 5 at 6:27am · Like · [1](#)

[View more comments](#)

# 100 CLUB 04



# BEWEST NIGHTSCOUT



**CP 01**

**CP 06**

**CP 07**

**CP 09**

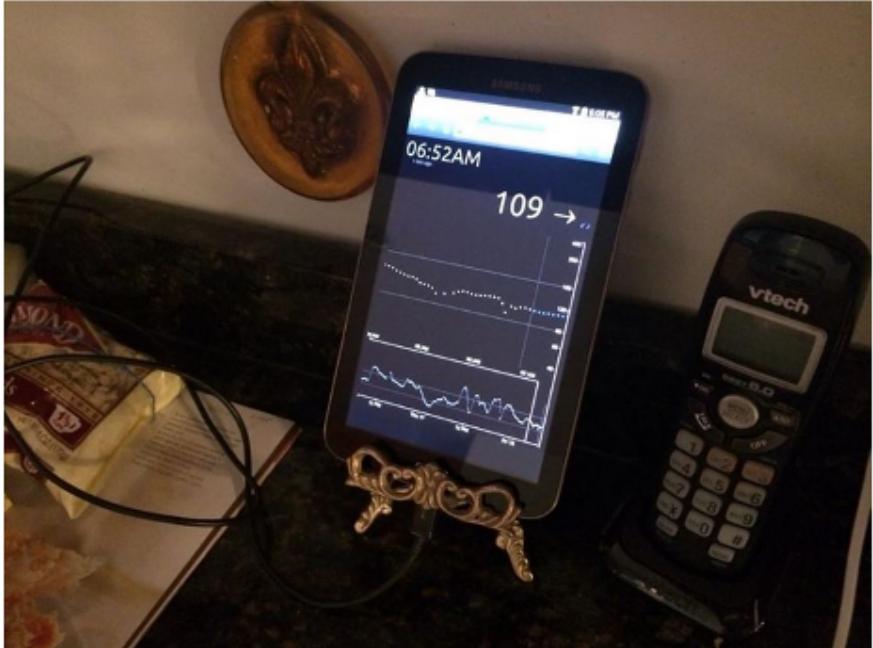
# FEATURE PREDICTION FADING



# FREEDOM TO PLAN

 and ► CGM in the Cloud  
July 18 at 5:02am · Inverness, IL · [Link](#)

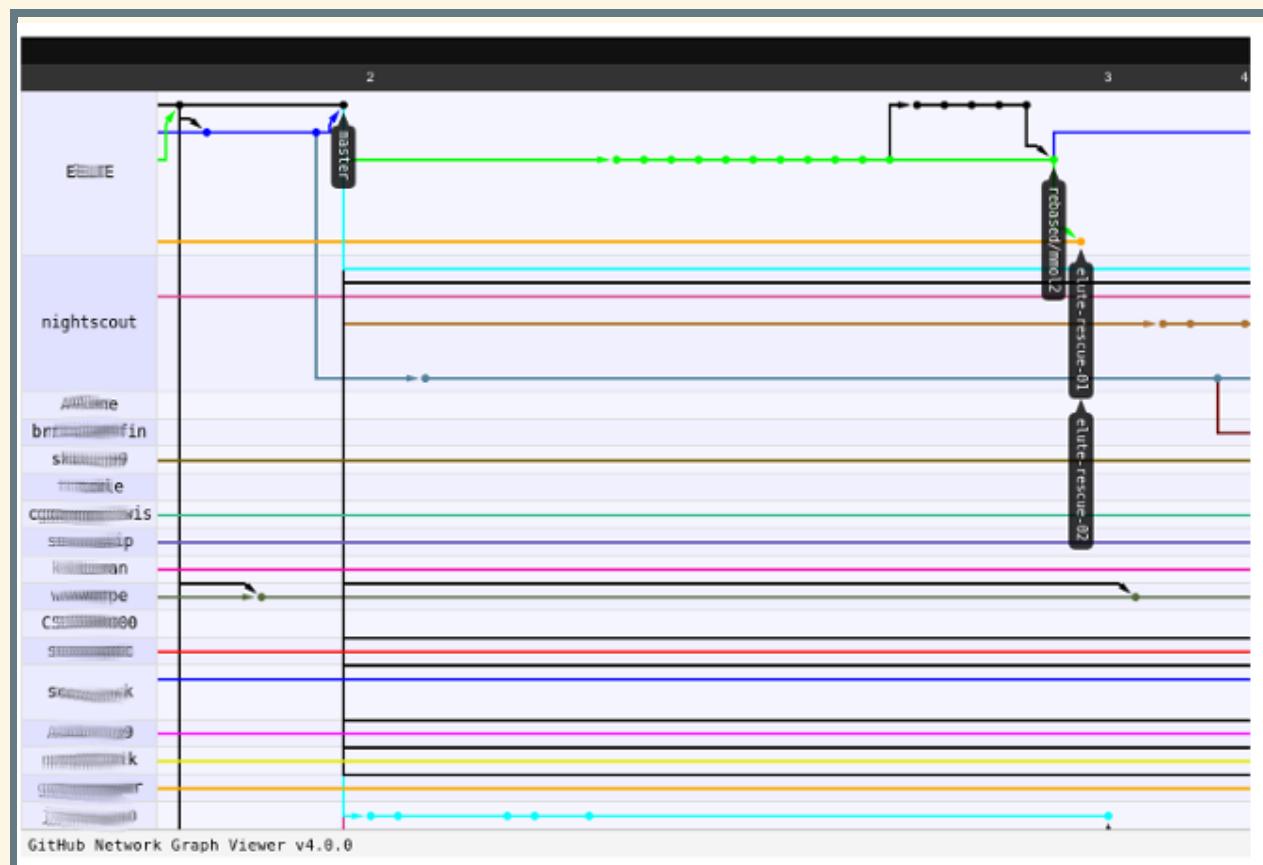
You guys have just changed my life! Words cannot express my gratitude. I have been up and running for about 6 hours and have already planned 12 sleepovers, 16 play dates, and a vacation. Thank you!



