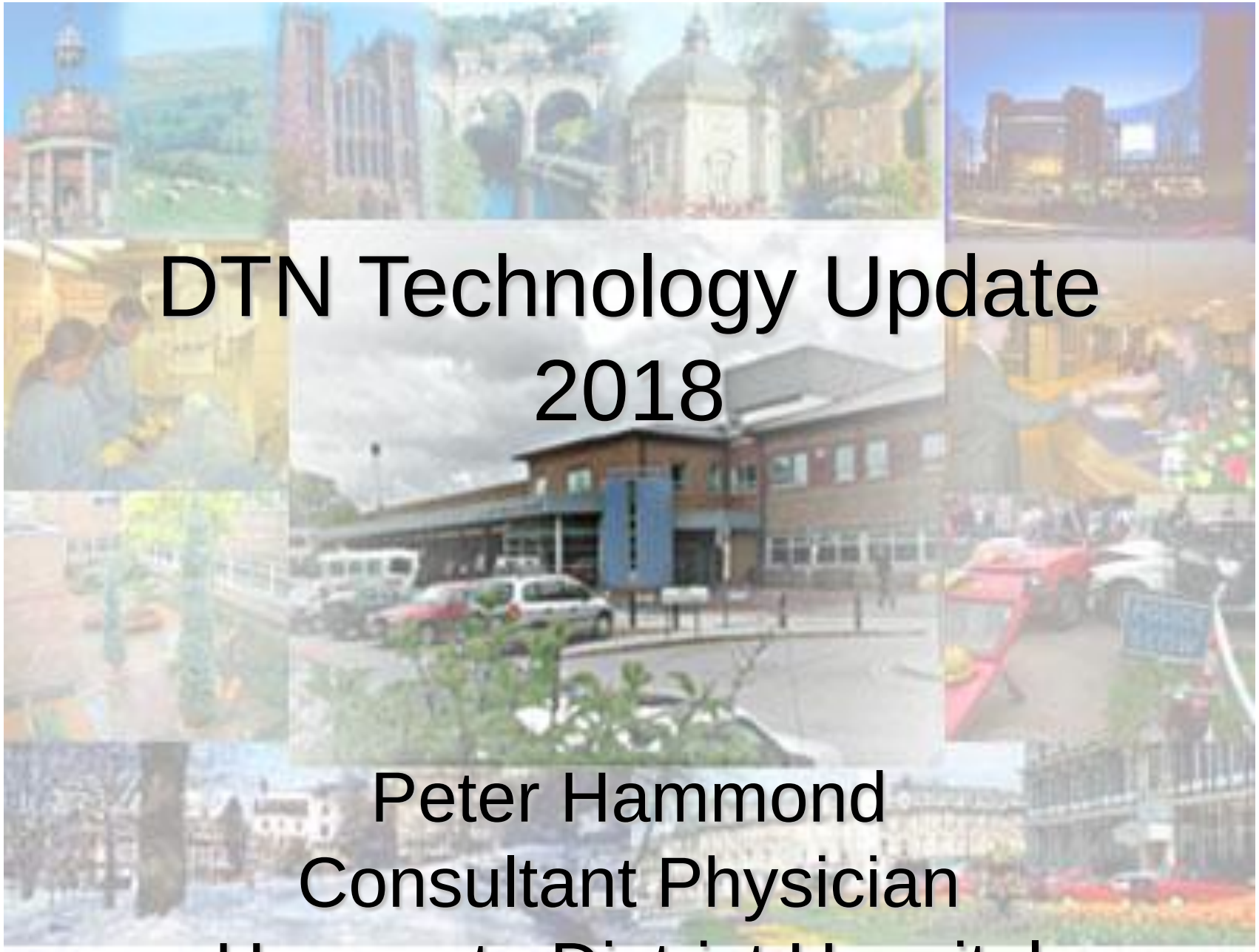

DTN Technology Update 2018

Peter Hammond
Consultant Physician
Harrogate District Hospital

DTN UK

Have you heard of GDPR?!

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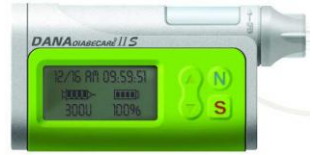
GDPR implications

- Specific, explicit patient consent to sharing data eg Carelink, Glooko/Diasend, Tidepool, Dexcom Clarity, Libre Link

- Unique login for all HCPs – departmental login not secure enough: patients need to know exactly who has accessed their data

	Roche Insight	Animas Vibe*	Medtronic 640G*	Omnipod patch pump	Cellnovo patch pump	Dana Diabecare R
Pump features						
Weight	122 g	105 g	96 g	25 g	30 g	63 g
Basal increment	0.01 U (0.02-25)	0.025 U (0.025-25)	0.025 U (0.025-35)	0.05 U (0.05-30)	0.05 U (0.05-5)	0.01 U
Basal rate/d	24	12	48	24 @ 30 min	24	24
Basal profiles	5	4	8	7	20	4
Basal deliver	3 min	3 min	10m (0.2-60)	0.05 u pulse	0.05 u pulse	4 min
Extended bolus	15 min steps up to 24 h	30 min steps up to 12 h	30 min steps up to 8 h	30 min steps up to 8 h	30 min steps up to 8 h	30 min steps up to 8 h
Bolus increments	0.05 U (max 25)	0.05 U (max 35)	0.1 U (max 75)	0.05 U (max 30)	0.05 U (max 30)	0.05 U
Occlusion alarm	< 2h	1.5-3h	2-3.8h	?	0.8 u missed = Max 16h	
Insulin vol	160 u	200 u	300 u	200 u	150 u	

