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Initiate Phase Training CareLink Interpretation Methodology

UC201503883EE

Medtronic Diabetes Integrated Therapy Management

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CareLink® Benefits

Efficiencies that save you time

- Review insulin pump, continuous glucose monitoring (CGM), and blood glucose meter data in one convenient place
- Link to your patient's CareLink® Personal account for simple data transfer and remote monitoring

More insights for better treatment decisions

- Generates easy-to-read reports that you can use to educate and motivate patients
- Highlights specific patient events and behaviors

The CareLink Software Platform

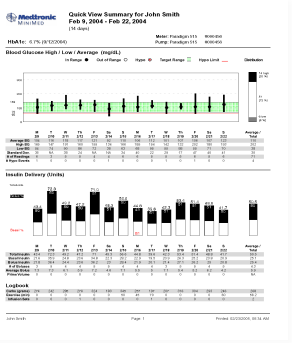
CareLink Personal
Patient's Home

CareLink Personal Database

Internet

Views Reports

Upload Device



Print Reports

CareLink Pro
Office Setting

Office CareLink® Pro Database

Device Upload

View Reports

Print Reports

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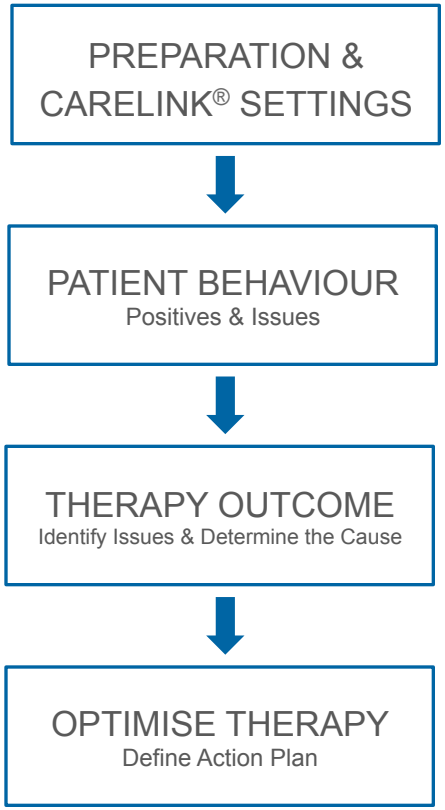
Overview of the Interpretation Methodology

- Developed by the CareLink Advisory Board which consists of 5 experienced HCPs who integrated CareLink in their daily practice.
- 4 Step methodology describing how you could use CareLink to optimise your patient's diabetes therapy
- For both patients on
  - CGM
  - SMBG



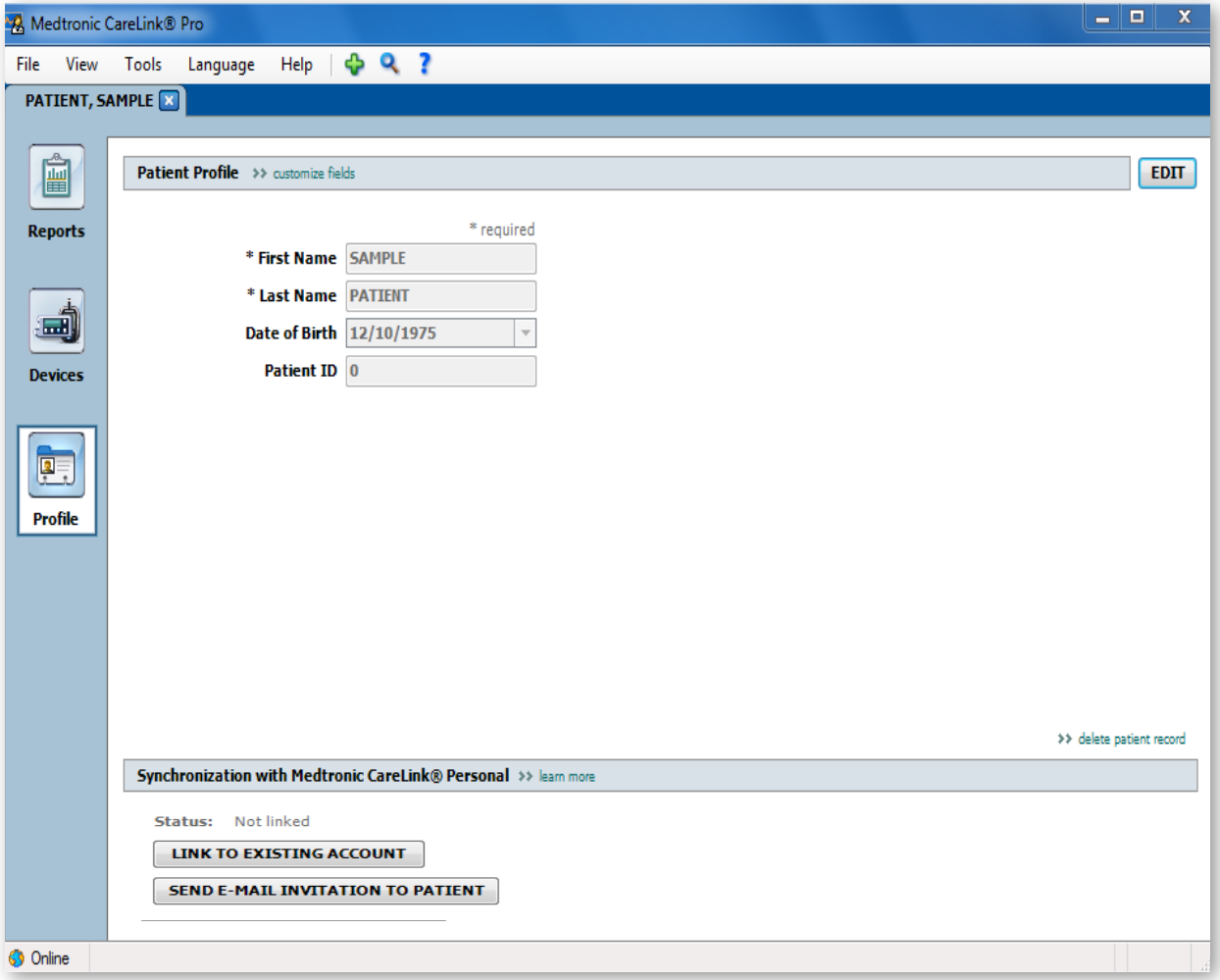
Preparation

- Make sure your patient has registered themselves in CareLink® Personal
  - Involve patient in treatment
  - Enables Tele-consultations

- Let the patient do the upload at home
  - Saves you time at the clinic
  - Ask patient to identify an issue

* [Corriveau E.A., Durso P.J., Kaufman E.D., et al. Effect of Carelink, an internet-based insulin pump monitoring system, on glycemic control in rural and urban children with type 1 diabetes mellitus. Pediatr Diabetes. 2008; 9(Part II): 360-366.]

Linking to a CareLink® Personal account



PREPARATION & CARELINK® SETTINGS

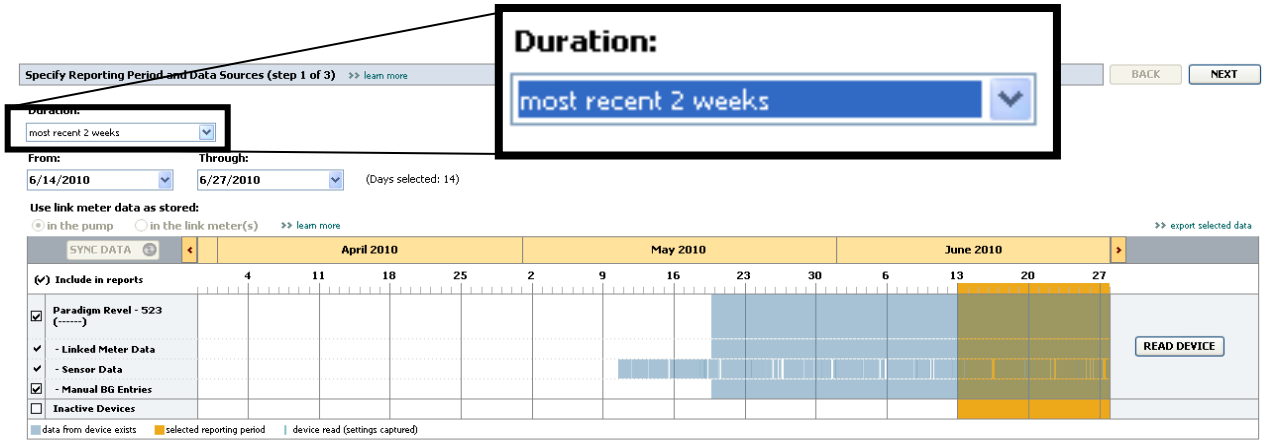
PATIENT BEHAVIOUR
Positives & Issues

THERAPY OUTCOME
Identify Issues & Determine the Cause

OPTIMISE THERAPY
Define Action Plan

CareLink® Pro Settings

- Data Selection
  - The patient won't remember more then two weeks
  - Select the two most recent weeks WITH DATA



