



PRODUCT REGISTRY REPORT

Compound(s): **Blutzuckermessgerät MyStar Extra[®]**

Registry Title: **Non-interventional observational study for usage of the new blood glucose meter MyStar Extra[®] as a possibility of early control of treatment process for patients in daily routine**

(Nicht-interventionelle Beobachtungsstudie zur Anwendung des neuen Blutzuckermessgeräts MyStar Extra[®] als Möglichkeit der frühzeitigen Therapieverlaufskontrolle für den Patienten unter Alltagsbedingungen)

Registry number: **MYSTEXTRL06882**

Registry name: **MyStarT**

Registry initiation date [date first patient in (FPI)]: **14-Mar-2014**

Registry completion date [last patient completed/last patient out (LPO)]: **17-Nov-2015**

Registry design: This is a multicenter, non-interventional observational study in which patients with insulin dependent diabetes mellitus type 1 or 2 and their treating physicians document parameters concerning the use of the blood glucose meter MyStar Extra[®] during daily routine conditions. For each patient the observational period lasts for a maximum of 24 weeks. During this time data of patient's satisfaction and handling regarding MyStar Extra[®] are recorded by patient questionnaires. The decision for use of MyStar Extra[®] is taken by the physician or diabetes assistance independently of the participation of a patient in this observational study. Data concerning diagnosis and therapy are documented according to routine procedures.

Report date: **15-Sep-2016**



This registry was performed in compliance with the guidelines for Good Epidemiology Practice. This report has been prepared based on the publication 'Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) – Guidelines for reporting observational studies – Ann Intern Med. 2007'.

Part or all of the information presented in this document may be unpublished material and should be treated as the confidential property of the Company. The use of this information or material must be restricted to the recipient for the agreed purpose and must not be disclosed to any unauthorized persons in any form, including publications and presentations, without the written consent of the Company.

TABLE OF CONTENTS

PRODUCT REGISTRY REPORT	1
TABLE OF CONTENTS.....	3
SYNOPSIS	5
APPENDICES	44
1 APPENDIX I – ADMINISTRATIVE AND LEGAL CONSIDERATIONS	45
1.1 ETHICAL CONSIDERATIONS	45
1.1.1 Ethical principles	45
1.1.2 Laws and regulations	45
1.2 DATA PROTECTION.....	45
1.3 RECORD RETENTION.....	45
1.4 THE COMPANY AUDITS AND INSPECTIONS BY COMPETENT AUTHORITIES (CA).....	45
1.5 CENTRAL LABORATORY.....	46
1.6 OWNERSHIP OF DATA AND USE OF REGISTRY RESULTS.....	46
1.7 STUDY CONSULTANTS	46
1.7.1 Scientific Committee and Charter	46
1.7.2 National coordination	46
1.7.3 Other experts/consultants	46
1.8 PARTICIPATING PHYSICIANS.....	47
1.9 STUDY PERSONNEL.....	47
1.9.1 Personnel involved in the registry	47
1.9.2 The Company Internal Staff	48
1.9.3 Contract Research Organization (CRO)	48
2 APPENDIX II – TABLES AND GRAPHS.....	49
3 APPENDIX III – SUPPORTIVE DOCUMENTS	77
3.1 PROTOCOL.....	77
3.2 STATISTICAL ANALYSIS PLAN (SAP).....	77
3.2.1 Final Statistical Analysis Plan	77
3.2.2 Changes from the final Statistical Analysis Plan.....	77

3.3	CASE REPORT FORM (CRF)/ PATIENT QUESTIONNAIRE.....	77
3.4	PATIENT INFORMED CONSENT	77
3.5	OTHER DOCUMENTS RELEVANT TO THE REGISTRY	77
3.6	OTHER REGISTRY INFORMATION.....	77
3.6.1	Safety reporting.....	77
3.6.1.1	(Serious) adverse events (AE).....	78
3.7	REGULATORY AUTHORITIES' SUBMISSIONS BY COUNTRY	78
3.8	REPORT APPROVAL.....	78
3.8.1	Coordinating physician's approval	78
3.8.2	The Company's approval	78
4	APPENDIX IV – PUBLICATIONS	79
4.1	REFERENCES.....	79
4.2	PUBLICATIONS/ABSTRACTS OF THE REGISTRY RESULTS	79
4.3	PUBLICATIONS CITED IN THE REFERENCE LIST	79
5	REFERENCES.....	80
ADDITIONAL APPENDIX MATERIALS:		
	APPENDIX III - SUPPORTIVE DOCUMENTS - Paragraph 3.1 Protocol.....	81
	APPENDIX III - SUPPORTIVE DOCUMENTS - Paragraph 3.2 Statistical Analysis Plan	101
	APPENDIX III – SUPPORTIVE DOCUMENTS - Paragraph 3.3 Case Report Form/ Patient Questionnaire	204
	APPENDIX III – SUPPORTIVE DOCUMENTS - Paragraph 3.4 Patient informed consent.....	240
	APPENDIX III - SUPPORTIVE DOCUMENTS - Paragraph 3.7 Regulatory authorities' submissions by country.....	244
	APPENDIX III - SUPPORTIVE DOCUMENTS - Paragraph 3.8.1 Coordinating physician's approval.....	246
	APPENDIX III - SUPPORTIVE DOCUMENTS - Paragraph 3.8.2 The Company's approval.....	248
	APPENDIX IV - PUBLICATIONS - Paragraph 4.2 Publications/Abstracts of the Registry Results.....	258
	APPENDIX IV - PUBLICATIONS - Paragraph 4.3 Publications cited in the Reference list	272

SYNOPSIS	
Title of the registry:	<p>Non-interventional observational study for usage of the new blood glucose meter MyStar Extra® as a possibility of early control of treatment process for patients in daily routine</p> <p>Registry number: MYSTEXTRL06882</p>
Design:	Non-interventional
Objectives:	<p>Primary objective:</p> <p>Collection of patient satisfaction regarding the blood glucose meter by means of Visual Analog Scale (VAS) at baseline (previous device, if used) and after 3 months (MyStar Extra®), as well as the general dealing with the disease (Empowerment scale [1]) at baseline and at the end of study (after approximately 6 months).</p> <p>Secondary objectives:</p> <ul style="list-style-type: none"> • Recording of handling, suitability and benefits of additional functionalities of MyStar Extra® when used by patient in daily routine. • Review of safety (potentially occurring incidents as well as complaints) and analysis of complaints according to degree of severity. • Reduction of HbA_{1c} value from study entry until end of study (if evaluated routinely). • Comparison of calculated HbA_{1c} and HbA_{1c} determined in laboratory (if compiled). • Change in fasting blood glucose values from study entry until end of study. • Change in daily basal insulin dose from study entry until end of study. • Evaluation of handling of insulin titration with MyStar Extra®. • Duration of training of patients on usage of MyStar Extra® including the number of additional telephone visits during observational period. • Comparison of number of prescribed test stripes at baseline and at end of study.
Treatment:	<p>Self-monitoring of blood glucose by patients with diabetes mellitus of type 1 or 2 using the MyStar Extra®</p> <p>At baseline anamneses data were collected.</p> <p>After approx. 12 and 24 weeks data concerning anti-diabetic therapy, HbA_{1c} value, use and satisfaction with blood glucose meter MyStar Extra® were recorded.</p>
Scientific committee	Not applicable.

and members:	
Publications (reference):	<p>DDG - 51. Jahrestagung der DDG, 04.-07. Mai 2016, Berlin</p> <p>B. Kulzer et al. Diabetologie & Stoffwechsel 2016; 11: S 68 (P244)</p> <p>H. Anderten et al. Diabetologie & Stoffwechsel 2016; 11: S 68 (P243)</p> <p>G. Freckmann et al. Diabetologie & Stoffwechsel 2016; 11: S 69 (P247)</p> <p>ADA - 76th scientific sessions, June 10–14, 2016, New Orleans, LA, USA</p> <p>B. Kulzer et al., Diabetes 2016; 65: Supp 1, A231 (900-P)</p> <p>H. Anderten et al. Diabetes 2016; 65: Supp 1, A564 (2228-PUB)</p> <p>G. Freckmann et al. Diabetes 2016; 65: Supp 1, A565 (2233-PUB)</p>
Introduction - Background/rationale:	<p>Self-monitoring of blood glucose by means of a blood glucose meter is a beneficial part of diabetes management and successfully used by patients with diabetes mellitus of type 1 and 2 for metabolic control. As part of the day-to-day routine it can help with necessary lifestyle and treatment choices as well as to monitor for symptoms of hypo- or hyperglycaemia. It could be shown in clinical trials that increase in frequency of blood glucose measure correlates with an improvement of HbA_{1c} values [2, 3]. But lack of adherence to diabetes therapy caused by inadequate knowledge of the management of diabetes or quick success of therapy may increase the risk for sequelae [4, 5]. Thus lasting motivation of patients is necessary for reaching their individual the goals. This may be approached with the use of MyStar Extra® which cannot only measure blood glucose values but gives patients the opportunity for independent therapy control by calculation of an estimated HbA_{1c} value including trends for HbA_{1c} as well as fasting blood values.</p> <p>HbA_{1c} which is usually determined in the laboratory every 3 months is the gold standard as marker for the long term blood sugar reflecting glucose control during the past 2-3 months [6]. Therefore patients normally do not know their actual HbA_{1c} value and cannot see the relation between blood glucose or life style and HbA_{1c}.</p> <p>The glucose meter MyStar Extra® with the new function of calculation of HbA_{1c} value and trend has been developed to give patients with diabetes the possibility of early control of therapy in daily routine. Through the calculation of the HbA_{1c} value and trend the patient gets a timely feedback of treatment and diabetes management and enables him to undertake action at an early stage.</p> <p>It has been shown before that patients who are informed about their HbA_{1c}- value promptly more often intensify their treatment leading to reduction of HbA_{1c} value and improvement of glycemic setting [7, 8, 9].</p> <p>In this open, non-controlled, non-interventional multicenter observational study the usage of the new glucose meter MyStar Extra® was observed over a maximum of 24 weeks for each patient. In particular the patient's satisfaction with MyStar Extra® as well as the handling, the appropriateness and the benefits of the added features of MyStar Extra® were investigated.</p>
Methodology:	(a) Site and patient selection:

It was planned to enroll a maximum of 4000 evaluable patients with diabetes mellitus of type 1 or 2. About 600 registered office based doctors with experience in the therapy of patients with diabetes and diabetologists in Germany (Section 2.1. Appendix II) who train patients within the anti-diabetic therapy to measure blood sugar could participate. Patients fulfilling the inclusion / exclusion criteria mentioned in the observational plan could be included (Main inclusion criteria were: patients with informed consent, aged > 18 years with type 1 or type 2 diabetes and HbA_{1c} ≤ 10.5% who were on any insulin therapy regimen and decided to use MyStar Extra® Device and had the ability and will to perform 7-point glucose profile measurements of blood glucose, main exclusion criteria were: patients with gestational diabetes or insulin pump therapy, patients with COPD (Chronic obstructive pulmonary disease) or with disorders/conditions leading to altered erythrocyte life span or affecting HbA_{1c} results, alcohol or drug abuse, psychiatric illness; Table 31, Appendix II):

(b) Data collection:

Each participating site could decide whether to use a paper or electronic case report form (CRF) for data capture.

