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Continuous glucose monitoring: A training programme for all age groups

Ulrike Thurm[1], Bernhard Gehr[2], Martin Holder[3], Bernd Kulzer[4], Karin Lange[5], Andreas Liebl[2], Claudia Sahm[6], Simone von Sengbusch[7], Sandra Schlüter[8], Thorsten Siegmund[9], Ralph Ziegler[10], and Guido Freckmann[11], Lutz Heinemann[12] for the SPECTRUM Group[1]

[1]Diabetologische Schwerpunktpraxis, Berlin, Germany; [2]m&i Fachklinik Bad Heilbrunn, Centre for Diabetes and Metabolism, Bad Heilbrunn, Germany; [3]Klinikum Stuttgart, Olgahospital, Stuttgart, Germany; [4]Forschungsinstitut Diabetes-Akademie Bad Mergentheim, Bad Mergentheim, Germany; [5]Hannover Medical School, Medical Psychology Unit, Hannover, Germany; [6]Diabetologische Schwerpunktpraxis, Herrsching, Germany; [7]Klinik für Kinder- und Jugendmedizin, UKSH Campus, Lübeck, Germany; [8]Diabetologische Schwerpunktpraxis, Northeim, Germany; [9]Klinik für Endokrinologie, Diabetologie und Angiologie, Städtisches Klinikum München-Bogenhausen, Munich, Germany; [10]Diabetologische Schwerpunktpraxis für Kinder und Jugendliche, Münster, Germany; [11]Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Ulm, Germany; [12]Science&Co, Düsseldorf, Germany

Optimal usage of continuous glucose monitoring (CGM) requires adequate preparation and training. Patients using a CGM system without special training often do not achieve their intended improvement of metabolic control. Some stop using the system due to disappointing results. For this reason a structured training programme called 'SPECTRUM' was developed in Germany to ensure a high-quality standard for the initiation of CGM systems. This programme is suitable for patients of all age groups and is applicable to all CGM systems and all forms of insulin therapy. Structured curricula (adults, parents of young children, adolescents) were developed enabling diabetes centres with less experience to offer comprehensive CGM training. Key requirements of SPECTRUM were (1) independent from manufactures and (2) product-neutrality enabling certification for reimbursement after formal evaluation within the framework of a large clinical trial. SPECTRUM was published in January 2016 in German and translations into other languages are planned.

Key words: Continuous glucose monitoring, CGM, Education programme, Diabetes, Children, Adolescents

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Introduction

Continuous glucose monitoring (CGM) represents a significant advance for the treatment of patients with insulin-dependent diabetes mellitus and help them to improve their glucose control.[1,2] Usage of CGM enables an increased understanding of the effects that various influences of daily life have on changes in glucose levels, for example, diet, insulin and physical exercise. However, patients' perception and experiences with usage of CGM systems in daily life was paid much attention for in the early years of CGM development and usage, the focus was more on technological aspects and not on usability and how they integrate the information into their diabetes therapy.[3]

Providing patients with a CGM system without providing them with special training and professional coaching does not usually improve their metabolic status.[4,5] Patients need a wide range of information and skills in order to use the full potential of a CGM system and also to avoid potential negative aspects, for example, overcorrection. At present such training services are mostly given in individual and often unstructured consultations by a physician/diabetologist or (more often) by a certified diabetes educator. These are not ideal conditions for a structured training session. Structured training sessions are not only necessary at the start of CGM usage, but also through the long-term use of CGM if the patients are unable to cope with the system or if the therapy targets are not achieved.

The Diabetes Technology working group (AGDT) and the Pediatric Diabetology working group (AGPD) of the German Diabetes Association (DDG) have recognized the need for a comprehensive and independent CGM training programme. A team of about 20 diabetes nurses, diabetologists and psychologists from both groups jointly developed a programme that:

- ensures a high-quality standard for the use of CGM systems
- is suitable and specifically adapted to needs of patients of all age groups
- is applicable to all CGM systems and all forms of insulin therapy and
- is manufacturer-independent (however, in the first stage of the development, representatives of the manufacturers were consulted about technical aspects).