PREPARATION & CARELINK® SETTINGS

PATIENT BEHAVIOUR
Positives & Issues

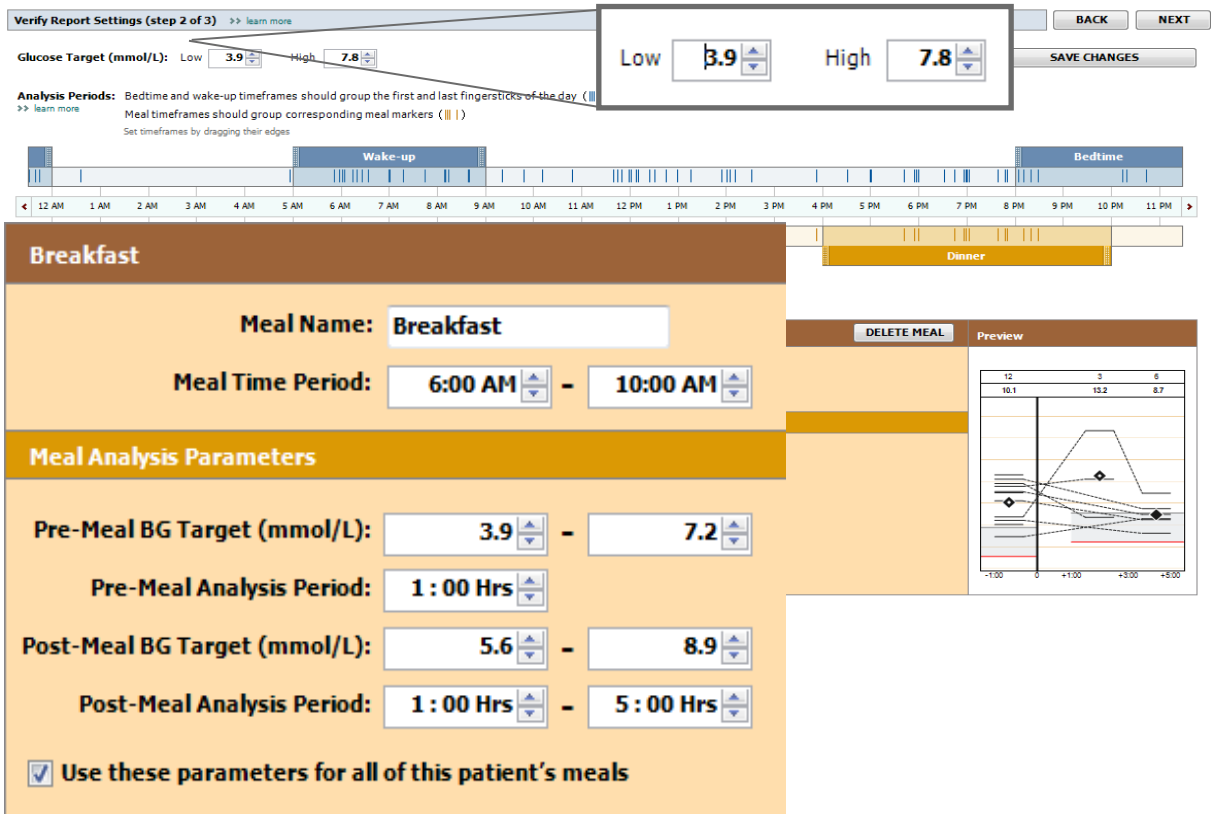
THERAPY OUTCOME
Identify Issues & Determine the Cause

OPTIMISE THERAPY
Define Action Plan

CareLink® Pro Settings

- Settings
  - Glucose Targets
  - Meal Times

Important as a number of graphs in the report will use these settings.



PREPARATION & CARELINK® SETTINGS

PATIENT BEHAVIOUR
Positives & Issues

THERAPY OUTCOME
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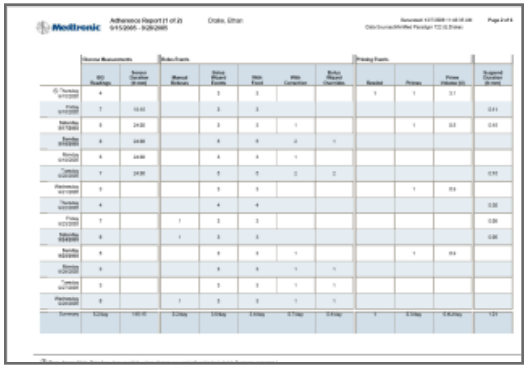
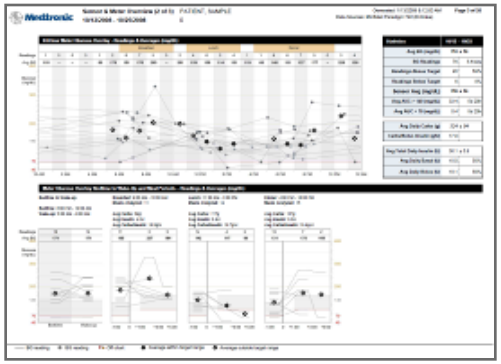
CareLink® Professional Reports

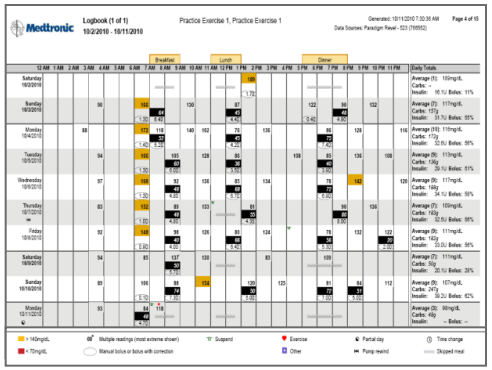
Adherence



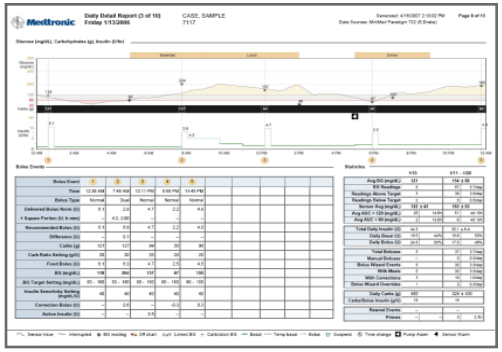
Sensor & Meter Overview



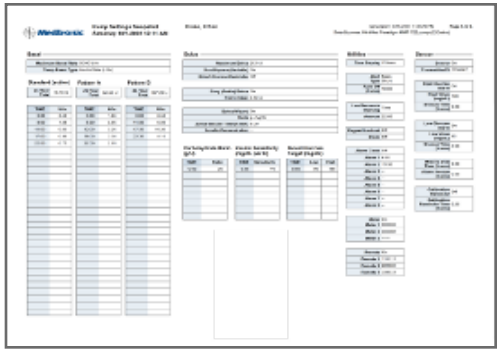
Logbook



Daily Detail



Device Settings



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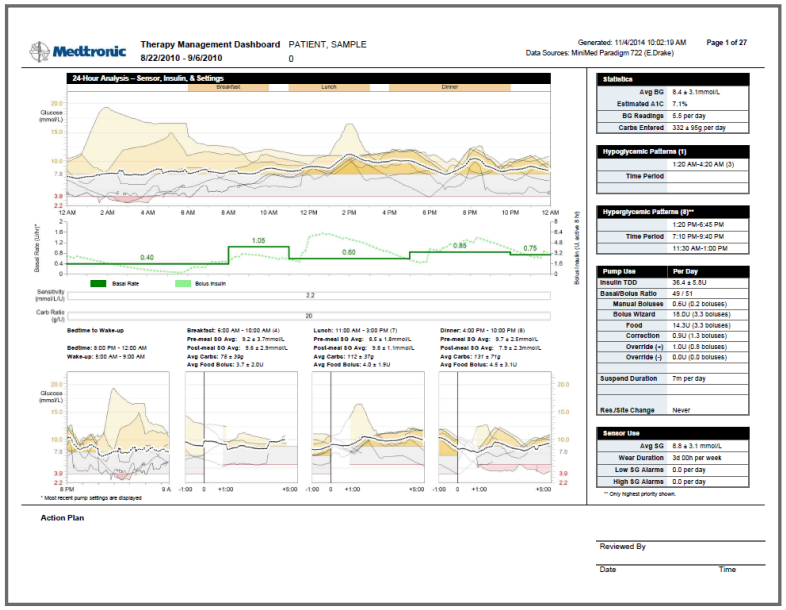
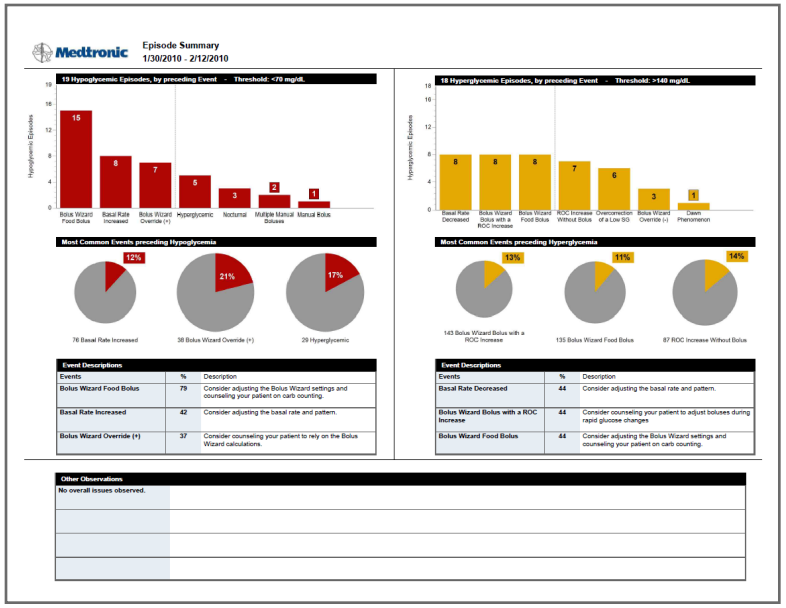
CareLink® Pro Sensor Reports