*Sensor augmentation option

DTN UK

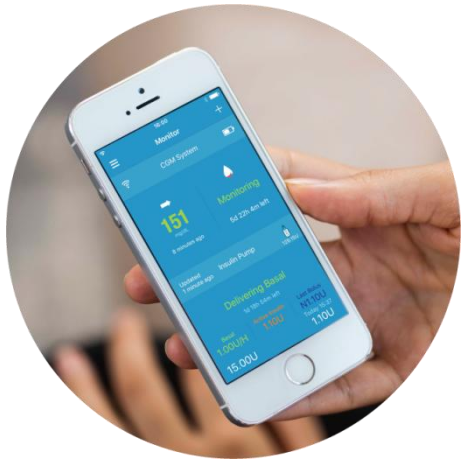
New pumps

DTN UK

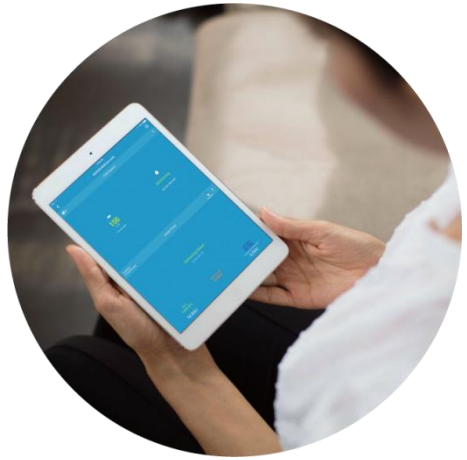
Remote View

Monitor loved one's glucose data remotely with free App.

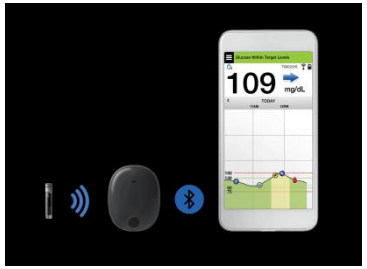
A6 TouchCare®



EasyTouch App
EasySense App
(Android and IOS)



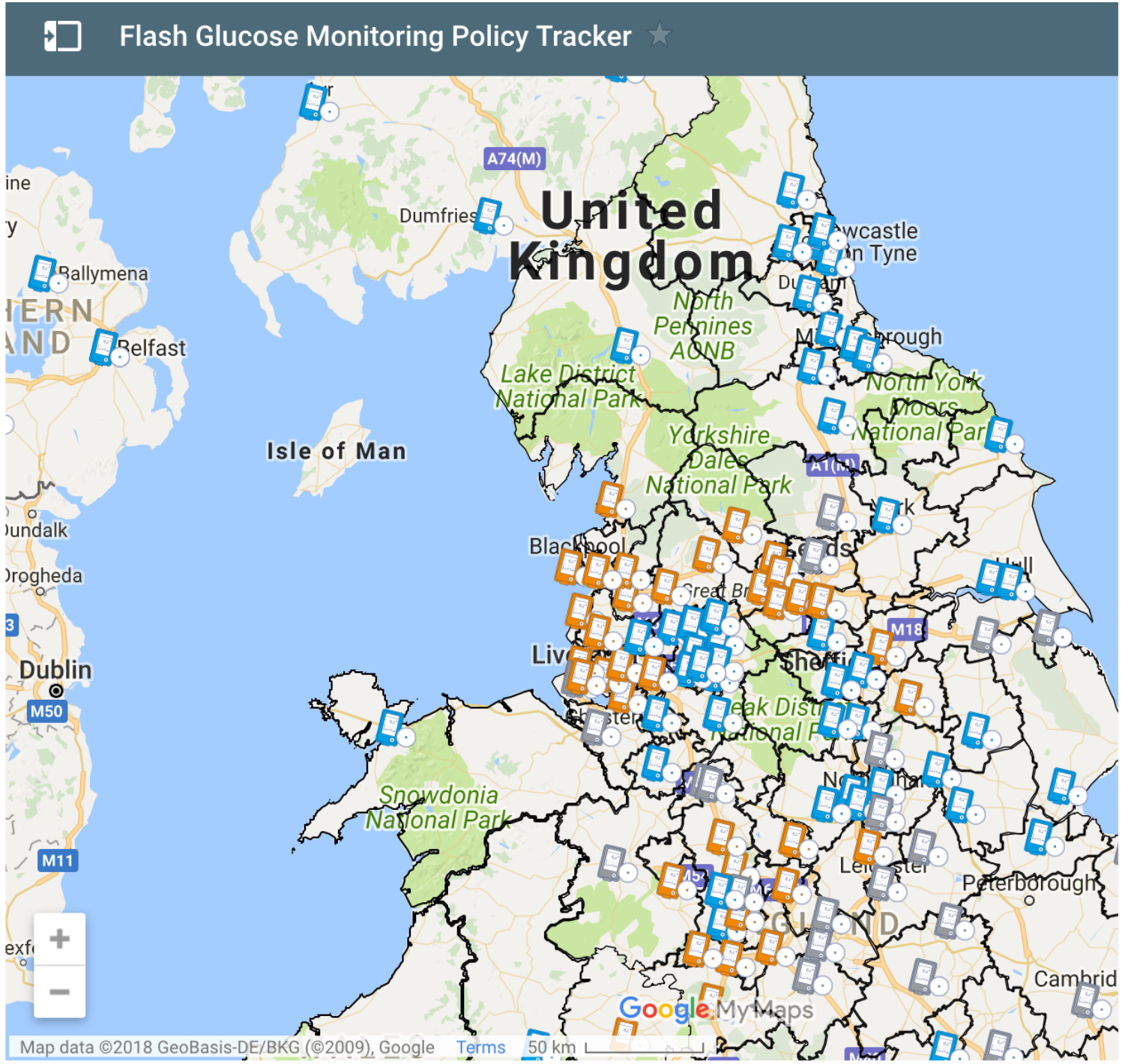
EasyFollow App
(Android and IOS)