If sites used paper CRF the completed CRFs were sent to the clinical research organization Alcedis GmbH. Data entry into the data base was performed by 2 trained employees of Alcedis.

If sites used electronic CRF (eCRF) data were entered directly into the data base by the site.

At baseline, week 12 and 24 paper questionnaires were handed out to the patients by the site. Patients filled in the questionnaires at the site. Completed questionnaires were sent to Alcedis, where data entry into the data base was performed by 2 independent employees.

(c) Safety data collection:

All complaints and incidents that occurred within the observation period of the study had to be documented within 24 hours after they had become known by the site on the respective reporting form, either in the eCRF or in the paper CRF. In case of documentation on paper CRF the reporting form had to be faxed by the site within 24 h to the complaints service of Sanofi-Aventis Deutschland GmbH. If sites used the eCRF for documentation the complaint / incident was transferred after saving the form automatically by fax to the complaints service of Sanofi-Aventis Deutschland GmbH. In case that electronic reporting was not possible, paper forms in the investigator's file were at the doctor's disposal for notification of complaints / incidents by conventional fax to the complaints service.

In addition to a complaint / incident the complained device had to be sent by the site to the responsible sales representative in order to have potentially necessary improvements implemented.

Further on adverse events occurring during observational period in patients who were taking medicine of SANOFI, Sanofi-Aventis, Winthrop, Zentiva or Genzyme and which are assessed as related to the medication by the investigator have to be notified to the pharmacovigilance department of Sanofi according to national law.

(d) Data management, review, validation:

If sites used the eCRF for documentation, validity of documented data was ensured by validations in the eCRF, which indicated missing or implausible data entries. Patients could only be registered if they had been informed about the trial by the treating physician and had given their written consent.

Paper CRFs and patient questionnaires were sent by the sites to Alcedis GmbH and were included into the eCRF by two trained persons. The double entry was checked for agreement.

To further ensure the validity of the data, telephone interviews were performed at 5% of participating sites by monitors of Alcedis GmbH according to the guidelines of Sanofi-Aventis.

(e) Statistical considerations:

Sample size justification was based on an estimated rate of return of 80% thus a maximum of 4000 patients had to be enrolled to yield 3200 evaluable patients. With this number of patients and an estimated standard deviation of 25 mm as has been shown in former observational studies [10], the two-sided 95% confidence interval for the mean VAS (0-100 mm) representing patient satisfaction have the length of 1.732 mm. For the empowerment-score (11-44) an estimated standard deviation of 8 as shown in a former study [11], a two-sided 95%-confidence interval for the estimated mean will have the length of 0.554. Furthermore, the sample size is great enough for subgroup-analysis and for detection of rare (1 / 1000; 0.1 %) and very rare (1 / 10000; 0.01 %) product technical complaints with a probability of 95.9 % and 27.4 %, respectively.

A descriptive statistical analysis of the documented data was performed by Alcedis GmbH. For categorical variables, summary tabulations of the number and percentage within each category (with a category for missing data) of the parameter were created. For continuous variables, the mean, median, standard deviation, minimum and maximum values were calculated. A 95% CI was calculated for the estimated rate of handling problems and for additional parameters if appropriate. In addition p-values from various statistical tests, e.g. test of mean change from baseline equal to zero within group or test of correlation coefficient equal to zero, were provided if appropriate. The analyses are of explorative character and no correction for multiple testing has taken place.

For some sites there was more than one physician questionnaire. Hence two different analyses were done. For the first analysis, one questionnaire per site was randomly selected for sites with more than one questionnaire. Only questionnaires with available satisfaction were considered if satisfaction was not available for all questionnaires from one site. These selected questionnaires were also used for the correlations in context of primary endpoint. For the second analysis, all filled questionnaires were analysed.

Efficacy and safety: Safety population (SP) = Full analysis set (FAS): All patients with insulin-dependent Diabetes mellitus type 1 or 2, who gave their informed consent and who were monitoring their blood glucose with MyStar Extra®.

Age at informed consent: Year of informed consent – Year of birth.

Time between onset of diabetes and informed consent: Year of informed consent – Year of onset of diabetes.

Rate of incidents/claims: Number of incidents/claims divided by number of patients.

Difference between laboratory HbA_{1c} value and HbA_{1c} estimator by MyStarExtra®: Laboratory HbA_{1c} value- HbA_{1c} estimator.

Empowerment scale: Each of the eleven items was scored on a four point scale measuring from 1 (=does not apply at all) to 4 (=strongly agree). For the calculation of the empowerment score, which ranges from 11-44, the values of the items were summarized. If less than half of the items were missing, missing values were replaced with the mean of the other values. If half or more than half were missing, no score was calculated. A higher score means a higher empowerment.

Missing values: Missing values, except for the empowerment scale, were not replaced.

RESULTS	
Participants (actual):	<p>(a) Overall participation status: Between April 2014 and March 2015 a total of 2262 patients were enrolled by 476 sites (clinics and medical practices) in Germany. For 1402 (62%) of them electronic documentation was chosen, and 860 patients (38%) were documented on paper CRF.</p> <p>(b) Participation per period of the registry: 2173 diabetes patients enrolled by 444 sites could be included into the analysis; of them 1324 patients (60.9%) were documented on electronic CRF, 849 patients (39.1%) on paper CRF. These patients had given informed consent to study participation and used the MyStarExtra®. In few patients (less than 3.5%) at least one inclusion / exclusion criteria were violated or not answered (Table 31 in Appendix II). Inclusion criterion 03 ($HbA_{1c} \leq 10.5\%$) and exclusion criterion 03 (Chronic obstructive pulmonary disease (COPD)) were the most violated criteria (0.2% and 0.5% of patients, respectively). 2009 patients (92.5%) were documented until the end of the study, 2166 patients (99.7%) had the diabetes anamnesis form filled in (Figure 1).</p>

	<pre> graph TD A[2262 patients enrolled] --> B[2260 patients with informed consent] A --> C[-2 patients: No informed consent] B --> D[2173 evaluable patients (Safety population / Full analysis set)] B --> E[-87 patients: MyStarExtra® not used] D --> F[2166 patients for analysis of diabetes anamnesis] D --> G[-7 patients: Without 'diabetes anamnesis' form] F --> H[2009 patients completed study] F --> I[-157 patients: Without 'end of study' form] </pre> <p>Figure 1: Patient overview</p>
<p>Participant characteristics and primary analyses:</p>	<p><u>Descriptive data:</u></p> <p>The majority of the 2173 patients were men (1209 patients, 55.6%), 960 (44.2%) were women and of 4 patients (0.2%) no information concerning sex was given. Patients had a median age of 62 years at date of informed consent, ranging from 18 to 97 years. More than 90% of the patients were older than 40 years (Table 32 in Appendix II). Table 1 gives an overview of patient baseline data.</p>

Table 1: Demographic data at baseline

Demographics at baseline	<i>N</i>	<i>Mean</i>	<i>Std</i>	<i>P1</i>	<i>P25</i>	<i>Median</i>	<i>P75</i>	<i>P99</i>	<i>Min</i>	<i>Max</i>	<i>Nmiss</i>
<i>Age [years]</i>	2163	60.76	13.72	23.00	53.00	62.00	71.00	86.00	18.00	97.00	10
<i>Height [cm]</i>	2160	171.03	9.26	151.00	164.00	170.00	178.00	193.00	142.00	210.00	13
<i>Weight [kg]</i>	2158	90.96	20.39	52.00	77.00	89.00	102.00	150.00	43.00	183.00	15
<i>BMI [kg/m²]</i>	2157	31.06	6.34	19.05	26.71	30.31	34.41	51.02	17.53	68.36	16
<i>Onset of diabetes to year of informed consent [years]</i>	1606	11.11	9.11	0.00	4.00	10.00	15.00	41.00	0.00	60.00	560

2166 patients had an available diabetes anamnesis. For 1606 patients, the year of onset of diabetes was documented. The median time between known onset of diabetes and the year of informed consent was 10 years (N=1606 patients). For the 560 patients with unknown year of diabetes onset, the estimated time period of diabetes was documented by the site, which amounts mostly to over 5 years (75.4% of the patients). Most of the patients (86.1%) with diabetes anamnesis had diabetes type 2. Only 9 patients (0.4%) had no documentation concerning type of diabetes.

The most common current insulin therapies were intensified insulin therapy (ICT, 45.3%) or basal-oral therapy (BOT, 34.2%) (Table 33 in Appendix II). Most used insulin was long-acting insulin analogues (73.6%; Table 34 in Appendix II) with a median dose of 20 units per day (Table 35 in Appendix II). Additionally, median number of mealtime insulin injections per day was 3 and median number of mixed insulin injections per day was 0 (Table 35 in Appendix II).

Only 9.2% of the patients with anamnesis did not use a glucose meter before study inclusion, whereas nearly 79% used other glucose meter before than MyStar Extra® (Table 2). About the same proportion of patients specified as reason for change to/start with MyStar Extra® 'would like a new device' (36.9%) and 'would like to use the additional functionalities of MyStar Extra®' (36.8%) (Table 36 in Appendix II).

Table 2: Previously used glucose meter

Previously used glucose meter	<i>N</i>	<i>%</i>	<i>N (adj.)</i>	<i>% (adj)</i>
<i>BGStar®/iBGStar®</i>	244	11.27	244	11.35
<i>Other glucose meter</i>	1706	78.76	1706	79.35
<i>No glucose meter</i>	200	9.23	200	9.30

<i>Missing</i>	16	0.74	-	.
Total	2166	100.00	2150	100.00

The great majority of physicians / medical staff advised as blood glucose target 'fasting blood glucose level' (86.7%) followed by 'HbA_{1c}' (85.1%) and 'postprandial blood glucose, less than 1.5 – 2 h after meal' (65.1%) (Table 37 in Appendix II). Median values for the advised blood glucose targets were 6.1 mmol/l for fasting blood glucose, 6.8% for HbA_{1c} and 8.3 mmol/l for postprandial blood glucose (Table 3).

Table 3: Glucose meter- Advised blood glucose targets

Advised blood glucose values	<i>N</i>	<i>Mean</i>	<i>Std</i>	<i>P1</i>	<i>P25</i>	<i>Median</i>	<i>P75</i>	<i>P99</i>	<i>Min</i>	<i>Max</i>	<i>Nmiss</i>
<i>Fasting blood glucose level (mmol/l)</i>	1875	6.50	4.78	0.39	5.55	6.11	6.66	9.99	0.06	130.00	2
<i>Postprandial blood glucose; less than (1.5 – 2 h after meal) (mmol/l)</i>	1408	8.38	1.18	6.11	7.77	8.33	8.88	12.21	0.17	14.43	2
<i>HbA_{1c} (%)</i>	1840	6.56	1.09	2.70	6.50	6.80	7.00	8.00	2.65	10.00	3

Kind of advised measurement was mostly fasting blood glucose level for 88.4% of the patients with 7 times per week as median advised time of measurement (Table 38 in Appendix II).