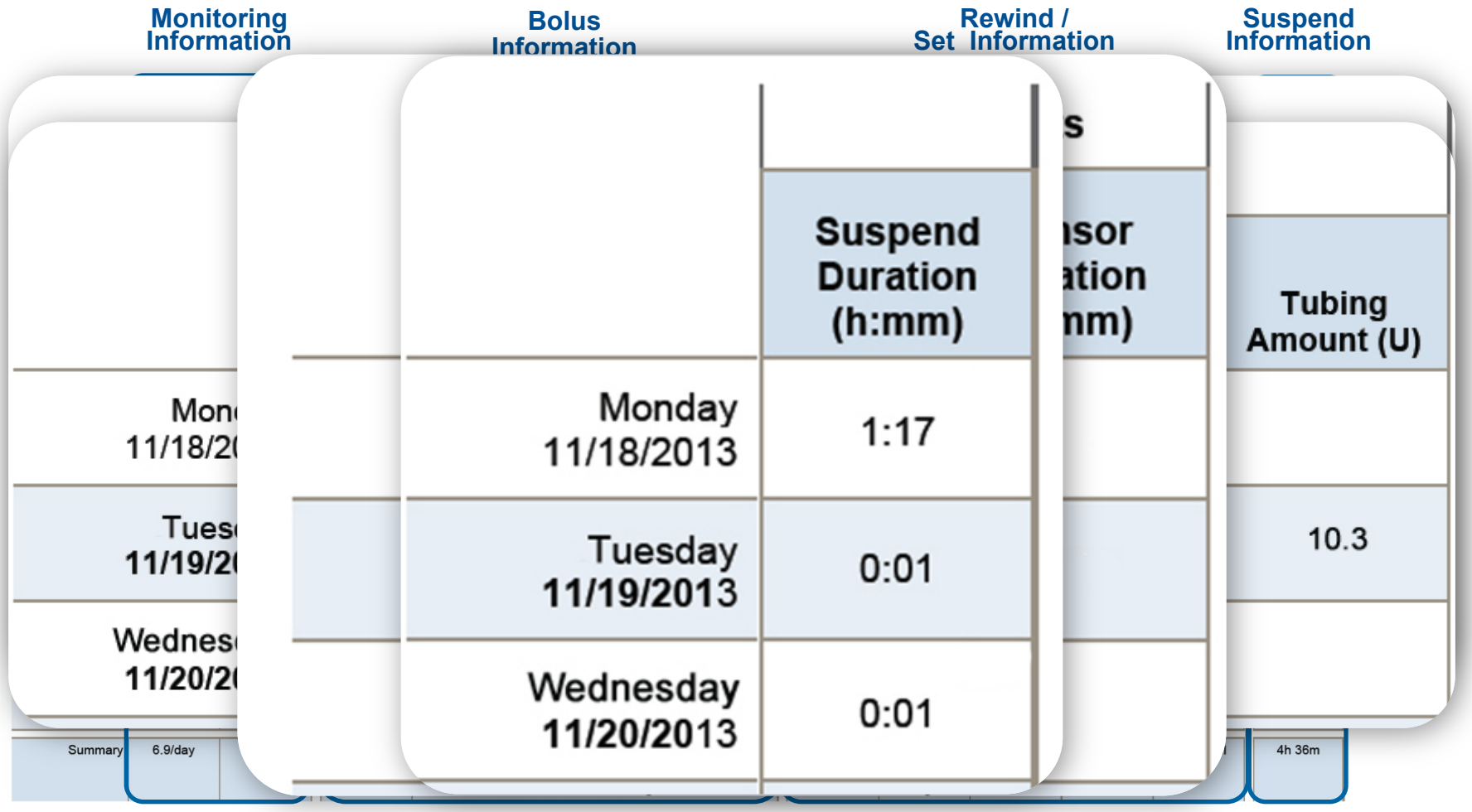
Therapy Management Dashboard



Episode Summary



Adherence Report



Sensor & Meter Overview Report

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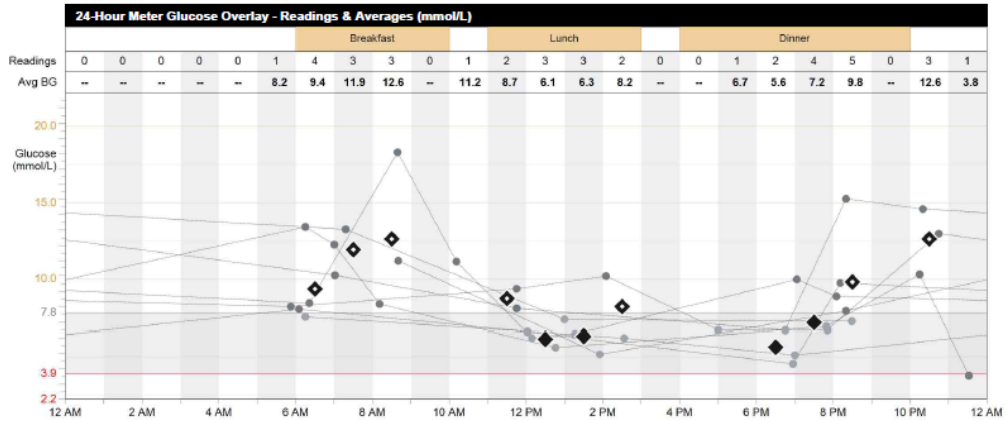
Sensor & Meter Overview (1 of 2) PATIENT, SAMPLE
8/28/2010 - 9/4/2010 0

Generated: 11/4/2014 10:08:57 AM **Page 2 of 13**
Data Sources: MiniMed Paradigm 722 (E.Drake)



Statistics	8/28 - 9/4	
Avg BG (mmol/L)	8.9 ± 3.2	
BG Readings	38	4.8/day
Readings Above Target	22	58%
Readings Below Target	1	3%
Sensor Avg (mmol/L)	--	
Avg AUC > 7.8 (mmol/L)	--	--
Avg AUC < 3.9 (mmol/L)	--	--

Avg Daily Carbs (g)	298 ± 62	
Carbs/Bolus Insulin (g/U)	17.3	

Avg Total Daily Insulin (U)	35.1 ± 5.2	
Avg Daily Basal (U)	17.9	51%
Avg Daily Bolus (U)	17.2	49%

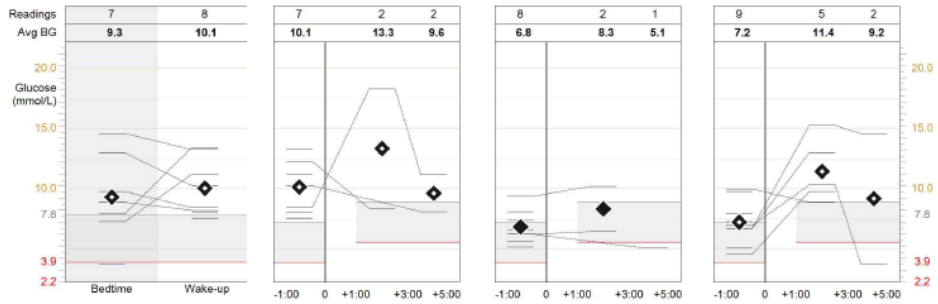
Meter Glucose Overlay Bedtime to Wake-Up and Meal Periods – Readings & Averages (mmol/L)

Bedtime to Wake-up
Bedtime: 8:00 PM - 12:00 AM
Wake-up: 5:00 AM - 9:00 AM

Breakfast: 6:00 AM - 10:00 AM
Meals Analyzed: 7
Avg Carbs: 66g
Avg Insulin: 4.6U
Avg Carbs/Insulin: 14.4g/U

Lunch: 11:00 AM - 3:00 PM
Meals Analyzed: 8
Avg Carbs: 125g
Avg Insulin: 6.3U
Avg Carbs/Insulin: 20.0g/U

Dinner: 4:00 PM - 10:00 PM
Meals Analyzed: 9
Avg Carbs: 99g
Avg Insulin: 4.9U
Avg Carbs/Insulin: 20.0g/U



BG reading | BG reading | Off chart | Average within target range | Average outside target range

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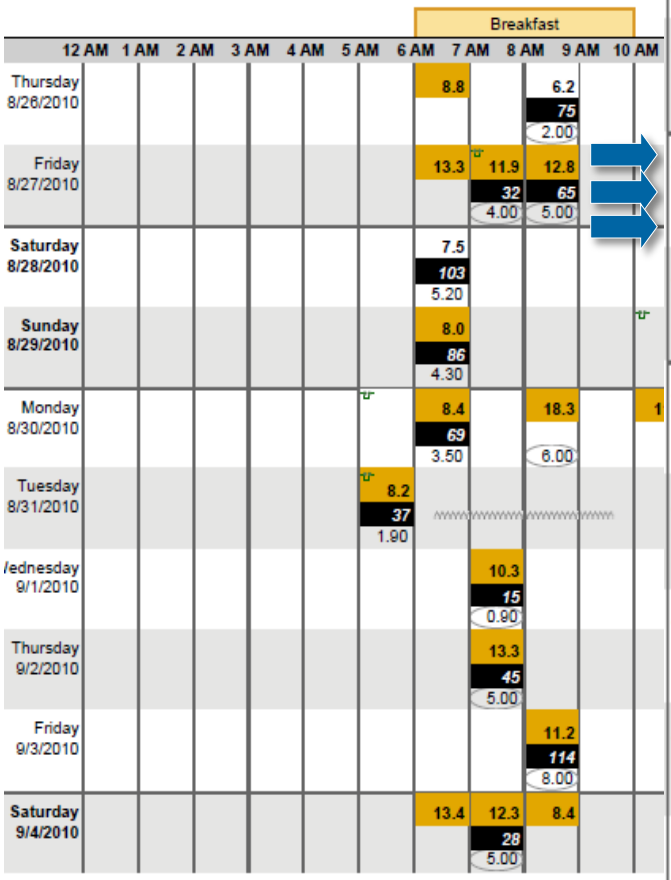
The Logbook Report