The programme is named 'SPECTRUM' (Structured patient education and treatment programme for self-reliant CGM, Figures 1 and 2). The members of the

Correspondence to: Ulrike Thurm, Diabeteszentrum am Sophie – Charlotte Platz, Bismarckstrasse 68, 10627 Berlin, Germany.
Email: ulrike.thurm@t-online.de

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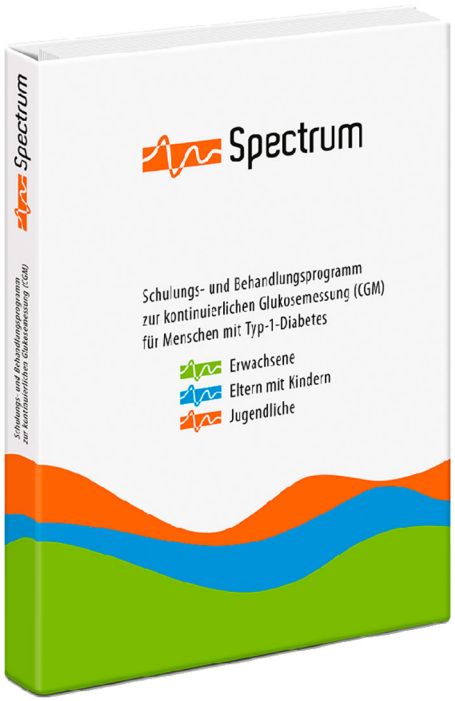

Figure 1 SPECTRUM training file with printed curricula and slides from the memory stick.

working group who developed SPECTRUM did not get any honorarium. This training and treatment programme is available in a version for adults, one for parents of mainly younger children and one for adolescents with Type 1 diabetes (T1DM) (see example in Figure 2). All three versions include detailed curricula adapted to age-specific needs and challenges in everyday life with T1DM or of patients with Type 2 diabetes on an intensified insulin therapy (IIT) or pregnant women on insulin therapy. The materials and didactic tools support diabetes centres with less CGM-experience to become capable of providing a comprehensive CGM training. The preparations for an evaluation study (CGM TRAIN) of SPECTRUM are completed and if the programme can be successfully evaluated, then reimbursement for using this programme in specialized diabetes practices can be achieved by the payers in Germany. This would be an important step forward in achieving more widespread acceptance and use of CGM systems.

Structure of SPECTRUM

To make the best use of CGM, the patients need to have a good understanding of a variety of physiological and technical aspects.[2] The most important aims of the training and treatment programme are:

- Support in improving the quality of life and somatic parameters through the use of CGM.
- Motivation and empowerment through the use of this new diagnostic option.
- Help with cognitive and emotional management to prevent from 'data overload'.
- Development of problem-solving abilities, for example, prevention of hypoglycaemic events and high postprandial glycaemic excursions, or the safe correction of hypoglycaemia and increased glucose values in everyday life while avoiding of overtreatment in those situations.
- Strengthening the individual ability to make decisions based on the interpretation of the current or saved CGM data and the adjustment of the alarm settings in everyday life.
- Optimization of the calibration procedure of CGM systems.

The adult version of SPECTRUM consists of an introductory module, followed by six training modules, each about 90 min long (Table 1). The paediatric versions (one for the adolescents and one for the parents with mainly younger children) consist of an introductory module and five training modules. No content was left out for the paediatric versions. The different number of training sessions is due to the different setting with smaller group size in the paediatric versions and more out-patient visits at follow-up.

The number of patients that should attend the training modules for adults is intended to be 2–6 patients; however, if needed, patients can also be trained individually. For parents of very young children the group size should be small, or individual training sessions should be offered.

For patients that are not hospitalized a time frame of about 8 weeks should be planned for participation in the whole training programme (a time range between 4 and 12 weeks can be considered, see Table 2). For children and teenagers, variations in the time frame are optional, in particular when used in the context of in-patient care or day clinics.

Performance of SPECTRUM

Patients who are interested in using a CGM system should first take part in the introductory module (Module 0). This module can be employed in different settings, for example, as part of an introductory meeting, or as part of a training session for patients to be trained in IIT or insulin pump therapy (CSII). This module is freely available on the internet (on the homepages of the AGDT and AGPD). Reimbursement of this introductory session will not be possible in Germany; therefore, this session is defined as 'module 0'.

After participation of this initial module, those patients who are seriously interested in CGM should speak to their diabetes team for further approach. When a patient or the parents of a child decide that they want to use a CGM system and the system is available to them, then the actual training programme can start (Table 1; an example based on the adult version of SPECTRUM).

