UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Abbott Diabetes Care Inc.
Petitioner,

v.

DexCom, Inc.
Patent Owner.

IPR2024-00840
Patent No. 9,119,528

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DECLARATION OF SYLVIA D. HALL-ELLIS, PH.D.

I. INTRODUCTION

1. My name is Sylvia D. Hall-Ellis. I have been retained as an expert by Abbott Diabetes Care Inc. ("Abbott").

2. I have written this report at the request of Abbott to provide my expert opinion regarding the authenticity and public accessibility of several journal publications, books, and documents. My report sets forth my opinions in detail and provides the basis for my opinions regarding the public accessibility of these publications.

3. I reserve the right to supplement or amend my opinions, and bases for them, in response to any additional evidence, testimony, discovery, argument, and/or other additional information that may be provided to me after the date of this report.

4. I am being compensated for my time spent working on this matter at my normal consulting rate of $400 per hour, plus reimbursement for any additional reasonable expenses. My compensation is not in any way tied to the content of this report, the substance of my opinions, or the outcome of this litigation. I have no other interests in this proceeding or with any of the parties.

5. All of the materials that I considered are discussed explicitly in this declaration.

II. QUALIFICATIONS

6. I am currently an Adjunct Professor in the School of Information at San José State University. I obtained a Master of Library Science from the University of North Texas in 1972 and a Ph.D. in Library and Information Science from the University of Pittsburgh in 1985. Over the last fifty-five years, I have held various positions in the field of library and information resources. I was first employed as a librarian in 1966 and have been involved in the field of library sciences since, holding numerous positions.

7. I am a member of the American Library Association (ALA) and its Association for Library Collections & Technical Services (ALCTS) Division (now known as CORE), and I served on the Committee on Cataloging: Resource and Description (which wrote the new cataloging rules) and as the chair of the Committee for Education and Training of Catalogers and the Competencies and Education for a Career in Cataloging Interest Group. I also served as the Chair of the ALCTS Division's Task Force on Competencies and Education for a Career in Cataloging. Additionally, I have served as the Chair for the ALA Office of Diversity's Committee on Diversity, as a member of the national Board of Directors for REFORMA, as a member of the Editorial Board for the ALCTS premier cataloging journal, *Library Resources and Technical Services,* a member of the Membership Committee for the Library Research Round Table (LRRT) of

the American Library Association, and a member of the LRRT Nominating Committee. Currently I serve as a member of the CORE Margaret Mann Citation Committee.

8. I have also given over one hundred presentations in the field, including several on library cataloging systems and Machine-Readable Cataloging ("MARC") standards. My current research interests include library cataloging systems, metadata, and organization of electronic resources.

9. My full curriculum vitae is attached hereto as Appendix A to this report.

III. LIBRARY CATALOGING PRACTICES

10. I am fully familiar with the library cataloging standard known as the MARC standard, which is an industry-wide standard method of storing and organizing library catalog information.[1] MARC was first developed in the 1960s by the Library of Congress. A MARC-compatible library is one that has a catalog consisting of individual MARC records for each of its items. Today, MARC is the primary communications protocol for the transfer and storage of bibliographic

[1] The full text of the standard is available from the Library of Congress at http://www.loc.gov/marc/bibliographic/

metadata in libraries.[2]

11. A MARC record comprises several fields, each of which contains specific data about the work. Each field is identified by a standardized, unique, three-digit code corresponding to the type of data that follow. For example, a work's title is recorded in field 245, the primary author of the work is recorded in field 100, an item's International Standard Book Number ("ISBN") is recorded in field 020, an item's International Standard Serial Number ("ISSN") is recorded in field 022, an item's Library of Congress call number is recorded in field 050, and the publication date is recorded in field 260 under the subfield "c." If a work is a periodical, then its publication frequency is recorded in field 310, and the publication dates (e.g., the first and last publication) are recorded in field 362, which is also referred to as the enumeration/chronology field.

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[2] Almost every major library in the world is MARC-compatible. *See, e.g.*, *MARC Frequently Asked Questions (FAQ)*, Library of Congress, https://www.loc.gov/marc/faq.html (last visited February 20, 2024) ("MARC is the acronym for MAchine-Readable Cataloging. It defines a data format that emerged from a Library of Congress-led initiative that began nearly fifty years ago. It provides the mechanism by which computers exchange, use, and interpret bibliographic information, and its data elements make up the foundation of most library catalogs used today."). MARC is the ANSI/NISO Z39.2-1994 (reaffirmed 2016) standard for Information Interchange Format.

12. The library that created the record is recorded in field 040 in subfield "a" with a unique library code. When viewing the MARC record online via Online Computer Library Center's ("OCLC") bibliographic database, hovering over this code with the mouse reveals the full name of the library. I used this method of "mousing over" the library codes in the OCLC database to identify the originating library for the MARC records discussed in this report. Where this "mouse over" option was not available, I consulted the Directory of OCLC Libraries to identify the institution that created the MARC record.[3]

13. MARC records also include several fields that include subject matter classification information. An overview of MARC record fields is available through the Library of Congress.[4] For example, 6XX fields are termed "Subject Access Fields."[5] Among these, for example, is the 650 field; this is the "Subject Added Entry – Topical Term" field.[6] The 650 field is a "[s]ubject added entry in which the entry element is a topical term." These entries "are assigned to a bibliographic record to provide access according to generally accepted thesaurus-building rules (e.g., *Library of Congress Subject Headings* (LCSH), *Medical*

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[3] https://www.oclc.org/en/contacts/libraries.html

[4] http://www.loc.gov/marc/bibliographic/

[5] http://www.loc.gov/marc/bibliographic/bd6xx.html

[6] http://www.loc.gov/marc/bibliographic/bd650.html

Subject Headings (MeSH))." Further, MARC records include call numbers, which themselves include a classification number. For example, the 050 field is the "Library of Congress Call Number."[7] A defined portion of the Library of Congress Call Number is the classification number, and "source of the classification number is *Library of Congress Classification* and the *LC Classification-Additions and Changes*." Thus, included in the 050 field is a subject matter classification. Each item in a library has a single classification number. A library selects a classification scheme (*e.g.*, the Library of Congress Classification scheme just described or a similar scheme such as the Dewey Decimal Classification scheme) and uses it consistently. When the Library of Congress assigns the classification number, it appears as part of the 050 field. If a local library assigns the classification number, it appears in a 090 field. In either scenario, the MARC record includes a classification number that represents a subject matter classification.

14. The OCLC was created "to establish, maintain and operate a computerized library network and to promote the evolution of library use, of libraries themselves, and of librarianship, and to provide processes and products for the benefit of library users and libraries, including such objectives as increasing

[7] http://www.loc.gov/marc/bibliographic/bd050.html

availability of library resources to individual library patrons and reducing the rate of rise of library per-unit costs, all for the fundamental public purpose of furthering ease of access to and use of the ever-expanding body of worldwide scientific, literary and educational knowledge and information."[8] Among other services, OCLC and its members are responsible for maintaining the WorldCat database,[9] used by independent and institutional libraries throughout the world.

15. OCLC also provides its members online access to MARC records through its OCLC bibliographic database. When an OCLC member institution acquires a work, it creates a MARC record for this work in its computer catalog system in the ordinary course of its business. MARC records created at the Library of Congress are directly uploaded or may be tape-loaded into the OCLC database through a subscription to MARC Distribution Services daily or weekly. Once the MARC record is created by a cataloger at an OCLC member institution or is tape-loaded from a participating institution, the MARC record is then made available to any other OCLC members online, and therefore made available to the public. Accordingly, once the MARC record is created by a cataloger at an OCLC member

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[8] Third Article, Amended Articles of Incorporation of OCLC Online Computer Library Center, Incorporated (available at https://www.oclc.org/content/dam/oclc/membership/articles-of-incorporation.pdf).

[9] http://www.worldcat.org/

institution or is tape-loaded from the Library of Congress or another library anywhere in the world, any publication corresponding to the MARC record has been cataloged and indexed according to its subject matter such that a person interested in that subject matter could, with reasonable diligence, locate and access the publication through any library with access to the OCLC bibliographic database or through the Library of Congress.

16. When an OCLC member institution creates a new MARC record, OCLC automatically supplies the date of creation for that record. The date of creation for the MARC record appears in the fixed field (008), characters 00 through 05. The MARC record creation date reflects the date on which, or shortly after which, the item was first acquired or cataloged. Initially, field 005 of the MARC record is automatically populated with the date the MARC record was created in year, month, day format (YYYYMMDD) (some of the newer library catalog systems also include hour, minute, second (HHMMSS)). Thereafter, the library's computer system may automatically update the date in field 005 every time the library updates the MARC record (*e.g.*, to reflect that an item has been moved to a different shelving location within the library). Field 005 is visible when viewing a MARC record via an appropriate computerized interface, but when a MARC record is printed to hardcopy, no "005" label appears. The initial field 005 date (*i.e.*, the date the MARC record was created) does appear, however,

next to the label "Entered."[10] The date upon which the most recent update to field 005 occurred also appears, next to the label "Replaced." Thus, when an item's MARC record has been printed to hardcopy—as is the case with the exhibits to this report—the date reflected next to the label "Entered" is necessarily on or after the date the library first cataloged and indexed the underlying item.

17. Once one library has cataloged and indexed a publication by creating a MARC record for that publication, other libraries that receive the publication do not create additional MARC records—the other libraries instead rely on the original MARC record. They may update or revise the MARC record to ensure accuracy, but they do not replace or duplicate it. This practice does more than save libraries from duplicating labor. It also enhances the accuracy of MARC records. Further, it allows librarians around the world to know that a particular MARC record is authoritative (in contrast, a hypothetical system wherein duplicative records were created would result in confusion as to which record is authoritative).

18. The date of creation of the MARC record by a cataloger at an OCLC

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[10] In this report, I sometimes refer to the "Entered" entry as Field 008, characters 00-05. Field 005 is visible when viewing a MARC record via an appropriate computerized interface. But when a MARC record is printed directly to hardcopy from the OCLC database, the "005" label is not shown. The date in the 005 field instead appears next to the label "Replaced."

member institution reflects when the underlying item is accessible to the public. Upwards of two-thirds to three-quarters of book sales to libraries come from a jobber or wholesaler for online and print resources. These resellers make it their business to provide books to their customers as fast as possible, often providing turnaround times of only a single day after publication. Libraries purchase a significant portion of the balance of their books directly from publishers themselves, which provide delivery on a similarly expedited schedule. In general, libraries make these purchases throughout the year as the books are published and shelve the books as soon thereafter as possible in order to make the books available to their patrons. Thus, books are generally available at libraries across the country within just a few days of publication.

19. Catalogers can create MARC records for all types of print, online, and digital resources. For example, MARC records cover serial publications, including both serially-published monographs and journals. OCLC hosts MARC records for more than 320 million serial publications. Serial publications are those publications that have the same collective title but are intended to be continued indefinitely with enumeration such as a volume or issue number (*e.g.*, magazines, journals, etc.). In the OCLC bibliographic database, the first issue or volume of the monographic serial is typically cataloged (*i.e.*, a corresponding MARC record is created), but the date is left open-ended with the use of a punctuation mark such

as a dash. MARC records for serial publications represent the entire run of the title. With knowledge of the first issue or volume published, future issues or volumes can be predicted based on the information provided in the MARC record, for example in field 362. In my extensive professional experience, is it highly unusual for a library to stop collecting and shelving a serial publication prior to the time of its cessation. If a subscription to a serial publication ends or is cancelled, the library will denote that it has stopped receiving new issues or volumes by filling in the end date in the MARC record.

20. The handling of printed journal subscriptions is shown on the covers of individual issues. As was the best practice among libraries, issues arrived at a central facility and were immediately received, verified as part of a subscription, checked in, and stamped with the institution's name and date. Determining that the issue was part of the library subscription ensured that the entire set of publications for the year had been received so that they could be professionally bound and retained. This process also verified that each of the published issues arrived so that the library staff did not have to request or claim an issue that did not arrive as expected. In large public libraries with branches and multi-campus libraries within academic institutions, the journals were sorted and delivered to the subscribing unit. The issues were frequently stamped again to acknowledge receipt. The new issue was placed in the public area; the older issue was stored so that it remained

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available.

21. The foregoing process has been standard library practice longer than I have been working in the profession. I first learned the steps in the process in the late 1970s and later supervised it. Although the checking in process has become automated and now links electronically to holdings records for the MARC record for each serial title, the manual stamping and placing the issue in a public area has not changed for 50 years. Unless I note otherwise below in reference to a specific serial publication, it is my expert opinion that this standard protocol was followed for each of the serial publications discussed below.

22. In preparing this report, I used authoritative databases, such as the OCLC bibliographic database and the Library of Congress Online Catalog, to confirm citation details of the various publications discussed.

23. *Indexing*. A researcher may discover material relevant to his or her topic in a variety of ways. One common means of discovery is to search for relevant information in an index of periodical and other publications. Having found relevant material, the researcher will then normally obtain it online, look for it in libraries, or purchase it from the publisher, a bookstore, a document delivery service, or other provider. Sometimes, the date of a document's public accessibility will involve both indexing and library date information. However, date information for indexing entries is often unavailable. This is especially true

for online indices.

24. Indexing services use a wide variety of controlled vocabularies to provide subject access and other means of discovering the content of documents. The formats in which these access terms are presented vary from service to service.

25. Online indexing services commonly provide bibliographic information, abstracts, and full-text copies of the indexed publications, along with a list of the documents cited in the indexed publication. These services also often provide lists of publications that cite a given document. A citation of a document is evidence that the document was publicly accessible and in use by researchers no later than the publication date of the citing document.

26. Before the widespread development of online databases to index articles in journals, magazines, conference papers, and technical reports, libraries purchased printed volumes of indices. Graduate library school education mandated that students learn about the bibliographic control of disciplines, the prominent indexing volumes, and searching strategies required to use them effectively and efficiently. Half of the courses that I studied in library school were focused on the bibliography and resources in academic disciplines.

27. Librarians consulted with information seekers to verify citations, check availability in union catalogs, printed books catalogs, the OCLC database, and make formal requests for materials (e.g., books, conference proceedings,

journal articles). Requests were transmitted using Telex machines, rudimentary email systems, and the United States Postal Service. During my career, I have performed and supervised staff who handled these resource sharing tasks.

28. A major firm known for the breadth of subjects and comprehensive treatment in the preparation of index volumes, the H. W. Wilson Company offered these reference resources since the firm was founded in 1898. The *Reader's Guide to Periodical Literature* is one of the best-known titles available from H. W. Wilson. Each volume includes a comprehensive index for 300 of the most popular and important periodicals published in the United States and Canada. Information seekers have subject access expressed in plain language terminology, author access, and cross references to find the desired results from their searches. The family of index titles included *Science & Technology Index*, *Business Periodicals*, *Applied Science & Technology Index, Humanities Index, Biological & Agricultural Index*, and *Industrial Arts Index*. These printed indices have been superseded by digital database offerings available to information seekers through Ebsco.

29. Information seekers also used printed versions of *Chemical Abstracts* and *Index Medicus* to locate articles, scientific reports, and research papers. *Chemical Abstracts* began publication in 1907 and by 2007 its databases

"contained more than 27 million records of journal and patent literature."[11] In 2010, *Chemical Abstracts* discontinued the print index. Access is now available through two electronic databases: *CAplus* and *Registry*.[12] *Index Medicus* is a bibliographic index to medical science information, started in 1879.[13] Currently, *PubMed* includes the content that had been published as *Index Medicus*.[14]

30. Established in 1836 as part of the Surgeon General of the Army's Office, the National Library of Medicine (NLM) has been instrumental in the

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[11] Chemical Abstracts Service, "CAS History," *available at* https://www.cas.org/about/cas-history (last accessed February 20, 2024); American Chemical Society, "Chemical Abstracts Service," *available at* https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/cas.html (last accessed February 20, 2024).

[12] American Chemical Society, "Chemical Abstracts Service," *available at* https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/cas.html (last accessed February 20, 2024).

[13] Stephen Greenberg and Patricia Gallagher, "The great contribution: *Index Medicus*, *Index-Catalogue*, and IndexCast," *Journal of Medical Library Association*, April 2009, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2670211/ (last accessed February 20, 2024).

[14] U.S. National Library of Medicine, "List of All Journals Cited in PubMed®," https://www.nlm.nih.gov/bsd/serfile_addedinfo.html (last accessed February 20, 2024).

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development of access to medical books, journals, and research publications. In the 1970s, NLM introduced MEDLINE, followed by "the establishment of the National Center for Biotechnology Information in 1988, the introduction of free MEDLINE in 1997, the creation of consumer-friendly MedlinePlus in 1998, and the introduction of ClinicalTrials.gov in 2000."[15]

31. Online indexing services such as *Google Scholar*[16] or *ScienceDirect*[17] commonly provide bibliographic information, abstracts, and full-text copies of the indexed publications, along with a list of the documents cited in the indexed publication. These services also often provide lists of publications that cite a given document. A citation of a document by another is evidence that the document was publicly accessible and in use no later than the publication date of the citing document.

32. *Internet Archive.* Founded in 1996, the Internet Archive, a 501(c)(3) non-profit, is building a digital library of Internet sites and other cultural artifacts in digital form.[18] Like a paper library, the Internet Archive provides free access to

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[15] U.S. National Library of Medicine, "A Brief History of NLM," available at https://www.nlm.nih.gov/about/briefhistory.html

[16] https://scholar.google.com/

[17] https://www.sciencedirect.com/

[18] https://archive.org/

researchers, historians, scholars, the print disabled, and the members of the public. The organization's mission is to provide Universal Access to All Knowledge.

33. The Internet Archive features 20+ years of web history accessible through the Wayback Machine and more than 625 library and other partners through our Archive-It program to identify important web pages. As the Internet Archive grew, so did its commitment to provide digital versions of other published works. Currently, the Internet Archive includes 330 billion web pages, 20 million books and texts, 4.5 million audio recordings (including 180,000 live concerts), 4 million videos (including 1.6 million Television News programs), 3 million images, and 200,000 software programs.

34. The Internet Archive maintains an archive of webpages collected from the Internet using software called a crawler. Crawlers automatically create a snapshot of webpages as they existed at a certain point in time. The WayBack Machine is an application using a crawler created by the Internet Archive to search its archive of Web page URLs and to represent, graphically, the date of each crawler capture. The Internet Archive captures data that is publicly accessible. Some sites are "not archived because they were password protected, blocked by robots.txt, or otherwise inaccessible to our automated systems. Site owners might

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have also requested that their sites be excluded from the WayBack Machine."[19] Many Internet Archive captures made by the WayBack Machine have a banner at the top with the capture date prominently displayed. Other dates when captures of the same URL have been made are indicated to the right and left of the date provided in the banner. Some captures may lack this banner. In any case, the URL for the capture begins with the identification of the Internet Archive page (e.g., http://web.archive.org/web/) followed by information that dates and time stamps the capture as follows: year in yyyy, month in mm, day in dd, time code in hh:mm:ss (e.g., 20071120082013, or November 20, 2007 at 8:20:13 a.m.). These elements are then followed by the URL of the original capture site. When links are active, the WayBack Machine is programed to produce the archived file with the closest available date (not the closest available prior date) to the page upon which the link appeared and was clicked. I and other librarian professionals are familiar with the Internet Archive and the Wayback Machine.[20]

IV. PRELIMINARIES

35. *Scope of this declaration.* I am not an attorney and will not offer opinions on the law. I am, however, rendering my expert opinion on the

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[19] https://help.archive.org/help/using-the-wayback-machine/.

[20] For more information about the Internet Archive see the WayBack Machine FAQ, https://archive.org/about/faqs.php#The_Wayback_Machine.

authenticity of the documents referenced herein and when and how each of these documents was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located the documents before October 30, 2012.

36. I am informed by counsel that a printed publication qualifies as publicly accessible as of the date it was disseminated or otherwise made available such that a person interested in and ordinarily skilled in the relevant subject matter could locate it through the exercise of ordinary diligence.

37. While I understand that the determination of public accessibility under the foregoing standard rests on a case-by-case analysis of the facts particular to an individual publication, I also understand that a printed publication is rendered "publicly accessible" if it is cataloged and indexed by a library such that a person interested in the relevant subject matter could locate it exercising reasonable diligence (*i.e.*, I understand that cataloging and indexing by a library in a manner that permits a person of ordinary skill in the relevant subject matter to locate the publication is sufficient, though there are other ways that a printed publication may qualify as publicly accessible). One manner of sufficient indexing is indexing according to subject matter category. I understand that the cataloging and indexing by a single library of a single instance of a particular printed publication is sufficient, even if the single library is in a foreign country. I understand that, even

if access to a library is restricted, a printed publication that has been cataloged and indexed therein is publicly accessible so long as a presumption is raised that the portion of the public concerned with the relevant subject matter would know of the printed publication. I also understand that the cataloging and indexing of information that would guide a person interested in the relevant subject matter to the printed publication, such as the cataloging and indexing of an abstract for the printed publication, is sufficient to render the printed publication publicly accessible.

38. I understand that routine business practices, such as general library cataloging and indexing practices, can be used to establish an approximate date on which a printed publication became publicly accessible.

39. *Persons of ordinary skill in the art*. I am told by counsel that the subject matter of this proceeding relates generally to researching and analyzing data from devices used to monitor glycemic levels and/or other analytes in biological fluids, or in the development of methods, devices, or algorithms to generate alarms for hypoglycemia, impending hypoglycemia, hyperglycemia, impending hyperglycemia, metabolites or analytes, or other findings relevant to care of people with diabetes and/or other medical conditions.

40. I have been informed by counsel that a "person of ordinary skill in the art at the time of the invention" (POSITA) is a hypothetical person who is

presumed to be familiar with the relevant field and its literature at the time of the inventions. This hypothetical person is also a person of ordinary creativity, capable of understanding the scientific principles applicable to the pertinent field.