	Guardian Connect	640G Smart Guard	DexCom G5 Mobile	Freestyle Libre	Eversense	Medtrum
						
Sensor life	6 days		7 days	14 days	180 days	7-14 days
Alarms	Multiple		1 high, low and trend	None	Multiple	Multiple
Predictive	Yes		No	N/A	Yes	Yes
Trends	Yes		Yes	N/A	Yes	Yes
Rate change	Yes		Yes	N/A	Yes	Yes
Calibration	12 hrly		2h, then 12 hrly	None	x4 at 2-12 h then12 hrly	12 hrly
MARD	9.64%		10.0%	9.7%	8.8%	9.1%

It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and deemed to meet one or more of the following:

1. **Patients who undertake intensive monitoring ≥8 times daily**
2. **Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy.**
3. **Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does currently not have that function.**
4. **Frequent admissions (>2 per year) with DKA or hypoglycaemia.**
5. **Those who require third parties to carry out monitoring and where conventional blood testing is not possible.**

In addition, all patients (or carers) must be willing to undertake training in the use of Freestyle Libre® and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered). Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced.


Flash Glucose Monitoring Policy Tracker
United Kingdom
Isle of Man
Dublin
Belfast
Ballymena
Dumfries
Blackpool
Peterborough
Cambrid
North Pennines AONB
Lake District National Park
Yorkshire Dales National Park
North York Moors National Park
Snowdonia National Park
A74(M)
M50
M11
M18
Google My Maps
Map data ©2018 GeoBasis-DE/BKG (©2009), Google
Terms
50 km

National Diabetes Insulin Pump Survey

Dear Colleagues,

The National Diabetes Audit (NDA) has been collecting data on people with diabetes since 2004. It routinely collects data from hospitals and GP practices, and measures the effectiveness of diabetes healthcare against NICE Clinical Guidelines and NICE Quality Standards, in England and Wales.

As part of the NDA Core data collection, information is collected for patients that also use an insulin pump.

The NDA have created a survey for secondary care / specialist service providers that may have patients using insulin pumps. This Type 1 diabetes and insulin pump survey includes a range of questions related to Type 1 diabetes care in your service. The findings will help to identify where services are performing well and any areas for improvement.

The results of the survey will be published in early 2019.

The survey can be accessed by using the link below and is open until 29 June 2018. Please be aware that you will need to complete any mandatory fields in order to move to the next section of the survey.

https://nhs-digital.citizenspace.com/carms/national-diabetes-audit-type-1-diabetes-insulin-pu/consultation/intro/

National Diabetes Audit Core Collection (2017-18) Data Landing now open for submissions

NHS Digital

Dear colleague,

We are pleased to announce that the online submission site for the National Diabetes Audit is **now open for 2017-18 submissions**.

Data Landing, for use by specialist diabetes, secondary and community care services, will remain open until **Friday 29th June 2018**.

All users will need to submit their data via the NDA Data Landing portal.

Guidance on how to register for an NDA Data Landing account has already been circulated, but can also be found here.

Please log into data landing and submit your data at: https://clinicalaudit.hscic.gov.uk/datalanding. Guidance for help with submitting data can be found here.

If you have any questions about the audit, please contact Gary Jevon (Clinical Audit Manager) or Elizabeth Eaves (Audit Coordinator) by emailing diabetes@nhs.net or calling 0300 303 5678. Lines are open Monday to Friday 9:00 – 17:00.

Safety of the batteries and power units used in insulin pumps: A pilot cross-sectional study by the Association for the Study of Innovative Diabetes Treatment in Japan

Table 3 | Types of trouble related to the batteries and the power units

	n	Rate (%)
(1) Termination of battery life within 72 h of use	33	50.0
(2) Suspension of the insulin pump	14	21.2
(3) Leakage of the battery fluid	3	4.5
(4) Usage of inappropriate batteries	1	1.5
(5) Others	15	22.7
Total	66	100

Table 4 | Types of error message (MiniMed 620G with continuous glucose monitoring sensor)

	n	Rate (%)
(1) Power error detected (Error 25)	17	38.6
(2) Insert battery (Delivery stopped)	2	4.5
(3) Low battery (Replace battery soon)	15	34.1
(4) Replace battery now (Delivery stopped)	4	9.1
(5) Replace battery (Battery life less than 30 min)	2	4.5
(6) Battery not compatible	0	0.0
(7) Battery failed (Insert a new battery)	1	2.3
(8) Pump error (Delivery stopped)	1	2.3
(9) Others	4	9.1
Total	46	100