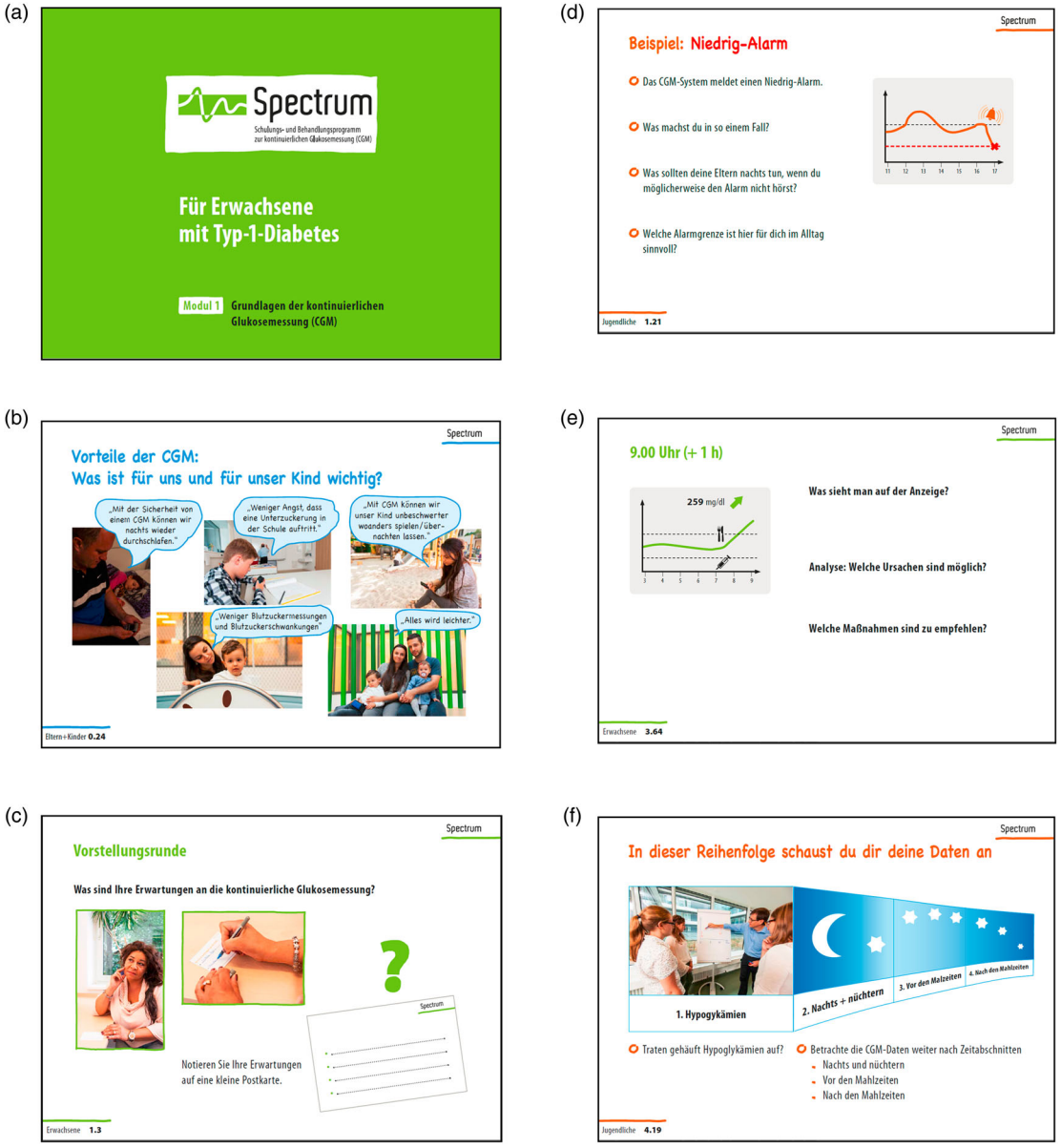

Figure 2 Examples of slides from the three versions of SPECTRUM for adults, for parents with young children and for adolescents with T1DM. Slide a: Opening slide of module 1 for adults. Slide b: Example of SPECTRUM for young kids and their parents. Possible advantages and challenges of CGM use are discussed prior to the decision on using CGM. Slide c: Patients are involved actively into the educational programme. In this example taken from the adult version of SPECTRUM the patients should note their personal expectations connected with CGM use on a special card. This card will be stored until the end of SPECTRUM by the diabetes team and then discussed again. Slide d: As strict product neutrality is crucial to achieve reimbursement of a patient educational programme in Germany, we developed a neutral CGM display. This example is taken from the adolescents' version of SPECTRUM and patients are asked to discuss the correct reaction to a low alarm. Slide e: This example is taken from the adult version of SPECTRUM and shows how patients are trained for interpreting their CGM display by discussing small 'real' cases. Patients are asked in a very structured way to describe what they see on the display, which causes may underlie and what the patient should do now in this situation. The next slides show the same case a few hours later (not shown). Slide f: The patients are suggested a structured way of interpreting CGM data (retrospective analysis) in four steps: Detect recurrent hypoglycaemia and assess glucose levels during night time, before and after meals. This algorithm is practiced with own CGM data during the training sessions.