Like · Comment ·  164  20

 and 161 others like this.

# NIGHTSCOUT VERSIONS GIT



# PULSE GITHUB

[nightscout / cgm-remote-monitor](#)

October 18, 2014 – November 18, 2014

Period: 1 month

Overview

31 Active Pull Requests

Merged Pull Requests: 22 | Proposed Pull Requests: 9

14 Active Issues

Closed Issues: 6 | New Issues: 8

Excluding merges, 11 authors have pushed 20 commits to master and 108 commits to all branches. On master, 22 files have changed and there have been 335 additions and 66 deletions.

2 Releases published by 1 person

Published: 0.5.0 Cookie Monster (0.5.0) 12 days ago

Published: 0.5.1 Cookie Monster (0.5.1) 8 days ago

22 Pull requests merged by 6 people

Merged: #255 Merge wip/add-ssl (and everything it inherited from dev) into wip/lob-cob 3 days ago

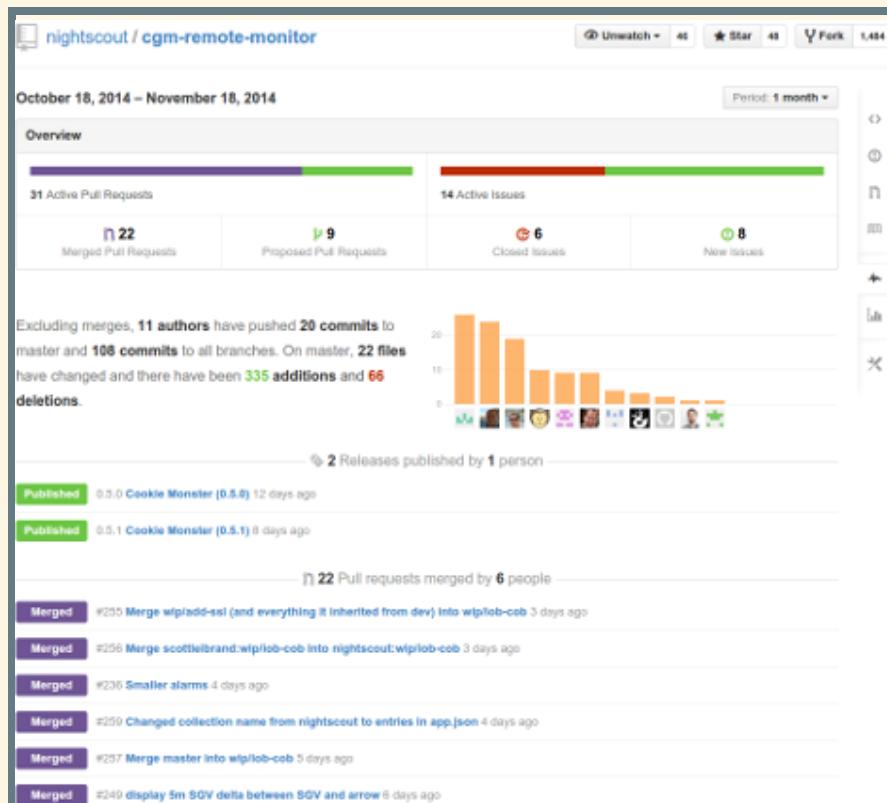
Merged: #256 Merge scottiebrand:wip/lob-cob into nightscout:wip/lob-cob 3 days ago