41. I am told by counsel that persons of ordinary skill in this subject matter or art would have had a Bachelor's degree in biomedical engineering, mathematics, statistics, or computer science (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, e.g., analyte sensors, including at least some experience in researching, developing, designing and/or evaluating (or supervising the same) methods, systems, or algorithms for providing indicators (e.g., alerts, alarms or other indicators) of analyte levels to users, or equivalent experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. Each of these POSITAs may be part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians involved in diagnosing, treatment and patient management relevant to the use of medical devices for measuring analyte levels, e.g., analyte sensors.

42. It is my opinion that such a person would have been engaged in research, learning through study and practice in the field and possibly through formal instruction the bibliographic resources relevant to his or her research.

Before October 30, 2012, such a person would have had access to a vast array of long-established print resources in development of methods, devices, or algorithms to generate alarms for hypoglycemia, impending hypoglycemia, hyperglycemia, impending hyperglycemia, metabolites or analytes as well as to a rich set of online resources providing indexing information, abstracts, and full text services for development of methods, devices, or algorithms to generate alarms for hypoglycemia, impending hypoglycemia, hyperglycemia, impending hyperglycemia, metabolites or analytes references.

43. Based on my experience working in research libraries with researchers having the qualifications described above, or even lesser qualifications, it is my opinion that such researchers would have been able to locate the material discussed herein on their own or with the assistance of a research librarian with relative ease using the tools and resources described herein.

V. PUBLICATIONS

A. Document 1: Exhibit 1006 ("Guerra")

44. Exhibit 1006 is a copy of the journal article "A Dynamic Risk Measure from Continuous Glucose Monitoring Data" by Stefania Guerra, Giovannni Sparacino, Andrea Facchinetti, Machele Schiavon, Chiara Dalla Man, and Claudio Cobelli (hereafter "Guerra"). The Guerra article was published in Volume 13, Number 8 of the journal *Diabetes Technology & Therapeutics* and was

found in the Indiana University South Bend Libraries (South Bend, Indiana). The Guerra article appears beginning on page 843 of this issue dated August 2011. Exhibit 1006 is a true and correct copy of the Guerra article (pages 843-852). Specifically, the text of the article is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. The Guerra article is also available in the National Library of Medicine,[21] from the publisher, Mary Ann Liebert,[22] and in the digital repositories *ResearchGate*[23] and *Semantic Scholar*.[24] Exhibit 1006 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1006 is a true and correct copy in a condition that creates no suspicion about its authenticity.

45. Attached hereto as Attachment 1A is a true and correct copy of the

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[21] https://pubmed.ncbi.nlm.nih.gov/21561370/

[22] https://www.liebertpub.com/doi/10.1089/dia.2011.0006?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[23] https://www.researchgate.net/publication/51116323_A_Dynamic_Risk_Measure_from_Continuous_Glucose_Monitoring_Data

[24] https://www.semanticscholar.org/paper/A-dynamic-risk-measure-from-continuous-glucose-Guerra-Sparacino/431b2aba36bc3a56ece95c1d3a5d4a8512465976

MARC record for the journal *Diabetes Technology & Therapeutics* at the Indiana University South Bend Libraries online catalog. Library ownership is indicated by the presence of the library's code ("IULA") in field 049. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 1A occurred on September 28, 2007, as shown in field 005 ("20070928"). I personally identified and retrieved the MARC record that is Attachment 1A.

46. Based on finding a print copy of Exhibit 1006 in the Indiana University South Bend Libraries and MARC record in its online library catalog attached as Attachment 1A, it is my opinion that the Guerra article published in the journal *Diabetes Technology & Therapeutics* was publicly accessible on or shortly after July 13, 2011, as shown on the publisher's website and July 27, 2011, as shown on the second page of Exhibit 1006. Attachment 1A also shows that Exhibit 1006 was catalogued with five descriptor terms reading "Diabetes $v Periodicals" (see Attachment 1B, Library of Congress subject heading sh2009123299), "Medical technology $v Periodicals" (see Attachment 1C, Library of Congress subject heading sh2010101256), "Diabetes Mellitus $x therapy $v periodicals" (see Attachment 1D, National Library of Medicine subject heading D003920), "Blood Glucose Self-Monitoring $v periodicals" (see Attachment 1E, National Library of Medicine subject heading D015190), and "Equipment and Supplies $v

periodicals" (see Attachment 1F, National Library of Medicine subject heading D004864) in the 650 fields.

47. As noted in the holdings information (362 field), the Indiana University South Bend Libraries has received the journal *Diabetes Technology & Therapeutics* since 1999 and continues to receive the publication. In view of the MARC record for Exhibit 1006, the Guerra article was publicly accessible on or shortly after July 27, 2011, because the serial title had been received, cataloged, and indexed at the Indiana University South Bend Libraries and made part of its online catalog database.

48. Attached hereto as Attachment 1G is a true and correct copy of the MARC record for the journal *Diabetes Technology & Therapeutics* obtained from the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 1G, that library code is "NSD," which means that the MARC record for this serial was cataloged as part of the National Serials Data Program at the Library of Congress. As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 39624503 on July 31, 1998, as shown in the "Entered" field ("19980731"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 1G occurred

on November 22, 2018, as shown in the "Replaced" field ("20181122"). I personally identified and retrieved the MARC record that is Attachment 1G. The "BLvl" entry in Attachment 2b is "s," which indicates that the journal *Diabetes Technology & Therapeutics* is a serial publication. Field 310 of Attachment 1G reads "Bimonthly, $b 2002-." Accordingly, the MARC record for Exhibit 1006 corresponds to the journal *Diabetes Technology & Therapeutics* from the time the serial title began and includes the date of the Guerra article.

49. Attachment 1G includes an entry in field 050 ("RC660.A1 $b.D528")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system) and an entry in field 060 ("W1 $b DI168D"), a subject matter consistent with the National Library of Medicine classification system. Attachment 1G further includes five descriptor terms reading "Diabetes $v Periodicals" (see Attachment 1B, Library of Congress subject heading sh2009123299), "Medical technology $v Periodicals" (see Attachment 1C, Library of Congress subject heading sh2010101256), "Diabetes Mellitus $x therapy $v periodicals" (see Attachment 1D, National Library of Medicine subject heading D003920), "Blood Glucose Self-Monitoring $v periodicals" (see Attachment 1E, National Library of Medicine subject heading D015190), and "Equipment and Supplies $v periodicals" (see Attachment 1F, National Library of Medicine subject

heading D004864) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 1G was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of July 31, 1998, the MARC record attached hereto as Attachment 1G was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly accessible on or before that same date through any library with access to the OCLC bibliographic database or through an individual library.

50. Attachment 1G indicates that the journal *Diabetes Technology & Therapeutics* as cataloged at the Library of Congress is currently available from 52 libraries. In view of the above, this issue of the journal *Diabetes Technology & Therapeutics* was publicly accessible on or shortly after July 27, 2011, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Indiana University South Bend Libraries. For these reasons, it is my opinion that Exhibit 1006 was published and accessible to the public on or shortly after July 27, 2011.

B. Document 2: Exhibit 1008 ("DexCom")

51. Attached hereto as Exhibit 1008 is a digital book, *DexCom™ STS™*

Continuous Glucose Monitoring System: User's Guide, (hereafter "DexCom") and issued by the firm DexCom, Inc. The DexCom book is identified as document LBL 9548 REV 03. I obtained the DexCom document from the Wayback Machine[25] and made the copies which comprise Exhibit 1008.[26] Specifically, the text of the DexCom document is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1008 was found within the custody of the issuing corporate entity – a place where, if authentic, a copy of this document would likely be.

52. The declaration prepared by Duncan Hall, Records Request Processor at the Internet Archive, indicates that the website on which the DexCom document can be found was available on October 23, 2007, and has been captured four times (Attachment 2A).

53. Based on the date recorded in the document, it is my opinion that the

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25 https://web.archive.org/web/20071023024953/http://www.dexcom.com/html/support_user_manuals.html

26 https://web.archive.org/web/20071009014038/http://www.dexcom.com/pdf/LBL9548rev03UsersGuide.pdf

digital book *DexCom™ STS™ Continuous Glucose Monitoring System: User's Guide* was available to the public on October 23, 2007, or shortly thereafter.

C. Document 3: Exhibit 1011 ("Sparacino")

54. Exhibit 1011 is a copy of the journal article "Glucose Concentration can be Predicted Ahead in Time from Continuous Glucose Monitoring Sensor Time-Series" by Giovanni Sparacino, Francesca Zanderigo, Stefano Corazza, Alberto Maran, Andrea Facchinetti, and Claudio Cobelli (hereafter "Sparacino"). The Sparacino article was published in Volume 54, Number 5 of the journal *IEEE Transactions on Bio-medical Engineering* and was found in the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The Sparacino article appears beginning on page 931 of this issue dated May 2007. Exhibit 1011 is a true and correct copy of the Sparacino article (pages 931-937). I obtained this copy of the article from the Linda Hall Library of Science, Engineering & Technology. Specifically, the text of the column is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1011 was found within the custody of a library – a place where, if authentic, a copy of this journal would likely be. Exhibit 1011 are true and correct copies in a condition that creates no suspicion about its authenticity.

55. The cover of the May 2007 issue of the journal *IEEE Transactions on*

Bio-medical Engineering has a stamp which shows that it was received, verified, and checked in on May 2, 2007. Therefore, in my experience, this issue of the journal *IEEE Transactions on Bio-medical Engineering* would have been available to users at the Linda Hall Library of Science, Engineering & Technology on that date.

56. Attached hereto as Attachment 3A is a true and correct copy of the MARC record for the journal *IEEE Transactions on Bio-medical Engineering* at the Linda Hall Library of Science, Engineering & Technology. Library ownership is indicated by the presence of the library's code ("LHL") in the 049 field. The most recent enhancement to Attachment 3A occurred on September 6, 2023, as shown in field 005 ("20230906"). I personally identified and retrieved the MARC record that is Attachment 3A. Attachment 3A also shows that Exhibit 1011 was catalogued with three descriptor terms reading "Biomedical engineering $v Periodicals" (see Attachment 3B, Library of Congress subject heading sh2007102015), "Medical electronics $v Periodicals" (see Attachment 3C, Library of Congress subject heading sh2010101221), and "Medical physics $v Periodicals" (see Attachment 3D, Library of Congress subject heading sh85083001 and Attachment 3E, Library of Congress subject heading sh85099890) in the 650 fields.

57. Based on finding a print copy of Exhibit 1011 in the Linda Hall

Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 3A, it is my opinion that the Sparacino article published in the journal *IEEE Transactions on Bio-Medical Engineering* was available at the Linda Hall Library of Science, Engineering & Technology on May 2, 2007.

58. As noted in the holdings information (field 362), the Linda Hall Library of Science, Engineering & Technology has received the journal *IEEE Transactions on Bio-Medical Engineering* since publication began under the current title in 1964 and continues to receive the publication.[27] In view of the MARC record for Exhibit 1011, the Sparacino article was publicly accessible in print on May 2, 2007, because the serial title had been received, cataloged, and indexed at the Linda Hall Library of Science, Engineering & Technology and made part of its catalog.

59. Attached hereto as Attachment 3F is a true and correct copy of the

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[27] The publication began under the title *Transactions of the IRE Professional Group on Medical Electronics* in January 1953, changed the title to the *IRE Transactions on Bio-Medical Electronics* in January 1955, and adopted the current title, *IEEE Transactions on Bio-Medical Engineering*, in January 1964. [28] https://journals.sagepub.com/doi/10.1177/193229681000400513?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

MARC record for the journal *IEEE Transactions on Bio-Medical Engineering* obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 3F. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 3F, that library code is "DLC," which means that the MARC record for this serial was cataloged at the Library of Congress. As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 1752544 on November 1, 1995. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 4f occurred on April 21, 2021, as shown in the "Replaced" field ("20210421"). The "BLvl" entry in Attachment 3F is "s," which indicates that the journal *IEEE Transactions on Bio-Medical Engineering* was a serial publication. Field 310 of Attachment 3F reads "Monthly, $b <Jan. 1979-." Accordingly, the MARC record for Exhibit 1011 corresponds to those issues of the journal *IEEE Transactions on Bio-Medical Engineering* during the time that the Sparacino article was published.

60. Attachment 3F further includes an entry in field 050 ("R895.A1 $b I25")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment 3F further includes an entry in field 060 ("W1

$b I223")—as described above, this includes a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 3F further includes three descriptor terms reading "Biomedical engineering $v Periodicals" (see Attachment 3B, Library of Congress subject heading sh2007102015), "Medical electronics $v Periodicals" (see Attachment 3C, Library of Congress subject heading sh2010101221), and "Medical physics $v Periodicals" (see Attachment 3D, Library of Congress subject heading sh85083001 and Attachment 3E, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 3F was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. Further, as of November 1, 1975, the MARC record attached hereto as Attachment 3F was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly accessible on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, the Sparacino article was publicly accessible in print as early as May 2, 2007, because by that time it had been received, cataloged, and indexed at the Linda Hall Library

of Science, Engineering & Technology.

61. Attachment 3F indicates that the journal *IEEE Transactions on Bio-Medical Engineering* as cataloged at the Library of Congress is currently available from 436 libraries. In view of the above, this issue of the journal *IEEE Transactions on Bio-Medical Engineering* was publicly accessible in print on May 2, 2007, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1011 was published and accessible to the public on May 2, 2007.

D. Document 4: Exhibit 1007 ("Hughes")

62. Exhibit 1007 is a copy of the journal article "Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green "Traffic" Lights Using Continuous Glucose Monitoring Abstract and Insulin Pump Data" by Colleen S. Hughes, Stephen D. Patek, Marc D. Breton, and Boris P. Kovatchev (hereafter "Hughes"). The Hughes article was published in Volume 4, Issue 5 of the open access *Journal of Diabetes Science and Technology* and was found in the National Library of Medicine (Bethesda, Maryland). The Hughes article appears beginning on page 1146 of this issue dated September 2010. Exhibit 1007 is a true and correct copy of the Hughes article (pages 1146-1155). I obtained this copy of the

article from the National Library of Medicine. Specifically, the text of the column is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1007 was found within the custody of a library – a place where, if authentic, a copy of this open access journal would likely be. Exhibit 1007 are true and correct copies in a condition that creates no suspicion about its authenticity.

63. Open access serials are published online and do not have traditional covers. Publishers indicate a publication date on their websites. Therefore, in my experience, this issue of the open access *Journal of Diabetes Science and Technology* would have been available to users at the National Library of Medicine on September 1, 2010, as indicated on the Sage Journals website.[28]

64. The Hughes article is also available through the National Library of Medicine[29] and the digital repository *ResearchGate*.[30]

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[28] https://journals.sagepub.com/doi/10.1177/193229681000400513?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[29] https://pubmed.ncbi.nlm.nih.gov/20920434/

[30] https://www.researchgate.net/publication/47335649_Hypoglycemia_Prevention_vi

65. Attached hereto as Attachment 4A is a true and correct copy of the MARC record for the open access *Journal of Diabetes Science and Technology* at the National Library of Medicine. Library ownership is indicated by the presence of the library's code ("DNLM") in the 935 field. The most recent enhancement to Attachment 4A occurred on February 9, 2024, as shown in field 005 ("20240209"). I personally identified and retrieved the MARC record that is Attachment 4A. Attachment 4A also shows that Exhibit 1007 was catalogued with a descriptor term reading "Diabetes Mellitus x| therapy v| Periodicals" (see Attachment 1D, National Library of Medicine subject heading D003920) in the 650 field.

66. Based on finding a digital copy of Exhibit 1007 in the National Library of Medicine and MARC record in its online library catalog attached as Attachment 4A, it is my opinion that the Hughes article published in the open access *Journal of Diabetes Science and Technology* was available at the National Library of Medicine on September 1, 2010.

67. As noted in the holdings information (field 362), the National Library of Medicine has received the open access *Journal of Diabetes Science and Technology* since publication began in January 2007 and continues to receive the

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a_Pump_Attenuation_and_Red-Yellow-Green_Traffic_Lights_Using_Continuous_Glucose_Monitoring_and_Insulin_Pump_Data

publication. In view of the MARC record for Exhibit 1007, the Hughes article was publicly accessible in digital form on September 1, 2010, because the serial title had been received, cataloged, and indexed at the National Library of Medicine and made part of its catalog.

68. Attached hereto as Attachment 4B is a true and correct copy of the MARC record for the open access *Journal of Diabetes Science and Technology* obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 4B. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 4B, that library code is "NSD," which means that the MARC record for this serial was cataloged as part of the National Serials Data Program at the Library of Congress. As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 70140637 on June 20, 2006. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 4B occurred on January 15, 2024, as shown in the "Replaced" field ("20240115"). The "BLvl" entry in Attachment 4B is "s," which indicates that the open access *Journal of Diabetes Science and Technology* was a serial publication. Field 310 of Attachment 4B reads "Bimonthly." Accordingly, the MARC record for Exhibit 1007 corresponds to those issues of the

open access *Journal of Diabetes Science and Technology* during the time that the Hughes article was published.

69. Attachment 4B further includes an entry in field 050 ("RC60.A1")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1")—as described above, this includes a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("616")—as described above, this includes a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 4B further includes two descriptor terms reading "Diabetes $v Periodicals" (see Attachment 1B, Library of Congress subject heading sh2009123299) and "Medical technology $v Periodicals" (see Attachment 1C, Library of Congress subject heading sh2010101256) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 4B was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. Further, as of June 20, 2006, the MARC record attached hereto as Attachment 4B was accessible through any library with access to the OCLC bibliographic database or the online catalog at a

library that subscribed to the open access serial, which means that the corresponding publication was publicly accessible on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, the Hughes article was publicly accessible in digital form as early as September 1, 2010, because by that time it had been received, cataloged, and indexed at the National Library of Medicine.

70. Attachment 4B indicates that the open access *Journal of Diabetes Science and Technology* as cataloged at the Library of Congress is currently available from 655 libraries. In view of the above, this issue of the open access *Journal of Diabetes Science and Technology* was publicly accessible on September 1, 2010, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1007 was published and accessible to the public on September 1, 2010.

E. Document 5: Exhibit 1010 ("Navigator Guide")

71. Attached hereto as Exhibit 1010 is a digital book, *FreeStyle Navigator® Guide Continuous Glucose Monitoring System User's Guide,* (hereafter "Navigator Guide") and issued by the firm Abbott Diabetes Care, Inc. The Abbott book is identified as document ART 16072 Rev. A and a May 2008 date, which is printed on the back cover ("05/08").

72. I downloaded the Abbott document from the Wayback Machine[31] and made the copies which comprise Exhibit 1010. The WayBack Machine indicates that Navigator Guide was posted on December 16, 2010. Specifically, the text of Navigator Guide is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1010 was found within the custody of the issuing corporate entity – a place where, if authentic, a copy of this document would likely be.

73. Further supporting my opinion that the Navigator Guide was available to the public is an affidavit prepared by Nathaniel E. Frank-White, Records Request Processor for the Internet Archive (Attachment 5). Mr. Frank-White provides the URL for the Navigator Guide which was captured by the WayBack Machine on December 16, 2010, at 3:05:36 a.m. (Exhibit B, page 4). The information in his affidavit supports the description of the Internet Archive and the WayBack Machine (see ¶ 32-34).

74. Based on the date recorded in the document, it is my opinion that the digital book *FreeStyle Navigator® Guide Continuous Glucose Monitoring System*

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31 https://web.archive.org/web/20101216030536/http://freestylenavigator.com/static/cms_workspace/document/FSN-User-Guide-ART16072_Rev-A-Web.pdf

User's Guide was accessible to the public at least by December 16, 2010.

VI. SUMMARY OF OPINIONS

75. In view of the foregoing, it is my opinion that the publications described above were publicly accessible at least by the corresponding date listed in the table below:

Document	Publication	Publicly Accessible
Exhibit 1006	Guerra, Stefania, Giovannni Sparacino, Andrea Facchinetti, Machele Schiavon, Chiara Dalla Man, and Claudio Cobelli. "A Dynamic Risk Measure from Continuous Glucose Monitoring Data." *Diabetes Technology & Therapeutics*, vol. 13, no. 8 (August 2011): 843-852.	July 27, 2011
Exhibit 1008	DexCom, Inc. *DexCom™ STS™ Continuous Glucose Monitoring System: User's Guide. LBL 9548 REV 03.* San Diego, CA: DexCom, c2006.	October 23, 2007
Exhibit 1011	Sparacino, Giovanni, Francesca Zanderigo, Stefano Corazza, Alberto Maran, Andrea Facchinetti, and Claudio Cobelli. "Glucose Concentration can be Predicted Ahead in Time from Continuous Glucose Monitoring Sensor Time-Series." *IEEE Transactions on Biomedical Engineering*, vol. 54, no. 5 (May 2007): 931-937.	May 2, 2007
Exhibit 1007	Hughes, Colleen S., Stephen D. Patek, Marc D. Breton, and Boris P. Kovatchev. "Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green "Traffic" Lights Using Continuous Glucose Monitoring Abstract and Insulin Pump Data." *Journal of Diabetes Science and Technology*, vol. 4, issue 5 (September 2010): 1146-1155.	September 1, 2010
Exhibit 1010	*FreeStyle Navigator Guide Continuous Glucose Monitoring System User's Guide.* ART 16072 Rev. A. Alameda, CA: Abbott Diabetes Care, Inc., c2008.	December 16, 2010

73. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

74. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

DATED: April 24, 2024

By: Sylvia D. Hall-Ellis

Sylvia D. Hall-Ellis, Ph.D.