After training the patient how to use the MyStar Extra® further documentation had to be performed 4 weeks, 12 weeks and 24 weeks later.

Figure 2 gives an overview of the planned time-points of the assessments / questionnaires.

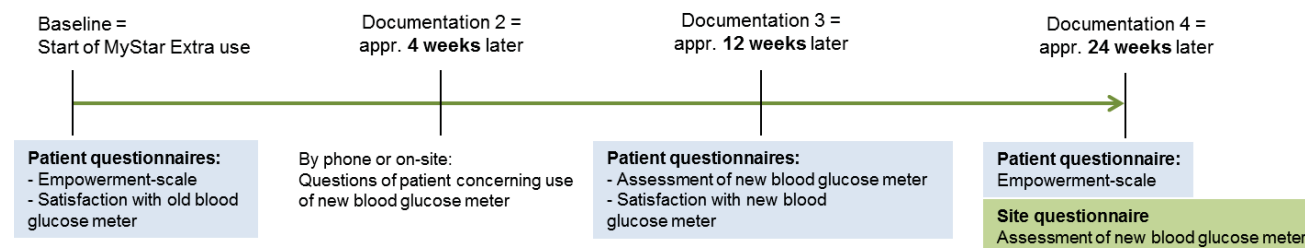


Figure 2: Planned time-points of assessment

Table 4 gives an overview of available documentation forms at the three time points.

Table 4: Status of available documentation

Form	Yes		No / Missing		Total	
	[N]	[%]	[N]	[%]	[N]	[%]
<i>Documentation 2 (approx.. 4 weeks after study start)</i>	2120	97.56	53	2.44	2173	100.00
<i>Documentation 3 (after 12 weeks)</i>	2147	98.80	26	1.20	2173	100.00
<i>Documentation 4 (after 24 weeks)</i>	2065	95.03	108	4.97	2173	100.00

Looking at the use of the MyStar Extra[®] during the documentation period it could be shown that the great majority of the patients (93.1%) still used the device 24 weeks after training (Figure 3). 'Device dislike' was the most frequently documented reason for change away from MyStar Extra[®] after 12 weeks (40.2%) as well as after 24 weeks of using the glucose meter (51.8%) (Table 39 in Appendix II). An overview of devices patients used afterwards is given in Table 40 in Appendix II.

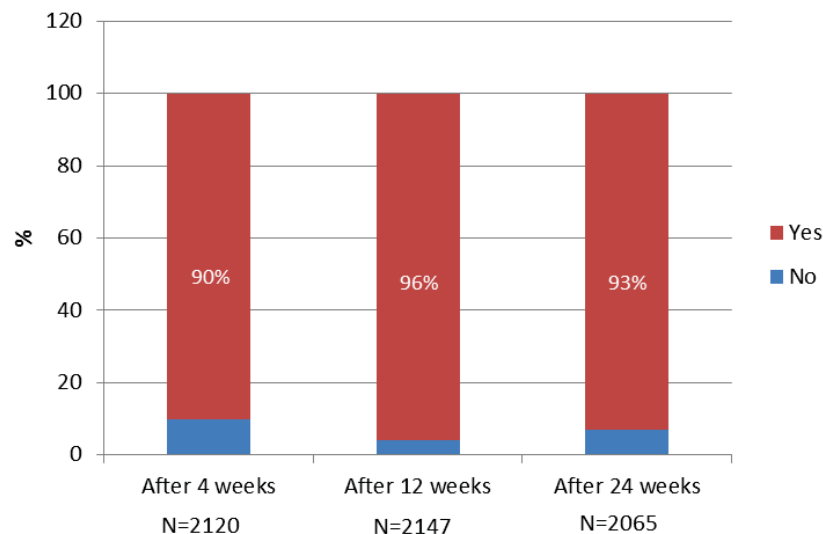


Figure 3: Use of MyStar Extra®

4 weeks after training, only 16.42% of patients had additional questions concerning functionality of MyStar Extra®, most information was required about the HbA_{1c} estimator (10.4% of available documentation forms).

Regarding the documentation after 12 and 24 weeks, 7.9% and 4.2% of the corresponding patients had changes in insulin therapy since initial documentation, respectively. About half of the patients with new insulin therapy received ICT as new therapy.

Primary endpoint

As primary endpoint patient satisfaction regarding the glucose meter by means of Visual Analog Scale (VAS) as well as the general handling of the disease at baseline and at the end of study (Empowerment scale) were investigated using patient questionnaires. VAS was used to assess the satisfaction with previous blood glucose meter (baseline) and with MyStar Extra® after 12 weeks of use. More than 76% of the evaluable patients returned the questionnaires 1 and 2 (Table 5). The median patient satisfaction with their previous glucose meter was 75 points (questionnaire 1 = baseline) and 85 points for MyStar Extra® after using it for 12 weeks (questionnaire 2).. Satisfaction increased in median by 10 points (p<0.0001, Wilcoxon Signed-Rank Test; Table 6). Patient's satisfaction was independent of age, since subgrouping according to age (18-40 years, >40-65 years, >65 years) did not yield statistically significant differences.

Table 5: Patient satisfaction with previous glucose meter / MyStar Extra®

Satisfaction	N	Mean	Std	P1	P25	Median	P75	P99	Min	Max	Nmiss
Questionnaire 1 (Baseline)	1655	70.93	23.01	10.00	51.00	75.00	90.00	100.00	0.00	100.00	518
Questionnaire 2 (After 12 weeks)	1678	78.65	21.16	7.00	70.00	85.00	94.00	100.00	0.00	100.00	495

Table 6: Patient satisfaction with previous glucose meter / MyStar Extra®- Changes from baseline

Satisfaction- Changes from baseline	N	Mean	Lower CI 95%	Upper CI 95%	Std	P1	P25	Median	P75	P99	Min	Max	Nmiss
Quest. 2	1432	8.71	7.15	10.27	30.08	-80.00	-5.00	10.00	27.00	80.00	-100.00	100.00	741

Wilcoxon Signed-Rank Test

p-Value <.0001

In addition to patients' satisfaction with MyStar Extra® device reported by questionnaires at week 12 (after start of MyStar Extra® use) each site was also asked to fill in a questionnaire after 24 weeks regarding their satisfaction with MyStar Extra®. The median degree of satisfaction of MyStar Extra® reported by physicians was 90 points, slightly higher than patients' satisfaction at week 12 (Table 7). There was a positive correlation between patient and physician satisfaction with MyStar Extra® (correlation coefficient of 0.4, p<0.0001; Table 8),

Table 7: Physician questionnaire- MyStar Extra®- Degree of satisfaction

Degree of satisfaction	N	Mean	Std	P1	P25	Median	P75	P99	Min	Max	Nmiss
-----------------------------------	----------	-------------	------------	-----------	------------	---------------	------------	------------	------------	------------	--------------

<i>Satisfaction</i>	374	83.32	16.88	2.00	80.00	90.00	93.00	100.00	1.00	100.00	23
---------------------	-----	-------	-------	------	-------	-------	-------	--------	------	--------	----

Table 8: Spearman rank correlation of patient and physician satisfaction with MyStar Extra®

<i>Variable</i>	<i>Correlation with</i>	<i>N</i>	<i>Correlation coefficient</i>	<i>CI 95%</i>	<i>p-Value</i>
Patient satisfaction	Physician satisfaction	1523	0.36	0.32- 0.41	<.0001

In figure 4, the patient and physician satisfaction with MyStar Extra® is shown graphically.

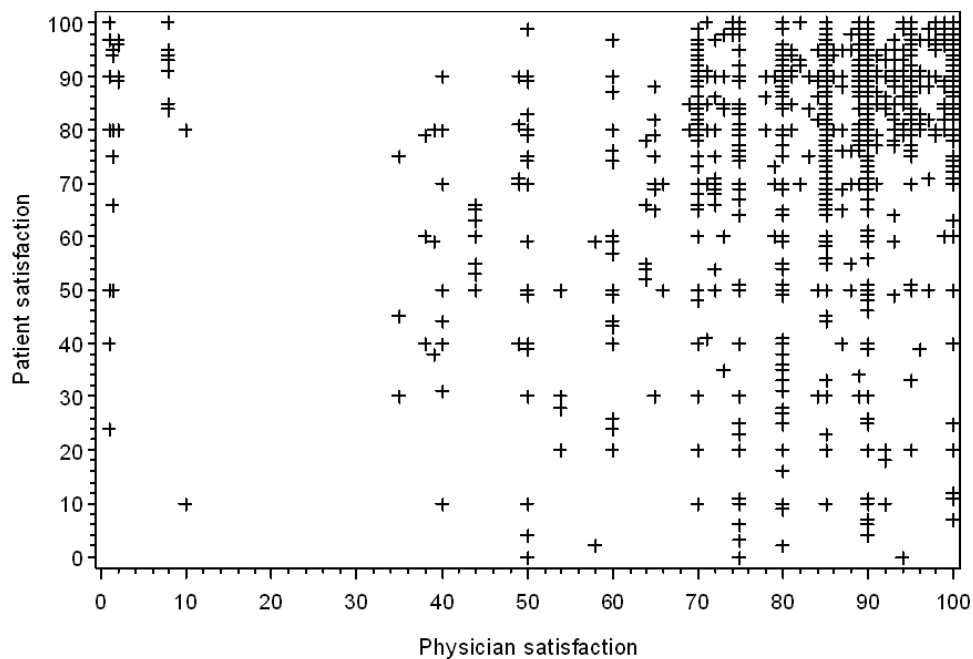


Figure 4: Patient and physician satisfaction with MyStar Extra®- Scatter plot

Furthermore the results of the linear regression of patient satisfaction with MyStar Extra® and frequency of use of HbA_{1c} estimation function are presented in Table 9 and Table 10, respectively. The results suggest that patients who used the device more frequently were more pleased with it.

Table 9: Linear regression- Patient satisfaction with MyStar Extra® and frequency of use of HbA_{1c} estimation function (questionnaire 2)-Type III SS

<i>Linear regression- Type III SS</i>	<i>p-Value</i>
Frequency of use	<.0001

Table 10: Linear regression- Patient satisfaction with MyStar Extra® and frequency of use of HbA_{1c} estimation function (questionnaire 2)-Estimates

<i>Linear regression</i>	<i>Reference value</i>	<i>Parameter</i>	<i>Estimate</i>	<i>Standard error</i>	<i>p-Value</i>
Frequency of use	No	Daily	18.638	3.060	<.0001
		Not evaluable	13.353	5.517	0.0156
		Once per month	16.949	1.220	<.0001
		Once per quartal	13.812	1.558	<.0001
		Several times per month	16.919	1.436	<.0001

At baseline and approx. 24 weeks after use of MyStar Extra® patients had to answer a questionnaire on their dealing with the diabetes disease during their daily life. Eleven items were scored on a four point scale measuring from 1 (=does not apply at all) to 4 (=strongly agree). The higher the number of points the best is the integration of the disease in the everyday life. The calculation of the empowerment score ranges from 11 (all questions answered with "does not apply at all") – 44 (all questions answered with "strongly agree").