Merged: #236 Smaller alarms 4 days ago

Merged: #259 Changed collection name from nightscout to entries in app.json 4 days ago

Merged: #257 Merge master into wip/lob-cob 5 days ago

Merged: #249 display 5m SGV delta between SGV and arrow 8 days ago



# NIGHTSCOUT IS MONGO DOWN 01



# NIGHTSCOUT IS MONGO DOWN 02



# NIGHTSCOUT IS MONGO DOWN 03



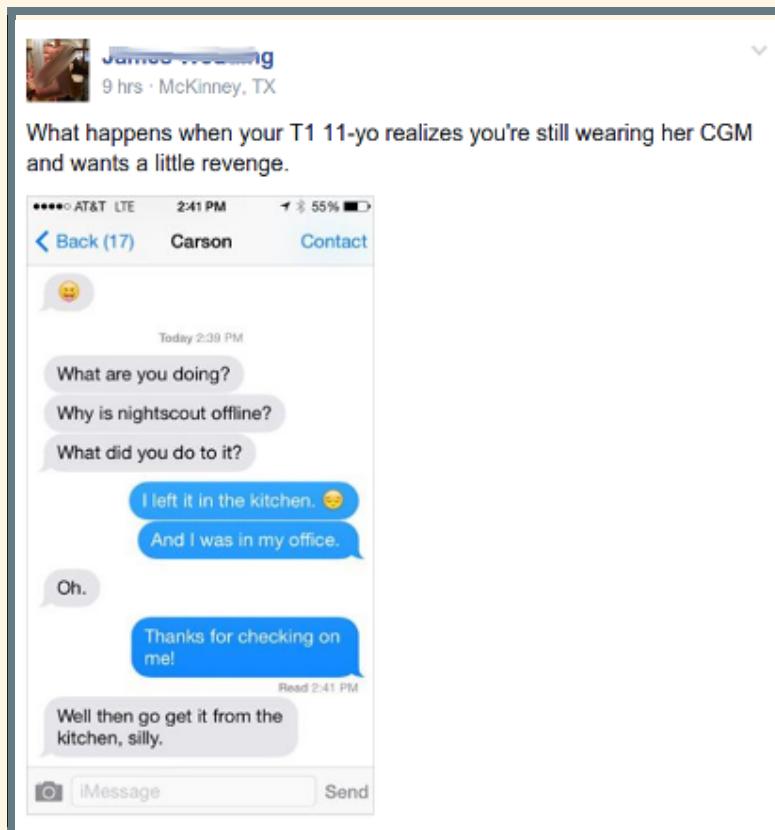
# NIGHTSCOUT IS MONGO DOWN 04



# NIGHTSCOUT CAT



# NIGHTSCOUT EMPATHY 2



# NIGHTSCOUT SOCIAL SUPPORT 01

# NIGHTSCOUT WALL CLOCK



# DANCE CAMP WITHOUT LOWS



# PEBBLE KAYAK



# PEBBLE POWER 01

The image consists of two parts. On the left is a photograph of two wrists, one wearing a black Pebble smartwatch and the other a white Pebble smartwatch. Both screens show a glucose reading of 92 mg/dL. On the right is a screenshot of a Facebook post from a page called 'CGM in the Cloud'. The post was made on July 18 and has 65 likes. A comment from a user named 'L' is visible, expressing happiness for the wearer. Another comment from 'L' on July 19 expresses admiration for the matching watches. There is also a link to see all comments.

Like · Comment · Get Notifications · Share

and 65 others like this.

Very happy for you both!

July 18 at 10:27am · Like

I am considering mother and son. I have to read a bit more about it. It seems overwhelming. Congrats!!!