Abbott Ex. 1027 - 43/400

Appendix A

CURRICULUM VITAE SYLVIA D. HALL-ELLIS

EDUCATION

Ph.D., University of Pittsburgh, Pittsburgh, Pennsylvania, 1985
M.P.S., University of Denver, Denver, Colorado, 2014
Post Graduate Studies, University of Texas – San Antonio, Texas, 1975-1976
M.L.S., University of North Texas, Denton, Texas, 1972
B.A., Rockford University, Rockford, Illinois, 1971

PROFESSIONAL EXPERIENCE

1981- **Consultant for higher education, non-profit organizations, and corporations.**

2002- **Adjunct Professor, School of Information, San José State University, San José, California.** Serve as part-time faculty member teaching graduate students in technical services (cataloging, bibliographic control, classification), "core courses," and special topics.

2014-2016 **Director, Grants and Resource Development, Colorado Community College System.** Provided leadership and vision to foster the continued growth of rigorous scholarship, innovative projects, and creative work for statewide system, 13 campuses, and 50 teaching sites serving 155,000 students. Responsible for leadership and ensured efficient functioning of contract and grants in compliance with state & federal requirements and successful implementation and management. Served as a subject matter expert and liaison for college Grant Directors for all issues relating to grants and subcontracts.

2010-2014 **Senior Grant Administrator, Morgridge College of Education, University of Denver (Colorado).** Provided leadership and vision to foster continued growth of rigorous scholarship, innovative research, and creative work in the Morgridge College of Education. Ensure that contract and grants processes function effectively and efficiently for 60 faculty and researchers with a focus on the successful progression and efficient management of grants totaling $13M. Worked effectively and collegially with Department Chairs and Program Coordinators on operational grant-related management activities and with a broad range of internal and external constituencies. Supported the dissemination and promotion of faculty research and scholarship to outside constituents at conferences and through publications. Assisted Principal Investigators and grant project teams by coaching, mentoring, and financial management.

2011-2013 **Interim Director & Assistant Dean, Westminster Law Library, Sturm College of Law, University of Denver.** Planned, organized, and directed all administrative activities for the library serving students, faculty, and alumni; oversaw the employment, retention, promotion, transfer and termination of library personnel; represented the library at professional conferences and public meetings; created and promoted a climate and culture of acceptance for new programs and services, a positive high-quality image of the law library, and that reflect the organization's values, encourage excellent performance, and reward high productivity and innovation; provided leadership and set strategic direction of the organization; ensured that the library provided excellent customer service through solution-oriented staff response to patron needs and by responsiveness and continuous improvement of the organization; promoted, developed, and maintained positive working relationships with colleagues and customers including key stakeholders and groups, higher education institutions, the legal community, other regional libraries and districts statewide, and national library organizations.

2007-2014 **Associate Professor, Library & Information Science, Morgridge College of Education, University of Denver (Colorado).** Served in leadership role and worked collaboratively in program, college, campus and community environments. Advised and supervised students, taught core and specialized courses at the graduate level in an integrative, student-centered learning environment. Served on LIS, College, and University committees, and maintained working relationships with colleagues in other academic units and information professionals in the Rocky Mountain region and beyond. Served on and chair doctoral student dissertation committees. Oversaw and facilitated the College and LIS graduate student association.

2002-2007 **Assistant Professor, Library & Information Science, College of Education, University of Denver (Colorado).** Served as tenure-track faculty member teaching graduate students in "core courses," resource description and access, service learning, and independent studies. Advised graduate students, participate on LIS and College committees, and serve on doctoral student dissertation committees. Oversaw and facilitated the LIS graduate student association and alumni association.

2000-2002 **Affiliate Faculty, Library & Information Science, College of Education, University of Denver (Colorado).** Served as part-time faculty member teaching graduate students in technical services (cataloging, bibliographic control, classification), "core courses," and special topics. Oversaw and facilitated the LIS graduate student association and alumni association.

2000-2001 **Special Assistant to the Secretary's Regional Representative, U.S. Department of Education, Region VIII, Denver, Colorado.** Served as the principal advisor and representative of the U. S. Secretary of Education's Regional Representative (SRR). Ensured the implementation of major goals of the SRR and the Secretary. Provided leadership on behalf of the SRR in contacts with high-level officials in Region VIII requiring sensitive policy interpretation in communication with senior Department officials to solve problems and resolve issues raised by State and local education officials. Served as the primary contact for School-to-Work/Career, Children's Health Insurance Program, and Safe and Drug-Free Schools. Delivered technical assistance to local education agencies and institutions of higher education in technology, professional development, and school construction.

1999-2000 **Catalog Librarian, Jefferson County Public Library, Lakewood, Colorado.** Performed original, copy cataloging and classification of library materials (English and Spanish) using standard library protocols; completed original descriptive cataloging and subject analysis; enhanced brief catalog and authority records in III.

1997-1999 **Development Officer, McREL International, Aurora, Colorado.** Served as senior member of corporate management team in strategic planning, development of proposals and contracts, implementation, and evaluation of new services, products, and programs for educational agencies. Provided creative leadership to corporate committees to solicit ideas, identify goals and objectives, plan, develop, present, and evaluate professional development opportunities.

1995-1997 **Education Specialist, Education Service Center, Region One, Edinburg, Texas.** Served as member of Administrative Cabinet team in strategic planning, development of proposals and contracts, implementation, and evaluation of telecommunications capabilities, services, products, and programs for 40 school districts serving 283,000 students in 7 counties. Provided creative leadership to regional and state committees to solicit ideas, identify strategic goals and objectives, plan, develop, present, and evaluate funding opportunities and professional development for 400 librarians.

1993-1996 **Assistant Professor of Library Science, Sam Houston State University, Huntsville, Texas.** Served a faculty member teaching 400 graduate students in technical services (cataloging, bibliographic control, classification), automation, and networking. Participated in distance education program and coordinated annual conference. Conducted university and Texas Library Association-funded field research focused on library collection development and academic achievement.

1992-1993 **Head Librarian, Rocky Mountain College of Art & Design, Denver, Colorado.** Responsible for the daily operation, selection and acquisition of materials, formulation of policies for library operations, media center, and photography/slides archives. Designed and implemented library automation and delivery of electronic resources to college community.

1981-1985 **Development Officer, PRLC, Inc., Pittsburgh, Pennsylvania.** Served as senior member of corporate management team in strategic planning, development of proposals and contracts, implementation, and evaluation of new services, products, and programs for 100 institutional member organizations. Coordinated the development of proposals and contracts totaling $4,000,000 annually. Provided creative leadership to corporate committees to solicit ideas, identify goals and objectives, plan, develop, present, and evaluate professional development opportunities.

1981 **Director of Library Development, Pennsylvania Department of Education, Harrisburg, Pennsylvania.** Responsible for statewide development, technical assistance, professional development, resource sharing, children's services, institutional library services, networking, and state aid program for all libraries throughout the Commonwealth. Functioned as liaison to Governor's Advisory Council, LSCA Advisory Council, District Administrators, private colleges, universities, consortia managers, and network directors. Supervised $14,000,000 formula-based state aid program and $3,000,000 grant awards to individual libraries, consortia, and networks.

1978-1981 **Assistant Director, Southern Tier Library System, Corning, New York.** Coordinated operation of system-wide programs (technical assistance, professional development, resource sharing, technical services, outreach) to 40 public libraries in 5 counties serving 500,000 residents. Solicited ideas, identified goals, sponsored, and evaluated professional development opportunities and technical assistance sessions.

1976-1978 **Division Librarian for Technical Services, Corpus Christi Public Libraries, Corpus Christi, Texas.** Provided leadership in acquisitions, cataloging, serials control, and processing for main library and 4 branches serving 250,000 residents. Participated as senior member of library management team. Compiled and prepared technical evaluations, reports, and statistical analyses of Division operations to measure the achievement and cost of annual goals, objectives, and staff performance.

1975-1976 **System Coordinator, San Antonio Major Resource Center, San Antonio, Texas.** Served as senior member of the management team for District X Office, charged to provide technical assistance, resource sharing, media services, and professional development to librarians and staff representing 30 public library jurisdictions in 21 counties serving 1,500,000 residents. Functioned as liaison to System Director, staff, and members of governing bodies with the System Board of Directors and the Texas State Library and Historical Commission. Prepared LSCA grant applications and monitored awards totaling $1,100,000 annually.

1973-1975	**Bilingual Branch Librarian, San Antonio Public Library, San Antonio, Texas.** Worked as librarian providing reference, information, and readers' advisory services in branch serving 50,000 Spanish-speaking residents in southwest San Antonio. Participated in collection development and resource acquisition activities, specializing in children's work, Spanish language resources, and multicultural studies.
1972-1973	**Librarian, Holding Institute, Laredo, Texas.** Worked as high school librarian serving 500 boarding students in Spanish-speaking environment of private school. Provided reference, research assistance, and library instruction to students and 35 faculty members.
1966-1971	**Rockford Public Library, Rockford, Illinois.** Worked in branches as part-time as a Library Assistant, Clerk, and Page in city library serving 150,000 residents.

PUBLICATIONS

Editor-reviewed Monographs (Completed and in Progress)

Hall-Ellis, Sylvia D., and Mary Beth Weber. *Contemporary Cataloging in an RDA Environment: A Handbook for Students and Practitioners.* Chicago, IL: American Library Association. Under contract & In development.

RDA Testing: Lessons Learned and Challenges Revealed. Sylvia D. Hall-Ellis and Robert O. Ellett, Jr., eds. Binghamton, N.Y.: Haworth, 2012. 128 p.

Hall-Ellis, Sylvia D., Stacey L. Bowers, Christopher D. Hudson, and M. Claire Williamson. *Librarian's Handbook for Seeking, Writing, and Managing Grants.* Santa Barbara, Calif.: Libraries Unlimited, 2011. 315 p.

Hall-Ellis, Sylvia D., with Ann Jerabek, and Merrie W. Valliant. *Contemporary Cataloging: A Handbook for Practitioners and Students.* Open access text. Athens, GA: University of Georgia System Regents, 2011. 767 p.

Grealy, Deborah S. and Sylvia D. Hall-Ellis. *From Research to Practice: The Scholarship of Teaching and Learning in LIS Education.* Westport, Conn.: Libraries Unlimited, 2009. 175 p.

Hall-Ellis, Sylvia D. with J. Ann Jerabek. *Grants for School Libraries.* Westport, Conn.: Libraries Unlimited, 2003. 197 p.

Hall-Ellis, Sylvia D., Doris Meyer, Frank W. Hoffmann, with J. Ann Jerabek. *Grant Writing for Small Libraries and School Library Media Centers.* Boulder, Colo.: NetLibrary, 2001. 173 p.

Hall-Ellis, Sylvia D., Doris Meyer, Frank W. Hoffmann, with J. Ann Jerabek. *Grant Writing for Small Libraries and School Library Media Centers.* Englewood, Colo: Libraries Unlimited, 2000. 173 p.

Editor-reviewed Chapters (Completed and In Progress)

Hall-Ellis, Sylvia D. "Prepared to Lead: Talent, Skills, and Competencies." In *Telling the Technical Services Story*. Chicago, IL: American Library Association, 2020. Program Presentation for Re-Accreditation by the American Library Association, School of Information, San Jose State University, 2022.

Hall-Ellis, Sylvia D. "Grant Writing and Sponsored Research Funding for Academic Librarians." In *The New Librarianship.* Vol. 4. Bradford Lee Eden, ed. New York: Scarecrow Press, 2015. (pp. 163-174)

Hall-Ellis, Sylvia D. "Organizing Information: Technical Services." In *Information Services Today: An Introduction.* Sandra Hirsch, ed. Lantham, Md.: Rowman and Littlefield, 2015. (pp. 139-148)

Hall-Ellis, Sylvia D. "Metadata, MARC, and More." In *Rethinking Technical Services, Considering Our Profession and Ourselves: What's the Future of Our Profession?* Mary Beth Weber, ed. Lantham, Md.: Rowman and Littlefield, 2015. (pp. 29-55)

Hall-Ellis, Sylvia D., ed. "Contingent Faculty: Non-Tenure Track Faculty Series." In the *Faculty Personnel Guidelines Relating to Appointment, Promotion, and Tenure.* November 2011. Denver, Colo.: University of Denver, 2011. 42 p.

Hall-Ellis, Sylvia D., ed. "Standard VII: Information Resources." In the *Sturm College of Law Self-Study Presentation for Accreditation by the American Bar Association.* Denver, Colo.: University of Denver, Sturm College of Law, 2011. 20 p.

Hall-Ellis, Sylvia D. "Applying for Grants from Foundations, Corporations, or Government." In *The Volunteers' Guide to Fundraising: Raise Money for Your School Team, Library or Community Group.* 1st ed. Ilona M. Bray, ed. Berkeley, Calif.: Nolo, 2011. (pp. 1-38 on accompanying disc)

Hall-Ellis, Sylvia D., ed. "Standard III: The Faculty." In the *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association.* Denver, Colo.: University of Denver, Morgridge College of Education, 2010. 22 p.

Hall-Ellis, Sylvia D. "Library and Information Science Programs and Education for Catalogers and Metadata Specialists: Challenges for the Twenty-first Century." In *Conversations with Catalogers in the Twenty-First Century.* Elaine R. Sanchez, ed. Santa Barbara, Calif.: ABC-Clio, 2010. (pp. 226-254)

Hall-Ellis, Sylvia D., ed. "Standard III: The Faculty." In the *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association.* Denver, Colo.: University of Denver, College of Education, 2003. 15 p.

Lesesne, Teri S. and Sylvia D. Hall-Ellis. "The Selection, Evaluation, and Integration of Culturally Authentic Texts: A Case for Making the Online Catalog Reflect Parallel Cultures." In *Literacy: Traditional, Cultural, Technological.* Pittsburgh, Pa.: International Association of School Librarianship, 1995. (pp. 110-113)

Lesesne, Teri S. and Sylvia D. Hall-Ellis. *The Selection, Evaluation, and Integration of Culturally Authentic Texts: A Case for Making the Online Catalog Reflect Parallel Cultures.* In *Conference Proceedings* of the 23rd Annual International Association of School Librarianship, Pittsburgh, Pennsylvania, July 17-22, 1994. ERIC Document ED374816. 17 p.

Hall-Ellis, Sylvia D. "Curriculum Folio for School Library Media Specialist Programs." In the *National Council for Accreditation of Teacher Education Self-Study for Sam Houston State University.* Huntsville, Tex.: Sam Houston State University, College of Education and Applied Science, 1994. 25 p.

Bruntjen, Scott and Sylvia D. Hall. "Attempting to Automate: Lessons Learned Over Five Years." In *Advances in Library Administration*. Volume 4. Weston, Conn.: JAI Press, 1985. (pp. 177-192)

Peer-Reviewed Journal Articles (Completed and In Progress)

Hall-Ellis-Sylvia D. "Job Design for Cataloging and Metadata Librarians." Submitted to *Journal of Library Administration.* In progress.

Hall-Ellis, Sylvia D. "The Relationship of Situational Leadership and the Dreyfus Model of Skill Acquisition for Supervisors in Cataloging and Metadata Services." To be submitted to *Library Resources and Technical Services.* In progress.

Hall-Ellis, Sylvia D. *The Relationship of Core Competencies on Learning Outcomes and Employers' Expectations for Catalog Librarians and Metadata Specialists.* To be submitted to the *Journal of Education for Library and Information Science.* In progress.

Hall-Ellis, Sylvia D. "Building Cataloger Competencies: The Dreyfus Model as a Prototype for the Education and Professional Development of Catalog Librarians and Metadata Specialists in Bibliographic Control." To be submitted to the *Cataloging & Classification Quarterly.* In progress.

Hall-Ellis, Sylvia D. "Descriptive Impressions of Entry-Level Cataloger and Metadata Specialists Positions, 2000-2016: Reflections and Trends." To be submitted to *Library Resources and Technical Services.* In progress.

Hall-Ellis, Sylvia D. "Competencies for Metadata and Cataloging Leaders: What Employers Expect as Reflected in Position Descriptions, 2000-2016." *Cataloging & Classification Quarterly.* In progress.

Hall-Ellis, Sylvia D. "Stackable Micro-credentials – A Framework for the Future." *The Bottom Line 29*, no. 4 (April 2016), http://www.emeraldinsight.com/doi/pdfplus/10.1108/BL-02-2016-0006
Ellis, Sylvia D. "Succession Planning and Staff Development – A Winning Combination." *The Bottom Line*, 28 no. 3 (May 2015): 95-98.

Hall-Ellis, Sylvia D. "Succession Planning and Staff Development – A Winning Combination." *The Informed Librarian Online* (September 2015), http://www.informedlibrarian.com/featuredArticle.cfm?FILE=succession_1509.pdf

Hall-Ellis, Sylvia D. "Nudges and Decision Making: A Winning Combination." *The Bottom Line 28*, no. 4 (July 2015): 133-136.

Hall-Ellis, Sylvia D. "Succession Planning and Staff Development – A Winning Combination." *The Bottom Line 28*, no. 3 (May 2015): 95-98.

Hall-Ellis, Sylvia D. "Metadata Competencies for Entry-Level Positions: What Employers Expect as Reflected in Position Descriptions, 2000-2013." *Journal of Library Metadata 15*, no. 2 (June 2015): 102-134.

Hall-Ellis, Sylvia D. "Onboarding to Improve Library Retention and Productivity." *The Bottom Line 27*, no. 4 (October 2014).

Hall-Ellis, Sylvia D. "Accept, Coach, and Inspire: A Formula for Success." *The Bottom Line 27*, no. 3 (July 2014): 103-106.

Hall-Ellis, Sylvia D. *Reward Systems for Staff in Higher Education Institutions: Case Studies of 15 Higher Education Institutions in Colorado.* Capstone Thesis. Denver, Colo.: University of Denver, University College, 2014.

Hall-Ellis, Sylvia D. "Reward Systems Promote High-Performance Work Teams Achieving Library Mission." *The Bottom Line 27*, no. 2 (April 2014): 66-69.

Hall-Ellis, Sylvia D. "Investment in Staff Development for Seeking External Grant Funds." *The Bottom Line 27*, no. 1 (January 2014): 22-25.

Hall-Ellis, Sylvia D. "Staff Investments for High Performance Teams." *The Bottom Line 26*, no. 4 (October 2013): 149-152.

Hall-Ellis, Sylvia D. and Deborah S. Grealy. "Service Learning in LIS Education: A Case for Holistic Assessment." *Catholic Library World* 82, no. 3 (March 2012): 178-187.

Hall-Ellis, Sylvia D., and Deborah S. Grealy. "The Dreyfus Model of Skill Acquisition: A Career Development Framework for Succession Planning and Management in Academic Libraries." *College and Research Libraries* (June 2012). http://crl.acrl.org/content/early/2012/06/19/crl12-349.full.pdf+html

Hall-Ellis, Sylvia D. "Cataloger Competencies…What Do Employers Require?" *Cataloging & Classification Quarterly* 46, no. 3 (2008): 305-330. http://ccq.haworthpress.com/doi:10.1080/01639370802034565

Hall-Ellis, Sylvia D. "Subject Access for Readers' Advisory Services: Their Impact on Contemporary Spanish Fiction in Selected Public Library Collections." *Public Library Quarterly* 27, no.1 (2007): 1-18. http://plq.haworthpress.com/doi:10.1080/01616840802122377

Hall-Ellis, Sylvia D. "Language Proficiencies among Catalogers and Technical Services Librarians." *Technical Services Quarterly* 25, no. 2 (2007) 31-47. http://tsq.haworthpress.com/doi:10.1300/J124v25n02_03

Hall-Ellis, Sylvia D. "Cataloging Electronic Resources & Metadata: Employers' Expectations as Reflected in *American Libraries and AutoCAT,* 2000-2005." *Journal of Education for Library and Information Science* 47, no. 1 (2006): 38-51.

Hall-Ellis, Sylvia D. "Descriptive Impressions of Managerial & Supervisory Cataloger Positions as Reflected in *American Libraries, AutoCAT,* and the *Colorado State Library Jobline,* 2000-2004: A Content Analysis of Education, Competencies, and Experience." *Cataloging & Classification Quarterly* 42, no. 1 (2006): 55-88.

Hall-Ellis, Sylvia D. "Descriptive Cataloging Proficiencies among Beginning Students: A Comparison among Traditional and Virtual Class Students." *Journal of Library & Information Services in Distance Education* 2, no. 2 (2005): 13-44.

Hall-Ellis, Sylvia D. "Descriptive Impressions of Entry-Level Cataloger Positions as Reflected in *American Libraries, AutoCAT,* and the *Colorado State Library Jobline,* 2000-2003." *Cataloging & Classification Quarterly* 40, no. 2 (2005): 33-72.

Hall-Ellis, Sylvia D. and Mary Ann Berry. "The Impact of Library Resource Centers on Academic Achievement in Selected Public Schools in South Texas: Preliminary Findings." *Texas Library Journal* 71, no. 2 (Summer 1995): 94-97.

Hall-Ellis, Sylvia D. "Visual Arts as Foundation for Successful Library Automation: The Rocky Mountain College of Art & Design Experience." *Art Reference Serials Quarterly* 4 (1994): 43-54.

Hall, Sylvia D. *High School Databases: An Examination of Bibliographic Data Elements*. Dissertation. Pittsburgh, Pa.: University of Pittsburgh, School of Library and Information Science, 1985.

Technical Reports

Hall-Ellis, Sylvia D. *Preparing Catalogers and Metadata Specialists Through Competency-Based Education: The San José State University iSchool Experience.* Report for the 2021 Re-Accreditation Program Presentation to the American Library Association. San José, Calif.: San José State University iSchool, 2020.

Hall-Ellis, Sylvia D. *Colorado Community College System Grant Handbook.* Denver, Colo.: Colorado Community College System, 2015.

.

Faculty Voices: Testimonials from the Frontiers of a Development Education Redesign. Elaine DeLott Baker, Marilyn Smith, and Sylvia D. Hall-Ellis, eds. Denver, Colo.: Colorado Community College System, 2014.

Lewis, Melanie, Jamie M. Van Leeuwen, and Sylvia D. Hall-Ellis. *Project Homeless Connect 7 Event Evaluation.* Denver, Colo.: University of Colorado Denver, 2009.