Regarding the patient's dealing with the disease, the median empowerment scale was 30 points at start of using MyStar Extra® (questionnaire 1 = baseline) and 32 points after 24 weeks (questionnaire 3, Table 11), median change from baseline amounted to 1 point (p<0.0001, Wilcoxon Signed-Rank Test; Table 12). Empowerment after 24 weeks correlated significantly with number of fasting blood glucose measurements after 12 weeks (documentation 3) and after 24 weeks (documentation 4) as well as with basal insulin modifications. The results of the linear regressions between empowerment after 24 weeks (Questionnaire 3) and titration of insulin as well as frequency of use of HbA_{1c} estimation function after 12 weeks of usage (Questionnaire 2) are displayed in Table 13 and Table 14.

Table 11: Empowerment scale

<i>Empowerment scale</i>	<i>N</i>	<i>Mean</i>	<i>Std</i>	<i>P1</i>	<i>P25</i>	<i>Median</i>	<i>P75</i>	<i>P99</i>	<i>Min</i>	<i>Max</i>	<i>Nmiss</i>
<i>Questionnaire 1</i>	2009	29.96	6.21	12.00	26.00	30.00	33.00	44.00	11.00	44.00	9
<i>Questionnaire 3</i>	1862	31.66	5.77	17.00	28.00	32.00	35.00	44.00	11.00	44.00	8

Table 12: Empowerment scale- Changes from baseline

<i>Empowerment scale- Changes from baseline</i>	<i>N</i>	<i>Mean</i>	<i>Lower CI 95%</i>	<i>Upper CI 95%</i>	<i>Std</i>	<i>P1</i>	<i>P25</i>	<i>Median</i>	<i>P75</i>	<i>P99</i>	<i>Min</i>	<i>Max</i>	<i>Nmiss</i>
<i>Questionnaire 3</i>	1839	1.78	1.52	2.05	5.80	-13.00	-1.00	1.00	5.00	18.00	-30.00	33.00	179

Wilcoxon Signed-Rank Test

p-Value <.0001

Table 13: Empowerment scale- Linear regressions between empowerment (Questionnaire 3) and chosen variables- Type III SS

<i>Empowerment scale- Linear regression- Type III SS</i>	<i>p-Value</i>
Titration of basal insulin	0.0002
Frequency of use of HbA _{1c} estimation function (Questionnaire 2)	0.0028

Table 14: Empowerment scale- Linear regressions between empowerment (Questionnaire 3) and chosen variables- Estimates

<i>Empowerment scale- Linear regression</i>	<i>Reference value</i>	<i>Parameter</i>	<i>Estimate</i>	<i>Standard error</i>	<i>p-Value</i>
Titration of basal insulin	No	Missing	-0.575	1.496	0.7008
		Yes	1.105	0.268	<.0001

	Frequency of use of HbA _{1c} estimation function (Questionnaire 2)	No	Daily	2.585	0.858	0.0026																																																						
			Not evaluable	0.483	1.375	0.7255																																																						
			Once per month	1.201	0.348	0.0006																																																						
			Once per quartal	0.902	0.444	0.0425																																																						
			Several times per month	1.068	0.400	0.0076																																																						
Other analyses:	<p><u>Secondary endpoints</u></p> <p>Concerning the measurements of pre-prandial blood glucose in the last 4 weeks before change to MyStar Extra® device (using the previous glucose meter) and before time points 4, 12 and 24 weeks after training date (using the MyStar Extra®) it could be shown, that most patients measured before each meal, with a slight increase if using the MyStar Extra® device (Table 15). But over the time period of MyStar Extra® use the amount of irregular measurement increased while amount of regular measurement 'before each meal' decreased.</p> <p>Table 15: Pre-prandial blood glucose- Number of measurements in the previous 4 weeks before...</p> <table border="1"> <thead> <tr> <th colspan="2">Pre-prandial blood glucose</th> <th>N</th> <th>%</th> <th>N (adj)</th> <th>% (adj)</th> </tr> </thead> <tbody> <tr> <td rowspan="5"><i>Anamnesis (Previous glucose meter)</i></td> <td><i>Never</i></td> <td>215</td> <td>9.93</td> <td>215</td> <td>12.64</td> </tr> <tr> <td><i>Before each meal</i></td> <td>927</td> <td>42.80</td> <td>927</td> <td>54.50</td> </tr> <tr> <td><i>Irregular</i></td> <td>527</td> <td>24.33</td> <td>527</td> <td>30.98</td> </tr> <tr> <td><i>Unknown</i></td> <td>32</td> <td>1.48</td> <td>32</td> <td>1.88</td> </tr> <tr> <td><i>Missing</i></td> <td>465</td> <td>21.47</td> <td>-</td> <td>.</td> </tr> <tr> <td></td> <td>Total</td> <td>2166</td> <td>100.00</td> <td>1701</td> <td>100.00</td> </tr> <tr> <td rowspan="3"><i>Documentation 2 (MyStar Extra®)</i></td> <td><i>Never</i></td> <td>104</td> <td>4.79</td> <td>104</td> <td>5.89</td> </tr> <tr> <td><i>Before each meal</i></td> <td>1079</td> <td>49.75</td> <td>1079</td> <td>61.13</td> </tr> <tr> <td><i>Irregular</i></td> <td>566</td> <td>26.09</td> <td>566</td> <td>32.07</td> </tr> </tbody> </table>						Pre-prandial blood glucose		N	%	N (adj)	% (adj)	<i>Anamnesis (Previous glucose meter)</i>	<i>Never</i>	215	9.93	215	12.64	<i>Before each meal</i>	927	42.80	927	54.50	<i>Irregular</i>	527	24.33	527	30.98	<i>Unknown</i>	32	1.48	32	1.88	<i>Missing</i>	465	21.47	-	.		Total	2166	100.00	1701	100.00	<i>Documentation 2 (MyStar Extra®)</i>	<i>Never</i>	104	4.79	104	5.89	<i>Before each meal</i>	1079	49.75	1079	61.13	<i>Irregular</i>	566	26.09	566	32.07
Pre-prandial blood glucose		N	%	N (adj)	% (adj)																																																							
<i>Anamnesis (Previous glucose meter)</i>	<i>Never</i>	215	9.93	215	12.64																																																							
	<i>Before each meal</i>	927	42.80	927	54.50																																																							
	<i>Irregular</i>	527	24.33	527	30.98																																																							
	<i>Unknown</i>	32	1.48	32	1.88																																																							
	<i>Missing</i>	465	21.47	-	.																																																							
	Total	2166	100.00	1701	100.00																																																							
<i>Documentation 2 (MyStar Extra®)</i>	<i>Never</i>	104	4.79	104	5.89																																																							
	<i>Before each meal</i>	1079	49.75	1079	61.13																																																							
	<i>Irregular</i>	566	26.09	566	32.07																																																							

	<i>Unknown</i>	16	0.74	16	0.91
	<i>Missing</i>	404	18.63	-	.
	Total	2169	100.00	1765	100.00
<i>Documentation 3 (MyStar Extra®)</i>	<i>Never</i>	119	5.54	119	6.54
	<i>Before each meal</i>	1038	48.35	1038	57.06
	<i>Irregular</i>	632	29.44	632	34.74
	<i>Unknown</i>	30	1.40	30	1.65
	<i>Missing</i>	328	15.28	-	.
	Total	2147	100.00	1819	100.00
<i>Documentation 4 (MyStar Extra®)</i>	<i>Never</i>	116	5.62	116	6.85
	<i>Before each meal</i>	939	45.47	939	55.43
	<i>Irregular</i>	613	29.69	613	36.19
	<i>Unknown</i>	26	1.26	26	1.53
	<i>Missing</i>	371	17.97	-	.
	Total	2065	100.00	1694	100.00

In contrast post-prandial blood glucose was mostly measured irregularly (at least 45% with the previous glucose meter and more than 50% using the MyStar Extra®).

HbA_{1c}

At planned time points (Anamnesis, documentation 3, documentation 4) HbA_{1c} was determined in at least 86.9% of all patients. Information about the method of determination for MyStar Extra® showed that for more than 80% of patients the analysis method was not changed. The median HbA_{1c} value decreased during the documentation (Table 16), which is shown by a median change of -0.2 between baseline and after 12 weeks of using MyStar Extra® (p<0.0001, Wilcoxon Signed-Rank Test) and of -0.3 between baseline and after 24 weeks using it (p<0.0001, Wilcoxon Signed-Rank Test; Table 17). In total, more than 50% of the patients with diabetes anamnesis (n=2166) had a reduction of the HbA_{1c} value until week 24.

Table 16: HbA_{1c} value

HbA_{1c} value	<i>N</i>	<i>Mean</i>	<i>Std</i>	<i>P1</i>	<i>P25</i>	<i>Median</i>	<i>P75</i>	<i>P99</i>	<i>Min</i>	<i>Max</i>	<i>Nmiss</i>
<i>Anamnesis (Previous glucose meter)</i>	2074	7.63	1.60	2.79	6.80	7.50	8.50	11.70	2.62	14.90	3
<i>Documentation 3 (MyStar Extra®)</i>	1881	7.33	2.66	2.75	6.60	7.20	8.00	11.40	2.54	84.10	22
<i>Documentation 4 (MyStar Extra®)</i>	1781	7.19	3.04	2.74	6.50	7.00	7.80	10.70	2.42	94.10	13

Table 17: HbA_{1c} value- Changes from baseline

<i>HbA_{1c}- Changes</i>	<i>N</i>	<i>Mean</i>	<i>Lower CI 95%</i>	<i>Upper CI 95%</i>	<i>Std</i>	<i>P1</i>	<i>P25</i>	<i>Median</i>	<i>P75</i>	<i>P99</i>	<i>Min</i>	<i>Max</i>	<i>Nmiss</i>
<i>Documentation 3</i>	1837	-0.32	-0.44	-0.20	2.68	-5.00	-0.70	-0.20	0.10	4.11	-8.64	81.36	329
<i>Documentation 4</i>	1733	-0.46	-0.61	-0.31	3.11	-5.80	-1.00	-0.30	0.10	4.11	-8.96	86.90	433

Wilcoxon Signed-Rank Test

Documentation 3 p-Value <.0001

Documentation 4 p-Value <.0001

HbA_{1c} estimator

After using MyStar Extra® for 12 weeks 59.3% of the patients estimated their HbA_{1c} with the device and 56.6% of the patients did so after using it for 24 weeks (Table 18). After 12 weeks of usage, the median HbA_{1c} was estimated to be 7.3% (range 6.00 – 10.00) and after 24 weeks 7.2% (range 6.00 – 10.00). In both cases, the median difference between laboratory HbA_{1c} value and HbA_{1c} estimator by MyStar Extra® amounted to -0.1 (Table 19).