July 18 at 8:10pm · Like

This made me smile. Mine t1 is little but look forward to having matching "watches" when she is older

July 19 at 10:20am · Like

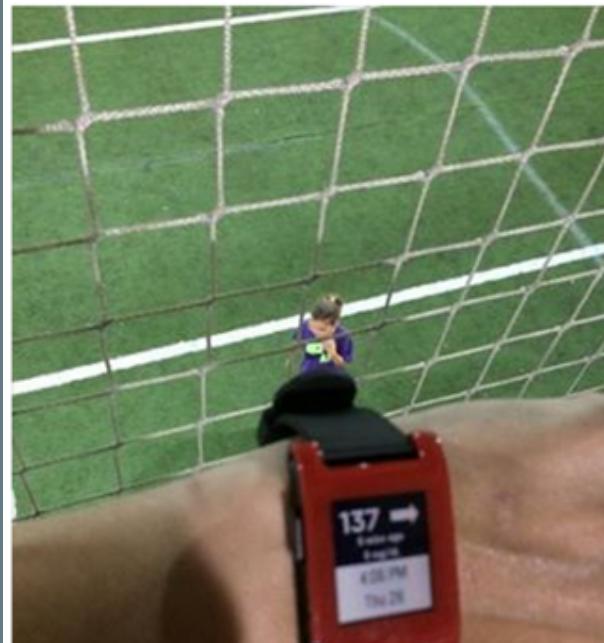
Write a comment... edit

See All

# PEBBLE SOCCER 02

This is worth every ounce of money and time for this setup! I can now relax while my daughter has soccer training. It's wonderful not asking her, "What does Dexie say?" She loves the new found freedom!

Thank you to all of the programmers and developers!



# PEBBLE SOCCER



# SAFER DRIVING

 I'm looking to take and carry with me 24/7. Yes I'm a type 1 to. Before scout I used to keep dex in my front jean pocket , but as you know out of sight out of mind. Also pushing the dex button 10,000 times a day gets old fast. Lol

11 mins · Like

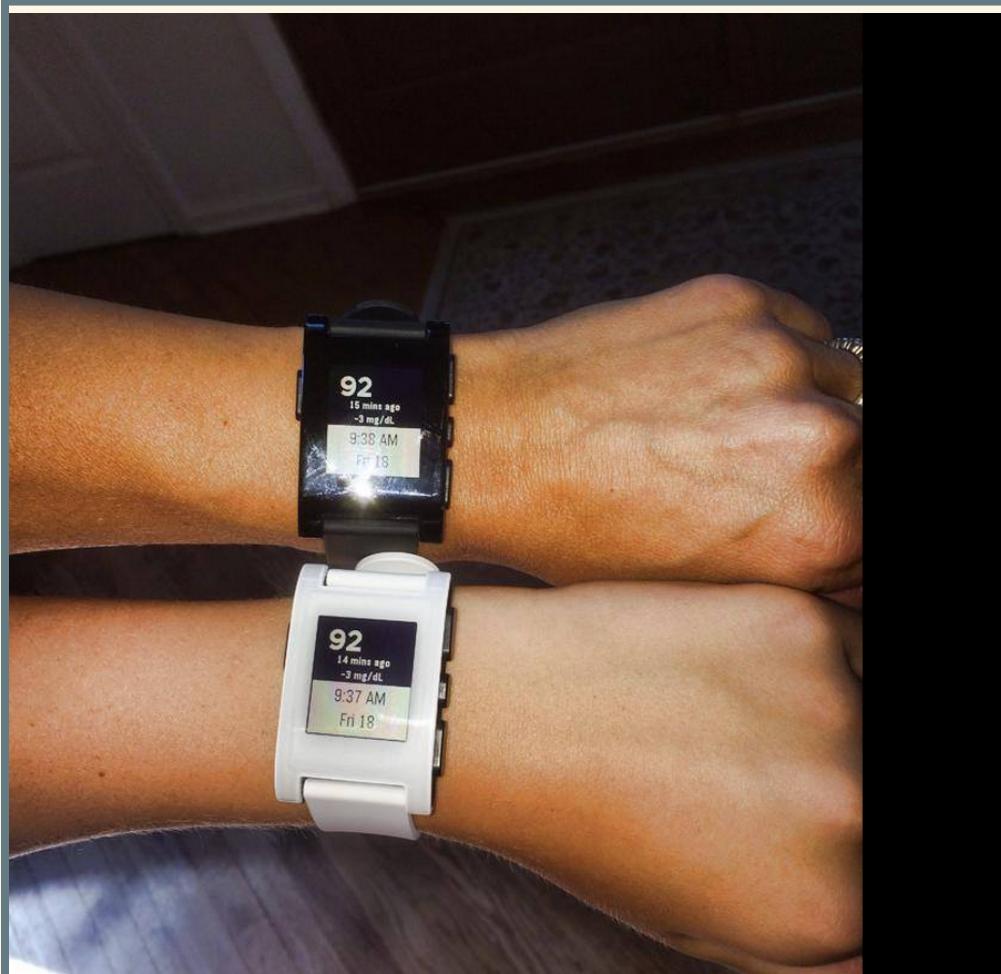
 Not to mention how much safer I feel driving now😊