Hall-Ellis, Sylvia D. *Grant Writing Tips and Resources.* Denver, Colo.: University of Denver, 2008-2014. http://portfolio.du.edu/grants

Hall-Ellis, Sylvia D. and Duan Zhang. *Project Homeless Connect 6 Event Evaluation.* Denver, Colo.: Center for Community Engagement and Service Learning, 2008.

Hall-Ellis, Sylvia D. *Strategic Plan for Denver Medical Library System: Final Report.* Denver, Colo.: HealthONE and Denver Medical Library, 2008.

Hall-Ellis, Sylvia D. and Duan Zhang. *Project Homeless Connect 5 Event Evaluation.* Denver, Colo.: Center for Community Engagement and Service Learning, 2008.

Hall-Ellis, Sylvia D. *Strategic Plan for Denver Medical Library System: Phase Two Report.* Denver, Colo.: HealthONE and Denver Medical Library, 2007.

Hall-Ellis, Sylvia D. and Duan Zhang. *Project Homeless Connect 4 Event Evaluation.* Denver, Colo.: Center for Community Engagement and Service Learning, 2007.

Hall-Ellis, Sylvia D. *Strategic Plan for Denver Medical Library System: Phase One Report.* Denver, Colo.: HealthONE and Denver Medical Library, 2007.

Hall-Ellis, Sylvia D. *Denver Public Library: Opportunities for Change.* Denver, Colo.: University of Denver, Colorado Community-Based Research Network & Metropolitan Organization of People, 2005.

Hall-Ellis, Sylvia D. *Resources in Grant Writing for Colorado Schools and Libraries.* Sponsored by the Colorado Department of Education, Educational Telecommunications Unit, 1999. Revised September 2000.

Hall-Ellis, Sylvia D. *Lewis & Clark Fellows Concept Paper for the Bicentennial Commemoration.* Vancouver, Wash.: Lewis and Clark Bicentennial Council, 1998.

Hall-Ellis, Sylvia D. and Mary Ann Berry. *The Impact of Library Resource Centers on Academic Achievement in Public Schools in Texas: The Final Report.* Prepared under the sponsorship of the Research Enhancement Fund award from Sam Houston State University, the Texas Association of School Librarians, the Children's Services Round Table, and the Young Adults' Services Round Table. Huntsville, Tex.: Sam Houston State University, College of Education and Applied Science, 1997.

Hall-Ellis, Sylvia D. *The Impact of Library Resource Centers on Academic Achievement in Selected Public Schools in Texas.* Huntsville, Tex.: Sam Houston State University, College of Education and Applied Science, 1997.

Hall-Ellis, Sylvia D. *Planning for Educational Technology: the Distance Education Implementation Phase: An Investigation of Technology and Telecommunication Needs for Region One Education Service Center, South Texas Community College, TCI Cablevision of South Texas, Inc., Tech Prep of the Rio Grande Valley, Inc., Texas State Technical College, Centro Cultural en el Valle de Texas, McAllen Independent School District, Harlingen Consolidated Independent School District, Donna Independent School District, Edinburg Consolidated Independent School District, La Joya Independent School District, Mercedes Independent School District, Pharr-San Juan-Alamo Independent School District, Sharyland Independent School District, Easter Seal Society of the Rio Grande Valley, Inc., and McAllen Memorial Library.* Harlingen, Tex.: Tech Prep of the Rio Grande Valley, 1996.

Hall-Ellis, Sylvia D. "Barcodes for the Texas Library Connection." Prepared under the sponsorship of the Office of Technology Services, Texas Education Agency. Austin, Tex.: TENET News and Conferences, March 1995.

Hall-Ellis, Sylvia D. *[et. al.] Planning for Educational Technology: A Study of Future Technology Needs for the Donna Independent School District, Region One Education Region Service Center, Tech Prep of the Rio Grande Valley, Inc. South Texas Community College, and the Department of Library Science, Sam Houston State University.* Research team: Sylvia D. Hall-Ellis, Ruth Ann Riggins, Noe Torres, Patricia G. Bubb, and Michael D. Bell. Harlingen, Tex.: Tech Prep of the Rio Grande Valley, 1994. Funded through a grant award from the Texas Education Agency.

Hall-Ellis, Sylvia D. and Mary Ann Berry. *The Impact of Library Resource Centers on Academic Achievement in Selected Public Schools in South Texas.* Huntsville, Tex.: Sam Houston State University, College of Education and Applied Science, 1993. Funded through a grant award from the Sam Houston State University Research Enhancement Fund.

Hall-Ellis, Sylvia D., Alice Krueger, and Linda Brannan. *Thesaurus Development for National Curriculum Materials Database at the Eisenhower National Clearinghouse for Mathematics and Science Education, Columbus, Ohio.* Developed under the sponsorship of Mid-Continent Regional Educational Laboratory Corporate Library, Aurora, Colo. Washington, D.C.: National Science Foundation; Columbus, Ohio: ERIC Clearinghouse for Mathematics and Science Education, 1993.

Hall-Ellis, Sylvia D. and Clarence L. Coffindaffer. *Partners in Progress: The 1992 Montana Library Federation Study Final Report*. Helena, Mont: Montana State Library and The Blue Bear Group, Inc., 1992.

Hall-Ellis, Sylvia D. and Clarence L. Coffindaffer. *Montana Federation Study Identification Paper*. Denver, Colo.: The Blue Bear Group, Inc., 1992.

Bruntjen, Scott and Sylvia D. Hall. *Recommendations on the Development of System-Wide Efforts of the Northern Waters Library Service.* Ashland, Wisc.: Northern Waters Library Service and The Blue Bear Group, Inc., 1989.

Hall, Sylvia D. *The Iowa Union List of Serials as A Part of The Iowa Locator: Planning Document*. Des Moines, Ia.: State Library of Iowa, 1988.

Hall, Sylvia D. *Iowa Computer-Assisted Network (ICAN Users' Manual. IBM Compatible Edition: Version 7.0.* Des Moines, Ia.: State Library of Iowa, 1988.

Hall, Sylvia D. *Iowa Computer-Assisted Network (ICAN Users' Manual. IBM Compatible Edition: Version 5.0.* Des Moines, Ia.: State Library of Iowa, 1986.

Hall, Sylvia D. *Iowa Computer-Assisted Network (ICAN Users' Manual. Apple MacIntosh Edition: Version 5.0.* Des Moines, Ia.: State Library of Iowa, 1986.

Bruntjen, Scott and Sylvia D. Hall. *The District of Columbia Public Library Planning for Retrospective Conversion of Bibliographic Records and Automation Issues for the 1990's: Final Report*. Central City, Colo.: The Blue Bear Group, Inc., 1986.

Bruntjen, Scott and Sylvia D. Hall. *The Iowa Locator: Final Report.* Central City, Colo.: The Blue Bear Group, Inc., 1986.

Bruntjen, Scott and Sylvia D. Hall. *Discovering Resource Sharing Treasures: Accessing Pennsylvania's High School Library Collections*. Harrisburg, Pa.: State Library of Pennsylvania, Bureau of School Library Media Resources, 1985.

Hall, Sylvia D. *Retrospective Conversion and the Completeness of Cataloging in Pennsylvania High School Libraries.* Pittsburgh, Pa.: PRLC, Inc., 1985.

Bruntjen, Scott and Sylvia D. Hall. *The Iowa Locator.* Des Moines, Ia.: State Library of Iowa, 1985- http://www.statelibraryofiowa.org/ld/silo/locator

Bruntjen, Scott and Sylvia D. Hall. *ICAN Analysis*. Des Moines, Ia.: State Library of Iowa, 1985.

Bruntjen, Scott and Sylvia D. Hall. *Zebras: Bar Codes, Standards, and Library Automation*. Central City, Colo.: The Blue Bear Group, Inc., 1985.

Hall, Sylvia D. and Scott Bruntjen. *Access Pennsylvania.* Harrisburg, Pa.: State Library of Pennsylvania, 1984- http://www.accesspa.org

Hall, Sylvia D. *Reconfiguration of the ITAC Cataloging Data Base to Machine Readable (MARC) Format*. Classified Document. Arlington, Va.: U. S. Army Intelligence and Threat Analysis Center, 1984.

Bruntjen, Scott and Sylvia D. Hall. *South Dakota Library Automation Plan: Final Report*. Pittsburgh, Pa.: PRLC, Inc., 1982. Reprinted by the South Dakota State Library, 1983.

Bruntjen, Scott and Sylvia D. Hall. *Altoona Automation Plan: Final Report prepared for the Altoona Area Public Library and the Altoona District Library Center*. Pittsburgh, Pa.: PRLC, 1983.

Bruntjen, Scott, Sylvia D. Hall and Paul J. Pugliese. *College Space Utilization Study*. Pittsburgh, Pa.: PRLC, Inc., 1983.

Hall, Sylvia D. *Pennsylvania Public Library Film Center Union Catalog Cataloging and Technical Services Procedures Manual*. Pittsburgh, Pa.: PRLC, Inc., 1982.

Hall, Sylvia D. *History of Library Development in Pennsylvania: A Review and Content Analysis of the Plans, 1955-1980*. Pittsburgh, Pa.: PRLC, Inc., 1982.

Hall, Sylvia D. *Newspapers on Microfilm: A Listing of Newspapers in Allegheny, Chemung, Schuyler, Steuben, and Yates Counties*. Ithaca, N.Y.: South Central Reference and Research Council, 1981.

Hall, Sylvia D. *OCLC/ILL Subsystem at Southern Tier Library System.* Albany, N.Y.: SUNY/OCLC Network, 1980.

Hall, Sylvia D. *Retrospective Conversion for Major Public Libraries in South Central New York State: A Technical Report*. 2 vols. Corning, N.Y.: Southern Tier Library System, 1979-1980.

Hall, Sylvia D. *The Librarian and the Mexican-American Patron in Texas.* Austin, Tex.: Texas State Library, 1978.

Other Publications

Hall-Ellis, Sylvia D., ed. *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association.* St. Paul, MN: St. Catherine University, 2017. 255 p.

Hall-Ellis, Sylvia D., and Robert O. Ellett, Jr., guest editors. *RDA Testing: Lessons Learned and Challenges Revealed: A Special Issue of Cataloging & Classification Quarterly* 49, no. 7-8 (November 2011).

Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Fundamentals of Cataloging I: An Online ALCTS Course.* Chicago, Ill.: American Library Association, 2009.

Hall-Ellis, Sylvia D., Angela J. Kinney and Martha Ann Bace, editors. *Best Practices in Cataloging Education Identified at the 2007 ALCTS Pre-conference: A Special Issue of the Journal for Library and Information Science Education* 49, no. 2 (Spring 2008).

Hall-Ellis, Sylvia D. *Cataloging Education: A New Emphasis for the Library and Information Science Curriculum.* Presentation delivered to the ALCTS Pre-conference, 132nd Annual Conference, American Library Association, Washington, D.C., June 22, 2007. http://www.loc.gov/aba/professional/

Hall-Ellis, Sylvia D. "*Cataloger Competencies: Do the Employers Require What the Professors Teach?*" Presentation delivered to the ALCTS CCS Heads of Cataloging Discussion Group, 131st Annual Conference, American Library Association, New Orleans, Louisiana, June 26, 2006. http://dlist.sir.arizona.edu/

Hall-Ellis, Sylvia D., guest editor, with Deborah S. Grealy, Clara L. Sitter, and Tassos Petrou. *Library Students' Voices in Colorado: An Issue of Colorado Libraries* 31:1 (Spring 2005).

Hall-Ellis, Sylvia D., ed. *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association.* Denver, Colo.: University of Denver, College of Education, 2003. 125 p. with CD-ROM.

Hall-Ellis, Sylvia D. and Deborah S. Grealy, guest editors. *Library Education in Colorado: An Issue of Colorado Libraries* 29, no. 2 (Summer 2003).

Hall-Ellis, Sylvia D., ed. *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association.* Denver, Colo.: University of Denver, College of Education, 2003.

Hall-Ellis, Sylvia D. "Adaptive Furniture for the ADA-Qualified: An Investigative Study." 2001. Unpublished manuscript.

Hall-Ellis, Sylvia D. "Cataloging Electronic Serials: A Study in User Access and Article Delivery." 2001. Unpublished manuscript.

Hall-Ellis, Sylvia D. "E-books: Acquisition and Circulation Issues in Public Libraries." 2001. Unpublished manuscript.

Hall-Ellis, Sylvia D. "Authority Control and Its Importance in School Library Media Online Catalogs." 1999. Unpublished manuscript.

Hall, Sylvia D. "Cooperation Improving Service in San Antonio System." *Texas Libraries* XXXVII (Spring 1976): 27-29.

Hall, Sylvia D. "Summer is Sea Monstrously Fun!" *Texas Library Journal* L (December 1974): 224-226.

Hall, Sylvia D. "A Brief Annotated Bibliography of Non-book Materials on the Mexican American." *Texas Library Journal* XLVIII (October 1972): 213-232.

Book Reviews

ALA Book of Library Grant Money. Ann Kepler, ed. 8th ed. Chicago, IL: American Library Association, 2011. 978-0-8389-1058-0, $175.00 [*Colorado Libraries,* June 2012]

Developing a Compensation Plan for Your Library. Paula M. Singer and Laura L. Francisco, comps. 2nd ed. Chicago, IL: American Library Association, 2009. 978-0-8389-0985-0, $57.00 [*Colorado Libraries,* March 2012]

Frugal Librarian. Carol Smallwood, ed. Chicago, IL: American Library Association, 2011. 978-0-83891-075-7, $42.00 [*Colorado Libraries,* February 2012]

Dowlin, Ken. *Getting the Money: How to Succeed in Fundraising for Public and Nonprofit Libraries.* Westport, Conn.: Libraries Unlimited, 2008. 978-1-59158-597-X, $50.00 [*Colorado Libraries,* February 2009]

Lundahl, Mats. *Bebo de Cuba; Bebo Valdés y Su Mundo*, by Mats Lundahl. Traducción de Linda Oakeshott Dragó. Barcelona: RBA Libros, 2008. 978-849-86-7259-6, $33.99 [*Críticas*, November 2008]

Bonelli, Florencia. *Marlene*, by Florencia Bonelli. Buenos Aires: Aguilar, Altea, Taurus, Alfaguara, 2008. 978-987-04-0995-3, $24.95 [*Críticas*, October 2008]

Keret, Etgar. Traducción de Ana María Bejarano. *Pizzería Kamikaze y Otras Relatos.* México, D.F.: Editorial Sexto Piso, 2008. 968-5679-29-0, no price given [*Críticas*, September 2008]

Littauer, Marita, and Florence Littauer. *Enriquece tu Comunicación. Miami, Fla.: Editorial Unilit, 2008.* 978-0-7899-1521-4, $11.99 [*Críticas*, August 2008]

Martínez, Guillermo. *La Muerte Lenta de Luciana B.* New York: Rayo Planeta, 2008. 978-0-06-156551-9, $14.95 [*Críticas*, May 2008]

Matthews, Joseph R. *The Evaluation and Measurement of Library Services.* Westport, Conn.: Libraries Unlimited, 2007. 978-1-59158-532-9, $50.00 [*Colorado Libraries,* April 2008]

Gómez-Jurado, Juan. *A Masacre de Virginia Tech: Anatomía de una Mente Torturada.* Barcelona: Ediciones El Andén, 2007. 978-84-935789-4-7, €16.50 [*Críticas*, February, 2008]

Matthews, Joseph R. *Library Assessment in Higher Education.* Westport, Conn.: Libraries Unlimited, 2007. 978-1-59158-531-2, $45.00 [*Colorado Libraries,* February 2008]

Chacón, Inma. *La Princesa India: Cuando el Viento Azul.* México: Alfaguara, 2006. 970-770398-9, $19.95 [*Críticas*, June 2006]

Vargas Llosa, Mario. *Israel/Palestina: Paz o Guerra Santa.* fotogs. by Morgana Vargas Llosa. Spain/U.S.: Aguilar: Santillana, 2006. 84-03-09691-7, paper, $19.95 [*Críticas*, May 2006]

Findlay, Diane. *Digging into Dewey.* Fort Atkinson, Wisc.: Upstart Books, 2005. 978-1-932146-18-9, $16.95 [*Colorado Libraries,* May 2006]

Pequeñas Resistencias 4: Antología del Nuevo Cuento Norteamericano y Caribeño. Menéndez, Ronaldo, Ignacio Padilla & Enrique del Risco, eds. Madrid**:** Páginas de Espuma, 2005. 84-95642-59-X, paper, $36.95 [*Críticas*, April 2006]

Rueda, André. *Vengo a Salvar a España: Biografía de Un Franco Desconocido.* Madrid**:** Nowtilus (Investigación Abierta), 2005. photogs., bibliog. 84-9763-202-8, paper, $23.95 [*Críticas*, March 2006]

Becerra, Ángela. *El Penúltimo Sueño.* 1st ed. Barcelona: Planeta, 2005. 84-08-05795-2, $25.95. [*Críticas*, January 2006]

Aguilar Camín, Héctor. *La Conspiración de la Fortuna.* 1st ed. México: Planeta, 2005. 970-37-0368-2, $19.95 [*Críticas*, October 2005]

México en Sus Libros. Enrique Florescano with Pablo Mijangos, editors & compilers. 1st ed. México, D.F.: Taurus Aguilar, 2004. 968-19-0783-3, $16.95 [*Críticas*, September 2005]

Historia Económica de México. Coordinator, Enrique Semo. México: Universidad Nacional Autónoma de México, Editorial Oceano de México, 2004. 13 vols. 970-32-0805+3 (obra completa), $9.25 each [*Críticas*, August 2005]

Czarnowsky, Christyne A. and Michael H. Williams. *Managing Your Wired Workforce: A Practical Guide.* Denver, Colo.: Bradford Pub., 2003. 1-883726-79-4, $24.95 [*Colorado Libraries,* 2004]

Abraham Lincoln. Colección Grandes Biografías. Madrid: Edimat Libros, 2003. 84-8403-858-0, €4.95 [*Críticas*, 2004]

Alponte, Juan María. *Colón: el Hombre, el Navegante, la Leyenda.* México, D.F.: Aguilar, 2003. 968-19-1260-8, $16.95 [*Críticas*, 2004]

Olcese Salvatecci, Alfieri. *Cómo Estudiar con Èxito: Téchnicas yHhábitos Para Aprender Major.* México, D.F.: Alfaomega Grupo Editor, 2002. 970-15-0764-9 [*Críticas*, 2003]

Mujeres Como Islas: Antología de Narradoras Cubanas, Dominicanas, Puertoriqueñas. Edición: Olga Marta Pérez, Thelma Jiménez, Andrés Blanco D., eds. Santo Domingo, República Dominicana: Ediciones Ferilibro, 2002. 959-209-419-5 [*Críticas*, 2003]

Tibol, Raquel. *Los Murales de Diego Rivera: Universidad Autónoma Chapingo.* México, D.F.: Editorial RM, Universidad Autónoma Chapingo, 2002. 968-5208-08-5 [*Críticas*, 2003]

Lindsay-Poland, John. *Emperors in the Jungle: the Hidden History of the U.S. in Panama.* Durham, N.C.: Duke University Press, 2003. 0-8223-3098-9, $18.95 [*Críticas*, 2003]

Kaplan, Allison G. and Ann Marlowe Riedling. *Catalog It! A Guide to Cataloging School Library Materials.* Worthington, Ohio: Linworth Pub., 2002. 1-58683-014-7, $44.95 [*Colorado Libraries,* 2002]

Bardach, Ann Louise. *Cuba Confidential: Love and Vengeance in Miami and Havana.* New York: Random, 2002. 0-375-50489-3, $25.95 [*Library Journal*, 2002]

Swan, James. *Fundraising for Libraries: 25 Proven Ways to Get More Money for Your Library.* New York: Neal Schuman, 2002. 1-55570-433-6, $69.95 [*Colorado Libraries,* 2002]

Puíg de Lange, Victoria. *Sol Con Agua.* Nashville, Tenn.: Editorial Vistazo/Ediciones Reio Negro, 2002. 0-9724506-0-2, $17.75 [*Críticas*, 2002]

The Encyclopedia of Latin American Politics. Edited by Diana Kapiszewski; assistant editor, Alexander Kazan. Westport, Conn.: Oryx Press, 2002. 1-57356-306-4, $74.95 [*Library Journal*, 2002]

Vargas Lizano, Isabel. *Y Si Quieres Saber de Mi Pasado.* Con la colaboración de J.C. Vales. Madrid: Santillana Ediciones Generales, S.L., 2002. 84-03-09278-4, $18.95 [*Críticas*, 2002]

Ruy Sánchez, Alberto. *Los Jardines Secretos de Mogador: Voces de Tierra.* México, D.F.: Alfaguara, S.A., 2001. 968-19-0879-1, $16.95 [*Críticas*, 2002]

Chávez, Ricardo and Celso Santajuliana. *El Final de las Nubes.* Barcelona: RBA Libros, S.A., 2001. 84-7901-760-0, $11.95 [*Críticas*, 2002]

The Power of Language / El Poder de la Palabra: Selected Papers from the Second REFORMA National Conference. Edited by Lillian Castillo-Speed and the REFORMA National Conference Publications Committee. Englewood, Colo.: Libraries Unlimited, 2001. 1-563089459, $35.00 [*Colorado Libraries,* 2001]

Martínez, Rubén. *Crossing Over: A Mexican Family on the Migrant Trail.* Metropolitan: Holt, 2001. 0-8050-4908-8, $26.00 [*Library Journal*, 2001]

Guevara, Ernesto "Che." *The African Dream: the Diaries of the Revolutionary War in the Congo.* Translated from the Spanish by Patrick Camiller. With an introduction by Richard Gott and a foreword by Aleida Guevara March. New York: Grove Press, 2001. 0-8021-3834-9, $13.00 [*Library Journal*, 2001]