Daily Totals

Average (5): 9.2mmol/L
Carbs: *215g*
Insulin: 28.6U **Bolus:** 33%

Average (7): 9.1mmol/L
Carbs: *377g*
Insulin: 39.9U **Bolus:** 58%

Average (3): 6.3mmol/L
Carbs: *242g*
Insulin: 30.7U **Bolus:** 39%

Average (4): 7.2mmol/L
Carbs: *283g*
Insulin: 32.1U **Bolus:** 44%

Average (7): 9.9mmol/L
Carbs: *418g*
Insulin: 46.1U **Bolus:** 59%

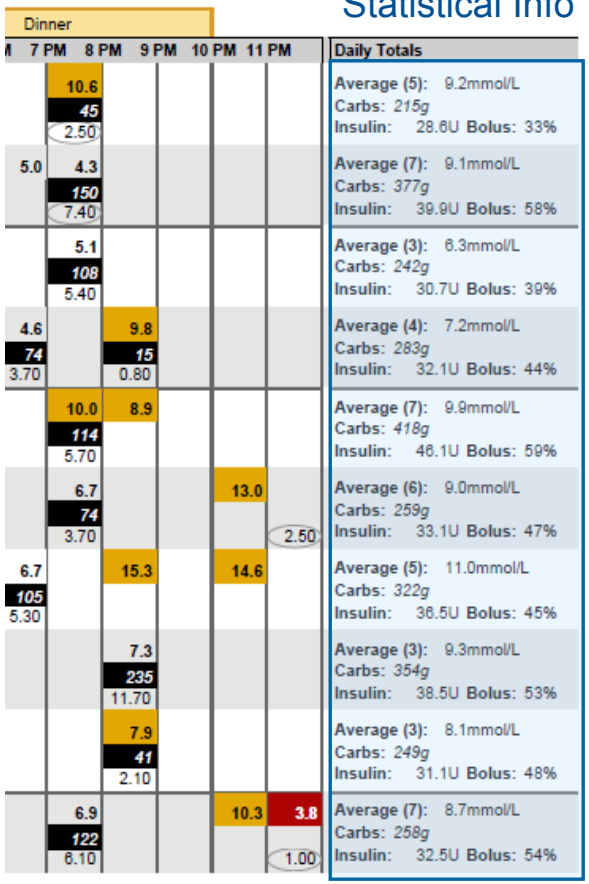
Average (6): 9.0mmol/L
Carbs: *259g*
Insulin: 33.1U **Bolus:** 47%

Average (5): 11.0mmol/L
Carbs: *322g*
Insulin: 36.5U **Bolus:** 45%

Average (3): 9.3mmol/L
Carbs: *354g*
Insulin: 38.5U **Bolus:** 53%

Average (3): 8.1mmol/L
Carbs: *249g*
Insulin: 31.1U **Bolus:** 48%

Average (7): 8.7mmol/L
Carbs: *258g*
Insulin: 32.5U **Bolus:** 54%



Daily Totals
Statistical Info

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Carbs: *377g*
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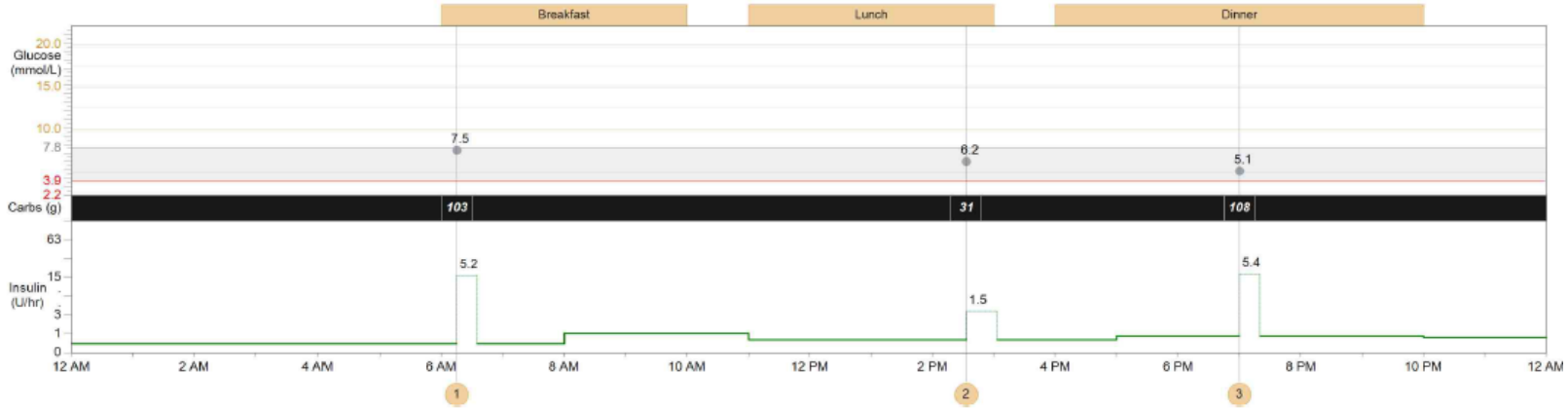
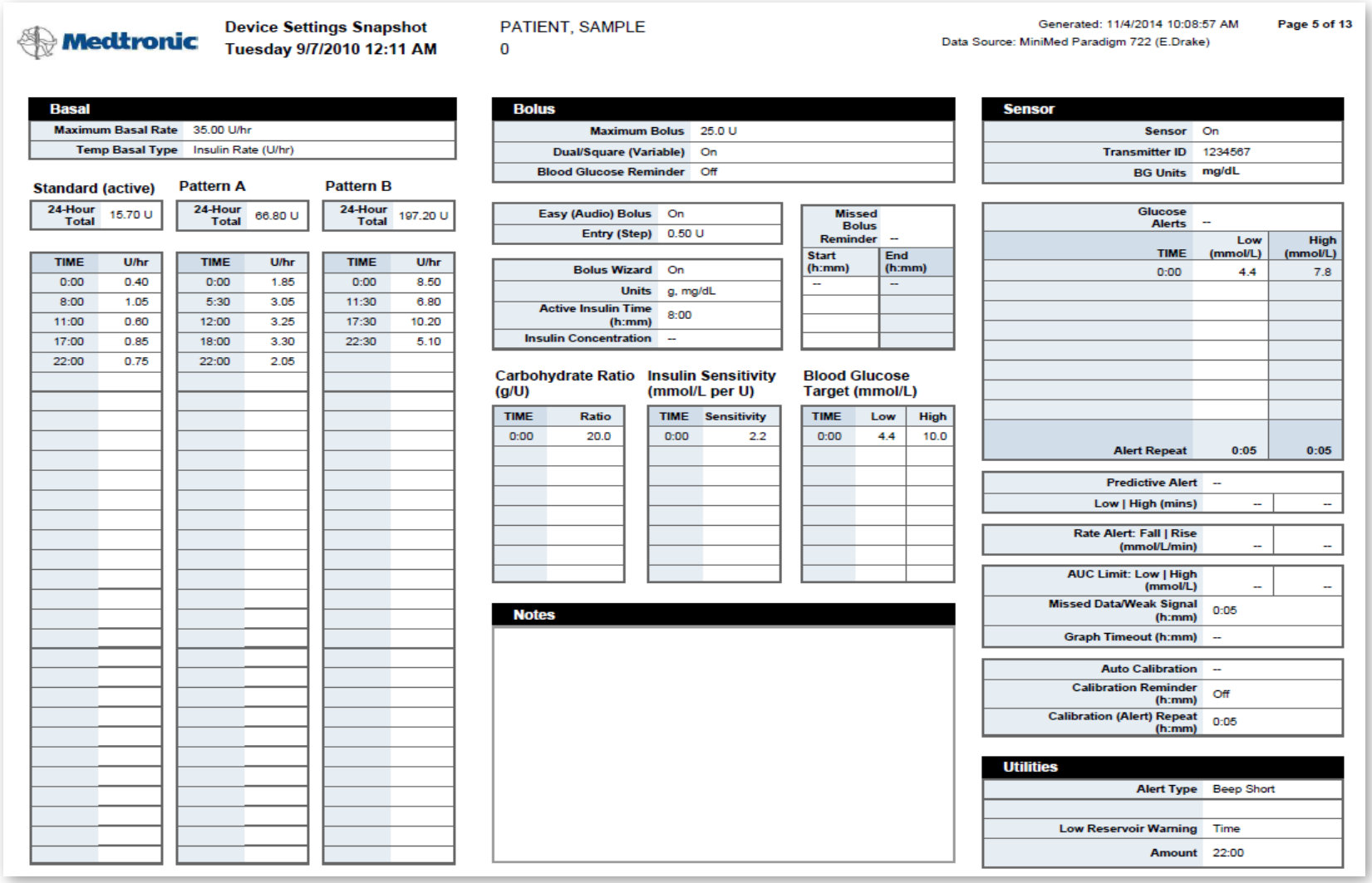
Daily Detail Report



Bolus Events	1	2	3							
Bolus Event										
Time	6:15 AM	2:33 PM	7:00 PM							
Bolus Type	Normal	Square	Normal							
Delivered Bolus Norm (U)	5.2	--	5.4							
+ Square Portion (U, h:mm)	--	1.5, 0:30	--							
Recommended Bolus (U)	5.2	1.5	5.4							
Difference (U)	--	--	--							
Carbs (g)	*103*	*31*	*108*							
Carb Ratio Setting (g/U)	20.0	20.0	20.0							
Food Bolus (U)	5.2	1.5	5.4							
BG (mmol/L)	**7.5**	**6.2**	**5.1**							
BG Target Setting (mmol/L)	4.4 - 10.0	4.4 - 10.0	4.4 - 10.0							
Insulin Sensitivity Setting (mmol/L per U)	2.2	2.2	2.2							
Correction Bolus (U)	--	--	--							
Active Insulin (U)	--	--	0.1							