Table 18: HbA_{1c} estimation with MyStar Extra® determined

HbA_{1c} estimation determined		<i>N</i>	<i>%</i>	<i>N (adj)</i>	<i>% (adj)</i>
<i>Documentation 3 (MyStar Extra®)</i>	<i>No</i>	806	37.54	806	38.75
	<i>Yes</i>	1274	59.34	1274	61.25

	<i>Missing</i>	67	3.12	-	.
	Total	2147	100.00	2080	100.00
<i>Documentation 4 (MyStar Extra®)</i>	<i>No</i>	786	38.06	786	40.23
	<i>Yes</i>	1168	56.56	1168	59.77
	<i>Missing</i>	111	5.38	-	.
	Total	2065	100.00	1954	100.00

Table 19: Differences between laboratory HbA_{1c} value and HbA_{1c} estimator by MyStar Extra®

Differences between laboratory HbA_{1c} value and HbA_{1c} estimator by MyStar Extra®	<i>N</i>	<i>Mean</i>	<i>Std</i>	<i>P1</i>	<i>P25</i>	<i>Median</i>	<i>P75</i>	<i>P99</i>	<i>Min</i>	<i>Max</i>	<i>Nmiss</i>
<i>Documentation 3 (MyStar Extra®)</i>	1147	-0.15	2.53	-5.01	-0.30	-0.10	0.20	1.60	-6.27	77.60	127
<i>Documentation 4 (MyStar Extra®)</i>	1055	-0.10	3.70	-5.37	-0.30	-0.10	0.20	1.40	-6.86	87.40	113

Fasting blood glucose level

At all planned time points of documentation, the fasting blood glucose level was determined in at least 82% of the corresponding patients (Table 41 in Appendix II), information about the method are shown in Table 20. Self-monitoring by patient increased from 37.4% (previous blood glucose meter) to more than 56% during use of MyStar Extra®.

Table 20: Laboratory- Fasting blood glucose level origin

<i>Fasting blood glucose level origin</i>	<i>N</i>	<i>%</i>	<i>N (adj)</i>	<i>% (adj)</i>
<i>Anamnesis (Previous glucose meter)</i>	<i>Self-monitoring by patient</i>	681	37.40	681 38.07
	<i>Measured by laboratory within practice</i>	458	25.15	458 25.60
	<i>Measured by external laboratory</i>	650	35.69	650 36.33
	<i>Missing</i>	32	1.76	- .
Total	1821	100.00	1789	100.00

<i>Documentation 3 (MyStar Extra®)</i>	<i>Self-monitoring by patient</i>	1039	56.68	1039	57.44
	<i>Measured by laboratory within practice</i>	344	18.77	344	19.02
	<i>Measured by external laboratory</i>	426	23.24	426	23.55
	<i>Missing</i>	24	1.31	-	.
	Total	1833	100.00	1809	100.00
<i>Documentation 4 (MyStar Extra®)</i>	<i>Self-monitoring by patient</i>	989	58.14	989	59.01
	<i>Measured by laboratory within practice</i>	304	17.87	304	18.14
	<i>Measured by external laboratory</i>	383	22.52	383	22.85
	<i>Missing</i>	25	1.47	-	.
	Total	1701	100.00	1676	100.00

The median fasting blood glucose level was 8.1 mmol/l at anamnesis (previous glucose meter) and 7.2 mmol/l after 24 weeks (MyStar Extra®). Median change was -0.5 mmol/l and -0.75 mmol/l between baseline and 12 weeks and between baseline and 24 weeks, respectively using the MyStar Extra® device, respectively. During the observation period, most of the patients (between 65.1% during anamnesis and 70% after 24 weeks) measured their fasting blood glucose level 7 times per week (Figure 5).

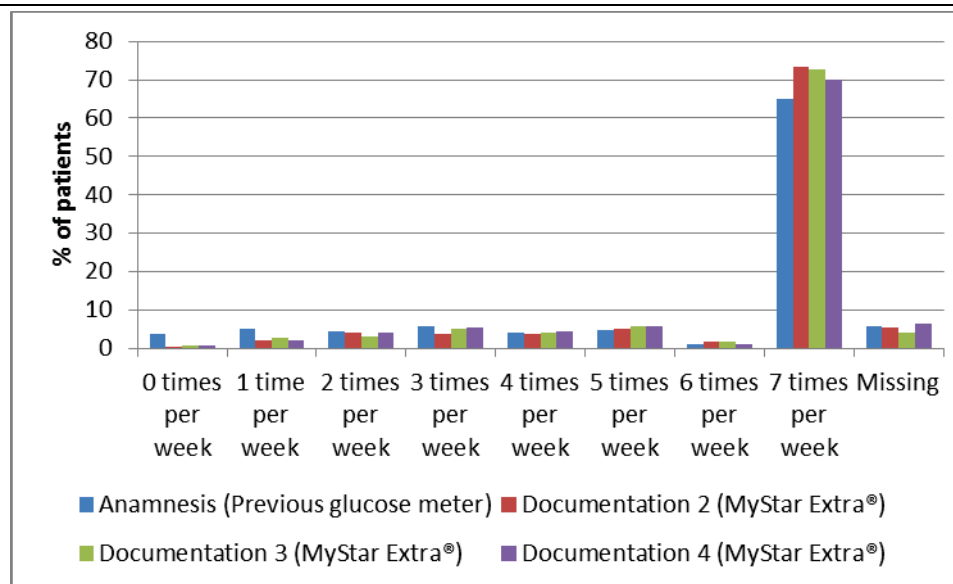


Figure 5: Number of measurements during previous 4 weeks

Basal insulin

At anamnesis, the median number of basal insulin injections was 1 per day (range, 0.00 – 20.00). Current insulin dose increased in median from 20 Units/day (at anamnesis) to 22 Units/day (after week 12 and 24). During observation, 48.6%, 51.8% and 51.0% of the titrations of basal insulin was done by physician/medical specialist in practice at time points anamnesis, after week 12 and after week 24, respectively.

The titrations of basal insulin were done by patient independent according to scheme (44.5% at anamnesis, 43.0% at week 12 and 42.0% at week 24).

Blood glucose test stripes

The median number of prescribed blood glucose test stripes per quartile was 250 at anamnesis and 300 after 24 weeks. The correlation coefficient of change in blood-sugar test stripes with the number of basal insulin modifications (after 12 and 24 weeks) was 0.1 (p<0.0001; Table 21).

Table 21: Change in blood-sugar test stripes- Spearman rank correlation with number of basal insulin modifications (Documentation 3+4)

<i>Variable</i>	<i>Correlation with</i>	<i>N</i>	<i>Correlation coefficient</i>	<i>CI 95%</i>	<i>p-Value</i>
Change in blood-sugar test stripes	Number of basal insulin modifications (Documentation 3+4)	1337	0.14	0.08- 0.19	<.0001

Product Technical Complaints (PTCs)

Documented PTCs were checked and evaluated by the complaints service of Sanofi. In total 52 PTCs occurred, thereof 51 had been reported by the sites to the CRO and one was reported directly to Sanofi:

According to documentation by sites only 2.2% of the evaluable 2173 patients had at least one PTC, in total 51 PTC occurred in 48 patients. One patient reported 3 and one patient 2 PTCs. These 51 PTCs reported to the CRO are shown in Table 42 in Appendix II.

In addition one PTC was reported directly to Sanofi by one site (without documentation in the CRF) This was added to the listing. All 52 PTCs are shown in Table 43 in Appendix II.

All 52 PTCs were evaluated by the complaints service of Sanofi. According to this evaluation only 25 of the reported 52 complaints were classified as PTCs by sanofi. Thereof 24 PTCs were related to MyStar Extra® and 1 PTC to the lancing device MyStar SylkFeel™. These 25 PTCs were reported by 24 patients with one patient having two PTCs documented. This yields to just 1.1% of the patients with a PTC. Seven patients terminated observational study due to the PTC, whereas five patients received a new MyStar Extra® device.

Incidents

PTCs related to MyStar Extra® were assessed by the manufacturer AgaMatrix whether they are incidents or not.

Of the 24 PTCs regarding MyStar Extra® and one PTC regarding the lancing device MyStar SylkFeel™ assessed by Sanofi, 3 cases (regarding MyStar Extra®) have been evaluated as incidents by the manufacturer and reported to the health authority BfArM (Table 43 in Appendix II).

Adverse Events (AEs)

Two complaints in relation to MyStar Extra® which resulted in symptoms of hypoglycaemia were captured as AE by Sanofi in the global PTC database and forwarded to the manufacturer.

No adverse events in relation to given Sanofi medication was reported during the observational study period.

Handling of functions of MyStar Extra®

23.4% of the 2120 patients with documentation after 4 weeks of using the new device had questions concerning 7-point daily profile, 64.6% measured the 7-point daily profile accordingly, 89.7% understood how to create a 7-point daily profile, 21.7% viewed the HbA_{1c} trend arrow and 49.9% viewed the average

HbA_{1c} estimation.

Training

About 90.0% of the 2166 patients with diabetes anamnesis had training on MyStar Extra® which did not exceed 30 minutes, 44.0% of the patients needed a training of 15-30 minutes.

56.7% and 21.2% gave the feedback of an easy and very easy training, respectively. After 12 weeks of using the new device 12.2% of the patients stated that they had to call the practice because of questions concerning the device, this share decreased to 5.6% of the patients after using MyStar Extra® for 24 weeks. In median the patient called the practice once during both times of documentation (range, 1-7 each). 12.5% of the patients had to redo MyStar Extra® training during the first 12 weeks of usage and 4.5% during the second 12 weeks.

Patient questionnaire 2 after 12 weeks of usage

With this questionnaire patients answered questions about their average use of the functions of MyStar Extra® in the last 4 weeks and about their satisfaction with this device in general. A total of 1923 patients filled in this questionnaire. On average, most of the patients who answered the questionnaire measured blood glucose level 7 times a week (Table 22). The great majority measured fasting blood glucose (75.1%) 7 times a week, only 28.9% did this before sleeping.

Table 22: Average number of measurements in the past 4 weeks:- 'Fasting blood glucose level' and 'Before sleeping'

<i>Measurement</i>	<i>Fasting blood glucose level measured</i>		<i>Before sleeping</i>	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
<i>0 times per week</i>	15	0.78	310	16.12
<i>1 time per week</i>	53	2.76	256	13.31
<i>2 times per week</i>	62	3.22	185	9.62
<i>3 times per week</i>	92	4.78	145	7.54
<i>4 times per week</i>	75	3.90	66	3.43
<i>5 times per week</i>	108	5.62	53	2.76
<i>6 times per week</i>	31	1.61	15	0.78

<i>7 times per week</i>	1444	75.09	551	28.65
<i>Not evaluable</i>	43	2.24	341	17.73
<i>Missing</i>	0	0	1	0.05
Total	1923	100.00	1923	100.00

55.0% of the 1923 patients measured pre-prandial blood glucose before each meal whereas post-prandial blood glucose was measured mostly irregularly (65.7%). In the night, most of the patients (52.9%) never measured the blood glucose level. If hypoglycaemia was expected, 42.5% of the patients regularly measured blood glucose level and 30.9% irregularly.