Cooper, Gail and Garry Cooper. *New Virtual Field Trips.* Englewood, Colo.: Libraries Unlimited, 2001. 1-56308-887-8, $27.50 [*Colorado Libraries,* 2001]

NATIONAL SERVICE & PROFESSIONAL AFFILIATIONS

American Library Association, Life Member
Association for Library Collections & Technical Services (now CORE)
Cataloging, Classification, and Metadata Section
ALCTS Editorial Board, Member, 2015-2019
Committee on Cataloging: Description and Access, Member, 2008-2012
Test Site for RDA, Manager, 2009-2011
Nominating Committee, Member, 2007-2008
Committee for Education and Training of Catalogers, Chair, 2006-2007, Member, 2003-2007
Competencies & Education for a Career in Cataloging Interest Group, Chair, 2010-2012; Member, 2010-
President's Program Committee, 2015-2016
Education Committee, Member, 2005-2007
Task Force on Competencies and Education for a Career in Cataloging, Chair, 2007-2009
2007 Annual Meeting Pre-conference, "What They Don't Teach in Library School: Competencies, Education and Employer Expectations for a Career in Cataloging," Steering Committee Chair
Fundraising Committee, Member, 2004-2006
Office of Diversity
Committee on Diversity, Chair, 2010-2011
Diversity Research Advisory Committee, Member, 2009-2010
Spectrum Scholar Mentor, 2009
Diversity Grants Review Committee, Member, 2007, 2010, 2012
Office of Statistics and Research
Research and Statistics Committee, Member, 2005-2007; Intern, 2003-2005
Library Research Round Table
Nominating Committee, 2022-2023
Membership Committee, 2019-2021
Board of Directors, Member At-Large, 2009-2012
Office of Accreditation
Accreditation Panel Member (training completed 2004)
Accreditation Review Panel Member (training completed 2004)

REFORMA, Life Member
National Board of Directors, 2005-2013
National Fundraising Chair, 2005-2013
National Recruiting and Mentoring Committee, 2008-2010
Colorado Chapter, Secretary, 2004-2005
Colorado Chapter Liaison to National Board of Directors, 2004-2013

American Association of Law Libraries (AALL), Life Member Online Audiovisual Catalogers Association (OLAC) Colorado Association of Law Librarians (CoALL)

American Association of University Women Association for Library and Information Science Education (ALISE)
University of Denver ALISE Representative, 2003-2008; 2010-2011
Membership Advisory Committee, 2007-2010
Technical Services Education Special Interest Group, 2003-
Garfield Doctoral Dissertation Award Reviewer, 2012
Garfield Doctoral Dissertation Scholarship Reviewer, 2014

American Association of University Professors (AAUP), 2006-

American Grant Writers Association, 2014- Grant Professionals Institute, 2016- National Grants Management Association, 2014-
Grant Reviewer (National and Regional Team Leader), U.S. Department of Education, 1998- Grant Reviewer, Broadband Technologies Opportunity Program, U.S. Department of Commerce, 2009
Grant Reviewer, Institute of Museum and Library Services, 1998-2000
Grant Reviewer, Colorado Department of Education, 2014-
Grant Reviewer, Colorado State Library, 1998-
Grant Reviewer, American Association of Community Colleges *Working Connections* program, 1999
Peer Reviewer, *Journal for Library and Information Science Education,* 2005-
Peer Reviewer, *Journal of Library Metadata,* 2009
Peer Reviewer, *International Journal of Library and Information Science,* 2011
Regular Columnist, *The Bottom Line*, 2013-2016
Book Reviewer, *Library Journal*, 2001
Book Reviewer, *Críticas*, 2002-2009
Book Reviewer, *Colorado Libraries,* 2000-2012

REGIONAL SERVICE & PROFESSIONAL AFFILIATIONS

Mountain Plains Library Association
Professional Development Grants Committee, Member, 2005-2006
Professional Development Policy and Guidelines Sub-committee Chair, 2006

Colorado Association of Libraries
"Student Voices" Column Editor, *Colorado Libraries,* 2005-2006
Conference Planning Committee, Member, 2002
Technical Services and Automation Division, Chair, 2002-2003; Member, 2000-
Academic Libraries Division, Peer Review Conference Papers Committee, Member, 2007-2009
Education Committee, Member, 1988-1993
Diverse Populations Committee, Member, 2009-2013

SERVICE TO THE UNIVERSITY OF DENVER
Center for Teaching and Learning Faculty Advisory Board, 2007-2008; 2010-2012
Center for Community Engagement and Service Learning Advisory Board, 2007-2012
Faculty Senate
Executive Committee, 2008-2013
Nominations, Rules & Credentials Committee, Chair, 2008-2013; Member 2007-2013
Appointment, Promotion, and Tenure Revision Committee, 2010-2012
Grievance Policy Committee Member, 2007-2010
Law Library Director Search Committee Chair, 2012-2013
PROF Grant Review, College Representative to the University Review Team, 2006, 2008
Project Homeless Connect Evaluations, Principal Investigator, 2006-2009
University Technology Council, 2007-2009
University of Denver Hyde Interviews for Incoming Freshmen, 2003-2012

SERVICE TO THE MORGRIDGE COLLEGE OF EDUCATION
Appointment, Tenure & Review Committee
Member, voting, 2003-2005; 2007- 2009
Chair, Clinical Faculty Promotion & Tenure Policy Subcommittee, 2008-2009
Member, Community Engagement Subcommittee, 2007-2009
Member, Tenure Review Panel, 2003
Advancement and Alumni Relations Committee, Chair, 2003-2007; Member, 2002-2007
College Building Committee Member, 2004-2010

College of Education Student Association, Faculty Advisor, 2004-2007; 2009-2010
Faculty Senator, 2007-2013
Research and Scholarship Committee, Chair, 2008-2009; Member, 2002-2003, 2008-2009
Research and Grant Mentoring Committee, Chair, 2009-2010
Research Task Force Member, 2010-2012
Search Committee Member, Assistant Professor for Curriculum & Instruction, 2010-2011
Workload Task Force Member, 2010-2011

SERVICE TO THE LIBRARY & INFORMATION SCIENCE PROGRAM

Library and Information Science Student and Alumni Association, Faculty Advisor, 2002-2008
ALA Student Chapter, Faculty Advisor, 2005-2008
Beta Phi Mu Phi Chapter, Faculty Advisor, 2004-2014
Steering Committee Member, Accreditation by the American Library Association, 2001-2004
Search Committee Member, Associate Professor for LIS, 2006
Search Committee Chair, Assistant Professors for LIS, 2003, 2005, 2006, 2007
Search Committee Ex-Officio Member, Director for LIS, 2004

SERVICE TO SAM HOUSTON STATE UNIVERSITY

Rio Roundup: South Texas Literature Conference, Conference Coordinator, 1993
External Relations, Fund Raising, Grants Committee, Chair, 1993-1995
Advisory Council Committee, Chair, 1993-1995
Students, Admissions, and Advisement Committee, Chair, 1994
Institutional Effectiveness Committee, Member, 1993-1995

SERVICE TO THE COLLEGE OF EDUCATION AND APPLIED SCIENCE

Faculty Affairs Committee, Member, 1993-1995
Curriculum Committee, Member, 1993-1995
Continuing Education Committee, Member, 1993-1995

SERVICE TO THE COMMUNITY

French Teacher & Student Exchange with Laon, France, Monarch High School, Boulder Valley School District (Boulder, Colorado), 2017-
Denver/Boulder Games 2022, Board of Directors, Secretary-Treasurer, 2015-2018
United Way Campaign Committee, College of Education, 2006
Arapahoe County, Election Judge for the County Clerk and Recorder, 2000-2005
Arthritis Foundation, Rocky Mountain Chapter, Certified Educator & Trainer, 1999-2008
Bonfils Blood Center, Silver Level Donor, 2000-2016
Denver Museum of Natural History, Docent, 1992
Tech Prep of the Lower Rio Grande Valley, Inc. (Harlingen, Texas) Board of Directors, 1995-1997
Executive Committee, 1996-1997; Chair, Development Committee, 1995-1997; Chair, Fiscal Agency Committee, 1995-1996; Chair, Colleges and Universities Committee, 1996-1997
Gilpin County (Colorado) Public Library Board of Trustees, 1986-1989; Vice President, 1987-1989
City of Central (Colorado) Economic Development Committee, 1987-1989
Columbine Family Health Centers, Inc. (Nederland and Black Hawk, Colorado) Board of Directors, 1988-1989

CERTIFICATION

Permanent Public Librarian Certificate - Pennsylvania, New York, Texas
Westlaw Expert Witness, 2008-
Certified Grant Writer®, 2016-

AWARDS AND HONORS

Advanced Practitioner for Service Learning and Community Engagement, University of Denver, 2011
Platinum Star Alumnae, College of Information, Library Science & Technologies, University of North Texas, 2009
Commendation for Integration of Technologies in Teaching & Learning Environment, University of Denver, 2006
Outstanding Adjunct Faculty Member Award, College of Education, University of Denver, 2002
Beta Phi Mu, Pi, University of Pittsburgh, 1985
Alpha Lambda Sigma, University of North Texas, 1972
Albert Nelson Marquis Lifetime Achievement Award, Who's Who in America
Who's Who in American Women
Who's Who of Women Executives
Dictionary of International Biography
Who's Who in the East
Who's Who in the South and Southwest
Who's Who in the World
Who's Who of Online Professionals
Who's Who in Library and Information Science
2,000 Notable Women
Who's Who of Emerging Leaders
Who's Who in Professional and Executive Women
Who's Who in American Education
International Who's Who of Professional and Business Women
International Leaders in Achievement
International Educator of the Year
Who's Who in Finance and Industry
Who's Who in Finance and Business

Invited International and National Conference Presentations

Driscoll, Margaret, Christy Confetti Higgins, Scott Brown, and Sylvia D. Hall-Ellis. *A View from Within: Open House Tour of Three Canvas Core Courses*. Presentation to be delivered at the School of Information, San José State University Professional Development Seminar, San José, California, October 17, 2019.

Hall-Ellis, Sylvia D. *Invest in Me -- I'm Your Future: Succession Planning for Libraries.* Keynote presentation delivered at the ALCTS President's Symposium, Boston, Mass., January 8, 2016.

Seidel, Kent E. and Sylvia D. Hall-Ellis. *Making Grants Work for You: Strategies for Doctoral Students and Early Career Scholars.* Presentation delivered at the University Council for Educational Administration, Early Career Scholars Session, Indianapolis, Ind., November 9, 2013.

Hall-Ellis, Sylvia D. *So You Want to be a Manager; Leadership Skills and Competencies for Technical Services Managers and Administrators.* Presentation delivered at the 138th Annual Conference, American Library Association, Chicago, Ill., June 29, 2013.

Seidel, Kent E., Karen S. Riley, Lyndsay Agans, Susan Korach, and Sylvia D. Hall-Ellis. *Making Grants Work for You (Instead of Just Working for Grants).* A panel discussion delivered at the University Council for Educational Administration, Early Career Scholars Session, Denver, Colo., November 17, 2012.

Hall-Ellis, Sylvia D. *After the Great TS Reorganization: The Westminster Law Library.* Presentation delivered at the 137th Annual Conference, American Library Association, Anaheim, Calif., June 23, 2012.

Hall-Ellis, Sylvia D. *Conversations with Catalogers in the 21st Century.* A panel discussion sponsored by the ALCTS Competencies for a Career in Cataloging Interest Group, delivered at the 137th Annual Conference, American Library Association, Anaheim, Calif., June 22, 2012.

Hall-Ellis, Sylvia D., moderator. *Mid-Career Leaders Program.* A panel discussion sponsored by the ALA Committee on Diversity delivered at the 136th Annual Conference, American Library Association, New Orleans, La., June 26, 2011.

Hall-Ellis, Sylvia D., moderator. *Diversity Town Hall.* A community conversation sponsored by the ALA Committee on Diversity delivered at the 136th Annual Conference, American Library Association, New Orleans, La., June 24, 2011.

LaBarre, Kathryn, Sylvia D. Hall-Ellis, Karen Anderson, Rick Hasenyager, Christopher Cronin, and Penny Baker. *Briefings from RDA Test Participants.* A panel discussion delivered at the Midwinter Conference, American Library Association, San Diego, Calif., January 7, 2011.

Miksa, Shawne, Marjorie Bloss, and Sylvia D. Hall-Ellis. *Educating the Next Generation of Catalogers: Teaching RDA.* A panel discussion delivered at the 97th Annual Conference, Association for Library and Information Science Education, San Diego, Calif., January 7, 2011.

Hall-Ellis, Sylvia D., Robert Maxwell, John Hostage, and George Prager. *RDA Panel: What Cataloging Managers Need to Know.* Presentation delivered at the 103rd Annual Conference, American Association of Law Librarians, Denver, Colo., July 12, 2010.

Hall-Ellis, Sylvia D. and Stacey L. Bowers. *Catalogers in the RDA Environment: Skill Sets, Expectations and Challenges.* Presentation delivered at the 103rd Annual Conference, American Association of Law Librarians, Denver, Colo., July 11, 2010.

Hall-Ellis, Sylvia D. *Comfortable in Your Cataloging and Metadata Specialist Skin? Or, So You Want to Hire a Cataloger.* Presentation delivered to the ALCTS Research Group at the 134th Annual Conference, American Library Association, Chicago, Ill., July 11, 2009.

Perez, Megan, Sylvia D. Hall-Ellis, and Denise Anthony. *From Novice to Expert: Collaboration for Succession Planning.* A "hot topic" presentation delivered at the 14th ACRL Conference, Seattle, Wash., March 13, 2009.

Hall-Ellis, Sylvia D. *Cataloging in the RDA Environment: Skill Sets, Expectations and Challenges.* Presentation delivered to the ALCTS Research and Publications Committee at the Midwinter Conference, American Library Association, Denver, Colo., January 24, 2009.

Hall-Ellis, Sylvia D. *LIS Cataloging Education for the 21st Century: Expectations and Challenges.* A panel discussion held at the 95th Annual Conference, Association for Library and Information Science Education, Denver, Colo., January 23, 2009.

Chu, Clara, Sylvia D. Hall-Ellis, and Mark Winston. *The Doctoral Degree & Building a Career.* A panel discussion delivered at the ALA Office of Diversity Spectrum Doctoral Fellows E.J. Josey Leadership Institute, Midwinter Conference, American Library Association, Denver, Colo., January 20, 2009.

Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Fundamentals of Cataloging Course: An Overview of the ALCTS Online Course.* Presentation delivered to the ALCTS Big Heads Group, 133rd Annual Conference, American Library Association, Anaheim, Calif., June 30, 2008.

Hall-Ellis, Sylvia D. *Employers' Expectations for Technical Services Librarians: What We Don't Know.* Presentation delivered to the ALCTS Research and Publications Committee Program, 133rd Annual Conference, American Library Association, Anaheim, Calif., June 28, 2008.

Hall-Ellis, Sylvia D., Virginia R. Maloney, and Mary Stansbury. *Institutional Responses to Engaged Scholarship: The Carnegie Foundation Engaged University Classification at Two Universities.* Presentation delivered to the 94th Annual Conference, Association for Library and Information Science Education, Philadelphia, Pa., January 11, 2008.

Hall-Ellis, Sylvia D. *Puzzles, Problems, and Predicaments.* Presentation delivered to the ALCTS Research Discussion Group, 132nd Annual Conference, American Library Association, Washington, D.C., June 23, 2007.

Hall-Ellis, Sylvia D. *Cataloging Education: A New Emphasis for the Library and Information Science Curriculum.* Presentation delivered to the ALCTS Pre-conference, 132nd Annual Conference, American Library Association, Washington, D.C., June 22, 2007. http://www.loc.gov/catdir/cpso/careercat.html

Ellett, Jr., Robert O. and Sylvia D. Hall-Ellis. *Copy Cataloging Done Smarter.* Presentation delivered to the International Conference on Interdisciplinary Information Sciences and Technologies (InSciT2006), October 25-28, 2006.

Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Cooperative Cataloging: Challenges and Opportunities for Defense Libraries.* Presentation delivered to the 1st Annual Conference of Defense Libraries, Spanish Ministry of Defense, Madrid, Spain, July 7, 2006.

Hall-Ellis, Sylvia D. *Cataloger Competencies: Do the Employers Require What the Professors Teach?* Presentation delivered to the ALCTS CCS Heads of Cataloging Discussion Group, 131st Annual Conference, American Library Association, New Orleans, La., June 26, 2006.

Grealy, Deborah S. and Sylvia D. Hall-Ellis. *From Research to Practice: The Scholarship of Teaching and Learning in LIS Education.* Presentation delivered to the at the 92nd Annual Conference, Association for Library and Information Science Education, San Antonio, Tex., January 18, 2006.

Hall-Ellis, Sylvia D. *Employers' Expectations for Entry-Level Catalogers: What Position Announcement Data Indicate.* Research paper delivered to the Technical Services Special Interests Group, 91st Annual Conference, Association for Library and Information Science Education, Boston, Mass., January 12, 2005. http://dlist.sir.arizona.edu/

Hall-Ellis, Sylvia D. *Common Errors in MARC Records Prepared by LIS Students: What Does It Mean?* Research paper delivered to the ALCTS CCS Cataloging Norms Discussion Group, Mid-Winter Conference, 90th American Library Association, San Diego, Calif., January 10, 2004.

Hall-Ellis, Sylvia D. *Visual Arts as Foundation for Successful Library Automation: The Rocky Mountain College of Art & Design Experience.* Paper delivered at the 6th Annual Conference of Higher Education, Charleston, S. C., 1993.

Hall, Sylvia D. *Design Elements for Bibliographic Databases: An Overview.* Paper delivered at the 14th Online National Conference, New York, 1983.

Invited Regional Conference Presentations

Hall-Ellis, Sylvia D., Hudson, Christopher D., Brittany Cronin, and Kathryn Michaels. "The Colorado Law Project: Meeting the Public's Need for Legal Information." Panel discussion delivered at the Mountain Plains Library Association Conference, Billings, Mont., April 9, 2011.

Grealy, Deborah S. and Sylvia D. Hall-Ellis. *Education for Information Professionals in New Mexico: Library & Information Science Graduate Education at the University of Denver.* Presentation delivered at the New Mexico Library Education Summit, Las Vegas, N.M., September 26, 2005.

Hall-Ellis, Sylvia D. *Public Library-School Library Partnerships.* Presentation delivered at the 3rd Annual Colorado Association of Libraries Conference with the Mountain Plains Library Association, Denver, Colo., October 22, 2004.

Hall-Ellis, Sylvia D. *Learn All You Can – Educational Partnership Opportunities for the Lewis and Clark Bicentennial Commemoration.* Paper delivered at the 3rd Annual Lewis and Clark Bicentennial Council National Planning Conference, Bismarck, N.D., April 26, 1998.

Invited State Conference Presentations

Grealy, Deborah S. and Sylvia D. Hall-Ellis. *Academic Library Leadership Changes: Using Succession Planning and Mentoring*. Presentation delivered at the Minnesota Library Education Conference, St. Cloud, Minn., October 10, 2013.

Hall-Ellis, Sylvia D., Merrie Valliant, and Melissa Powell. *RDA: What Is It and What Do You Need To Do With It At Your Library?* Presentation delivered at the Colorado Library Consortium Spring Conference, Ft. Morgan, Colo., April 26, 2013.

Hall-Ellis, Sylvia D. *Service Learning and the Library & Information Science Graduate Education at the University of Denver.* Presentation delivered at the 4th LEADS Scholars Orientation, Denver, Colo., August 5, 2009.

Hall-Ellis, Sylvia D. *Service Learning: Enhancement to Library & Information Science Graduate Education at the University of Denver.* Presentation delivered at the 3rd LEADS Scholars Orientation, Denver, Colo., June 2008.

Hall-Ellis, Sylvia D. *Law Librarianship: A Community Conversation.* Sponsored by the Colorado Association of Law Libraries. Paper delivered at the Colorado Supreme Court Library, Denver, Colo., May 14, 2008.

Hall-Ellis, Sylvia D. *Opportunities and Challenges in Law Librarianship: A Community Conversation.* Presentation delivered at the Sturm College of Law, Denver, Colo., November 7, 2007.

Ellis, Sylvia D. *Grant Writing Resources for Nursing Professionals.* Presentation delivered at the Presbyterian / St. Luke's Health One Medical Center 1st Annual Research Symposium, Denver, Colo., October 17, 2007.

Hall-Ellis, Sylvia D. *Project Homeless Connect 4 Event Evaluation – Insights and Lessons Learned.* Presentation delivered at the Homelessness Research Symposium: What is DU Doing about Homelessness in Denver, Denver, Colo., September 14, 2007.

Hall-Ellis, Sylvia D. *Service Learning and the Library & Information Science Graduate Education at the University of Denver.* Presentation delivered at the 2nd LEADS Scholars Orientation, Denver, Colo., August 10, 2007.

Hall-Ellis, Sylvia D. *Education for Information Professionals in a Digital Environment: Library & Information Science Graduate Education at the University of Denver.* Presentation delivered at the 15th Spring Mountains and Plains Parapros Conference, Denver, Colo., February 24, 2007.

Hall-Ellis, Sylvia D. *Public Library Service to Spanish-Speaking and Latino Residents in Denver: A Case Study.* Presentation delivered at the 4th Annual Colorado Association of Libraries Conference, Denver, Colo., November 10, 2005.

Hall-Ellis, Sylvia D. *Education for Information Professionals in a Digital Environment: Library & Information Science Graduate Education at the University of Denver.* Presentation delivered at the 14th Annual Mountains and Plains Parapros Conference, Aurora, Colo., July 29, 2005.

Hall-Ellis, Sylvia D. *Educational Opportunities: Library & Information Science Graduate Education at the University of Denver.* Presentation delivered at the 13th Annual Mountains and Plains Parapros Conference, Centennial, Colo., August 6, 2004.