Murata T et al. *J Diabetes Investig* 2017;doi:10.1111/jdi.12765

DTN UK

Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

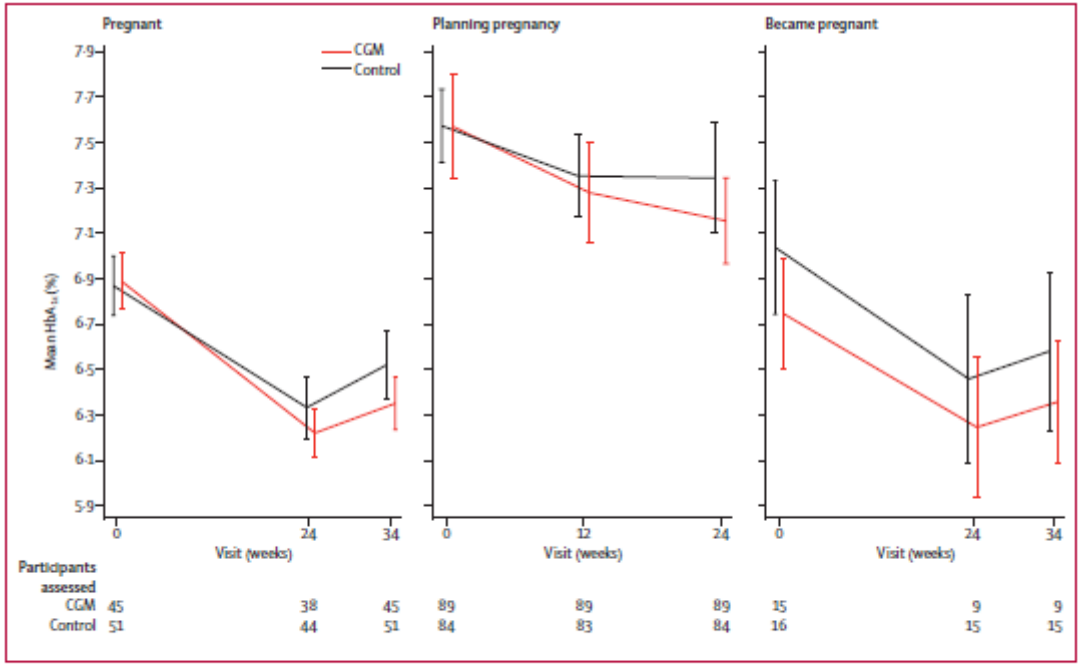


Figure 2: **Primary glycaemic outcome showing participants' HbA_{1c} levels according to pregnancy status**
Mean HbA_{1c} (95% CI) is shown at each assessment time for participants who had data at baseline and the time of the outcome assessment (24 and 34 weeks' gestation in the pregnancy trial and at 12 and 24 weeks from randomisation or at time of confirmed pregnancy in the pregnancy planning trial). Data are also shown for participants in the planning pregnancy trial who conceived before 24 weeks and stayed in the trial during pregnancy. CGM=continuous glucose monitoring. HbA_{1c}=glycated haemoglobin.

	CGM	Control	p value
Baseline	6·83% (0·67)	6·95% (0·66)	–
24 weeks' gestation	6·23% (0·53)	6·40% (0·68)	–
Change from baseline to 24 weeks	−0·67 (0·58)	−0·52 (0·55)	0·0374
34 weeks' gestation	6·35% (0·57)	6·53% (0·70)	–
Change from baseline to 34 weeks	−0·54 (0·62)	−0·35 (0·65)	0·0372
Achieved HbA_{1c} ≤6·5% (48 mmol/mol) at 34 weeks	63/95 (66%)	48/92 (52%)	0·0601

Data are mean percentage (SD). Assessed in 99 participants in the CGM group and 96 participants in the control group at baseline, and in 95 participants in the CGM group and 92 participants in the control group at baseline and 34 weeks' gestation. Percentage point changes are either cross-sectional on participants with data for baseline, week 24, and week 34 values, or summaries of change on participants with data at the relevant timepoints. p values are from linear regression (HbA_{1c}) or logistic regression (HbA_{1c} ≤6·5%) on available data, controlling for baseline HbA_{1c} and method of insulin delivery. CGM=continuous glucose monitoring. HbA_{1c}=glycated haemoglobin.

Table 2: **Glycaemic control of pregnancy trial participants based on available HbA_{1c} data**

Feig DS et al. *Lancet* 2017;390:2347-59

DTN UK

Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

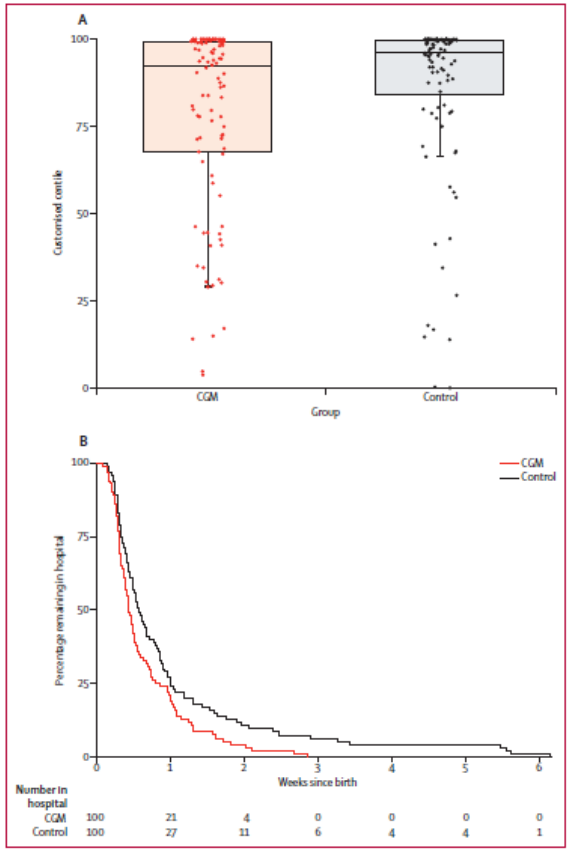


Figure 3: **Neonatal outcomes of pregnancy trial participants**
(A) Neonatal birthweight centiles are shown with box plots. The horizontal line in the middle of each box represents the median, and the lower and upper boundaries of the box represent the 25th and 75th percentiles, respectively. Whiskers are drawn to the smallest value that is within 1·5 x IQR below the 25th percentile. Values outside of the whiskers are drawn individually. These data are based on customised growth charts (gestation-related optimal weight) that adjust infant birthweight for maternal parity, ethnicity, height, and weight, and for infant sex and gestational age.[28] (B) The Kaplan-Meier plot shows infants' length of hospital stay from delivery until hospital discharge.