About 90.5% of patients assessed design and characteristics of the device as 'very good' or 'good'. Similar values were achieved for the handling. Almost two third of patients assessed the additional functions of the device as 'very good' or 'good' (from 63.0% for HbA1c trend arrow to 69.2% for fasting blood glucose trend, Figure 7 A – Figure 9 A in Appendix II).

61.8% of the patients used the trend arrow presentation for fasting blood glucose with 49.4% using this function several times per month. 43.0% had an increasing and 47.6% a decreasing arrow during the 12 weeks. Asked, if in consultation with the treating physician, if there have been drawn any consequences of changing trend arrow for fasting blood glucose, the majority answered with 'No' (Table 23).

Table 23: Patient questionnaire 2- MyStar Extra®- Drawn consequences from fasting blood glucose trend arrow

MyStar Extra®- Drawn consequences from fasting blood glucose trend arrow		N	%
<i>Increasing arrow</i>	<i>No</i>	962	50.03
	<i>Yes</i>	599	31.15
	<i>Not evaluable</i>	362	18.82
	Total	1923	100.00
<i>Constant arrow</i>	<i>No</i>	1333	69.32
	<i>Yes</i>	191	9.93
	<i>Not evaluable</i>	399	20.75
	Total	1923	100.00
<i>Decreasing arrow</i>	<i>No</i>	1065	55.38

	Yes	445	23.14
	Not evaluable	413	21.48
	Total	1923	100.00

For patients with consequences the favorite adaptation was 'Adjustment of therapy' followed by 'change in diet'. Benefits of this function are summarized in Table 24. Most patients agreed with a benefit in better therapy control. The highest disagreement was stated with the 'Change in extent of physical exercise'.

Table 24: Fasting blood glucose trend arrow function benefits (N=1923 patients)

Parameters for benefit		N	%
<i>Feel secure</i>	<i>Agree fully / Agree</i>	1036	53.87
	<i>Agree partially</i>	428	22.26
	<i>Disagree / Disagree completely</i>	195	10.14
	<i>Not evaluable</i>	264	13.73
<i>Better therapy control</i>	<i>Agree fully / Agree</i>	1056	54.92
	<i>Agree partially</i>	384	19.97
	<i>Disagree / Disagree completely</i>	207	10.76
	<i>Not evaluable</i>	276	14.35
<i>Better adjustment of insulin dose</i>	<i>Agree fully / Agree</i>	876	45.56
	<i>Agree partially</i>	438	22.78
	<i>Disagree / Disagree completely</i>	315	16.38
	<i>Not evaluable</i>	294	15.29
<i>Change in eating behavior</i>	<i>Agree fully / Agree</i>	815	42.38
	<i>Agree partially</i>	489	25.43
	<i>Disagree / Disagree completely</i>	344	17.89

	<i>Not evaluable</i>	275	14.30
<i>Change in extent of physical exercise</i>	<i>Agree fully / Agree</i>	741	38.54
	<i>Agree partially</i>	526	27.35
	<i>Disagree / Disagree completely</i>	379	19.71
	<i>Not evaluable</i>	277	14.40
<i>Motivated to follow through therapy</i>	<i>Agree fully / Agree</i>	911	47.37
	<i>Agree partially</i>	467	24.28
	<i>Disagree / Disagree completely</i>	265	13.78
	<i>Not evaluable</i>	280	14.56
<i>Fast recognition if change of therapy leads to desired effect</i>	<i>Agree fully / Agree</i>	1010	52.52
	<i>Agree partially</i>	401	20.85
	<i>Disagree / Disagree completely</i>	232	12.07
	<i>Not evaluable</i>	280	14.56

Only 17.1% of the patients used the 3-day fasting blood glucose average value for self-titration. Benefit was also given only for about 30.0%-40.0% of patients, with 39.5% as highest value for agreement for the statement 'Helps to better control therapy'.

In contrast, 'HbA_{1c} value function' was evaluated as 'Very important' and 'Important' by about 90% of patients. The importance of the HbA_{1c} value is stressed further by the fact that HbA_{1c} laboratory value was part of the physician-patient conversation for 92.0% of the patients. In contrast to the relevance of HbA_{1c} value for use in therapy controls it was determined in median only 4 times (range, 0 – 10) by physician in the previous year. The HbA_{1c} value estimated by MyStar Extra® was for 59.6% part of the physician-patient conversation.

Possible benefits of the HbA_{1c}-function were part of the patient's questionnaire 2. Results are presented in Table 25. About 50% of patients agree with the presented proposals for benefit. Mostly agreed was the statement 'More security about blood glucose settings quality'. But concerning the consequences drawn from the HbA_{1c} estimated value nearly the same number of the patients draw consequences or did not. 'Change of nutrition', 'Change of physical activity' and 'Adaption of therapy after consultation with physician' were the most often mentioned aspects with 26.3%, 22.8% and 23.0%, respectively. 57.6% are pleased with the HbA_{1c} trend arrow given in addition to the estimated value.

Table 25: Benefits of the HbA_{1c} estimated value (N=1923 patients)

MyStar Extra®- Benefits of the HbA_{1c} estimated value		N	%
<i>More security about blood glucose settings quality</i>	<i>Agree fully / Agree</i>	1122	58.34
	<i>Agree partially</i>	358	18.62
	<i>Disagree / Disagree completely</i>	182	9.46
	<i>Not evaluable</i>	261	13.57
<i>Possibility to keep track of metabolism settings</i>	<i>Agree fully / Agree</i>	1067	55.49
	<i>Agree partially</i>	386	20.07
	<i>Disagree / Disagree completely</i>	197	10.24
	<i>Not evaluable</i>	273	14.20
<i>More active and independent in diabetes therapy</i>	<i>Agree fully / Agree</i>	953	49.55
	<i>Agree partially</i>	452	23.50
	<i>Disagree / Disagree completely</i>	248	12.90
	<i>Not evaluable</i>	270	14.04
<i>Better evaluation of course of therapy</i>	<i>Agree fully / Agree</i>	1069	55.59
	<i>Agree partially</i>	378	19.66
	<i>Disagree / Disagree completely</i>	203	10.55
	<i>Not evaluable</i>	273	14.20
<i>More motivation to follow through therapy</i>	<i>Agree fully / Agree</i>	966	50.23
	<i>Agree partially</i>	423	22.00
	<i>Disagree / Disagree completely</i>	254	13.21
	<i>Not evaluable</i>	280	14.56
<i>Motivation to measure blood glucose more frequently and structured</i>	<i>Agree fully / Agree</i>	929	48.31
	<i>Agree partially</i>	441	22.93
	<i>Disagree / Disagree completely</i>	278	14.45

	<i>Not evaluable</i>	275	14.30
<i>Recognize issues or successes of therapy early on</i>	<i>Agree fully / Agree</i>	996	51.79
	<i>Agree partially</i>	426	22.15
	<i>Disagree / Disagree completely</i>	227	11.81
	<i>Not evaluable</i>	274	14.25
<i>Fast recognition if change of therapy leads to desired effect</i>	<i>Agree fully / Agree</i>	1054	54.81
	<i>Agree partially</i>	359	18.67
	<i>Disagree / Disagree completely</i>	233	12.12
	<i>Not evaluable</i>	277	14.40
<i>Drawn consequences from HbA_{1c} estimated value</i>	<i>No</i>	816	42.43
	<i>Yes</i>	855	44.46
	<i>Not evaluable</i>	252	13.10

68.8% (1323 patients) of the 1923 patients used the 'HbA1c estimated value' function of MyStar Extra®. Most frequently this function was used once per month (47.1%), followed by several times per month (27.9%). Daily use was the less frequent answer with 3.9%.

Altogether, about 85% of the patients would recommend the device (very likely and likely) (Table 26).

Table 26: Recommendation of MyStar Extra® (N=1923 patients)

MyStar Extra® recommendation	N	%
Very likely	786	40.87
Likely	847	44.05
Unlikely	128	6.66
Very unlikely	41	2.13

Not evaluable	121	6.29
---------------	-----	------

Physician questionnaire

In addition to patients' assessment, each participating site had to answer a questionnaire concerning the design, features and applications of the device, too. Some sites, who had chosen paper CRF for documentation, had answered this questionnaire more than once. For these sites, one questionnaire per site was randomly selected for analysis. Altogether 397 questionnaires were included in the analysis, thus 89.4% of the 444 sites with evaluable patients answered this questionnaire. Figure 7 B – Figure 9 B in Appendix II give an overview of the physicians' assessment. More than 90% of sites assessed design and characteristics of the device as 'very good' or 'good'. Similar values were achieved for the handling. Fewer sites (about 80%) assessed the additional functions of the device as 'very good' or 'good'.

In the following the assessment of benefits of special functions of the device by the sites is presented.

81.6% of the sites recommended the use of the trend arrow presentation for fasting blood glucose. The benefit assessment is presented in Table 27. Disagreement with the possible benefit parameters was < 5% each. In general most sites agreed with the benefits. 76.3% discussed the trend arrow for fasting blood glucose with the patient.

Table 27: Fasting blood glucose trend arrow function benefits (N=397 sites)

Possible benefits		N	%
<i>Helps to better control therapy</i>	<i>Agree fully / Agree</i>	305	76.83
	<i>Agree partially</i>	76	19.14
	<i>Disagree / Disagree completely</i>	11	2.77
	<i>Not evaluable</i>	4	1.01
	<i>Missing</i>	1	0.25
<i>Helps to better follow through with therapy</i>	<i>Agree fully / Agree</i>	278	70.03
	<i>Agree partially</i>	101	25.44
	<i>Disagree / Disagree completely</i>	12	3.02
	<i>Not evaluable</i>	5	1.26
	<i>Missing</i>	1	0.25

	<i>Impetus for possible therapy adjustments</i>	<i>Agree fully / Agree</i>	289	72.79
		<i>Agree partially</i>	85	21.41
		<i>Disagree / Disagree completely</i>	17	4.28
		<i>Not evaluable</i>	5	1.26
		<i>Missing</i>	1	0.25
	<i>Impetus for lifestyle interventions</i>	<i>Agree fully / Agree</i>	271	68.26
		<i>Agree partially</i>	103	25.94
		<i>Disagree / Disagree completely</i>	18	4.53
		<i>Not evaluable</i>	4	1.01
		<i>Missing</i>	1	0.25
	<i>Trend arrow part of patient discussion</i>	<i>No</i>	86	21.66
		<i>Yes</i>	303	76.32
		<i>Not evaluable</i>	6	1.51
		<i>Missing</i>	2	0.50
	<p>About half of the sites (49.6%) assessed the 7-day average value of blood glucose as useful. The display of average values for blood glucose is recommended by 36.3% at mealtime tag 'sober' whereas before or after meal is recommended by 17.5% and 17.8%, respectively.</p> <p>Concerning benefits of the 3-day-fasting blood glucose average value the assessment of the sites is shown in Table 28. '<i>Impetus for possible therapy adjustments</i>' and '<i>Good support in basal insulin dose adjustments</i>' were estimated by physicians as major benefits with 70,3% and 67,0%, respectively.</p>			
<p>Table 28: Benefits of 3-day fasting blood glucose average value (N=397 sites)</p>				
Possible benefits			N	%
<i>Helps to better control therapy</i>	<i>Agree fully / Agree</i>		237	59.70
	<i>Agree partially</i>		130	32.75