9 mins · Like





# TWIN PEBBLES



**Andrew Mollica** ► CGM in the Cloud

July 18

[Like](#) · [Comment](#) · [Get Notifications](#) · [Share](#)

Jason Calabrese and 65 others like this.



**Laurie Schwartz** Very happy for you both!

July 18 at 10:27am · [Like](#)



**Lucy Block** I am considering mother and son. I have to read a bit more about it. It seems overwhelming. Congrats!!!

July 18 at 8:10pm · [Like](#)



**Michelle Lee Scott** This made me smile. Mine t1 is little but look forward to having matching "watches" when she is older

July 19 at 10:20am · [Like](#)



[Write a comment...](#)

[edit](#)

**Games You May Like**

[See All](#)



# FDA 820 REGS

TITLE 21-FOOD AND DRUGS  
CHAPTER I-FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H-MEDICAL DEVICES

**PART 820: QUALITY SYSTEM REGULATION**

**Subpart A-General Provisions**  
[§ 820.1 - Scope.](#)  
[§ 820.3 - Definitions.](#)  
[§ 820.5 - Quality system.](#)

**Subpart B-Quality System Requirements**  
[§ 820.20 - Management responsibility.](#)  
[§ 820.22 - Quality audit.](#)  
[§ 820.25 - Personnel.](#)

**Subpart C-Design Controls**  
[§ 820.30 - Design controls.](#)

**Subpart D-Document Controls**  
[§ 820.40 - Document controls.](#)

**Subpart E-Purchasing Controls**  
[§ 820.50 - Purchasing controls.](#)

**Subpart F-Identification and Traceability**  
[§ 820.60 - Identification.](#)  
[§ 820.65 - Traceability.](#)

**Subpart G-Production and Process Controls**  
[§ 820.70 - Production and process controls.](#)  
[§ 820.72 - Inspection, measuring, and test equipment.](#)  
[§ 820.75 - Process validation.](#)

**Subpart H-Acceptance Activities**  
[§ 820.80 - Receiving, in-process, and finished device acceptance.](#)  
[§ 820.88 - Acceptance status.](#)

**Subpart I-Nonconforming Product**  
[§ 820.90 - Nonconforming product.](#)

**Subpart J-Corrective and Preventive Action**  
[§ 820.100 - Corrective and preventive action.](#)

**Subpart K-Labeling and Packaging Control**  
[§ 820.120 - Device labeling.](#)  
[§ 820.130 - Device packaging.](#)

**Subpart L-Handling, Storage, Distribution, and Installation**  
[§ 820.140 - Handling.](#)  
[§ 820.150 - Storage.](#)  
[§ 820.160 - Distribution.](#)  
[§ 820.170 - Installation.](#)

**Subpart M-Records**  
[§ 820.180 - General requirements.](#)  
[§ 820.181 - Device master record.](#)  
[§ 820.184 - Device history record.](#)  
[§ 820.186 - Quality system record.](#)  
[§ 820.188 - Complaint files.](#)