Hall-Ellis, Sylvia D. *Library Education & Training: Focus on the West: An LIS Faculty Member's Personal Response*. Presentation delivered at the 1st Annual Colorado Association of Libraries Conference, Keystone, Colo., October 18, 2002.

Hall-Ellis, Sylvia D. *Grant Writing for School Librarians.* Presentation delivered at the 2002 Annual Colorado Education Media Association Conference, Colorado Springs, Colo., February 15, 2002.

Hall-Ellis, Sylvia D. *Grants – Opportunities for the Future.* Paper delivered at the Southeast Regional Accountability Annual Conference, Lamar, Colo., November 12, 1998.

Hall-Ellis, Sylvia D. *The Texas Library Connection and Interlibrary Loan: An Experiment in Resource Sharing.* Paper delivered at the Texas Computer Educators' Association Annual Conference, Austin, Tex., February 6, 1997.

Hall-Ellis, Sylvia D. *Finding Grant Sources on the Internet: A Guide for Librarians.* Paper delivered at the 2nd Annual Institute for School Library Personnel, Pharr-San Juan-Alamo North High School, Pharr, Tex., July 29, 1996**.**

Hall-Ellis, Sylvia D. *Mathematical and Logical Thinking: A Critical Intelligence.* Paper delivered at the 3rd Annual Paraprofessional Conference at the University of Texas - Pan American, Edinburg, Tex., March 8, 1996.

Hall-Ellis, Sylvia D. *Cataloging Trends and Issues: Update Session.* Paper delivered at the 1st Annual Institute for School Library Personnel, South Texas Community College, McAllen, Tex., July 19, 1995.

Hall-Ellis, Sylvia D. *Grant Writing: Tips and Encouragement for School Librarians.* Paper delivered at the 1st Annual Institute for School Library Personnel, South Texas Community College, McAllen, Tex., July 18 and 19, 1995.

Hall-Ellis, Sylvia D. *How to Become an Expert Grant Writer.* Paper delivered at the 3rd Annual High School Principals' Academy, South Padre Island, Port Isabel, Tex., June 19, 1995.

Texas Library Study: Results from Regions I and II. Paper delivered at the 3rd Annual Technology Conference, Texas A&M University, College Station, Tex., November 18, 1994.

Hall-Ellis, Sylvia D. *Academic Achievement and Middle School Students.* Paper delivered at the 8th Annual Young Adult Conference, Sam Houston State University, Huntsville, Tex., November 5, 1994.

Hall-Ellis, Sylvia D. *Multimedia Resources for Library Leaders.* Paper delivered at the Institute for Librarians in A Multicultural Environment, Sam Houston State University, Huntsville, Tex., June 10, 1994.

Hall-Ellis, Sylvia D. *Finding the Resource: Empowering the User, or, the Case for Curriculum Based Subject Access to Learning Resource Center Collections.* Paper delivered at the 81st Annual Texas Library Association Conference, Corpus Christi, Tex., April 12-16, 1994.

Hall-Ellis, Sylvia D. and William H. Pichette. *Sam Houston State University Makes Use of OCLC/AMIGOS Collection Analysis CD.* Paper delivered at the 81st Annual Texas Library Association Conference, Corpus Christi, Tex., April 12-16, 1994.

Hall, Sylvia D. *Funding and Library Development in Pennsylvania: A Symbiotic Relationship.* Paper delivered at the Annual Graduate Student Colloquia, University of Pittsburgh, School of Library and Information Science, 1982.

Hall, Sylvia D. *Leadership for Public Library Trustees.* Paper delivered for the Trustees Division, Pennsylvania Library Association Annual Conference, Lancaster, Penn., 1981.

Seminar and Professional Development Presentations

Taylor, Meredith, and Sylvia D. Hall-Ellis. *Talent Management and Succession Planning.* ALCTS eForum, held March 22, 2017.

Hirsh, Sandra, Heather O'Brien, Michelle Holschuh Simmons, Michael Krasulski, and Sylvia D. Hall-Ellis. *Information Services Today: An Introduction. Part 3: Information Services: Roles in the Digital Age*. Rowan and Littlefield in partnership with Library Journal webinar, recorded February 5, 2015.

Hall-Ellis, Sylvia D. and Jennifer Sweda. *Copy Cataloging in an RDA Environment.* ALCTS eForum, held May 14 and 15, 2013.

Hall-Ellis, Sylvia D. *Law Librarianship: A Community Conversation.* Sponsored by the Colorado Association of Law Libraries, presented at the Colorado Supreme Court Library, Denver, Colo., May 14, 2008.

Hall-Ellis, Sylvia D. and Beatrice Z. Gerrish. *Reading and Libraries: Recent Research in Reading.* Presentation at the Ricks Center for Gifted Education, Denver, Colo., March 4, 2008.

Hall-Ellis, Sylvia D. *Cataloger Competencies: Do the Employers Require What the Professors Teach?* Presentation for the School of Library and Information Science, San José State University, February 12, 2008.

Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Cooperative Cataloging: Rules, Tools, and Conventions for Building a Multi-institutional Catalog.* Sponsored for the Spanish Ministry of Defense, Madrid, Spain, July 10, 2006.

Hall-Ellis, Sylvia D. *Cash for Kids: Grant Writing Opportunities for Youth Services Librarians.* Sponsored by the Colorado Young Adult Librarians; presented at Bemis Memorial Library, Littleton, Colo., November 13, 2002.

Hall-Ellis, Sylvia D. *MARC Records and Authority Control: Planning for Bibliographic Database Migration.* Sponsored and held at the Douglas County Public Library, Castle Rock, Colo., May 28, 2002.

Grant Writing: A Refresher for Librarians. Sponsored by Library and Information Science Program, College of Education, University of Denver; presented at University Center at Chaparral, August 12, 2000.

Hall-Ellis, Sylvia D. *Shaking the Money Tree – Basic Grant Writing for Colorado Educators.* Sponsored by the Office of Educational Telecommunications of the Colorado Department of Education.
Pikes Peak Community College, Colorado Springs, Colo., November 16, 1998.
Pueblo School District 60, Pueblo, Colo., November 12, 1998.

University of Northern Colorado, Greeley, Colo., November 10, 1998.
United Technology Educational Partnership, Grand Junction, Colo., November 9, 1998.

Hall-Ellis, Sylvia D. *Cataloging Multimedia, Kits, Globes and Map Materials in USMARC.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., April 24, 1997 and December 12, 1996.

Hall-Ellis, Sylvia D. *New Standards for School Library Media Centers.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., April 15, 1997.

Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future.* Sponsored and hosted by Pharr-San Juan-Alamo Independent School District, Pharr, Tex., April 4, 1997.

Hall-Ellis, Sylvia D. *Cataloging Sound Recordings and Audio Materials in USMARC.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., March 20, 1997 and November 21, 1996.

Hall-Ellis, Sylvia D. *Evaluating and Selecting CD-ROMS for School Library Media Collections.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., March 18, 1997.

Hall-Ellis, Sylvia D. *Cataloging Audiovisual Materials in USMARC.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., February 27, 1997, November 7, 1996 and October 24, 1996.

Hall-Ellis, Sylvia D. *Introduction to Dialog: Basic Searching Strategies.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., February 14, 1997.

Hall-Ellis, Sylvia D. *Cataloging Books in USMARC.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., January 30, 1997, October 10, 1996, September 26, 1996 and August 8, 1996.

Hall-Ellis, Sylvia D. *Advanced Internet Searching Techniques for Librarians.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., January 21, 1997.

Hall-Ellis, Sylvia D. *Texas Library Connection Full-Text Searching.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., December 13, 1996 and October 25, 1996.

Hall-Ellis, Sylvia D. *Developing Evaluation Strategies for Grants and Proposals.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., December 10, 1996.

Hall-Ellis, Sylvia D. *Developing Needs Assessment for Grants and Proposals.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., November 12, 1996.

Hall-Ellis, Sylvia D. *Texas Library Connection Union Catalog Searching.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., November 8, 1996 and September 6, 1996.

Hall-Ellis, Sylvia D. *Grant Resources on the Internet.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., October 23, 1996.

Hall-Ellis, Sylvia D. *Preparing a Response to the Telecommunications Infrastructure Fund Board: Needs Assessment, Professional Development Framework, and Evaluation Strategies.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., October 16, 1996.

Hall-Ellis, Sylvia D. *Texas Library Connection: Building the Districtwide Bibliographic Database.* Sponsored and hosted by Mercedes Independent School District, Mercedes, Tex., September 13, 1996 and August 8, 1996. Sponsored and hosted by Los Fresnos Consolidated Independent School District, Los Fresnos, Tex., August 12, 1996.

Hall-Ellis, Sylvia D. *School-to-Work and Special Education: An Inclusive Partnership for Success.* Sponsored and hosted by the Office of Special Education, Region One Education Service Center, Edinburg, Tex., September 11, 1996.

Hall-Ellis, Sylvia D. *Telecommunications Infrastructure Fund Board: An Overview of Funding for Secondary Schools.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., August 31, 1996.

Hall-Ellis, Sylvia D. *Cataloging Books, Multimedia, and Realia in USMARC.* Sponsored and hosted by Edinburg Consolidated Independent School District, Edinburg, Tex., August 6, 1996.

Hall-Ellis, Sylvia D. *Internet Resources for Grant Writers.* Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., April 20, 1996.

Hall-Ellis, Sylvia D. *Enhanced Grant Writing Skills for Mathematics Educators: Writing Skills for Campus Teams.* Sponsored and hosted by the Office of General Education, Region One Education Service Center, Edinburg, Tex., March 22, 1996.

Hall-Ellis, Sylvia D. *Internet Resources for Grant Writers.* Sponsored and hosted by the College of Education and Applied Science, Sam Houston State University, Huntsville, Tex., March 9, 1996.

Hall-Ellis, Sylvia D. *Grant Writing for Mathematics Educators: A Development Process for Campus Teams.* Sponsored and hosted by the Office of General Education, Region One Education Service Center, Edinburg, Tex., March 4, 1996.

Hall-Ellis, Sylvia D. *Shaking the Money Tree: Preparing Successful Technology Grant Applications.* Sponsored and hosted by the Office of Technology and Media Services, Region One Education Service Center, Edinburg, Tex., February 29, 1996 and April 29, 1996.

Hall-Ellis, Sylvia D. *District-wide Technology Planning: Technical Assistance for the Texas Education Agency Initiative.* Sponsored and hosted by the Office of Technology and Media, Region One Education Service Center, Edinburg, Tex., February 2, 1996.

Hall-Ellis, Sylvia D. *Enhanced Grant Writing Skills.* Sponsored and hosted by Pharr-San Juan-Alamo Independent School District, Pharr, Tex., January 27, 1996.

Hall-Ellis, Sylvia D. *United States Copyright Act of 1976, Video Transmissions, Computer Software and the Internet.* Sponsored and hosted by the Office of Technology and Media, Region One Education Service Center, Edinburg, Tex., January 24, 1996.

Hall-Ellis, Sylvia D. *The Grant Writing Development Process.* Sponsored and hosted by Pharr-San Juan-Alamo Independent School District, Pharr, Tex., January 20, 1996.

Hall-Ellis, Sylvia D. *MARC Cataloging of Materials for Library Media Centers.* Sponsored and hosted by the Office of Media Services, Region One Education Service Center for the Donna Independent School District, Donna, Tex., August 17, 1995.

Hall-Ellis, Sylvia D. *Classification.* Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., May 10, 1995.

Hall-Ellis, Sylvia D. *Library Technical Services.* Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., April 26, 1995.

Hall-Ellis, Sylvia D. *Grant Writing: An Introduction for Public School Administrators.* Sponsored and hosted by the Office of Administrative Services, Region One Education Service Center, Edinburg, Tex., April 19, 1995.

Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future.* Sponsored and hosted by the United Independent School District, Laredo, Tex., March 31, 1995.

Hall-Ellis, Sylvia D. *Using USMARC.* Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., March 29, 1995.

Hall-Ellis, Sylvia D. *Library Media Center Policies and Guidelines: How to Prepare for School Board Adoption.* Sponsored and hosted by the Office of Technology and Media Services, La Joya Independent School District, La Joya, Tex., March 10, 1995.

Hall-Ellis, Sylvia D. *Developing District-wide Policies and Guidelines for Library Media Centers.* Sponsored and hosted by the Office of Technology and Media Services, La Joya Independent School District, La Joya, Tex., January 10, 1995.

Hall-Ellis, Sylvia D. *MARC Cataloging of Audiovisual Materials for Library Media Centers.* Sponsored and hosted by the Office of Library Media and Technology Services, Cypress-Fairbanks Independent School District, Houston, Tex., December 1, 1994.

Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future.* Sponsored and hosted by United Independent School District, Laredo, Tex., October 14, 1994.

Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future.* Sponsored and hosted by the Laredo Independent School District, Laredo, Tex., October 7, 1994.

Hall-Ellis, Sylvia D. *MARC Cataloging for Library Media Centers.* Sponsored by the Office of Library Media and Technology Services, Cypress-Fairbanks Independent School District, Houston, Tex., October 5, 1994.

Hall-Ellis, Sylvia D. *Jump to the Head of the Class: Undergraduate Library Resources Available at Sam Houston State University.* Sponsored by the Office of the Associate Vice President for Student Services, Sam Houston State University, Huntsville, Tex., October 4, 1994.

Hall-Ellis, Sylvia D. *CD-ROMs - 1994's Newest and the Best for Secondary Level Media Centers.* Sponsored and hosted by Clear Lake Independent School District, Houston, Tex., June 3, 1994.

Hall-Ellis, Sylvia D. *Introduction to Classification.* Sponsored by AJ Seminars, Rockville, Maryland; presented at Holiday Inn, Market Center, Dallas, Tex., May 18, 1994.

Hall-Ellis, Sylvia D. *Basic Descriptive Cataloging.* Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., May 4, 1994.

Hall-Ellis, Sylvia D. *Shaking the Money Tree - Part II: Writing Successful Grant Applications.* Sponsored by Donna Independent School District, Donna, Texas, and Region One Education Service Center Edinburg, Texas; presented at South Texas Community College Library, McAllen, Tex., April 29, 1994.

Hall-Ellis, Sylvia D. *Using MARC.* Sponsored by AJ Seminars, Rockville, Maryland; presented at Holiday Inn, Market Center, Dallas, Tex., April 6, 1994.

Hall-Ellis, Sylvia D. *Automated Authority Control.* Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., March 23, 1994.

Hall-Ellis, Sylvia D. *Automating the District School Library Media Centers: Choices and Opportunities.* Sponsored and hosted by the Office of Technology and Library Media Services, Fort Bend Independent School District, Sugar Land, Tex., March 4, 1994.

Hall-Ellis, Sylvia D. *Shaking the Money Tree - Part I: Preparing Successful Grant Applications.* Sponsored and hosted by the Office of Library Media Services, Donna Independent School District, Donna, Tex., February 4, 1994.

GRADUATE COURSES TAUGHT

San José State University, School of Library and Information Science
INFO 249 – Advanced Cataloging and Classification (Fall 2015, 2016; Summer 2016)
INFO 287 – Special Topics in Cataloging and Classification (Spring 2017, 2018, 2019, 2020, 2021, 2022, 2023; Fall 2020, 2021, 2022, 2023)
LIBR 248 – Beginning Cataloging and Classification (Summer 2002, 2003, 2004, 2005, 2006)
LIBR 249 – Advanced Cataloging and Classification (Summer 2003; Fall 2014; Summer 2015)

University of Denver, University College
Grant Writing Certificate Seminar for Non-Profit Organizations (Fall 2020, 2021; Spring 2021)

University of Denver, Morgridge College of Education HED
5991 – Grant Writing in Higher Education (Spring 2011)
LIS 4010 – Organization of Information (Fall 2002-2009; Winter 2005; Spring 2004-2006)
LIS 4020 – Professional Principles and Ethics (Summer 2000)
LIS 4040 – Management of Libraries and Information Centers (Fall 2010; Spring 2003, 2009 (DS); Winter 2005)
LIS 4070 – Cataloging and Classification (Winter 2008, 2009, 2010, 2011, 2012; Fall 2009 (DS)) LIS
4321 – Collection Management (Spring 2005)
LIS 4326 – LIS Research (Winter 2009 (DS); Spring 2009 (DS))
LIS 4350 – Adult Materials and Services (Summer 2006, 2009)
LIS 4379 – Social Sciences Resources (Spring 2009)
LIS 4400 – Cataloging and Classification (Spring 2000, 2001; Winter 2002-2009; Summer 2005, 2006 – course renumbered LIS 4070, September 2007)
LIS 4401 – Descriptive Cataloging (Winter 2001; Spring 2002, 2003, 2006-2009; Summer 2005)
LIS 4402 – Subject Cataloging (Spring 2001, 2009; Summer 2005, 2006, 2007, 2008)
LIS 4403 – Classification Schemes (Fall 2007, 2008, 2009 (DS)) LIS
LIS 4405 – Authority Control (Winter 2009)
LIS 4510 – Materials and Services for Children (Winter 2004; Summer 2005)
LIS 4620 – Grant Writing and Fundraising (Summer 2000, 2002, 2004, 2010; Winter 2006; Fall 2006-2009)
LIS 4700 – Seminar in Technical Services (Fall 2001)
LIS 4700 – Seminar in Public Libraries (Summer 2002)
LIS 4804 – Management of Electronic Records (Spring 2004; Fall 2005)
LIS 4902 – Capstone Projects (Winter 2003, Spring 2008, 2009, 2011)
LIS 4910 – Independent Study (every quarter Winter 2000 through Spring 2011)
LIS 4920 – Service Learning (every quarter Summer 2004 through Spring 2011)
RMS 4954 – Grant Writing (Summer 2013, 2014)
RMS 4959 – Content Analysis Methodology (Spring 2015)
QRM 4978 – Grant Writing (Summer 2011, 2012)

Rutgers University, School of Communication and Information
SC&I 522 – Cataloging and Classification (Summer 2013)

University of Arizona, College of Behavioral and Social Sciences
LIS 602 – Cataloging and Classification (Summer 1995)
LIS 612 – Advanced Online Search and Retrieval (Summer 1995)

Sam Houston State University, College of Education & Applied Science
LIS 532 - Cataloging and Classification (Fall 1993, 1994, 1995)
LIS 563 - Advanced Cataloging and Classification (Summer 1994)
LIS 567 - Research Methods (Spring 1994, Spring 1995)
LIS 591 - Educational Technology (Spring 1994, 1995)
LIS 596 - Networking and Computer Technologies in Education (Fall 1993, Summer 1994, Fall 1995)

Dissertations at the University of Denver

Bowers, Stacey L. *Library Anxiety of Law School Students: A Study Utilizing the Multidimensional Library Anxiety Scale.* Chair, May 5, 2010.

Fattor, Melissa M. *Student Engagement Differences by Ethnicity and Scale for Ninth Grade Students.* Chair, November 1, 2010.

Fulton, Roseanne. *A Case Study of Culturally Responsive Teaching in Middle School Mathematics.* Kent Seidel, Chair, June 18, 2009, Outside Chair.

Grealy, Deborah S. *Tribes and Territories in Library and Information Studies Education.* Bruce Uhrmacher, Chair, June 10, 2008, Committee Member.

McCord, J. Michael. *Developing a Standard of Care for Educational Malpractice.* Chair, April 15, 2011.

Priebe, Sarah J. *Distinguishing Effects of Domain and General Knowledge on Passage Fluency and Comprehension.* Jan Keenan, Chair. July 21, 2011, Outside Chair.

Snyder-Mondragon, Sandra M. *Institutional Factors that Impact the Retention of Graduate Students of Color in Schools of Library and Information Science: A Metaregression of Accredited Library School Statistics on Student Retention and Graduation Rates.* Kathy Green, Chair, July 24, 2009, Committee Member.

Taylor, Karen Pickles. *Effective Teaching.* Elinor Katz, Chair, July 15, 2009, Outside Chair.

Thompson, Jennifer. *Distinguishing a Western Women's College: A History of the Curriculum and Student Experience at Colorado Women's College.* Edith W. King, Chair, July 16, 2010, Committee Member.

Walker, Emelda. *Influence of Organizational Factors on Job Satisfaction of Disability Service Providers at Postsecondary Institutions.* Chair, April 29, 2010.

Dissertation Proposals at the University of Denver

Bowers, Stacey L. *Library Anxiety of Law School Students: A Study Utilizing the Multidimensional Library Anxiety Scale.* Chair, November 5, 2009.

McCord, J. Michael. *Developing a Standard of Care for Educational Malpractice.* Edith W. King, Chair. April 23, 2010.

Thompson, Jennifer. *History of Colorado Women's College.* Edith W. King, Chair, October 30, 2008. Committee Member.

Walker, Emelda. *Influence of Organizational Factors on Job Satisfaction of Disability Service Providers at Postsecondary Institutions.* Chair, July 21, 2009.

Dissertations at Other Institutions

Rodríguez-Mori, Howard. *The Information Behavior of Puerto Rican Immigrants to Central Florida, 2003-2009: Grounded Analysis of Six Case Studies Use of Social Networks during the Migration Process.* Kathleen Burnett, Chair, April 10, 2009, Florida State University, Committee Member.

Schwartz, Brian *More than a Look-up Skill: Medical Information Literacy Education in Osteopathic Medical Schools.* D. Mirah Dow, Chair, July 18, 2017. Emporia State University, Committee Member.

Snow, Karen. *A Study of the Perception of Cataloging Quality among Catalogers.* Shawne D. Miksa, Chair, August 1, 2011. University of North Texas, Committee Member.

Dissertation Proposals at Other Institutions

Schwartz, Brian *More than a Look-up Skill: Medical Information Literacy Education in Osteopathic Medical Schools.* D. Mirah Dow, Chair, December 4, 2015. Emporia State University, Committee Member.

Snow, Karen. *A Study of the Perception of Cataloging Quality among Catalogers.* Shawne D. Miksa, Chair, May 11, 2010. University of North Texas, Committee Member.