		<i>Disagree / Disagree completely</i>	21	5.29
		<i>Not evaluable</i>	8	2.02
		<i>Missing</i>	1	0.25
	<i>Helps to better follow through with therapy</i>	<i>Agree fully / Agree</i>	235	59.19
		<i>Agree partially</i>	133	33.50
		<i>Disagree / Disagree completely</i>	19	4.78
		<i>Not evaluable</i>	9	2.27
		<i>Missing</i>	1	0.25
	<i>Good support in basal insulin dose adjustments</i>	<i>Agree fully / Agree</i>	266	67.00
		<i>Agree partially</i>	104	26.20
		<i>Disagree / Disagree completely</i>	16	4.03
		<i>Not evaluable</i>	9	2.27
		<i>Missing</i>	2	0.50
	<i>Impetus for possible therapy adjustments</i>	<i>Agree fully / Agree</i>	279	70.27
		<i>Agree partially</i>	90	22.67
		<i>Disagree / Disagree completely</i>	17	4.28
		<i>Not evaluable</i>	9	2.27
		<i>Missing</i>	2	0.50
	<i>Impetus for lifestyle interventions</i>	<i>Agree fully / Agree</i>	259	65.24
		<i>Agree partially</i>	107	26.95
		<i>Disagree / Disagree completely</i>	20	5.03
		<i>Not evaluable</i>	10	2.52
		<i>Missing</i>	1	0.25
	<i>3-day fasting blood glucose average value for self-</i>	<i>No</i>	176	44.33

<i>titration of basal insulin advised</i>	<i>Yes</i>	214	53.90
	<i>Not evaluable</i>	6	1.51
	<i>Missing</i>	1	0.25

85.4% of the physicians recommended their patients the use of the HbA_{1c} estimated value function which was assessed as "very good" or "good" by 81.9% of them. The greatest benefit was seen with 'Possibility to keep track of metabolism settings' and 'More active and independent in diabetes therapy' with 70.3% each. 83.4% of the physicians used the estimated HbA_{1c} value in the conversation with the patient.

Table 29: Benefits of the HbA_{1c} estimated value (N=397 sites)

Benefits of the HbA_{1c} estimated value		<i>N</i>	<i>%</i>
<i>More security about blood glucose settings quality</i>	<i>Agree fully / Agree</i>	275	69.27
	<i>Agree partially</i>	103	25.94
	<i>Disagree / Disagree completely</i>	11	2.78
	<i>Not evaluable</i>	6	1.51
	<i>Missing</i>	2	0.50
<i>Possibility to keep track of metabolism settings</i>	<i>Agree fully / Agree</i>	279	70.28
	<i>Agree partially</i>	97	24.43
	<i>Disagree / Disagree completely</i>	13	3.28
	<i>Not evaluable</i>	6	1.51
	<i>Missing</i>	2	0.50
<i>More active and independent in diabetes therapy</i>	<i>Agree fully / Agree</i>	279	70.28
	<i>Agree partially</i>	97	24.43
	<i>Disagree / Disagree completely</i>	13	3.27
	<i>Not evaluable</i>	6	1.51
	<i>Missing</i>	2	0.50

	<i>Better evaluation of course of therapy</i>	<i>Agree fully / Agree</i>	269	67.76
		<i>Agree partially</i>	108	27.20
		<i>Disagree / Disagree completely</i>	12	3.02
		<i>Not evaluable</i>	6	1.51
		<i>Missing</i>	2	0.50
	<i>More motivation to follow though therapy</i>	<i>Agree fully / Agree</i>	260	65.49
		<i>Agree partially</i>	117	29.47
		<i>Disagree / Disagree completely</i>	11	2.77
		<i>Not evaluable</i>	7	1.76
		<i>Missing</i>	2	0.50
	<i>Motivation to measure blood glucose more frequently and structured</i>	<i>Agree fully / Agree</i>	260	65.49
		<i>Agree partially</i>	109	27.46
		<i>Disagree / Disagree completely</i>	19	4.78
		<i>Not evaluable</i>	7	1.76
		<i>Missing</i>	2	0.50
	<i>Recognize issues or successes of therapy early on</i>	<i>Agree fully / Agree</i>	257	64.73
		<i>Agree partially</i>	112	28.21
		<i>Disagree / Disagree completely</i>	17	4.28
		<i>Not evaluable</i>	8	2.02
		<i>Missing</i>	3	0.76
<i>Fast recognition if change of therapy leads to desired effect</i>	<i>Agree fully / Agree</i>	267	67.25	
	<i>Agree partially</i>	101	25.44	
	<i>Disagree / Disagree completely</i>	19	4.78	
	<i>Not evaluable</i>	6	1.51	

		<i>Missing</i>	4	1.01
<i>Occasion for physician-patient consultation</i>		<i>Agree fully / Agree</i>	261	65.74
		<i>Agree partially</i>	102	25.69
		<i>Disagree / Disagree completely</i>	23	5.80
		<i>Not evaluable</i>	8	2.02
		<i>Missing</i>	3	0.76
<i>HbA_{1c} estimated value part of physician-patient consultation</i>		<i>No</i>	52	13.10
		<i>Yes</i>	331	83.38
		<i>Not evaluable</i>	10	2.52
		<i>Missing</i>	4	1.01

The HbA_{1c} trend arrow was advised by 39.3% of sites. This question was not answered by 47.9% of the sites, thus referring to the answered questionnaires only, the value was 75.4%. 73.0% of the sites that answered the question estimated this function as 'very good' or 'good'. Table 30 presents the assessment of the sites who answered the questions concerning this function. In general the function 'HbA_{1c} trend arrow' is favoured less by the sites than the function 'HbA_{1c} estimated value'. Only 70.3% of the sites that answered the question included this topic in the conversation with the patient.

Table 30: Benefits of the HbA_{1c} trend arrow (N=397 sites)

MyStar Extra[®] - Benefits of the HbA_{1c} trend arrow		N	%
<i>Possibility to react early on to changes of HbA_{1c} value</i>	<i>Agree fully / Agree</i>	248	62.47
	<i>Agree partially</i>	120	30.23
	<i>Disagree / Disagree completely</i>	19	4.79
	<i>Not evaluable</i>	7	1.76
	<i>Missing</i>	3	0.76
<i>More active and independent in diabetes therapy</i>	<i>Agree fully / Agree</i>	242	60.96
	<i>Agree partially</i>	128	32.24

		<i>Disagree / Disagree completely</i>	17	4.28
		<i>Not evaluable</i>	7	1.76
		<i>Missing</i>	3	0.76
	<i>Better evaluation of course of therapy</i>	<i>Agree fully / Agree</i>	250	62.97
		<i>Agree partially</i>	118	29.72
		<i>Disagree / Disagree completely</i>	18	4.53
		<i>Not evaluable</i>	8	2.02
		<i>Missing</i>	3	0.76
	<i>Possibility to keep track of metabolism settings</i>	<i>Agree fully / Agree</i>	251	63.22
		<i>Agree partially</i>	118	29.72
		<i>Disagree / Disagree completely</i>	16	4.03
		<i>Not evaluable</i>	8	2.02
		<i>Missing</i>	4	1.01
	<i>More motivation to follow through therapy</i>	<i>Agree fully / Agree</i>	243	61.21
		<i>Agree partially</i>	121	30.48
		<i>Disagree / Disagree completely</i>	22	5.54
		<i>Not evaluable</i>	7	1.76
		<i>Missing</i>	4	1.01
	<i>Recognize issues or successes of therapy early on</i>	<i>Agree fully / Agree</i>	245	61.72
		<i>Agree partially</i>	126	31.74
		<i>Disagree / Disagree completely</i>	14	3.53
		<i>Not evaluable</i>	8	2.02
		<i>Missing</i>	4	1.01
	<i>Fast recognition if change of therapy leads to desired</i>	<i>Agree fully / Agree</i>	256	64.48

<i>effect</i>	<i>Agree partially</i>	113	28.46	
	<i>Disagree / Disagree completely</i>	16	4.03	
	<i>Not evaluable</i>	8	2.02	
	<i>Missing</i>	4	1.01	
	<i>HbA_{1c} trend arrow part of patient discussion</i>	<i>No</i>	83	20.91
		<i>Yes</i>	279	70.28
		<i>Not evaluable</i>	29	7.30
		<i>Missing</i>	6	1.51
<u>Subgroup analysis</u>				
<u>I. Patients with at least one independent / no independent titration of basal insulin during observation period</u>				
<p>At least one independent titration was recorded for 1108 patients, whereas 1033 had no independent titration. Patients with no independent titration were significantly older than those with at least one independent titration with a median age of 64 and 61 years, respectively (Table 44 in Appendix II). Median time of diabetes duration of patients with at least one independent / no independent titration was 10 years / 9 years (Table 45 in Appendix II). Among the group with no independent titration there were more patients with type 2 diabetes than in the group with at least one independent titration: 89.6% and 82.8%, respectively (Table 46 in Appendix II).</p> <p>Median value of empowerment scale improved by 1 point in subgroup of patients with at least one independent titration from baseline to approx. 24 weeks later, whereas for the group with no independent titration an improvement by 2 points could be seen (Table 47 in Appendix II).</p> <p>70.9% and 66.8% of the patients with at least one or no independent titration, respectively, used HbA_{1c} estimated value function of MyStar Extra®.</p>				
<u>II. Patients who achieved / did not achieve their recommended HbA_{1c} value</u>				
<p>Only 22.5% (488 patients) of the evaluable patients achieved their recommended HbA_{1c} value during the observational period.</p> <p>Patients, who achieved their recommended HbA_{1c} value were in median significantly older than patients who did not achieve it: 64 years compared to 62 years, respectively (Table 48 in Appendix II). In the group of patients who achieved the recommended HbA_{1c} value there were significantly more men compared to those who did not achieve the recommended HbA_{1c} value (Table 49 in Appendix II) and more patients of group who achieved their recommended HbA_{1c} value used HbA_{1c} estimation value daily (Table 50 in Appendix II).</p>				
<u>III. Patients with HbA_{1c} <7.5%/ ≥7.5%</u>				

59.6% (1296 patients) of the evaluable patients had an HbA_{1c} <7.5% during observation period. Median age of these patients was 63 years (range, 18-94 years), whereas patients with HbA_{1c} ≥7.5% had a median age of 62 years (range, 18-97 years) (Table 51 in Appendix II). The latter had in median a longer period of diabetes disease with 11 years compared to 9 years for patients with HbA_{1c} <7.5%. Patients with HbA_{1c} <7.5% were less satisfied with their previous blood glucose meter. Median satisfaction with MyStar Extra®-after usage of 12 weeks was the same in both subgroups (Table 52 in Appendix II).