Statistics	8/28		8/28 - 9/4	
Avg BG (mmol/L)	**6.3**		**8.9 ± 3.2**	
BG Readings	3		38	4.8/day
Readings Above Target	--	0%	22	58%
Readings Below Target	--	0%	1	3%
Sensor Avg (mmol/L)	--		--	
Avg AUC > 7.8 (mmol/L)	--	--	--	--
Avg AUC < 3.9 (mmol/L)	--	--	--	--
Daily Carbs (g)	*242*		*298 ± 62*	
Carbs/Bolus Insulin (g/U)	20.0		17.3	
Total Daily Insulin (U)	30.7		35.1 ± 5.2	
Daily Basal (U)	18.6	61%	17.9	51%
Daily Bolus (U)	12.1	39%	17.2	49%
Primes	1	0.9U	2	1.8U

Device Settings Report



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Device Settings Snapshot
Tuesday 9/7/2010 12:11 AM

PATIENT, SAMPLE
0

Generated: 11/4/2014 10:08:57 AM
Data Source: MiniMed Paradigm 722 (E.Drake)

Basal

Maximum Basal Rate	35.00 U/hr
Temp Basal Type	Insulin Rate (U/hr)

Standard (active)

24-Hour Total	15.70 U

TIME	U/hr
0:00	0.40
8:00	1.05
11:00	0.60
17:00	0.85
22:00	0.75

Pattern A

24-Hour Total	66.80 U

TIME	U/hr
0:00	1.85
5:30	3.05
12:00	3.25
18:00	3.30
22:00	2.05

Pattern B

24-Hour Total	197.20 U

TIME	U/hr
0:00	8.50
11:30	6.80
17:30	10.20
22:30	5.10

Bolus

Maximum Bolus	25.0 U
Dual/Square (Variable)	On
Blood Glucose Reminder	Off

Easy (Audio) Bolus	On
Entry (Step)	0.50 U

Bolus Wizard	On
Units	g, mg/dL
Active Insulin Time (h:mm)	8:00
Insulin Concentration	--

Missed Bolus Reminder	--
Start (h:mm)	End (h:mm)
--	--

Carbohydrate Ratio (g/U)

TIME	Ratio
0:00	20.0

Insulin Sensitivity (mmol/L per U)

TIME	Sensitivity
0:00	2.2

Blood Glucose Target (mmol/L)

TIME	Low	High
0:00	4.4	10.0

Notes

Sensor

Sensor	On
Transmitter ID	1234567
BG Units	mg/dL

Glucose Alerts	--	
TIME	Low (mmol/L)	High (mmol/L)
0:00	4.4	7.8
Alert Repeat	0:05	0:05

Predictive Alert	--	
Low | High (mins)	--	--

Rate Alert: Fall | Rise (mmol/L/min)	--	--

AUC Limit: Low | High (mmol/L)	--	--
Missed Data/Weak Signal (h:mm)	0:05	
Graph Timeout (h:mm)	--	

Auto Calibration	--
Calibration Reminder (h:mm)	Off
Calibration (Alert) Repeat (h:mm)	0:05

Utilities

Alert Type	Beep Short
Low Reservoir Warning	Time
Amount	22:00

Patient Behaviour

- Encourage the good (or positive) behaviour
  - Use the ‘adherence report’ to find some positives in the patient behaviour
  - Prevent focusing too much on therapy outcomes.

- Determine Data Quality and Behaviour Issues
  - Check for issues in the ‘adherence report’ and find out more on the behaviour by asking questions like:
    - “Does the patient eat without giving a bolus?”
    - “Does the patient use the SG-value or the BG-value as input for the bolus wizard?”,

Patient Behavior

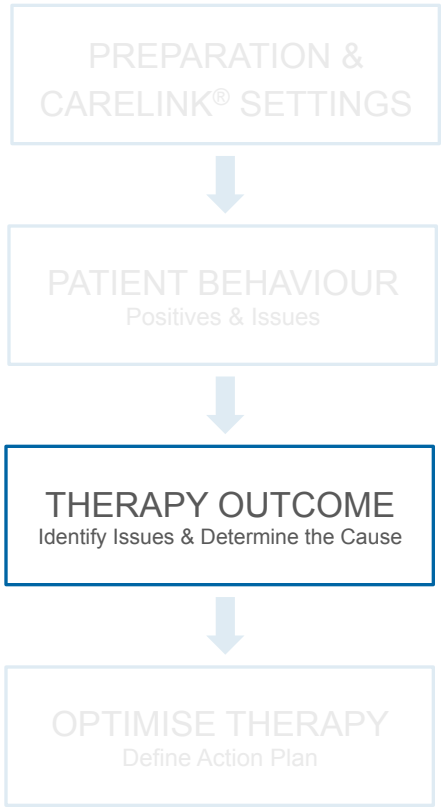
Parameters	Impact on Data Quality
Infusion set change frequency [Fill Events]	If the infusion set is not changed regularly (as described in the instructions) proper insulin infusion cannot be guaranteed.
BG Reading frequency [BG Readings]	Sensor accuracy strongly depends on good and frequent calibration. If the patient does not use a sensor, the number of blood glucose readings are also very important for proper data analysis.
Sensor Use [Sensor Duration]	If sensor duration is low, the average, pre- and post-prandial glucose values cannot be determined accurately.
Bolus Frequency [Bolus Events]	If there are two few bolus events, the pump is probably not used appropriately. The patient might use the priming function to deliver boluses.
Bolus Type	Manual or Bolus Wizard® Overrides: Assessment of the Carbohydrate Ratio and/or the sensitivity settings should be done carefully taking into account the manual boluses and the overrides.

Patient Behavior – Adherence Report

	Glucose Measurements		Bolus Events					Fill Events					
	BG Readings	Sensor Duration (h:mm)	Manual Boluses	Bolus Wizard Events	With Food	With Correction	Overridden	Rewind	Cannula Fills	Cannula Amount (U)	Tubing Fills	Tubing Amount (U)	Suspend Duration (h:mm)
Monday 11/18/2013	6		1	4	4	4							1:17
Tuesday 11/19/2013	7		1	6	3	6	1	1	1	0.5	1	10.3	0:01
Wednesday 11/20/2013	8			6	4	6							0:01
Thursday 11/21/2013	8		3	5	4	5	2						
Friday 11/22/2013	9			6	3	6	1	1	1	0.5	1	12.1	0:01
Saturday 11/23/2013	5			4	4	4	1						2:57
Sunday 11/24/2013	6			4	4	3	1						0:05
Monday 11/25/2013	7		1	5	4	4	1	1	1	0.5	1	11.5	0:12
Tuesday 11/26/2013	7		1	4	4	4	1						0:01
Wednesday 11/27/2013	8			7	4	7	1						0:02
Thursday 11/28/2013	5		1	4	4	4	2	1	1	0.5	1	13.7	0:01
Friday 11/29/2013	6		1	6	4	6	1						
Summary	6.9/day	0m	0.9/day	5.0/day	78.3%	95.0%	23.3%	3	4	0.5U /fill	4	11.9U/fill	4h 36m

Therapy Outcome

- Identify the therapy related issues
- Determine a cause for each of these issues
  - Form a hypothesis
  - Test the hypothesis



Therapy Outcome: Identify the Issues

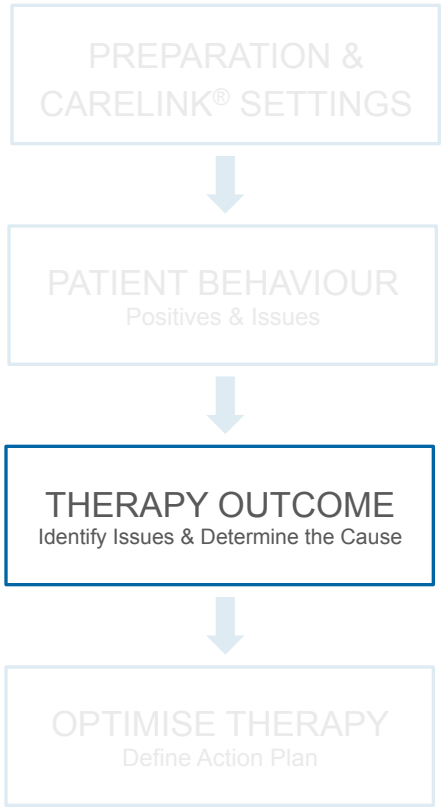
WHEN IDENTIFYING THE ISSUES LOOK FOR:

- Nocturnal Hypoglycaemic episodes
- Pre-prandial Hypoglycaemic episodes
- Post-prandial Hypoglycaemic episodes