Master's Thesis at the University of Denver

Hemingson, Jeff. *Recital Paper.* Lamont School of Music, February 2010, Outside Chair.

Capstones at the University of Denver

Anthony, Alisa. *Correlation of Library and Information Science Program outcomes and Vacant Position Qualifications Listed on the Colorado State Library Jobline by Employers During the Period September 1, 2000 through August 31, 2002.* Chair, Winter Quarter, 2003.

Borden, Donna M. *Improving Emergency Communications Systems: Is a Radio Communications Network the Answer?* Fall Quarter, 2014.

Bowden, Heather L.M. *Exploring Biological Models for Long-term Data Preservation.* Chair, Spring Quarter, 2008.

Casenada, Cassandra Y. *Challenges to the Recruitment, Education, and Retention of Librarians of Color*. Chair, Spring Quarter, 2008.

Chang, Jennifer C. *Legal Research Practice and Preference: A Law Firm Perspective.* Chair, Spring Quarter 2011.

Ellis, Megan S. Fitzgerald. *Design of a Public Library Adult Volunteer Recruitment Program and Training Curriculum.* Chair, Winter Quarter, 2003.

Kircher, Kathy. *Development of a Library Pathfinder for Exobiology and Posting it on the Internet.* Chair, Winter Quarter, 2003.

Melhado, Loretta. *Design of St. John's Episcopal Church Library.* Chair, Spring Quarter, 2008.

Radcliff, Kathy. *Original Cataloging of Archival materials in the HERS Collection in Penrose Library.* Chair, Winter Quarter, 2003.

Sass, Carol Ann. *ACT Periodical Index: Access to Catholic Thinking Periodical Index: Web Index to Select Catholic Periodicals.* Spring Quarter 2000.

Stone, Sergio D. *Conducting Community Analysis for the Bemis Public Library (Littleton, Colorado) Using 2002 U.S. Census Data and the Online Outcome-Based Evaluation Toolkit.* Chair, Winter Quarter, 2003.

Tureson, Tamara. *Design and Use of an Information Audit Tool for Use in a Law Library.* Chair, Winter Quarter, 2003.

Tweed, Beth. *Evaluation of Email Reference Service in a Consumer Health Library Environment.* Chair, Winter Quarter, 2003.

GRANTS AND CONTRACTS

Student Learning in Agriculture STEM through Teacher Professional Development. Research team: Stanton Gartin (PI) and Cyndi Hofmeister, Northeast Junior College; Jeff Cash, Cheryl Sánchez, Anne-Marie Crampton, Lamar Community College; Suzanna Spears, Morgan Community College; Jack Wiley, Kerry Gabrielson, Trinidad State Junior College; Michael J. Miller, Colorado State University; Michael Womochil (Co-PI), Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Agriculture, Agriculture and Food Research Initiative, Food, Agriculture, Natural Resources and Human Sciences Education and Literacy Initiative, $404,460 (2017-2020)

Leading and Achieving: the Colorado Agriculture Regional Consortium. Research team: Jack Wiley (PI), Kerry Gabrielson, Trinidad State Junior College; Jeff Cash (PI), Cheryl Sánchez, Anne-Marie Crampton, Lamar Community College; Suzanna Spears, Morgan Community College; Cyndi Hofmeister, Northeast Junior College; Michael Womochil (Co-PI), Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Agriculture, Hispanic Serving Institutions Education Grants Program, $504,414 (2017-2020)

Cyber Prep Program Planning Grant. Research team: Debbie Sagen (PI), Brenda Lauer, Pikes Peak Community College; Gretchen Martin, Koiosa Insights; and, Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Commerce, Regional Alliances and Multi-stakeholder Partnerships to Stimulate (RAMPS) Cybersecurity Education and Workforce Development, $199,681 (2016-2018)

Career and Technical Education in Colorado: Pathways to Education and Employment. Research team: Heather McKay (PI), Rutgers University; Sarah Heath, Casey Sacks, Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Education, Institute of Education Sciences, $1,400,000 (2017-2021)

Pre-Alliance Planning Grant Colorado Community College Alliance. Research team: Victor Vialpondo (PI) and Janel Highfill, Community College of Aurora; Heidi Loshbaugh (Co-PI), Community College of Denver; Rick Reeves, Bill McGreevy, Liz Cox, and Kristin Aslin, Red Rocks Community College; Cathy Pellish, Front Range Community College; Samuel DeVries, Arapahoe Community College; Sylvia D. Hall-Ellis, Colorado Community College System. National Science Foundation, Louis Stokes Alliance for Minority Participation (LSAMP), $86,817 (2016-2017)

Towards Scalable Differentiated Instruction Using Technology-enabled, Competency-based, Dynamic Scaffolding. Research team: Karen Wilcox (PI) and Vijay Kumar, Center for Computational Engineering, Massachusetts Institute of Technology; Flora McMartin, Broad-based Knowledge; Quinsigamond Community College; and, Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Education, First in the World Developmental Grant, $2,891,882 (2015-2019)

Colorado Strategic Partnerships Emergency Grant. Research team: Elise Lowe-Vaughn (PI), Amy Hodson, Celia Hardin, Barbara McBride, James Newby, Christopher Dewhurst, Nina Holland, Kate Anderson, MaryAnn Roe, Chrystalynn Chrystalynn, Elaine Edon, Mona Barnes, Tom Morgan, Rob Hanni, and Marie Valenzuela, Colorado Department of Labor and Employment; Steve Anton, Joelle Brouner, and, Katie Griego, Colorado Department of Human Services; Rebecca Holmes, Judith Martinez, and Jennifer Jirous, Colorado Department of Education; Emily Templin Lesh, Colorado Workforce Development Council; Cory Everett, Colorado Department of Regulatory Agencies; and, Casey Sacks and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Labor, Strategic Partnerships Emergency Grant, $5,000,000 (2015-2017)

CAEL Jump Start Program: Competency-Based Education. Research team: Jerry Migler (PI), Casey Sacks, Debra Cohn, Thomas Hartman, and Sylvia D. Hall-Ellis, Colorado Community College System; Matt Jamison, Front Range Community College; Mike Coste, Red Rocks Community College; Amanda Corum, Pueblo Community College; Janet Colvin, Pikes Peak Community College; and, MaryAnn Matheny, Community College of Denver. Council for Adult and Experiential Learning, $15,000 (2015)

Summit on the Redesign of Developmental Education. Research team: Jerry Migler (PI), Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System; Chip Nava, Pueblo Community College; Kim Moultney, Arapahoe Community College; Debbie Ulibarri, Trinidad State Junior College; and, Kris Bernard, Front Range Community College. American Association of Community Colleges, $15,000 (2015-2016)

Equity in Excellence at Colorado Community Colleges. Research team: Keith Howard (PI) and Sylvia D. Hall-Ellis, Colorado Community College System; Estela Mata Bensimon, Center for Urban Education, University of Southern California; and Kerry Gabrielson, Trinidad State Junior College. Colorado Department of Higher Education, Colorado Opportunity Scholarship Program, $150,000 (2015-2016)

MBA High School of Business in Colorado. Research team: Laurie Urich (PI) and Sylvia D. Hall-Ellis, Colorado Community College System; Rudolph Sumpter and Beatrice Gerrish, Boulder Valley Schools; Keith Curry Lance, RSL Research Group. Colorado Department of Higher Education, Colorado Opportunity Scholarship Program, $501,295 (2015-2016)

Fullbridge Program in Colorado. Research team: Keith Howard (PI) and Sylvia D. Hall-Ellis, Colorado Community College System; Suzanna Spears, Fort Morgan Community College; and, Cheryl Sánchez and Anne-Marie Compton, Lamar Community College. Colorado Department of Higher Education, Colorado Opportunity Scholarship Program, $300,000 (2015-2017)

Colorado Community College System Alternative Credit Program. Research team: Jerry Migler (PI), Keith Howard, and Sylvia D. Hall-Ellis, Colorado Community College System. American Council on Education, $13,000 (2015)

Internationalization in Higher Education. Researcher: Samuel D. Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, $8,000 (2014-2015)

International Perspectives on Bilingual Education. Researcher: Sharolyn Pollard-Durodola. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, $3,700 (2014-2015)

Cultivating Culturally Relevant and Responsive Curriculum and Pedagogy in College. Researcher: Samuel Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, iRise Grant, $5,000 (2014-2015)

Project EMERGE (Educational Model for Evaluation and Replicability in Gifted Environments). Research team: Norma Hafenstein (PI) and Bruce Uhrmacher. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Lynde and Harry Bradley Foundation, $235,000 (2014-2015)

Collecting Asian American Refugee Stories. Researcher: Samuel Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. American Educational Research Association, Research Grant, $5,000 (2014-2015)

Developing Expertise in Teaching K-5 Mathematics. Research team: Julie Sarama (PI) and Douglas H. Clements (Co-PI), in partnership with the School of Education at the University of Michigan. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, $130,344 (2013-2015)

Investigation of the Long-Term Outcomes for Special Education Students. Researcher: Antonio Olmos-Gallos. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Jefferson County School District, Office of Assessment, $40,000 (2014)

Refugee Community Collaboration. Researcher: Vicki Tomlin (PI) in partnership with the African Community Center and Jewish Family Service. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, $14,854 (2014-2015)

Access to Mathematics for All. Research team: Richard S. Kitchen (PI), Nicole M. Russell (Co-PI), and Terrence Blackman (Co-PI), Curriculum Studies and Teaching Program, Morgridge College of Education; Álvaro Árias (Co-PI, Department of Mathematics); and, James Gray (Co-PI), Department of Mathematics, Community College of Aurora. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, The Robert Noyce Scholarship Program, Capacity Building Project, $349,926 (2014-2016)

Cognitive Test Battery for Intellectual Disabilities. Research team: Karen Riley (PI), Lyndsay Agans, Jessica Lerner, and Karin Dittrick-Nathan in partnership with David Hessl (PI), The MIND Institute at the University of California – Davis, and Elizabeth Berry-Kravis, Rush University Medical Center. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Institutes of Health, Outcome Measures for Use in Treatment Trials for Individuals with Intellectual and Developmental Disabilities (R01), $2,499,996 ($588,672 at DU) (2014- 2019)

Broadening Participation in Engineering among Women and Latino/as: A Longitudinal, Multi-Site Study. Researcher: Patton Garriott (PI) in partnership with the University of North Dakota and the University of Missouri. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, HER Core Research, $677,390 ($69,992 at DU) (2014-2019)

Designing a Teacher Evaluation System to Improve Teacher Effectiveness for Culturally and Linguistically Diverse Learners. Research team: María del Carmen Sálazar (PI), Jessica Lerner, and Kathy Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, $29,988 (2014-2016)

Developing a College-Going Culture in Latina/O Families: Exploring the Influence of Funds of Knowledge on Family Outreach Programs. Researcher: Judy Marquez Kiyama. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, $18,720 (2014-2016)

Assessment of Quality of Life in Neutral Implantation Surgery for the Treatment of Parkinson's Disease. Researcher: Cynthia McRae. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, $3,967 (2014-2015)

Pura Vida: Cloud Forest, Curriculum and Cross-Cultural Study. Research team: Norma Hafenstein (PI) and Bruce Uhrmacher (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, $8,000 (2014-2015)

Online Course Development for Curriculum and Instruction. Researcher: Ruth Chao. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, $3,000 (2014)

Online Course Development for Curriculum and Instruction. Researcher: María del Carmen Sálazar. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, $3,000 (2014)

Online Course Development for Curriculum and Instruction. Researcher: Jessica Lerner. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, $3,000 (2014)

Online Course Development for Curriculum and Instruction. Researcher: Duan Zhang. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, $3,000 (2014)

The Mathematics Education of African Americans, 1866 – 1954. Researcher: Nicole M. Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Academy of Education, Spencer Foundation Postdoctoral Fellowship, $55,000 (2014-2016)

Early Childhood Care and Education Study. Research team: Carrie Germeroth (PI), Melissa Mincic, and Douglas H. Clements. Technical reviewer for MCE: Sylvia D. Hall-Ellis. State of North Dakota, Department of Public Instruction, $73,500 (2013-2014)

Graduate Level Specialty in Addiction Counselor Training with Emphasis on Integration of Native American Specific Content. Research team: Ruth Chao (PI) and Michael J. Faragher (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. The Galena Foundation, $289,732 (2013-2016)

The Collecting Asian American and Pacific Islander Refugee Stories (CARS) Project. Researcher: Samuel Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, $15,000 (2014)

Parents in Transition: A Multiple Case Study of Parent and Family Orientation Programs. Researcher: Judy Marquéz Kiyama. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, $1,500 (2014-2015)

The Sistah Network: Black Women Graduate Students Supporting and Retaining Each Other. Researcher; Nicole M. Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, $2,708 (2014-2015)

Evaluation of the Northeast Denver Babies Ready for College Program. Research team: Carrie Germeroth (PI), Melissa Mincic, and Douglas H. Clements. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Mile High Montessori, $9,922 (2013-2014)

Developing Teaching Expertise in K-5 Mathematics. Research team: Julie Sarama (PI) and Douglas Clements (University of Denver), in partnership with Timothy Boerst (PI), Meghan Shaughnessy, Deborah Ball, Hyman Bass (School of Education at the University of Michigan). Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, $449,827 ($130,344 at the University of Denver (2013-2015)

Early Learning Care and Education Study Program Grant for the State of North Dakota. Research team: Carrie Germeroth (PI), Melissa Mincic, and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. State of North Dakota Department of Public Instruction, $73,500 (2013-2014)

Local Professional Learning Community for School Leaders. Research team: Susan Korach (PI), Kristina Hesbol, and Rebecca McClure. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Education Development Center, $10,950 (2013)

Healthy Eaters, Lifelong Movers 2: Implementing Evidence-Based School Environment, Policy, and Curricular Changes to Increase Opportunities for Healthy Eating and Physical Activity in Low Income, Rural Colorado. Research team: Elaine Berlansky, University of Colorado at Denver (PI), Nicholas Cutforth, University of Denver (Co-PI), and Allison Reeds. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Health Foundation, $3,103,108 (2013-2017)

Hughes Rare Books Library Room Renovation in the Sturm College of Law. Project team: Patti H. Marks, Sylvia D. Hall-Ellis, and Leigh Elliott. Mabel T. Hughes Charitable Trust, $34,000 (2013-2014)

The Promise Center Partnership with the Marsico Institute for Early Learning and Literacy and the City and County of Denver. Research team: Karen Riley (PI), Douglas H. Clements (Co-PI), and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. The Piton Foundation, $223,468 (2013-2014)

Center of Excellence for Problem Gambling. Research team: Ruth Chao (PI) and J. Mike Faragher. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Behavioral Health, $68,021 (2012-2013)

United Way Implementation and Validation Review. Research team: Douglas H. Clements (PI), Amanda Moreno, and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Mile High United Way, $19,737 (2013)

Math/Science Partnership in Rural Districts. Research team: Kristen Bunn (PI, Eagle County Schools), Paul Michalec (Co-PI), and Alegra Reiber. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Education, Colorado's Mathematics and Science Partnership Program, $750,000 (2013-2014)

Mathematics and Science Education of African Americans. Research team: Nicole Russell (PI), Sylvia D. Hall-Ellis, Steve Fisher (Penrose Library). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, $29,994 (2013-2015)

Online Course Development for Curriculum and Instruction. Researcher: Nicole Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, $3,000 (2013)

Discourse and Opportunity: Undocumented Students and Higher Education Policy. Researcher: Ryan Gildersleeve. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Academy of Education, Spencer Foundation Postdoctoral Fellowship, $55,000 (2012-2014)

An Anthropological Study of the Latino Graduation Ceremony. Researcher: Ryan Gildersleeve. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Spencer Foundation, $39,900 (2012-2013)

Fragile-X and Pharmaceutical Company: Clinical Trial of AFQ056. University of California – Davis Children's Hospital MIND Institute (Sacramento), Children's Hospital Denver, and Rush Children's Hospital at Rush University Medical Center (Chicago). Karen Riley, PI. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Novartis Pharmaceuticals Corporation, $394,206 (2012-2014)

Project Engage, Phase 2, a DAPRA Grant in partnership with Total Immersion Systems, Inc., and Texas A&M University. Research team: Karen Riley (PI) and Lyndsay Agans (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Defense, $60,000 (2011-2013)

International School Psychology Practicum Exchange. Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, $14,951 (2012-2013)

Online Course Development for Curriculum and Instruction. Research team: Bruce Uhrmacher (PI) and Norma Hafenstein (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, $18,193 (2012-2014)

Writers in the Schools. Research team: Karen Riley (PI) and Amanda Moreno (Co-PI).Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Humanities, $4,965 (2012-2013)

Learning Ecosystem Validation Grant. Research team: Karen Riley (PI), Lyndsay Agans, Kent Seidel, and Shimelis Assefa. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Bill & Melinda Gates Foundation, $315,000 (2012-2013)

Project Words of Oral Reading and Language Development (WORLD). Research team: Jorge E. Gonzalez (PI), Texas A&M University; Laura Saenz (Co-PI), University of Texas – Pan American; and, Sharolyn Pollard-Durodola (Co-PI), University of Denver. Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Education, Institute of Education Sciences, $53,354 (2012-2015); award $640,718, transfer from Texas A&M University

Increasing the Efficacy of an Early Mathematics Curriculum with Scaffolding Designed to Promote Self-Regulation. Research team: Douglas H. Clements (PI) and Julie Sarama (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Education, Institute of Education Sciences, $1,445,315 (2008-2014); award $4,541,975, transfer from University at Buffalo, The State University of New York

Using Rule Space and Poset-based Adaptive Testing Methodologies to Identify Ability Patterns in Early Mathematics and Create a Comprehensive Mathematics Ability Test. Research team: Douglas H. Clements (PI) and Julie Sarama (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, $323,791 (2010-2014); award $1,194,944, transfer from University at Buffalo, The State University of New York

Comprehensive Postdoctoral Training in Scientific Education Research. Researcher: Julie Sarama (PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Education, Institute of Education Sciences, $133,458 (2010-2014); award $613,353, transfer from University at Buffalo, The State University of New York

Longitudinal Study of a Successful Scaling Up Project: Extending TRIAD. Research team: Douglas H. Clements (PI), Julie Sarama (Co-PI), and Abt Associates (Carolyn Layzer, Fatih Unlu, Laurie Bozzi, Lily Fesler, Alina Martinez, Cristofer Price, James van Orden). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Institute of Education Sciences, $384,940 (2011-2015; award $1,250,286, transfer from University at Buffalo, The State University of New York

Early Childhood Education in the Context of Mathematics, Science, and Literacy. Research team: Julie Sarama (PI), Douglas H. Clements (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, $990,020 (2010-2014; award $2,285,228, transfer from University at Buffalo, The State University of New York

Early Childhood Clearinghouse Information Center Redesign. Research team: Karen Riley (PI) and Amanda Moreno (Co-PI).Technical reviewer for MCE: Sylvia D. Hall-Ellis. Office of the Lt. Governor of Colorado, $12,000 (2012-2013)

Morgridge Rural Educational Leadership Initiative. Research team: Lyndsay Agans (PI), Linda Brookhart (Co-PI), Susan Korach, and Rebecca McClure. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Morgridge Family Foundation, $100,000 (2012-2014)

Center of Excellence for Problem Gambling. Research team: Patrick Sherry (PI) and J. Mike Faragher. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Behavioral Health, $55,000 (2012-2013)

Intermodal Transportation Institute Research Initiatives. Researcher: Patrick Sherry. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University Transportation Centers Program, Research and Innovative Technology Administration, U.S. Department of Transportation. $600,000 (2012-2014)

Mile High United Way Social Innovation Fund Early Literacy Initiative. Gloria L. Miller, PI, Amanda Moreano, Kim Hartnett-Edwards, and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Mile High United Way, $89,992 (2012-2013)

International School Psychology Practicum Exchange. Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, $1,000 (2012-2013)

Refugee Student Art Outreach. Researcher: Karin Dittrick-Nathan. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, $3,000 (2012-2013)

Resistance, Resilience, and Reciprocity: Centering the Voices of Black Doctoral Women with Faculty Aspirations. Researcher: Nicole M. Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, $2,965 (2012-2013)

Assessing Learning through Student Notebooks. Research team: Keith Miller, Nancy Sasaki, and Kathy Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, $30,000 (2012-2014)

International School Psychology Practicum Exchange. Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, $2,000 (2012-2013)

ELO in Colorado. Research team: Cynthia Hazel and Duan Zhang. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Legacy Foundation, $150,000 (2012-2013)

Creating Online LIS Courses. Research team: Mary C. Stansbury (PI), Shimelis Assefa, Denise Anthony, Xiao Hu, and Krystyna Matusiak. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Teaching and Learning, $15,000 (2011-2013)

Maritime Piracy Seminar. Researcher: Ved Nanda, The Nanda Center, Sturm College of Law. Technical reviewer for Sturm College of Law: Sylvia D. Hall-Ellis. Arsenault Family Foundation, $15,000 (2012-2013).