IV. Baseline HbA_{1c}

Considering the HbA_{1c} value at baseline it could be seen, that patients with a value of ≥7.5% were less satisfied with their previous blood glucose meter and more satisfied with the MyStar Extra® device than patients with a value of <7.5% (Table 53 in Appendix II). During observation, reduction of HbA_{1c} value was greater in patients with a higher baseline value compared to patients with baseline value of <7.5% who did not show any change in median (Table 54 in Appendix II). Patients with a HbA_{1c} ≥7.5% even decreased their values further after 24 weeks of observation.

V. Age

In a further analysis patients were stratified into 3 groups according to age: 18-40 years, >40-65 years and >65 years. It could be shown that the median empowerment value at baseline decreases with higher age (Table 55 in Appendix II): 32.0 points, 31.0 points and 29.7 points for the groups 18-40 years, >40-65 years and >65 years, respectively. Using MyStar Extra® for approx. 24 weeks the median empowerment increased in all age groups

Considering the median HbA_{1c} values in the 3 age groups during the observation period it could be seen that these decreased in all groups (Table 56 in Appendix II and Figure 6). Highest median HbA_{1c} at baseline was evaluated in the age group >40-65 years, whereas the lowest median HbA_{1c} baseline value was assessed in patients >65 years.

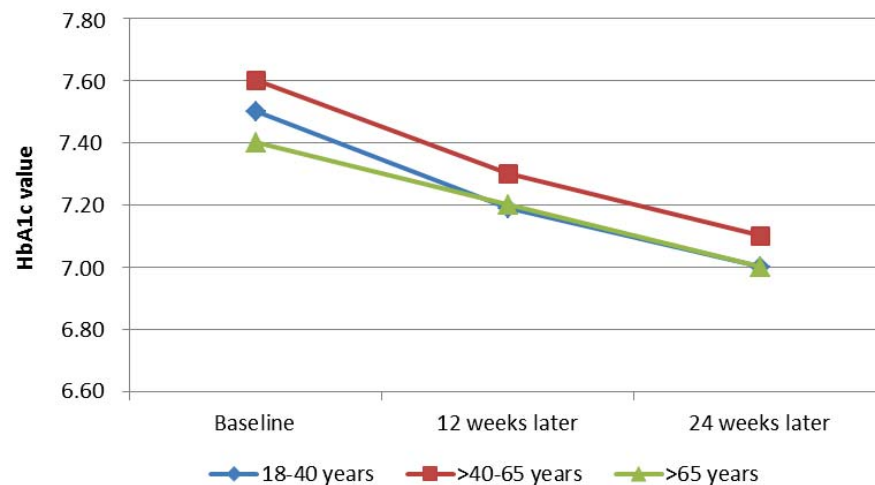


Figure 6: Median HbA_{1c} values at baseline and after 12 and 24 weeks using MyStar Extra®

Discussions:

Monitoring blood glucose level is of high importance for patients with type 1 diabetes and for patients with type 2 diabetes using insulin with the aim to minimize late damages (e.g. diabetic neuropathy and blood vessel damage) which may result of too high blood glucose levels. Self-monitoring is a prerequisite for a close monitoring and has several benefits: It promotes personal responsibility and provides opportunities for better control; it allows for detection of blood glucose extreme levels, thus helping to reduce blood glucose fluctuations [12].

Devices with very high accuracy and user-friendliness are needed for this. Patients who are satisfied with the device and are able to use it correctly may adhere to self-monitoring for a longer time period.

New devices do not only provide exact blood glucose values but have additional functions like HbA_{1c} estimation or calculation of trend lines, which are valuable estimated parameters for diabetes therapy control. It can be used to assess the metabolic state of the last 2-3 months. According to German guideline for type 2 diabetes an HbA_{1c} value between 6.5% and 7.5% is recommended to prevent health complications [13].

In this prospective non-interventional observational study the use of the new glucose meter MyStar Extra® was evaluated by patients and physicians. Patients with diabetes of type 1 or 2 who have used no or another device for blood glucose monitoring previously and who switched to MyStar Extra® were asked to participate in this study. In particular the patient's satisfaction with MyStar Extra® as well as the device handling, the appropriateness and the benefits of the added features of MyStar Extra® were investigated.

Of the enrolled 2262 patients, 2173 (96.1%) were evaluable for the primary and secondary objectives. The median age at informed consent was 62 years;

	<p>more than 90% of the patients were older than 40 years with slightly more male (55.6%) than female patients. 2166 patients had an available diabetes anamnesis. Most patients suffered at least 5 years of diabetes. The great majority of them had diabetes type 2. The most used insulin was long-acting insulin analogues (73.6%) with a median dose of 20 units per day.</p> <p>Nearly 80% of the patients used another blood glucose meter previously than MyStar Extra[®], only 9.2% did not use any before. The most reported reason for change to MyStar Extra[®] was that the patient 'would like a new device' (36.9%), followed by 'Patient would like to use the additional functionalities of MyStar Extra[®]' (36.8%) and 'prior device outdated or defect' (27.2%). Most physicians advised their patients to measure fasting blood glucose level (86.7%; median FBG target value 6.1 mmol/l), HbA_{1c} (85.1%; median HbA_{1c} target value 6.8%) and postprandial blood glucose, less than 1.5 - 2 h after meal (65.1%; median 8.3 mmol/l). As for the kind of measurement more than 50% of physicians recommended a 7-point daily profile.</p> <p>Training on how to use the new device MyStar Extra[®] did not exceed 30 minutes for about 90% of the patients. After 12 weeks of using MyStar Extra[®] 12.2% of the patients had to call the practice for further information about the device, this share decreased to 5.6% after 24 weeks. Therefore training with MyStar Extra[®] was relatively short in time and easy understandable even for older patients which seems is a positive aspect for the physicians, too.</p> <p>More than 90% of the patients used MyStar Extra[®] after 24 weeks; this may in part related to patient's and/or physician's satisfaction with this device. This was stressed further by the patient evaluation of the device. More than 80% assessed the device in general and the handling as 'very good' or 'good'. Fewer patients (> 70%) rated the additional functions as 'very good' / 'good'.</p> <p>This was stressed further by direct estimation of patients' satisfaction with the MyStar Extra[®] device after 12 weeks using a Visual Analog Scale. Compared to the previous device, there was a median increase of 10 points reaching a median of 85 points for MyStar Extra[®]. This increase in satisfaction was independent of age. Patients who used the device daily were more pleased with it than those who used it once per month or quartal. Using a device more frequently may improve its handling, and likely yielding greater satisfaction using it. After using MyStar Extra[®] for 24 weeks there was also a slight increase in the empowerment scale from a median of 31 points to a median of 32 points (of a maximum of 44 points). The easiness of use of MyStar Extra[®] with its additional functions may facilitate life with diabetes. Changing to the new device led to an increase in pre-prandial glucose measurement before each meal, but this increase declines over the observation period of 24 weeks. But number of patients who never measured pre-prandial blood glucose was reduced by nearly 50% compared to previous blood glucose meter even after 24 weeks. Self-monitoring of fasting blood glucose levels increased, too, with the use of MyStar Extra[®] compared to the previous device. Result was a reduction of fasting blood glucose levels from anamnesis (8.1 mmol/l) to time point 24 weeks later (7.2 mmol/l).</p> <p>Most of the patients measured blood glucose level 7 times per week. 62% used the function of trend arrow presentation of fasting blood glucose and in case of increasing or decreasing arrow 31% and 23%, respectively, draw consequences, mainly 'adjustment of therapy' and 'change in diet'.</p> <p>Regarding the HbA_{1c} estimation feature of the device more than 60% used this function. Comparison of the estimated HbA_{1c} values with those determined in laboratory showed that the difference between both only deviated by a median of -0.1. Therefore the estimated HbA_{1c} value was considered reliable and could be used by patients for self-monitoring. HbA_{1c} values as determined in laboratory were reduced during observation period from a median of 7.5% at baseline to 7.0% after 24 weeks.</p> <p>In summary the use of the MyStar Extra[®] device with its additional features showed a positive effect on the daily life diabetes management of the patients and a responsible handling with the disease. As a consequence values for glucose and HbA_{1c} were improved. These results are also in agreement with studies showing that HbA_{1c} are lower if glucose is tested more frequently [14]. Diabetes patients are self-responsible and willing for changes in their daily life thus ameliorating blood glucose levels.</p>
--	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

	<p>This statement is emphasized by the positive assessment of the additional functions of the device by the patients. The great majority agreed that the additional functions have benefits for themselves. Lowest benefit was given for the 3-day fasting blood glucose average value which was also used by 17.1% of patients only for self-titration.</p> <p>General satisfaction with the device was shown by about 85% of patients who would recommend MyStar Extra®.</p> <p>Considering PTCs; only 1.1% of evaluable patients (24 of 2173 patients) had at least one PTC. A total of 52 reports were assessed by the complaints service of Sanofi. Of these, 25 cases were evaluated as PTCs, with one patient having two PTCs documented.</p> <p>Of the 25 PTCs (24 PTCs regarding MyStar Extra® and one PTC regarding the lancing device MyStar SylkFeel™) assessed by Sanofi, 3 cases have been evaluated as incidents by the manufacturer and reported to the health authority BfArM.</p> <p>Although no AEs occurred in relation to any Sanofi medication during observational study there were two PTCs resulting in an AE related to MyStar Extra®, which was in both cases 'symptoms of hypoglycaemia'. These AEs were listed in the global PTC database and forwarded to the manufacturer by Sanofi.</p> <p>Self-monitoring by patients has to be supported by physicians who determine target values and discuss findings with their patients. Thus also physicians have to know the device the patients use and especially which additional functions it has. This aspect is not only important for the training of the patients and the answering of questions in case of requests. It is also necessary to give recommendations for additional functions being useful for an individual patient.</p> <p>Therefore after 24 weeks physicians had to give an estimation of their satisfaction with MyStar Extra® and in median their satisfaction was with 90 points even higher than satisfaction of the patients. Regarding the additional features of MyStar Extra® 'HbA_{1c} estimator function of MyStar Extra®' was assessed as "good/very good" by about 78%. Further on, 'fasting blood glucose trend function' was advised by about 81% of the physicians and about 33% of them judged this function as "very good". 'HbA_{1c} estimated value' was advised by about 85% of the physicians and judged as "very good" by about 39% of them. Results of features of the MyStar Extra® were also used by physicians for discussion with patients, e.g. 76.3% discussed the trend arrow for fasting blood glucose with the patients.</p>
<p>Conclusions:</p>	<p>In this observational study the blood glucose meter MyStar Extra® was tested in daily life by diabetes patients. This device has additional functions which should facilitate diabetes management.</p> <p>It could be shown that diabetes patients were able to improve blood glucose and HbA_{1c} values during self-monitoring with the use of MyStar Extra®. Patients and physicians evaluated the device and its additional functions as positive and used them for patient's self-monitoring or for patient's discussion. The handling of MyStar Extra® was shown to be easy even for the older age group of diabetes patients.</p>
<p>Date of report:</p>	<p>15-Sep-2016</p>