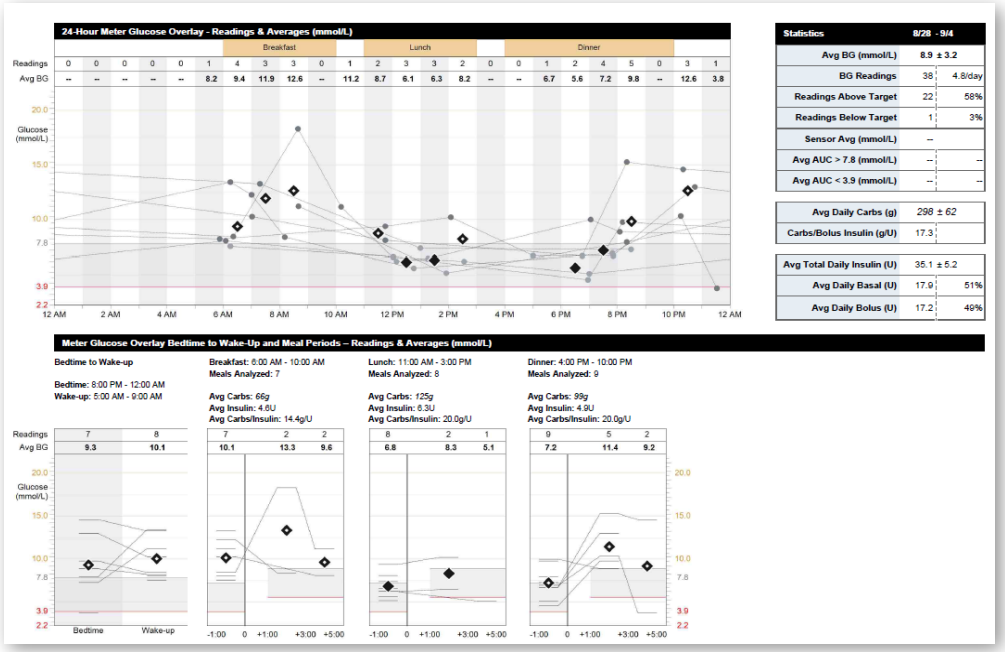
- Nocturnal Hyperglycaemic episodes
- Pre-prandial Hyperglycaemic episodes
- Post-prandial Hyperglycaemic episodes

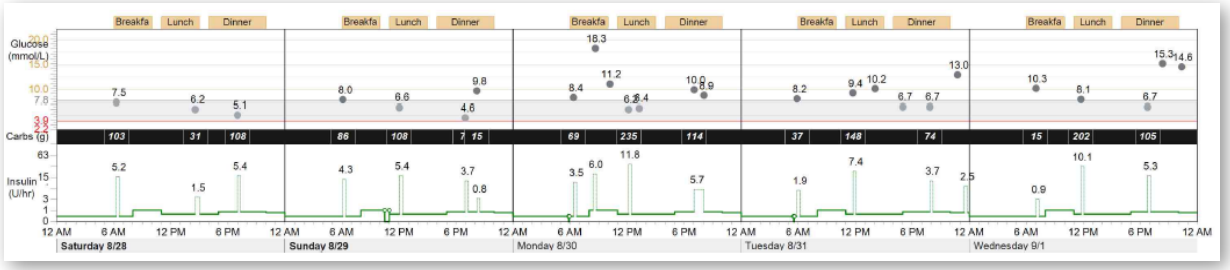
- Hyperglycaemia followed by Hypoglycaemia
- Hypoglycaemia followed by Hyperglycaemia

- Mean daily blood glucose and glucose variability (SD).
- Check for ingested carbohydrates; Is the amount appropriate?
- Check for insulin doses and distribution of % of basal or bolus.
- How many times did the patient change the temporary basal rate.



Therapy Outcome: Identify the Issues - SMBG





PREPARATION & CARELINK® SETTINGS

PATIENT BEHAVIOUR
Positives & Issues

THERAPY OUTCOME
Identify Issues & Determine the Cause

OPTIMISE THERAPY
Define Action Plan

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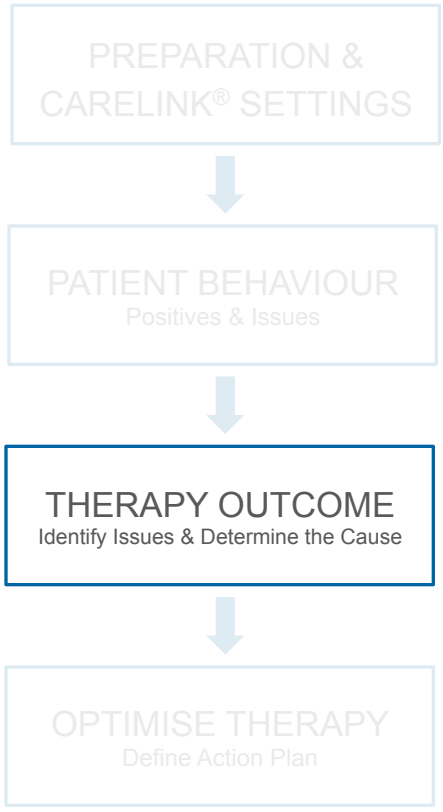
Therapy Outcome: Determine the Cause

- What happened?….
- What could be the reason?

Note

- CareLink® only shows data from the device(s)
- Displayed pump settings are settings at the moment of upload



Therapy Outcome: Determine the Cause

HYPO'S

Patterns	Common contributing factors
Nocturnal Hypoglycaemia	• Too high overnight Basal Rate • Evening Boluses • Exercise without adapted insulin delivery • Alcohol consumption without adapted insulin delivery
Post-Prandial Hypoglycaemia	• Incorrect carbohydrate counting • Too low carbohydrate ratio • Manual boluses instead of Bolus Wizard® • Unawareness on active insulin and insulin stacking • Too high Basal Rate • Bolus during falling sensor values only for patients on CGM • Incorrect Bolus Type (dual wave / normal / square wave)
Hypoglycaemia preceded by Hyperglycaemia	• Too low insulin sensitivity • Manual bolus used to correct for hyperglycaemic episodes • Unawareness on active insulin and insulin stacking • Multiple boluses to correct hypoglycaemia • Bolus during falling rate of change alert? Only for patients on CGM
Pre-Prandial/Other Hypoglycaemia	• Too high Basal Rate • Exercise without adapted insulin delivery • Alcohol consumption without adapted insulin delivery

PREPARATION & CARELINK® SETTINGS

PATIENT BEHAVIOUR
Positives & Issues

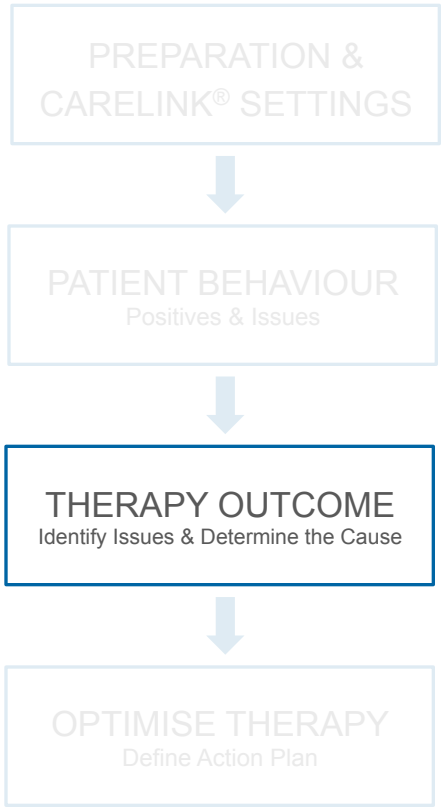
THERAPY OUTCOME
Identify Issues & Determine the Cause

OPTIMISE THERAPY
Define Action Plan

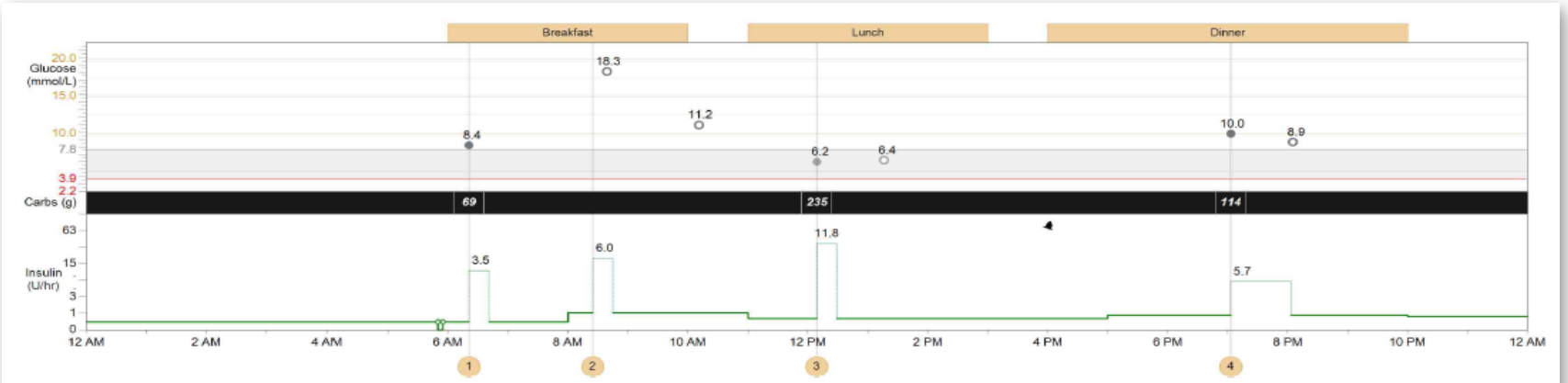
Therapy Outcome: Determine the Cause

HYPERS

Patterns	Common contributing factors
Nocturnal Hyperglycaemia	• Too high overnight Basal Rate • Evening snack without a Bolus • Manual or Bolus Wizard® overrides for late night snacks • Incorrect carbohydrate counting for late night snacks • Patient is afraid of hypoglycaemia through the night • Infrequent infusion set changes • Incorrect Bolus type
Post-Prandial Hyperglycaemia	• Incorrect carbohydrate counting • Too low carbohydrate ratio • Manual boluses instead of Bolus Wizard® • Too low Basal Rate • Patient is afraid of hypoglycaemia • Infrequent infusion set changes • Bolus with rising rate of change alert? (only for patients on CGM)
Hyperglycaemia preceded by Hypoglycaemia	• Overcorrection of a hypoglycaemic episode with glucose • Overcorrection of a hypoglycaemic episode with pump suspension
Pre-Prandial/Other Hyperglycaemia	• Too low Basal Rate • Illness • Stressful episodes • Patient is afraid of hypoglycaemia • Infrequent infusion set changes • Rising sensor rate of changes • Patient suffers from the dawn phenomenon or the Somogyi effect • Patient was in the pre-menstrual period • Patient was taking medication that could influence glucose levels and/or insulin sensitivity?
Intermittent high readings	• Patient missed boluses • Infrequent infusion set changes