	CGM	Control	p value
Maternal outcomes			
Number assessed	100	102	..
Hypertensive disorders	18 (18%)	28 (27%)	0·13
Worsening chronic	2 (2%)	4 (4%)	0·68
Gestational	8 (8%)	9 (9%)	1·0
Pre-eclampsia	9 (9%)	18 (18%)	0·10
Caesarean section	63 (63%)	74 (73%)	0·18
Maternal weight gain (kg)*			
Entry to 34 weeks	13·1 (9·9–16·6)	13·7 (10·9–17·6)	0·22
From 16 to 34 weeks	8·9 (6·6–11·3)	9·7 (8·3–11·8)	0·09
Maternal length of stay (days)	3·5 (2·6–5·3)	4·2 (2·9–6·8)	0·10
Neonatal outcomes			
Number assessed	105	106	..
Pregnancy loss <20 weeks	5 (5%)	4 (4%)	1·0
Stillbirth	0	1	..
Termination	0	1	..
Congenital anomaly†	2	3	..
Preterm births			
Number assessed	100	102	..
Preterm <37 weeks	38 (38%)	43 (42%)	0·57
Early preterm <34 weeks	5 (5%)	11 (11%)	0·19
Gestational age at delivery‡	37·4 (36·7–38·1)	37·3 (36·0–38·0)	0·50
Birthweight			
Number assessed	100	100	..
Birthweight (g)	3545·4 (649·0)	3582·7 (777·0)	0·37
Median customised centile§	92 (68–99)	96 (84–100)	0·0489
Small for gestational age (<tenth centile)	2 (2%)	2 (2%)	1·0
Large for gestational age (>90th centile)	53 (53%)	69 (69%)	0·0210
Extremely large for gestational age (>97·7th centile)	36 (36%)	44 (44%)	0·31
Macrosomia (≥4000 g)	23 (23%)	27 (27%)	0·62
Neonatal complications			
Number assessed	100	100	..
Birth injury	1 (1%)	0	1·0
Shoulder dystocia	1 (1%)	0	1·0
Neonatal hypoglycaemia requiring intravenous dextrose	15 (15%)	28 (28%)	0·0250
Hyperbilirubinaemia	25 (25%)	31 (31%)	0·43
Respiratory distress	9 (9%)	9 (9%)	1·0
High-level neonatal care (NICU) >24 h	27 (27%)	43 (43%)	0·0157
Infant length of hospital stay	3·1 (2·1–5·7)	4·0 (2·4–7·0)	0·0091
Composite neonatal outcome¶	45 (42·9%)	56 (52·8%)	0·17

Values are mean (SD) and median (IQR) as appropriate. CGM=continuous glucose monitoring. NICU=neonatal intensive care unit. *Entry weight was self-reported or recorded pre-pregnancy weight, or both. The weight from 16 to 34 weeks was measured. †Congenital anomalies were aortic stenosis and hypospadias grade 1 (CGM group) and hypoplastic right heart syndrome (termination of pregnancy), aberrant right subclavian artery, and bilateral hydronephrosis (control group). ‡Gestational age at delivery was calculated only for the 100 pregnancies in the CGM group and the 101 pregnancies in the control group that were ongoing after 24 weeks' gestation. §Based on gestation-related optimal weight customised growth charts. ¶Composite outcome comprises pregnancy loss (miscarriage, stillbirth, and neonatal death); birth injury; neonatal hypoglycaemia; hyperbilirubinaemia; respiratory distress; and high-level neonatal care for more than 24 h.

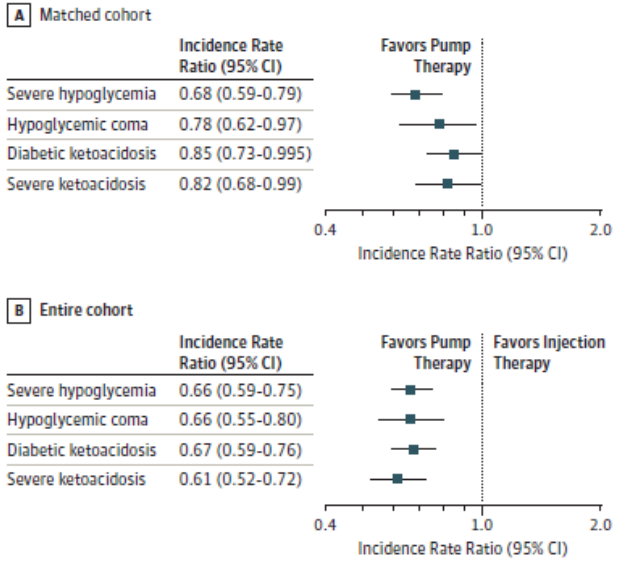
Table 4: **Obstetric and neonatal health outcomes of pregnancy trial participants**

Feig DS et al. *Lancet* 2017;390:2347-59

DTN UK

Association of Insulin Pump Therapy vs Insulin Injection Therapy With Severe Hypoglycemia, Ketoacidosis, and Glycemic Control Among Children, Adolescents, and Young Adults With Type 1 Diabetes

Figure 2. Incidence Rate Ratios of Severe Hypoglycemia and Diabetic Ketoacidosis for Pump Therapy vs Injection Therapy



Incidence rate ratios and 95% CIs are presented to show the risk of severe hypoglycemia, hypoglycemic coma, diabetic ketoacidosis (pH <7.3), and severe ketoacidosis (pH <7.1) in patients using insulin pump therapy compared with the risk in patients using insulin injection therapy. Error bars indicate 95% CIs. A, Analysis in the propensity score–matched cohort including 9814 patients using injection therapy and 9814 patients using pump therapy. B, Analysis with propensity score inverse probability of treatment weighting of the entire cohort (16 460 patients using injection therapy, 14 119 patients using pump therapy). Estimates are derived from negative binomial regression analyses.