- In Module 1, the most important basic CGM principles are covered (e.g., CGM display, difference between glucose levels in interstitial fluid and blood, calibration).
- In Module 2 the patients insert for the first time a glucose sensor, programme the first alarm settings and learn the 'start rules' for the first days with CGM.

Table 1 Basic structure of the adult version of SPECTRUM.

Module 0	*Introduction* Module 0 offers the participant a solid knowledge of the basic principles of CGM so that they can make an informed decision whether or not to use a CGM system. An explanation is given of how a CGM system works, the advantages and disadvantages are discussed, an overview of available CGM systems is given and the process for reimbursement of costs is explained. Module 0 can be used in a variety of settings (large or small groups or individual consultations).
Module 1	*Basic principles of CGM* The participants are told in detail about how CGM systems work. The characteristics of tissue glucose measurements are discussed comprehensively. Basic knowledge with respect to the precision of the CGM system, alarm settings and calibration are also presented.
Module 2	*CGM start* Participants start working with their CGM system; they insert the first sensor and receive hints on how to make it safely through the first days of CGM use. Together with the trainer, sensible alarm settings are programmed and the calibration procedure is discussed.
Module 3	*CGM display and alarms* At the beginning of this module the participants exchange their first experiences with using the system in daily life. They also reflect upon their own experiences with the system. The participants learn to analyse and correctly interpret the data displayed by the CGM system so that they can make informed decisions on the appropriate therapy.
Module 4	*CGM analysis 1* The main aim of module 4 is to learn the methodology needed to evaluate the stored data. An overview analysis of the glucose trace over several days is carried out. An in-depth analysis of the individual days will then be performed. Finally, conclusions and therapy targets, which should be achieved by the next module, will be defined by the participants themselves.
Module 5	*CGM analysis 2* The prime objective of module 5 is to practice the learn methodology for the evaluation of CGM data. Again all of the data of each participant are evaluated (but not rated). By practicing together, the participants can gain confidence on how to deal with the 'flood' of data and possible uncertainties can be reduced.
Module 6	*CGM advanced training* Problems that have occurred when changing the sensor (e.g., where they should be applied, adhesion problems, skin reactions) are discussed retrospectively. The participants gather more information, for example CGM in conjunction with physical exercise, swimming, use in the sauna, on holiday or in hospital.

Table 2 Timeline for the training modules based on the adult version.

Module	0	1	2	3	4	5	6
ca. point in time	In advance	–1 week	0	+1 week	+2 weeks	+4 weeks	+6 weeks
time period	–	In total about 4–12 weeks					

- In Module 3 the interpretation of the data shown on the CGM display is discussed and the alarm settings are adapted to the first experiences.
- In Modules 4 and 5 CGM data are analysed together with the trainer and practical experiences exchanged from the first few weeks of CGM usage are discussed.
- In Module 6 patients receive support for long-term CGM use and for special situations.

To address typical paediatric challenges, several psychological elements were included in the paediatric modules with worksheets on realistic expectations and targets for adolescents and parents. In addition, several paediatric aspects of CGM in everyday life are addressed, e.g. CGM in nursery, school, child appropriate explanation, CGM in challenging social situations, alerts at night and day, skin protection, pain reduction at sensor insertion. However, psychological aspects that are of relevance for adult patients are also addressed in SPECTRUM.

To enhance patient motivation and empowerment, SPECTRUM was designed as a varied mix of facts, exercises, feedback and reflection on expectations and initial experiences with CGM. Patients do not only work with hypothetical cases but also with their own CGM data and are to constantly review and improve their personal alarm settings and calibration procedures. This should enable the participants to an optimal cognitive and emotional CGM management.

Diabetes nurses that are interested in teaching SPECTRUM in their practices are trained themselves in doing so in a one-day training course. In this course they are learning how to use the training material provided for SPECTRUM.

Materials used by SPECTRUM

This training and treatment programme consists of specific sets of slides for adults (introductory session + 6 training modules), for parents with younger children and adolescents (introductory session + 5 training modules for each version). The slides are digitally available on a memory stick and in two different measurement units (mg/dl or mmol/l). In addition, a SPECTRUM folder is available that contains the detailed curricula in printed form for each of the three versions. The memory stick also contains a range of worksheets and checklists for the patients that can be printed for each participant in their required

measurement unit. SPECTRUM has been published in German language in January 2016 by Kirchheim Verlag, Mainz. Translations into other languages are planned.