**Subpart N-Servicing**  
[§ 820.200 - Servicing.](#)

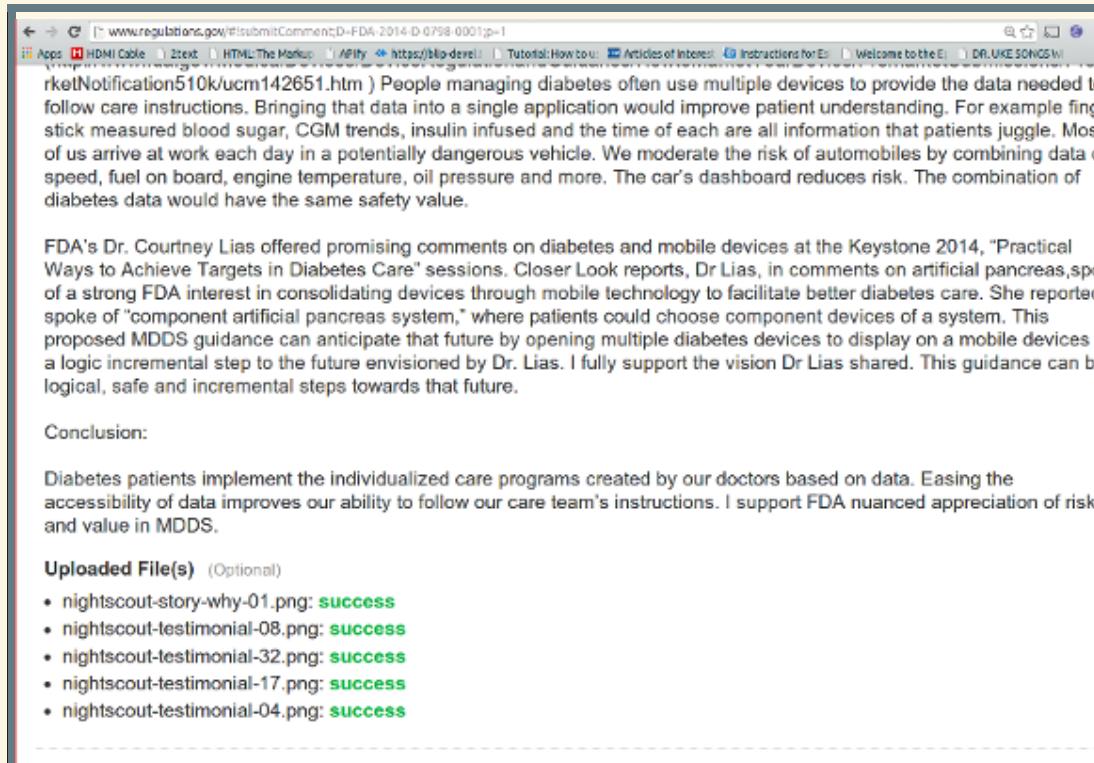
**Subpart O-Statistical Techniques**  
[§ 820.250 - Statistical techniques.](#)

# MDDS FDA GUIDANCE HEAD SUCCESS

The screenshot shows a computer browser displaying the regulations.gov website. The URL in the address bar is [www.regulations.gov/#submitComment;D=FDA-2014-D-0798-0001;p=1](http://www.regulations.gov/#submitComment;D=FDA-2014-D-0798-0001;p=1). The page title is "regulations.gov Your Voice in Federal Decision-Making". The main content area displays a success message: "Your comment was submitted successfully!" with a speaker icon. Below this, there is a link to "The Food and Drug Administration (FDA) Notice: Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability". There is also a link to "Open Docket Folder". At the bottom, there is a section titled "3 Your Receipt" with three tabs: "Your Information", "Your Preview", and "Your Receipt". The "Your Receipt" tab is selected. It shows a tracking number "1jy-8dhz-2ycp" and a note: "Your comment will be viewable on Regulations.gov after the agency has reviewed it, which may be an indefinite amount of time. Use your tracking number to find out the status of your comment." Below this, there are fields for "Your comment:", "Comment:", and "Support:". A large block of text at the bottom states: "I am encouraged by the FDA's draft guidance on MDDS. I support the FDA's position that technologies that transport data, without changing values, are low risk. I believe that access to medical data should be available on multiple platforms that are accessible to both medical professionals and patients. Access to this type of data is becoming an increasingly essential in".

# MDDS GUIDANCE FEEDBACK

# MDDS GUIDANCE FEEDBACK TAIL



The screenshot shows a web browser window with the URL [www.regulations.gov/#/submitComment;D-FDA-2014-D-0758-0001;p-1](http://www.regulations.gov/#/submitComment;D-FDA-2014-D-0758-0001;p-1). The page content discusses the integration of multiple diabetes devices into a single application to improve patient understanding and reduce risk. It quotes Dr. Courtney Lias's comments from the Keystone 2014 conference. Below the text, there is a 'Conclusion:' section, a 'Diabetes patients implement the individualized care programs created by our doctors based on data. Easing the accessibility of data improves our ability to follow our care team's instructions. I support FDA nuanced appreciation of risk and value in MDDS.' A 'Uploaded File(s) (Optional)' section lists five files: 'nightscout-story-why-01.png', 'nightscout-testimonial-08.png', 'nightscout-testimonial-32.png', 'nightscout-testimonial-17.png', and 'nightscout-testimonial-04.png', all marked as 'success'.