Table 3. Secondary Outcomes: Metabolic Control and Insulin Treatment–Related Parameters With Injection Therapy vs Pump Therapy[a]

Outcome	Matched Cohort (n = 19 628)[b]				Entire Cohort (N = 30 579)[c]			
	Injection Therapy (n = 9814)	Pump Therapy (n = 9814)	Between-Group Difference (95% CI)[d]	*P* Value[e]	Injection Therapy (n = 16 460)	Pump Therapy (n = 14 119)	Between-Group Difference (95% CI)[d]	*P* Value[e]
HbA_{1c}				<.001				.001
% (95% CI)	8.22 (8.18 to 8.25)	8.04 (8.00 to 8.07)	-0.18 (-0.22 to -0.13)		8.17 (8.14 to 8.19)	7.99 (7.96 to 8.01)	-0.18 (-0.21 to -0.15)	
mmol/mol (95% CI)	66.30 (65.95 to 66.66)	64.38 (64.02 to 64.73)	-1.93 (-2.38 to -1.47)		65.74 (65.43 to 66.04)	63.78 (63.47 to 64.09)	-1.96 (-2.32 to -1.59)	
Total daily insulin dose, U/kg/d (95% CI)	0.979 (0.973 to 0.985)	0.838 (0.832 to 0.844)	-0.14 (-0.15 to -0.13)	<.001	0.960 (0.955 to 0.965)	0.822 (0.816 to 0.827)	-0.14 (-0.15 to -0.13)	<.001
Prandial to total insulin ratio, % (95% CI)	54.90 (54.66 to 55.14)	59.89 (59.65 to 60.13)	4.99 (4.65 to 5.33)	<.001	55.58 (55.36 to 55.80)	60.55 (60.33 to 60.77)	4.97 (4.70 to 5.25)	<.001
Use of rapid-acting insulin analogues, No. (%) [95% CI]	7294 (74.32) [73.45 to 75.18]	9372 (95.50) [95.07 to 95.89]	21.18 (19.97 to 22.23) OR, 7.30 (6.58 to 8.13)	<.001	12 108 (74.15) [73.26 to 75.03]	13 464 (95.50) [95.13 to 95.85]	21.35 (20.10 to 22.59) OR, 7.41 (6.76 to 8.13)	<.001
Frequency per day of self-monitoring of blood glucose level, No. (95% CI)	5.89 (5.83 to 5.95)	6.57 (6.51 to 6.63)	0.68 (0.59 to 0.76)	<.001	5.95 (5.90 to 6.01)	6.76 (6.70 to 6.81)	0.80 (0.73 to 0.87)	<.001
BMI, SD score (95% CI)[f]	0.30 (0.28 to 0.32)	0.32 (0.30 to 0.34)	0.02 (-0.004 to 0.05)	.10	0.31 (0.30 to 0.33)	0.31 (0.30 to 0.33)	-0.001 (-0.02 to 0.02)	.95

Abbreviations: BMI, body mass index; HbA_{1c}, glycated hemoglobin; OR, odds ratio.

[a] Values estimated from linear regression analysis (for outcomes HbA_{1c} level, total daily insulin dose, prandial to total insulin ratio, frequency of self-monitoring of blood glucose level, BMI) or logistic regression analysis (for use of rapid-acting insulin analogues) with matched pairs (matched cohort) or treatment center (entire cohort) as a random factor.

[b] The propensity score–matched cohort included 9814 patients for each therapy, except for analysis of HbA_{1c} level (9999 patients each) and BMI (9873 patients each).

[c] The entire cohort was included in propensity score inverse probability of treatment weighting analysis.

[d] Absolute differences between pump therapy and injection therapy.

[e] Identical *P* values were obtained after adjusting for multiple comparisons.

[f] An SD score of zero corresponds to the 50th percentile (median), and an SD score of +2 corresponds to the 97.7th percentile of an age- and sex-specific reference group.

Karge B et al. *JAMA* 2017;318:1358-66.

A Randomized Clinical Trial of the Effect of Continuous Glucose Monitoring on Nocturnal Hypoglycemia, Daytime Hypoglycemia, Glycemic Variability, and Hypoglycemia Confidence in Persons with Type 1 Diabetes Treated with Multiple Daily Insulin Injections (GOLD-3)

Arndís F. Ólafsdóttir, RN, PgD,[1,2] William Polonsky, PhD,[3] Jan Bolinder, MD, PhD, FRCPE,[4] Irl B. Hirsch, MD,[5] Sofia Dahlqvist,[1] Hans Wedel, PhD,[6] Thomas Nyström, MD, PhD,[7] Magnus Wijkman, MD, PhD,[8] Erik Schwarcz, MD, PhD,[9] Jarl Hellman, MD,[10] Tim Heise, MD,[11] and Marcus Lind, MD, PhD,[1,2]

Diabetes Technol Ther 2018;20:274-84.

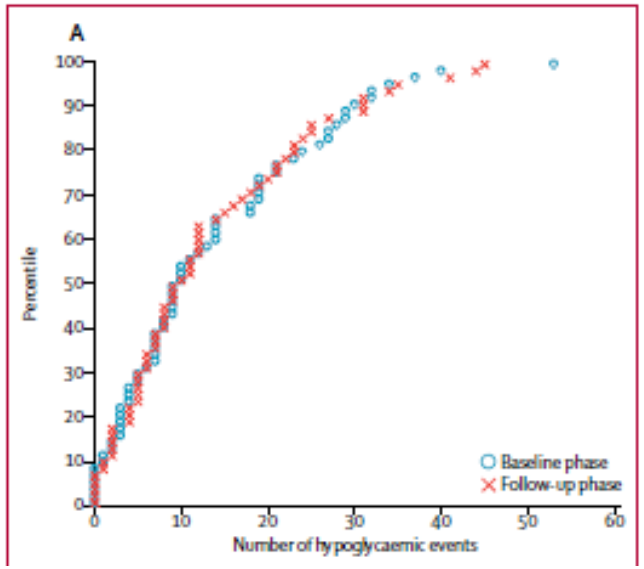
A randomized controlled pilot study of continuous glucose monitoring and flash glucose monitoring in people with Type 1 diabetes and impaired awareness of hypoglycaemia

M. Reddy, N. Jugnee, A. El Laboudi, E. Spanudakis, S. Anantharaja and N. Oliver

Diabet Med 2018;35:483-90.