Summary

SPECTRUM, a training and treatment programme for CGM, has been developed for patients with diabetes to make best use of CGM in daily life. To our knowledge SPECTRUM is the first comprehensive and product neutral CGM training and treatment programme for patients of all age groups. In view of the paucity of training programmes for CGM usage and that none was evaluated appropriately that far, we cannot comment on shortcomings and limitations that our programme might have; however, we hope that more such programme will become available in the next years as we believe in a much more widespread usage of CGM in the future.

Members of the SPECTRUM group (adult version)

- Dr med. Bernhard Gehr, Diabetes- und Stoffwechselzentrum, Fachklinik Bad Heilbrunn (Overall coordinator, coordinator for SPECTRUM for Adults, coordinator for Module 1)
- Dr med. Eberhard Biermann, München
- Sabine Carstensen, Diabetologische Schwerpunktpraxis, Bremen (until 2/2014)
- Dr med. Guido Freckmann, Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm
- Prof. Dr rer. nat. Lutz Heinemann, Düsseldorf
- Elke Kerth, Diabetologische Schwerpunktpraxis, Ludwigshafen (organization and coordination of the photo shootings)
- Dr med. Ralf Kolassa, Diabetologische Schwerpunktpraxis, Bergheim
- Prof. Dr phil. Dipl.-Psych. Bernhard Kulzer, Forschungsinstitut Diabetes-Akademie Bad Mergentheim (Coordinator for Module 0)
- Dr med. Andreas Liebl, Diabetes- und Stoffwechselzentrum, Fachklinik Bad Heilbrunn
- Rosalie Lohr, Diabetologie Campus Innenstadt, Ludwig-Maximilians-Universität München
- Dipl.-Psych. Berthold Maier, Forschungsinstitut Diabetes-Akademie Bad Mergentheim (editorial preparation of the slides and the curricula; organization and coordination of the photo shootings)
- Kerstin Remus, Kinder- und Jugendkrankenhaus auf der Bult, Hannover
- Claudia Sahm, Diabetologische Schwerpunktpraxis, Herrsching (Coordinator for Modules 4, 5 and 6)
- Dr med. Sandra Schlüter, Diabetologische Schwerpunktpraxis, Northeim
- Marcella Schulz-Braun, Saarlandklink Kreuznacher Diakonie, Fliedner Krankenhaus Neunkirchen
- Dr med. Thorsten Siegmund, Klinik für Endokrinologie, Diabetologie und Stoffwechsel, Isarklinikum München (Coordinator for Module 3)
- Ulrike Thurm, Diabetologische Schwerpunktpraxis, Berlin (Coordinator for Module 2)
- Marita Wernsing, Christliches Krankenhaus Quakenbrück

Members of the SPECTRUM group (paediatric version)

- Dr med. Martin Holder, Olgahospital, Klinikum Stuttgart (Coordinator for the paediatric version of SPECTRUM; organization and coordination of the paediatric photo shootings)
- Dr med. Dorothee Deiss, Endokrinologikum Berlin
- Dr med. Bettina Heidtmann, Katholisches Kinderkrankenhaus Wilhelmstift, Hamburg
- Prof. Dr rer. nat. Karin Lange, Medizinische Psychologie, Medizinische Hochschule Hannover (Editor of the paediatric curricula)
- Dr med. Carmen Ludwig-Seibold, Klinik für Kinder und Jugendliche, Oberschwabenklinik, Ravensburg
- Kerstin Remus, Kinder- und Jugendkrankenhaus auf der Bult, Hannover
- Dr med. Simone von Sengbusch, Klinik für Kinder- und Jugendmedizin, Universitätsklinikum Schleswig-Holstein, Campus Lübeck
- Tanja Wadien, Olgahospital, Klinikum Stuttgart (organization and coordination of the paediatric photo shootings)
- Dr med. Ralph Ziegler, Diabetologische Schwerpunktpraxis für Kinder und Jugendliche, Münster

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U.T. reported advisory activities for Roche Diagnostics and received speaking fees and reimbursement of travel costs from Abbott, Animas, Dexcom, Johnson & Johnson, Nintamed, Roche Diagnostics, Medtronic and Ypsomed.

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ORCID

Andreas Liebl http://orcid.org/0000-0002-0900-1160
Simone von Sengbusch http://orcid.org/0000-0003-4903-3711

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