Therapy Outcome: Verify the Cause



Bolus Events

Bolus Event	1	2	3	4
Time	6:21 AM	8:25 AM	12:09 PM	7:03 PM
Bolus Type	Normal	Normal	Normal	Square
Delivered Bolus Norm (U)	3.5	6.0	11.8	--
+ Square Portion (U, h:mm)	--	--	--	5.7, 1:00
Recommended Bolus (U)	3.5	--	11.8	5.7
Difference (U)	--	--	--	--
Carbs (g)	*69*	--	*235*	*114*
Carb Ratio Setting (g/U)	20.0	--	20.0	20.0
Food Bolus (U)	3.5	--	11.8	5.7
BG (mmol/L)	**8.4**	--	**6.2**	**10.0**
BG Target Setting (mmol/L)	4.4 - 10.0	--	4.4 - 10.0	4.4 - 10.0
Insulin Sensitivity Setting (mmol/L per U)	2.2	--	2.2	2.2
Correction Bolus (U)	--	--	--	--
Active Insulin (U)	--	--	--	--

Statistics	8/30		8/28 - 9/4	
Avg BG (mmol/L)	9.9		8.9 ± 3.2	
BG Readings	7		38	4.8/day
Readings Above Target	5	71%	22	58%
Readings Below Target	--	0%	1	3%
Sensor Avg (mmol/L)	--		--	
Avg AUC > 7.8 (mmol/L)	--	--	--	--
Avg AUC < 3.9 (mmol/L)	--	--	--	--
Daily Carbs (g)	*418*		*298 ± 62*	
Carbs/Bolus Insulin (g/U)	15.5		17.3	
Total Daily Insulin (U)	46.1		35.1 ± 5.2	
Daily Basal (U)	19.1	41%	17.9	51%
Daily Bolus (U)	27.0	59%	17.2	49%
Primes	--	--	2	1.8U

Sensor trace · BG reading · Linked BG · Basal · Bolus · Suspend · Time change · Exercise · Glucose alert
Interrupted · Off chart · Calibration BG · Temp basal · Pump rewind · Injected insulin (U) · Other · Alarm

MiniMed™ Academia

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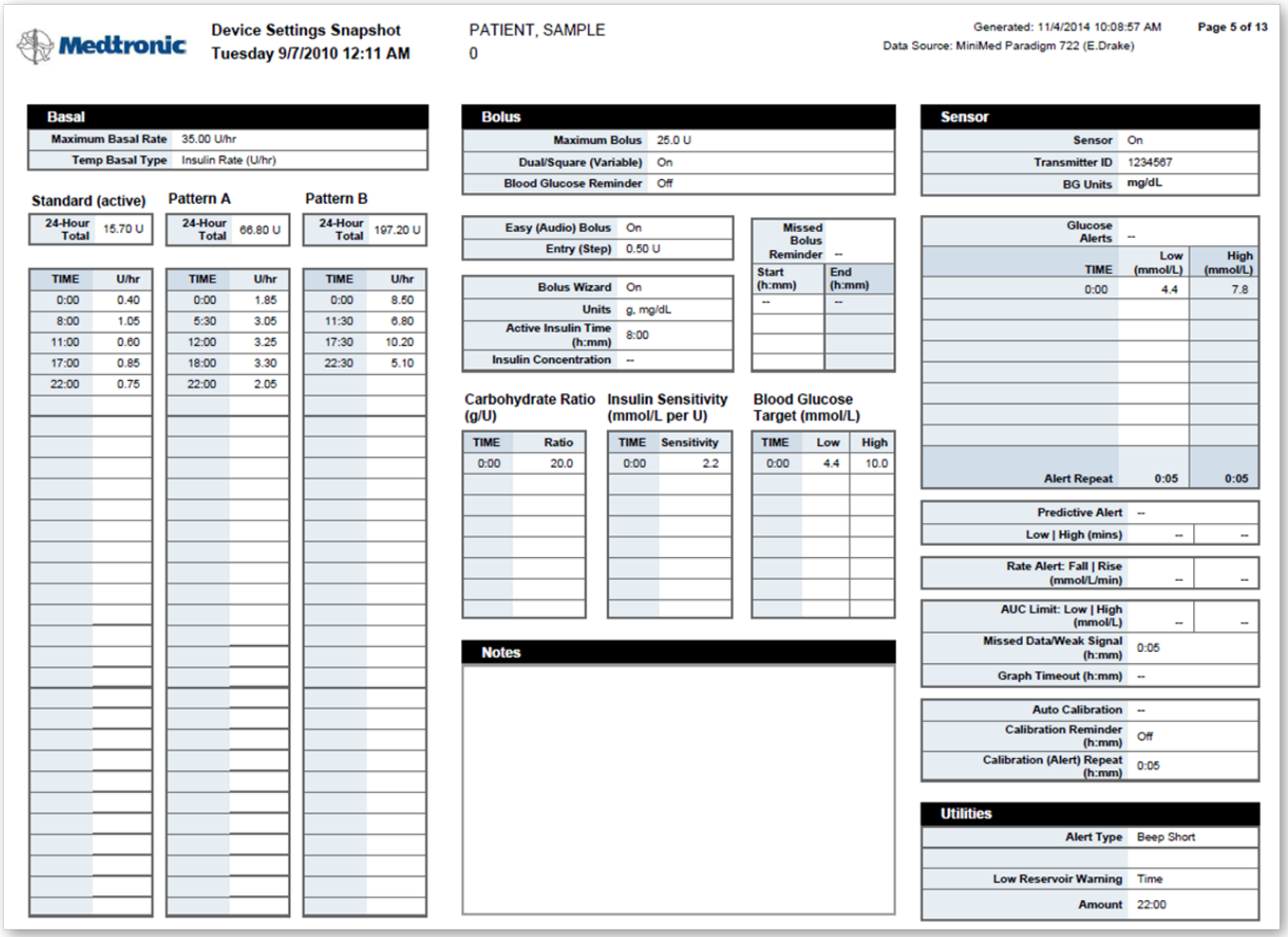
Optimise Therapy

- Discuss the identified issues with the patient and define together an action.
- Document all the identified issues and agree with the patient on a treatment strategy.
- Make sure to also discuss how to follow-up.

Optimise Therapy



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Device Settings Snapshot
Tuesday 9/7/2010 12:11 AM

PATIENT, SAMPLE
0

Generated: 11/4/2014 10:08:57 AM
Data Source: MiniMed Paradigm 722 (E.Drake)

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Basal

Maximum Basal Rate	35.00 U/hr
Temp Basal Type	Insulin Rate (U/hr)

Standard (active)		Pattern A		Pattern B	
24-Hour Total	15.70 U	24-Hour Total	66.80 U	24-Hour Total	197.20 U

TIME	U/hr
0:00	0.40
8:00	1.05
11:00	0.60
17:00	0.85
22:00	0.75

TIME	U/hr
0:00	1.85
5:30	3.05
12:00	3.25
18:00	3.30
22:00	2.05

TIME	U/hr
0:00	8.50
11:30	6.80
17:30	10.20
22:30	5.10

Bolus

Maximum Bolus	25.0 U
Dual/Square (Variable)	On
Blood Glucose Reminder	Off

Easy (Audio) Bolus	On
Entry (Step)	0.50 U

Bolus Wizard	On
Units	g, mg/dL
Active Insulin Time (h:mm)	8:00
Insulin Concentration	--

Missed Bolus Reminder --

Start (h:mm)	End (h:mm)
--	--

Carbohydrate Ratio (g/U)

TIME	Ratio
0:00	20.0

Insulin Sensitivity (mmol/L per U)

TIME	Sensitivity
0:00	2.2

Blood Glucose Target (mmol/L)

TIME	Low	High
0:00	4.4	10.0

Notes

Sensor

Sensor	On
Transmitter ID	1234567
BG Units	mg/dL

Glucose Alerts	--	
TIME	Low (mmol/L)	High (mmol/L)
0:00	4.4	7.8
Alert Repeat	0:05	0:05

Predictive Alert	--	
Low | High (mins)	--	--
Rate Alert: Fall | Rise (mmol/L/min)	--	--
AUC Limit: Low | High (mmol/L)	--	--
Missed Data/Weak Signal (h:mm)	0:05	
Graph Timeout (h:mm)	--	
Auto Calibration	--	
Calibration Reminder (h:mm)	Off	
Calibration (Alert) Repeat (h:mm)	0:05	