marketNotification510k/ucm142651.htm ) People managing diabetes often use multiple devices to provide the data needed to follow care instructions. Bringing that data into a single application would improve patient understanding. For example finger stick measured blood sugar, CGM trends, insulin infused and the time of each are all information that patients juggle. Most of us arrive at work each day in a potentially dangerous vehicle. We moderate the risk of automobiles by combining data of speed, fuel on board, engine temperature, oil pressure and more. The car's dashboard reduces risk. The combination of diabetes data would have the same safety value.

FDA's Dr. Courtney Lias offered promising comments on diabetes and mobile devices at the Keystone 2014, "Practical Ways to Achieve Targets in Diabetes Care" sessions. Closer Look reports, Dr Lias, in comments on artificial pancreas, spoke of a strong FDA interest in consolidating devices through mobile technology to facilitate better diabetes care. She reported spoke of "component artificial pancreas system," where patients could choose component devices of a system. This proposed MDDS guidance can anticipate that future by opening multiple diabetes devices to display on a mobile devices a logical incremental step to the future envisioned by Dr. Lias. I fully support the vision Dr Lias shared. This guidance can be logical, safe and incremental steps towards that future.

Conclusion:

Diabetes patients implement the individualized care programs created by our doctors based on data. Easing the accessibility of data improves our ability to follow our care team's instructions. I support FDA nuanced appreciation of risk and value in MDDS.

**Uploaded File(s) (Optional)**

- nightscout-story-why-01.png: **SUCCESS**
- nightscout-testimonial-08.png: **SUCCESS**
- nightscout-testimonial-32.png: **SUCCESS**
- nightscout-testimonial-17.png: **SUCCESS**
- nightscout-testimonial-04.png: **SUCCESS**

# NIGHTSCOUT TESTIMONIAL 42



July 31 at 9:51pm · San Marcos, CA

Hi everyone,

1. I did my FDA submittal 😊
2. My 8 y/o daughter has her VERY first playdate with 'Scout' tomorrow.
3. xoxo

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 and 34 others like this.

# NS 820 QUALITY

## Welcome to Nightscout process's documentation!

- Quality controls
  - About
    - Audience
      - Contractors
      - Supplier/Client/other
      - Regulators
    - General references
      - Glossary
        - Terms
          - Definitions and denominations
          - Issues
          - Requirements
          - Continuous Testing
          - Analysis
          - Revisions
        - Technical
          - Correcting the issue
          - Confirmation
          - Suspection
          - Trace
        - Standards
          - NIST based Foundation
      - Deliverables
        - Deliver planning
        - Deliver input
        - Deliver output
        - Deliver review
        - Deliver verification
        - Deliver validation
        - Design transfer
        - Design changes
        - Design history file
      - Documentation controls
        - Changes in the system
          - process controls
          - configuration controller
          - traceable
          - log remote monitor
          - log controller
          - log monitor
        - Identification and traceability
        - Production and process controls
        - Nonconforming product
          - Crash reporting
            - ACRA application
            - Another
            - 2015-01
      - Corrective and preventive actions
        - threshold-updater
        - app-public
        - app-remote-monitor
        - chrome-updater
        - location-updater
        - labeling/Packaging
          - threshold-updater
          - traceable
          - unique identifier
          - document-shader
          - inventory
        - Documentation controls
          - configuration controller
          - traceable
          - log remote monitor
          - log controller
          - log monitor
        - Preventive
        - Preventive
        - Glucose meter control
        - Glucose history control
        - Quality system control
        - Configuration files
        - Service

# NS 820 REGS 02

- Record keeping
  - Device master record
  - Device history record
  - Quality system record
  - Complaint files
- Servicing
- Operations logs
- 2014 Operations
  - Nightscout created
  - FDA and Nightscout
- 2015 Operations
  - Overview
  - Process description
    - How quickly are changes or problems addressed
    - How is information on updates distributed
    - How are updates tracked
  - Process
    - General process
    - Projects
  - Ongoing development
    - Common problems
    - Ongoing concerns
  - Nexus timing change
  - Case studies
  - Feedback

**WE ARE NOT WAITING  
DISTANCE**