DTN UK

Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial



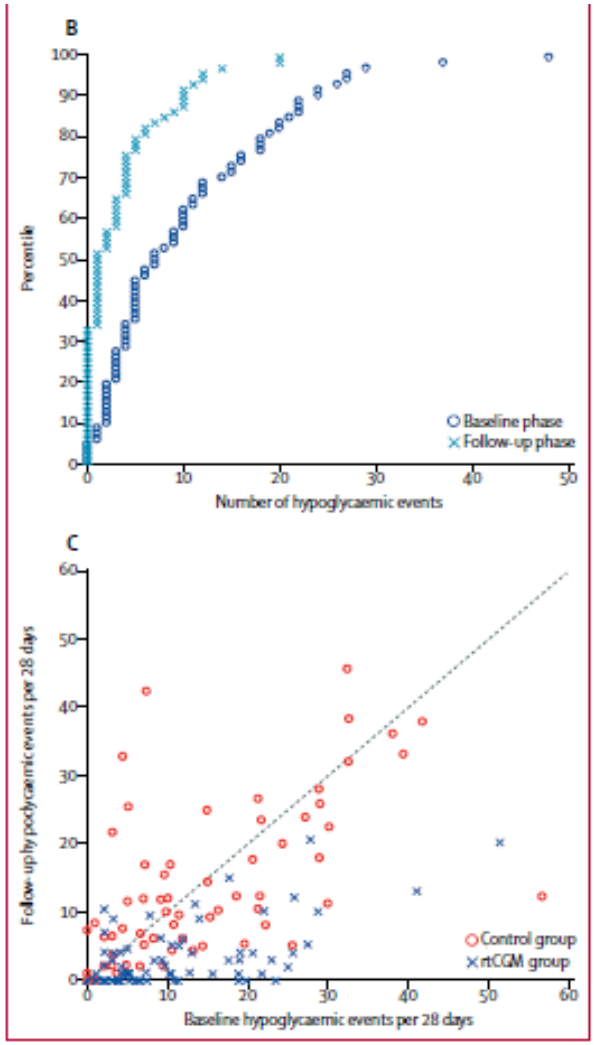


Figure 3: **Hypoglycaemic values during the baseline phase and the follow-up phase for the rtCGM group and control group**
Cumulative distribution of hypoglycaemic events per 28 days at baseline and follow-up in the control group (A) and in the real-time continuous glucose monitoring (rtCGM) group (B). For any given number of hypoglycaemic events (x-axis) the percentage of participants with the number of events at that level or lower in baseline and follow-up phase (y-axis) can be determined from the graph. Scatterplot of hypoglycaemic events of all individual patients during baseline and follow-up phases (C). Points below the diagonal line represent participants in whom the number of events during the follow-up phase was lower than during the baseline phase.

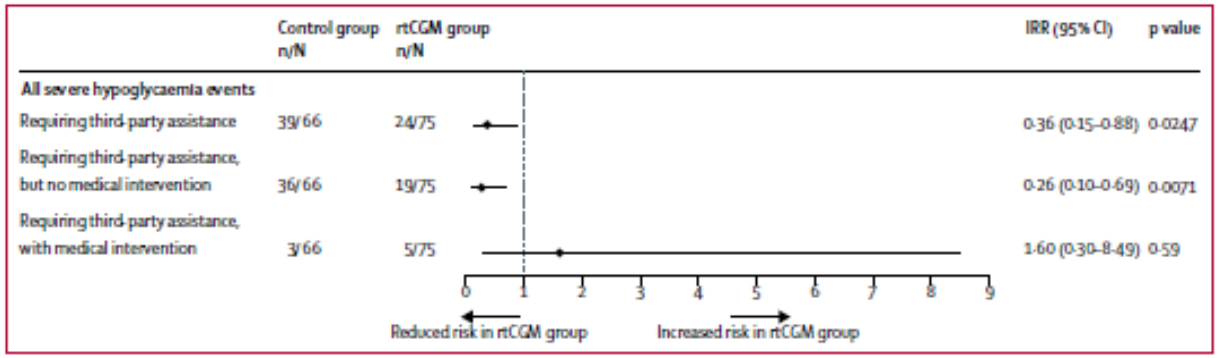


Figure 4: **Severe hypoglycaemia events in the rtCGM group and the control group**
rtCGM=real-time continuous glucose monitoring. IRR=incidence rate ratio.

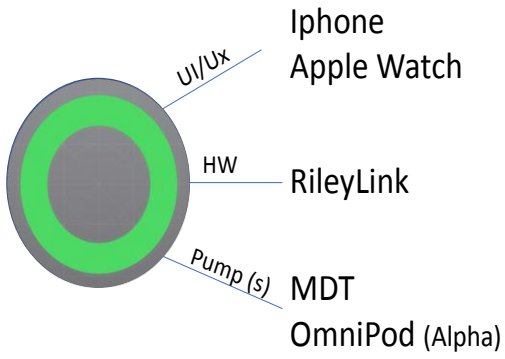
Heinemann L et al. *Lancet* 2018;391:1367-77.

Do you know what Open APS is?

DTN UK

Open APS

A reminder of different APS systems….