Utilities

Alert Type	Beep Short
Low Reservoir Warning	Time
Amount	22:00

CareLink Pro
THERAPY MANAGEMENT SOFTWARE FOR DIABETES

PATIENT BEHAVIOUR
Positives & Issues

Positives	Issues

THERAPY OUTCOME
Identify Issues & Determine the Cause

I

C

OPTIMISE THERAPY
Define Action Plan

A

Comments

MiniMed™ Academia

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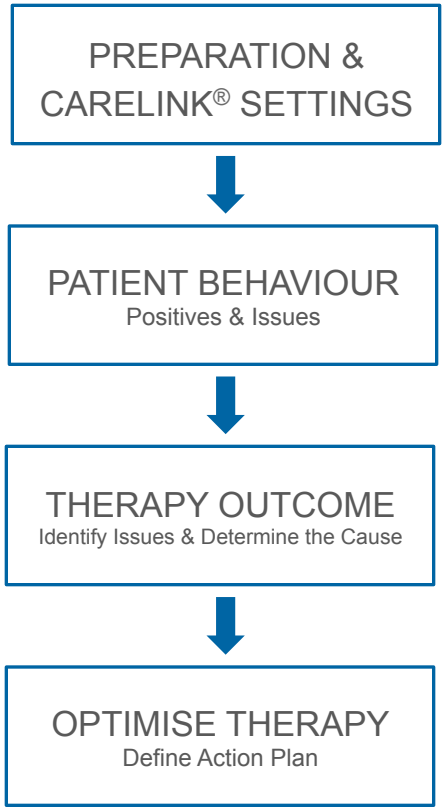
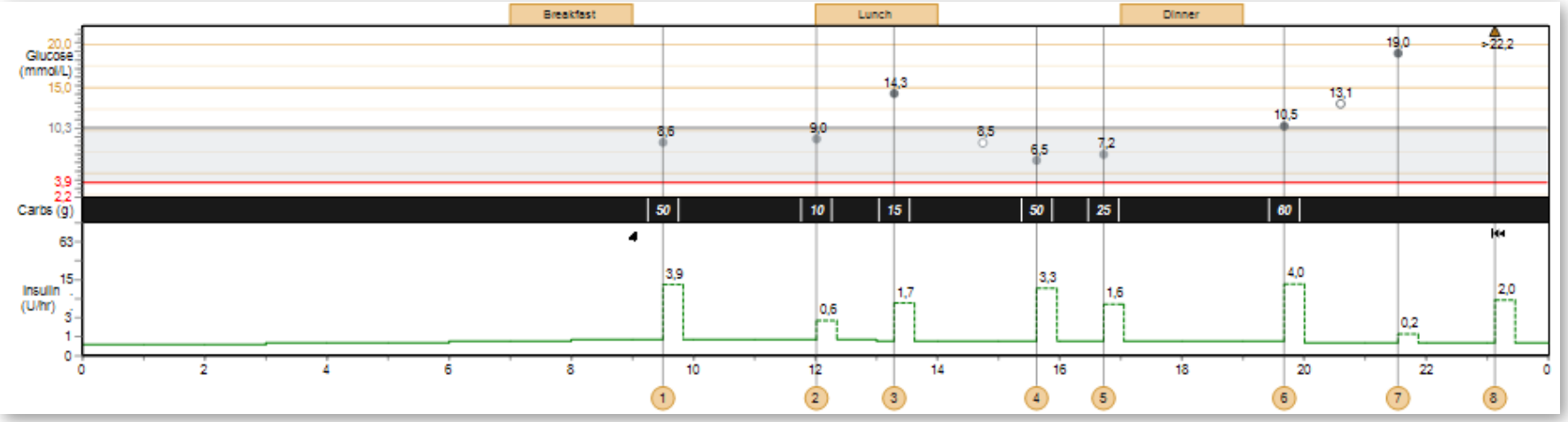
Summary


PREPARATION & CARELINK® SETTINGS
PATIENT BEHAVIOUR
Positives & Issues
THERAPY OUTCOME
Identify Issues & Determine the Cause
OPTIMISE THERAPY
Define Action Plan

Short Examples: 2 - Adherence

	Glucose Measurements		Bolus Events					Priming Events			
	BG Readings	Sensor Duration (h:mm)	Manual Boluses	Bolus Wizard Events	With Food	With Correction	Bolus Wizard Overrides	Rewind	Primes	Prime Volume (U)	Suspend Duration (h:mm)
Wednesday 5/2/2007	2		2	3	3						
Thursday 5/3/2007	5	20:05	3	3	2	1	1				0:01
Friday 5/4/2007	4	15:40	2	3	2	1	3	1	1	14.7	
Saturday 5/5/2007	5	17:30	2	2	2						
Sunday 5/6/2007	1		4	1	1	1					
Monday 5/7/2007	6	21:40	2	2	2	1	1				
Tuesday 5/8/2007	2	22:15	2	3	3		1				
Wednesday 5/9/2007	4	18:20	3	2	1	1					
Thursday 5/10/2007	1		6	1	1			1	2	16.2	
Friday 5/11/2007	3		2	2	2	1	1				
Saturday 5/12/2007	6	2:05	2	7	5	4	3				0:01
Sunday 5/13/2007	8	15:45	1	3	2	3	2				
Monday 5/14/2007	6	21:55	4	2	1	2					
Tuesday 5/15/2007	3	24:00	4	3	3	1	3				
Summary	4.0/day	179:15	2.8/day	2.6/day	2.1/day	1.1/day	1.1/day	2	0.2/day	2.2U/day	0:02

Short Examples: 3 – Infusion set



- Untreated Hyperglycaemia

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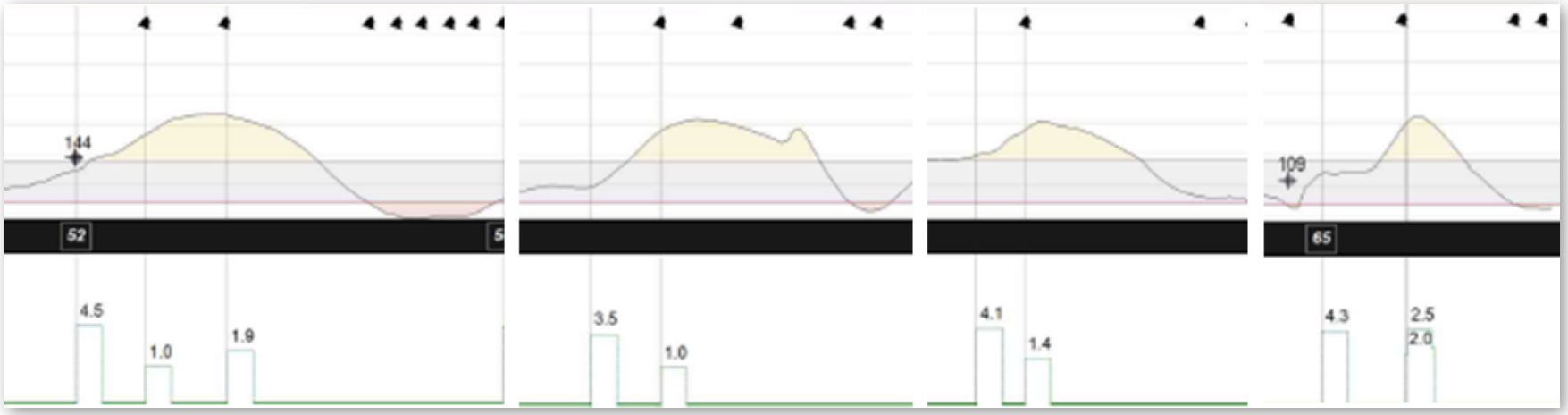
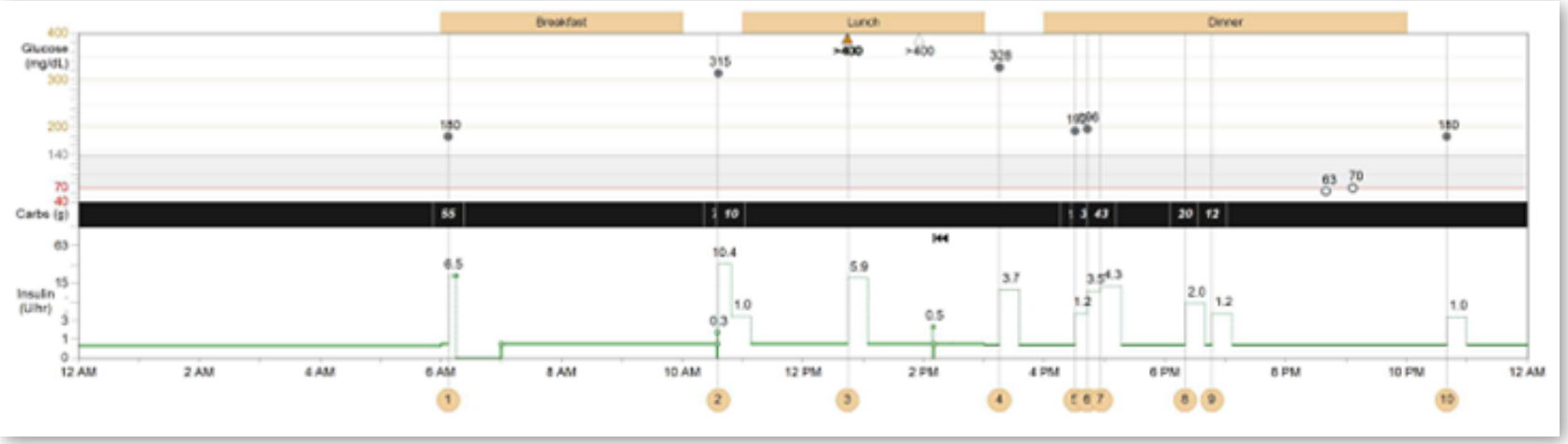
Short Examples: 4 – BW and Active Insulin



- Patient did not structurally use the Bolus Wizard®
- When BolusWizard® is used, several correction boluses are needed to treat the post-prandial hyperglycaemia.
  - Low confidence in the Bolus Wizard® and therefore not using it.
- Patient might have some problems with carbohydrate counting or,
- The carbohydrate ratio is programmed too high.
- Giving the manual correction boluses without taking into account the active insulin results in hypoglycaemia.

Short Examples: 8 - Sensitivity Factor



- Example of a patient who, despite the large number of correction boluses, suffers from hyperglycaemia during the day, which in this case was caused by a incorrect sensitivity factor (too high) and a too low basal rate (between 6AM and 6PM).