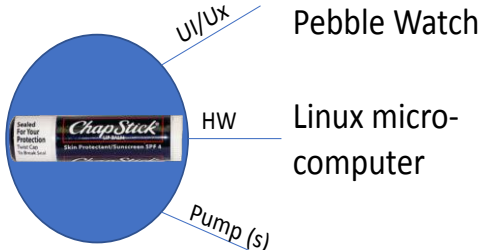


Iphone
Apple Watch

RileyLink

MDT
OmniPod (Alpha)

Loop

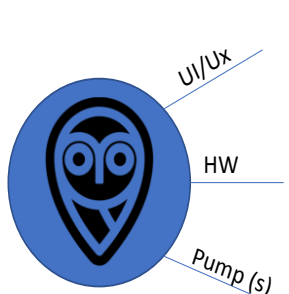


Pump
Pebble Watch

Linux micro-computer

MDT

OpenAPS



Android Phone
SmartWatch

None

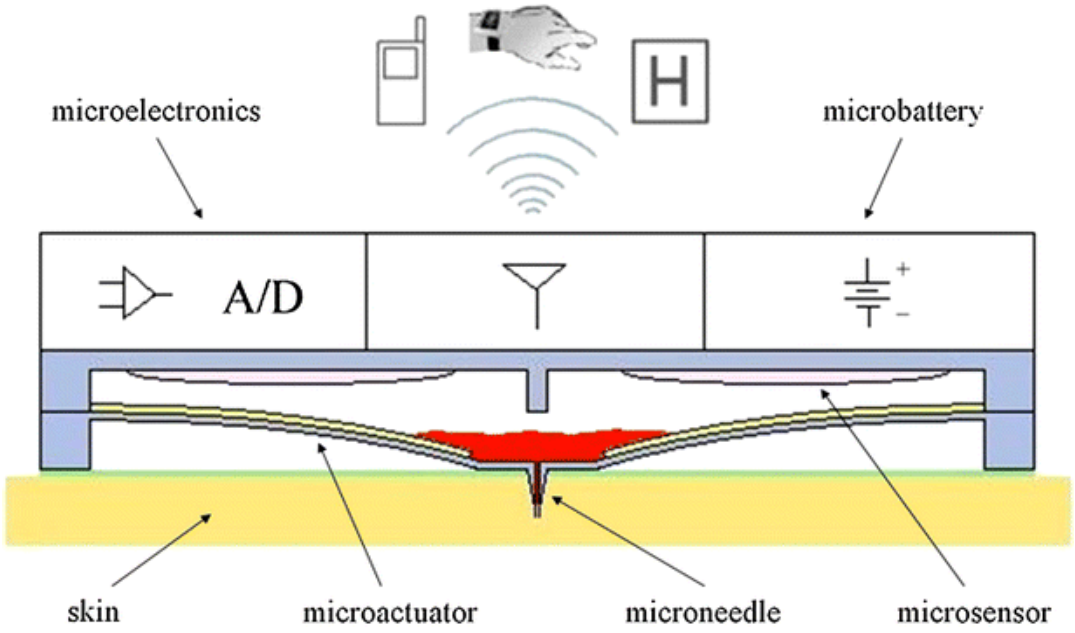
Dana R
Dana RS
Combo

AndroidAPS

Should pump services support Open APS users?

DTN UK

The e-mosquito



Wang G et al. IEEE Transactions Biomed Circ Sys 2017;11:979-87

The contact lens

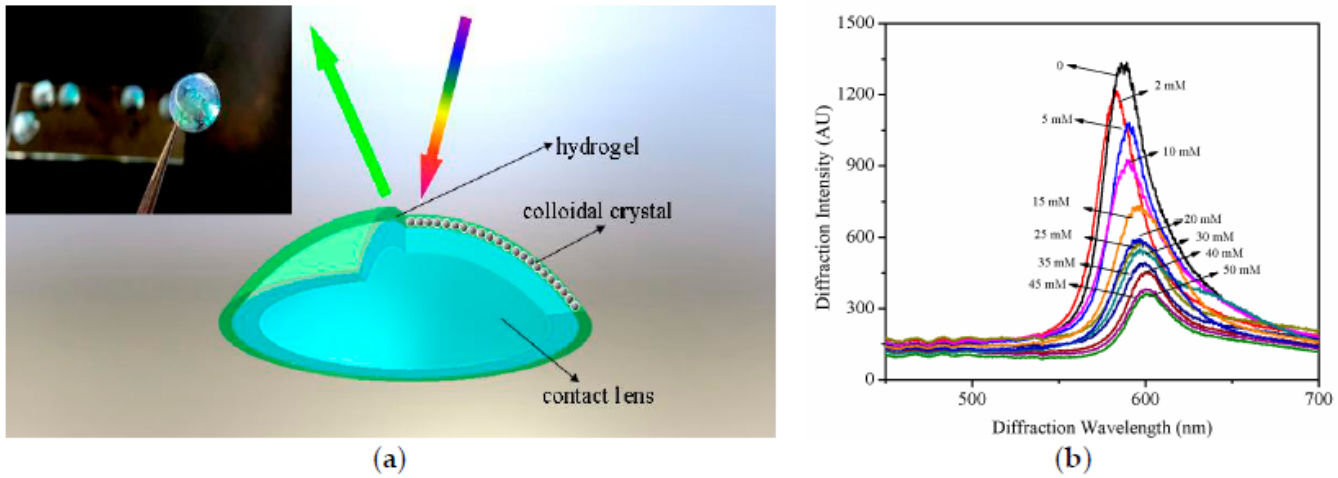


Figure 6. (a) Diagram and photograph (insert) of a physical hydrogel photonic crystal sensing lens; (b) Diffraction wavelength shifts with the variation of the glucose concentration in artificial tear solution.

Chen C et al. *Sensors* 2017;17:182

DTN UK

Thought for the year!

- Technology moving fast:
  - New players in the CSII and CGM markets
  - Increasing use of Cloud for uploading

- So challenges:
  - Data security: GDPR
  - Health economics: Libre or 670 G for all?!
  - Ensure equity and quality service provision