Early Childhood Librarianship: An Interdisciplinary, Experiential Learning MLIS. Researcher: Mary C. Stansbury (PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Laura Bush's 21st Century Librarians Program, Institute for Museums and Library Services, $249,066 (2012-2014)

Learning Ecosystem Planning Grant. Research team: Karen Riley (PI), Lyndsay Agans, Kent Seidel, and Shimelis Assefa. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Bill & Melinda Gates Foundation, $281,217 (2011-2012)

Advanced Service Learning Practitioner Faculty Grant, Sylvia D. Hall-Ellis, University of Denver, Center for Community Engagement and Service Learning, $400 (2011)

Evaluating and Enhancing the EspeciallyMe Program. Research team: Lori D. Patton and Nicole Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, Public Good Fellowship Grant, $24,780 (2012)

Choosing Excellence: Let Every Child Bloom. Research team: Shimelis Assefa (PI) and Mary C. Stansbury (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, Public Good Grant, $7,657 (2012)

K-8 STEM Content Specific Professional Development to Improve Elementary Student Achievement. Research team: Kent Seidel (PI), Nicole Russell (Co-PI), Kimberly Hartnett-Edwards, Paul Michalec, Jeff Farmer, Keith Miller, Alegra Reiber, and Nancy Sasaki. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Education, Improving Teacher Quality Grant, (Title II ESEA), $307,299 (2011-2012)

Building a Better Principal Pipeline to Boost Student Achievement. Researcher: Susan Korach. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Denver Public Schools; a subcontract from the Wallace Foundation Grant, $170,000 (2011-2017)

Center of Excellence for Problem Gambling. Research team: J. Mike Faragher (Co-PI) and Bobbie Vollmer (PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Behavioral Health, $79,999 (2011-2012)

An Exploration of Novice Teachers' Core Competencies: Impacts on Student Achievement, and Effectiveness of Preparation. Research team: Kent Seidel (PI), Kathy Green (Co-PI), Kimberly Hartnett-Edwards, and Duan Zhang. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Institute of Education Sciences, Effective Teachers and Effective Teaching, $990,987 (2012-2015)

Project Engage, a DAPRA Grant in partnership with Total Immersion Systems, Inc., and Texas A&M University. Research team: Karen Riley (PI) and Lyndsay Agans (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Defense, $49,964 (2011-2014)

User-centered Evaluation of Music Search Engines. Researcher: Xiao Hu. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, $2,931 (2011-2012)

Educational Practicum in Vietnam and China to Promote the Inclusion of Young Children with Disabilities. Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, $5,000 (2011-2012)

Evaluation of Colorado's Enhancing Quality in Infant-Toddler (EQIT) Initiative. Research team: Virginia R. Maloney and Amanda Moreno. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Buell Foundation, $395,884 (2011-2013)

Creating Engaging Environments to Teach Pre-Algebra Mathematics to Elementary Students. Research team: Álvaro Arias, Mario López, María del Carmen Salazar, and Lyndsay Agans. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver Interdisciplinary Grant, $60,000 (2011-2012)

Morgridge Education Technology Accessible (META) Resource Project. Research team: Lyndsay Agans (PI) and Shimelis Assefa (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Morgridge Family Foundation, $36,000 (2011)

MCE Connect: A 21st Century Framework for Faculty Development. Research team: Bruce Uhrmacher (PI), Shimelis Assefa (Co-PI), Lyndsay Agans (Co-PI), Kimberly Hartnett-Edwards, Norma Hafenstein, Xiao Hu, Paul Michalec (Co-PI), María del Carmen Salazar (Co-PI), and Sandra Snyder-Mondragon. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Teaching and Learning, $22,355 (2011-2012)

Parent Education and Parent Leadership and Advocacy. Research team: Virginia Maloney (PI) and Amanda Moreno, Marsico Institute for Early Learning and Literacy. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Health Foundation, $27,358 (2010-2011)

Intentional School Culture. Researcher: Cynthia Hazel. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Denver Public Schools, $38,040 (2010-2011)

Healthy Eaters, Lifelong Movers: Implementing Evidence-Based School Environment, Policy, and Curricular Changes to Increase Opportunities for Healthy Eating and Physical Activity in Low Income, Rural Colorado. Research team: Elaine Berlansky, University of Colorado at Denver (PI), Nicholas Cutforth, University of Denver (Co-PI), and Allison Reeds. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Health Foundation, $1,683,277 (2011-2014)

Second Life Learning Community. Research team: Don McCubbrey (PI), Sylvia D. Hall-Ellis (Co-PI), Walter LaMendola, and Paul Novak. University of Denver, Center for Teaching and Learning, $13,000 (2010-2011)

Reintroducing the Value of Law Librarians to Academic and Public Librarians in Colorado through the Identification and Use of Emerging Technologies. Research team: Sylvia D. Hall-Ellis (Co-PI), Stacey L. Bowers (PI), and Christopher Hudson, in partnership with Denver Public Library, Arapahoe Library District, and the Colorado State Supreme Court Library. University of Denver, Center for Community Engagement and Service Learning, $5,773 (2010-11)

Reintroducing the Value of Law Librarians to Public Librarians through the Identification and Use of Emerging Technologies and Resources. Research team: Stacey Bowers (PI) and Sylvia D. Hall-Ellis (Co-PI). American Association of Libraries, Wolters Kluwer Law & Business Grant Program, $2,725 (2010-2011)

Faculty Service Learning Pod. Research team: María del Carmen Salazar and Nicholas Cutforth (Curriculum and Instruction Program), Frank Tuitt (Higher Education Program), Cynthia Hazel and Gloria Miller (Child, Family, and School Psychology Program), and Sylvia D. Hall-Ellis (Library and Information Science Program). University of Denver, Center for Community Engagement and Service Learning, $8,000 (2010-2011)

Lincoln Collaborative. Research team: Antonio Esquibel (Principal, Lincoln High School), María del Carmen Salazar (Curriculum and Instruction Program), and. Sylvia D. Hall-Ellis. School Improvement Grant, Denver Public Schools, $375,000 (2010-2012)

Future LEADers of America: Leaders III. Research team: Denver Public Library (Kristen Svendson, PI), the University of Denver (Sylvia D. Hall-Ellis), the Colorado Chapter of REFORMA (Orlando Archibeque), and the Colorado Association of Libraries (Martin Garnar). Laura Bush's Recruiting Librarians for the 21st Century Program, Institute for Museums and Library Services, $988,366 (2009-2012)

Teaching for Success in the Library Environment: LIS 4030 in Library 2.0. Research team: Deborah S. Grealy (PI) and Sylvia D. Hall-Ellis (Co-PI). University of Denver, Center for Teaching and Learning, $ 9,350 (2009-10)

Writing Group Faculty Grant, Sylvia D. Hall-Ellis, University of Denver, Center for Community Engagement and Service Learning, $750 (2008-2009)

Collaborative Learning Faculty Grant, Sylvia D. Hall-Ellis, University of Denver, Center for Teaching and Learning, $1,500 (2008)

Connecting Information Literacy to Learning. Research team: Lori Micho, Merrie Valliant, Amanda Samland, and Sylvia D. Hall-Ellis. Colorado State Library, LSTA Discretionary Grant Program, $19,548 (2008-2009)

Law Librarianship Fellows Program. Research team: Sylvia D. Hall-Ellis (PI), Stacey Bowers (Co-PI), and Christopher Hudson, Westminster Law Library. Laura Bush's 21st Century Librarians Program, Institute for Museums and Library Services, $999,370 (2008-2012)

Grant Writing in a Cooperative Learning Environment. Sylvia D. Hall-Ellis. University of Denver, Center for Teaching and Learning, $2,000 (2008-2009)

Project Homeless Connect 6 Event Evaluation. Research team: Sylvia D. Hall-Ellis and Duan Zhang. University of Denver Center for Community Engagement and Service Learning, $9,785 (2008)

Project Ecuador: International Learning Service Libraries – A Faculty Development Experience in Ecuador. Sylvia D. Hall-Ellis, Office of Internationalization, University of Denver, $600 (2007)

Project Ecuador: International Learning Service Libraries – A Faculty Development Experience in Ecuador. Sylvia D. Hall-Ellis, International Service Learning Office, University of Denver, $400 (2007)

Project Homeless Connect 5 Event Evaluation. Research team: Sylvia D. Hall-Ellis and Duan Zhang. University of Denver Center for Community Engagement and Service Learning, $1,000 (2007)

Project Homeless Connect 4 Event Evaluation. Research team: Sylvia D. Hall-Ellis and Duan Zhang. University of Denver Center for Community Engagement and Service Learning, $4,595 (2007)

Future LEADers of America: Leaders II. Research team: Denver Public Library (Kristen Svendson, PI), the University of Denver (Sylvia D. Hall-Ellis), and the Colorado Chapter of REFORMA (Orlando Archibeque). Laura Bush's Recruiting Librarians for the 21st Century Program, Institute for Museums and Library Services, $988,518 (2007-2010)

Strategic Planning Assistance for the Denver Medical Library. Sylvia D. Hall-Ellis. Denver Medical Library, Inc., $30,000 (2006-2007)

Destiny Software for JMAC Student Lab. Sylvia D. Hall-Ellis, gift from the Sagebrush Corporation, Minneapolis, Minnesota, $10,000 (2006)

Libraries: Tools for Education and Development Worldwide: A Faculty Development Experience in France. Sylvia D. Hall-Ellis, Office of Internationalization, University of Denver, $800 (2005)

Denver Public Library: Opportunities for Change. Sylvia D. Hall-Ellis, Colorado Community Based Research Network, $2,000 (2005)

Future LEADers of America. Research team: Denver Public Library (Letty Icolari and Steve Taylor, PIs), Emporia State University (Jim Agee), and the University of Denver (Sylvia D. Hall-Ellis). Recruiting Librarians for the 21st Century Program, Institute for Museums and Library Services, $670,315 (2005-2008)

American Association of University Professors Summer Institute Professional Development Grant. Sylvia D. Hall-Ellis, American Association of University Professors, $300 (2005)

Beta Phi Mu Alumni Tea. Sylvia D. Hall-Ellis, gift from the Office of Alumni and Parent and Relations, University of Denver, $2,000 (2005)

Spectrum Software for LIS Student Lab. Sylvia D. Hall-Ellis, gift from the Sagebrush Corporation, Minneapolis, Minnesota, $5,000 (2005)

Developing Research Capacity in Community Organizations and Residents through Training and Technical Assistance. Nicholas J. Cutforth (PI) and Sylvia D. Hall-Ellis. Piton Foundation, $25,000 (2005-2006)

Libraries: Tools for Education and Development Worldwide: A Faculty Development Experience in Argentina. Sylvia D. Hall-Ellis, Office of Internationalization, University of Denver, $500 (2004)

Developing Research Capacity in Community Organizations and Residents through Training and Technical Assistance. Research team: Nicholas J. Cutforth (PI), Gary Lichtenstein and Sylvia D. Hall-Ellis, Piton Foundation, $25,000 (2003-2004)

Increasing Spanish-Speaking and Hispanic Diversity among Library and Information Science Students at the University of Denver: Development of a Student Recruitment Model. Researcher: Sylvia D. Hall-Ellis (PI), Office of Multicultural Excellence, University of Denver, $2,750 (2003-2004)

Collection Development Enrichment to Support the Cataloging & Classification Specialization and School Librarianship within the Library & Information Science Program at the University of Denver. Research team: Sylvia D. Hall-Ellis (PI) and Deborah S. Grealy. Women's Library Association, University of Denver, $4,000 (2003)

Collection Development Enrichment to Support the Library & Information Science Program at the University of Denver. Research team: Deborah S. Grealy (PI) and Sylvia D. Hall-Ellis. Women's Library Association, University of Denver, $4,000 (2001)

Wireless LAN for Library Education. Research team: Deborah S. Grealy (PI) and Sylvia Hall-Ellis. University of Denver, Center for Teaching and Learning, $24,000 (2001-2002)

Upward Bound – A Program for South Texas Youth. Research team: Monte Churchill, Executive Director of Community Relations; Gary R. Sauceda, Outreach Coordinator; Raymond Hernandez, (PI) Associate Dean for Student Success; and Sylvia D. Hall-Ellis, South Texas Community College (McAllen, Texas). U.S. Department of Education, Office of Postsecondary Education, $2,672,003 (1999-2003)

Write Now! Improving Elementary Students' Writing Skills. Research team: Caryl G. Thomason, Assistant Superintendent (PI); Karen Tankersley, Principal; and, Hal Anderson, Director of Technology, Cheyenne Mountain School District 12 (Colorado Springs, Colorado); and Sylvia D. Hall-Ellis. Colorado Department of Education, Educational Telecommunications Unit, $189,453 (1999-2001)

Operation Quick Start -- Distance Learning in Rural Colorado. Research team: Randal Weigum, Technology Coordinator (PI); Bonnie Barns, Director of Federal Programs and Staff Development; and, Adam "Joe" Raskop, Executive Director, Southeastern Board of Cooperative Educational Services (Lamar, Colorado); and Sylvia D. Hall-Ellis. Colorado Department of Education, Educational Telecommunications Unit, $400,000 (1999-2001)

Advanced Technological Training for Information Professionals for the 21st Century. Research team: Mario Reyna, Division of Business Director (PI) and Sylvia D. Hall-Ellis, South Texas Community College (McAllen, Texas). Phi Delta Kappa and the National Science Foundation, $250,000 (1999-2001)

Working Connections – Training Information Technologies Professionals for the 21st Century. Research team: Mario Reyna, Division of Business Director (PI) and Sylvia D. Hall-Ellis, South Texas Community College (McAllen, Texas). Microsoft Corporation and the American Association of Community Colleges, $1,147,775(1999-2001)

The ROAD (Research Oriented Amplification of Development to Literacy) Program. Research team: Deborah J. Leong (PI), Metropolitan State University; Elena Bodrova, Metropolitan State University; Dmitri Semenov, Robert J. Marzano, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Hewlett-Packard Foundation, $25,000 (1998-1999)

Press to Literacy. Research team: Deborah J. Leong (PI), Metropolitan State University; Elena Bodrova, Metropolitan State University; Dmitri Semenov, Robert J. Marzano, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). The Denver Post and the Robert S. McCormick Foundation, $49,818 (1998-1999)

International Telementor Center. Research team: David Neils, David B. Frost (PI), and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Hewlett-Packard Philanthropy, $100,000 (1998-1999)

America Reads: Providing Tutor Training for the America Reads Challenge. Research team: Louis F. Cicchinelli (PI) and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Department of Education, Office of Educational Research and Improvement, $306,000 (1998-1999)

Comprehensive School Reform. Research team: Louis F. Cicchinelli (PI), J. Timothy Waters, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Department of Education, Office of Educational Research and Improvement, $285,000 (1998-1999)

Sustainable Energy Education (SEE) Program for Grades 4-8: Preparing Today's Youth for Lifelong Learning and Responsible Actions in Energy Conservation. Research team: Mary Gromko, Colorado Department of Education; Gene McCarthy, Rocky Flats Field Office, U.S. Department of Energy; Gina Kissell, National Renewable Energy Laboratory; and Barbara L. McCombs (PI), Janet L. Bishop, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). State of Colorado Governor's Office for Energy Conservation, $499,936 (1997-1999)

Review of Kansas Curriculum Standards in Mathematics and Language Arts. Research team: Robert J. Marzano (PI), John S. Kendall, David B. Frost, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Submitted to the Kansas State Department of Education, $25,903 (1998)

International Telementor Center. Research team: David Neils, John Kuglin, Chris Rapp, David B. Frost (PI), and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Hewlett-Packard Company, $54,752 (1998)

Genesis Mission: Education Public Outreach. Developed in partnership by the Jet Propulsion Laboratory, California Institute of Technology, Los Alamos National Laboratory, Lockheed Martin Astronautics, and the Mid-continent Regional Educational Laboratory (Aurora, Colorado). Research team: John T. Sutton (PI), Alice Krueger, Martha Henry, Greg Rawls, Shae Isaacs, Jeff Johnson, Deb Jordan, Arlene Mitchell, David B. Frost, Jana Caldwell, J. Timothy Waters, and Sylvia D. Hall-Ellis. National Aeronautics and Space Administration, $139,700,000; subcontract award, $4,750,000 (1997-2007)

North Dakota Mathematics Assessment Project. Developed in partnership by the North Dakota Department of Education and Mid-continent Regional Educational Laboratory (Mid-continent Regional Educational Laboratory). Research team: Ann Clapper, Clarence Bina, Greg Gallagher, North Dakota Department of Education; Don Burger (PI), Hillary Michaels, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Office of Education, $1,618,214; subcontract award, $389,076 (1997-2001)

Pacific Resources for Education and Learning Distance Education: Project Evaluation. Developed in partnership by the Pacific Educational Community, the Pacific Resources for Education and Learning (PREL), and Mid-continent Regional Educational Laboratory (McREL). Research team: John W. Kofel (PI), Executive Director, PREL; J. Timothy Waters, Executive Director; Joan Buttram, Robert Keller, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Office of Education, Star Schools Program, $10,000,000; subcontract award, $500,000 (1997-2002)

Identification of Bilingual Gifted and Talented Children: A Comprehensive School Grants for Bilingual Education. Developed in partnership by Hidalgo (Texas) ISD, Los Fresnos (Texas) CISD, Progreso (Texas) ISD, University of Texas – Pan American (Edinburg, Texas), and Education Service Center, Region One (Edinburg, Texas). Research team: Hilda Medrano, Dean, College of Education, University of Texas – Pan American; Linda Phemister (PI), Janie Navarro, and Sylvia D. Hall-Ellis, Education Service Center, Region One. U.S. Department of Education, Office of Bilingual Education and Minority Languages Affairs, $1,670,633 (1997-2002)

Academics 2000: First Things First -- The Texas Goals 2000. Developed for Jim Hogg (Hebbronville, Texas) County ISD, Mirando City (Texas) ISD, and San Isidro (Texas) ISD. Research team: Hilda Medrano, Dean, College of Education, University of Texas - Pan American (Edinburg, Texas); Angie Lehmann, Amy Mares, Ellen Gonzalez (PI), and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg, Texas). Texas Education Agency, $339,987 (1997-2000)

Southwestern Bell's Learning Communities Initiative. Developed for Tech Prep of the Rio Grande Valley, Inc. (Harlingen, Texas); the Center for Professional Teacher Development, University of Texas – Brownsville; Teach for America – Rio Grande Valley (McAllen, Texas); and Education Service Center, Region One (Edinburg, Texas). Research team: Patricia G. Bubb, Executive Director (PI), Tech Prep of the Rio Grande Valley; Martin Winchester, Executive Director, Teach for America – Rio Grande Valley; Aileen Johnson, Director, School of Education, University of Texas – Brownsville; and Sylvia D. Hall-Ellis. Southwestern Bell Foundation, $100,000 (1997-1998)

Texas School to Work: Regional Implementation. Developed for Tech Prep of the Rio Grande Valley, Inc. (Harlingen), South Texas Community College (McAllen), Texas State Technical College (Harlingen), Texas Southmost College (Brownsville), Empowerment Zone of the Rio Grande Valley (Mercedes), Project VIDA (Weslaco), Youth Fair Chance (McAllen), and Education Service Center, Region One (Edinburg). Research team: Patricia G. Bubb (PI), Tech Prep of the Rio Grande Valley; Stephen Vassberg, Texas State Technical College; Ellen Trevino, Youth Fair Chance; Wanda Garza, Project VIDA; Leonardo Olivares, University of Texas – Pan American; Michael Bell, South Texas Community College; and Sylvia D. Hall-Ellis. Texas Workforce Commission, $4,250,000 (1997-2002).

Comprehensive Bilingual Education Grant for Hidalgo ISD and Roma ISD. Developed for Hidalgo (Texas) ISD, Roma (Texas) ISD, College of Education, University of Texas – Pan American (Edinburg, Texas), and Education Service Center, Region One (Edinburg, Texas). Research team: Tomas Thomas (PI), Director, Office of Bilingual Education and Sylvia D. Hall-Ellis. U.S. Department of Education, Office of Bilingual Education and Minority Languages Affairs, $1,531,361 (1997-2002)

Lopez High School, Porter High School, Rivera High School, Central Middle School, and Perkins Middle School, Brownsville (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $1,473,611 (1997-1998)

Donna High School, Todd Middle School, and Solis Middle School, Donna (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $704,052 (1997-1998)

Memorial Middle School and Nellie Schunior Middle School, La Joya Independent School District (Texas). Telecommunications Infrastructure Fund Board, $293,641 (1997-1998)

Martin High School, Christen Middle School, Cigarroa Middle School, Lamar Middle School, Laredo (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $1,200,000 (1997-1998).

Lasara Middle School, Lasara (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $246,210 (1997-1998)

Los Fresnos High School and Resaca Middle School, Los Fresnos (Texas) Consolidated Independent School District. Telecommunications Infrastructure Fund Board, $500,000 (1997-1998)

Lyford Junior High School, Lyford (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $354,997 (1997-1998)

Travis Middle School, McAllen (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $269,139 (1997-1998)

Mission High School, Mission (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $297,010 (1997-1998)

Progreso High School, Progreso (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $300,000 (1997-1998)

San Perlita High School, San Perlita (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $293,490 (1997-1998)

Myra Green Junior High School, Raymondville (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $225,000 (1997-1998)

Rio Grande City High School, Ringgold Middle School, Gruella Middle School, Rio Grande City (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $809,934 (1997-1998)

Rio Hondo Junior High School, Rio Hondo (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $297,024 (1997-1998)

Roma High School, Roma (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $333,178 (1997-1998)

San Benito High School, Miller Jordan Junior High School, San Benito (Texas) Consolidated Independent School District. Telecommunications Infrastructure Fund Board, $547,000 (1997-1998)

Santa Maria High School and Santa Maria Middle School, Santa Maria (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $400,000 (1997-1998)

Salvador High School, United Independent School District (Laredo, Texas). Telecommunications Infrastructure Fund Board, $250,879 (1997-1998)

Weslaco High School, Cabaza Middle School, Cuellar Middle School, Weslaco (Texas) Independent School District. Telecommunications Infrastructure Fund Board, $874,242 (1997-1998)

Principals' Assessment and Training Center. Developed for Education Service Center, Region One (Edinburg, Texas). Research team: Roberto Zamora, Leonel Barrera, William H. Parry, and Sylvia D. Hall-Ellis. Texas Principals' Leadership Initiative, Texas Association of Secondary School Principals, Texas Association of Elementary School Principals, and the Sid Richardson Foundation. $461,439 (1996-1998)

The Texas Library Connection -- Integrating and Sharing Resources. Developed for Hidalgo County Library System (McAllen), Cameron County Library System (Brownsville), South Texas Community College (McAllen), the University of Texas - Pan American (Edinburg), University of Texas – Brownsville, and Education Service Center, Region One (Edinburg). Research team: William R. McGee, Coordinator, Hidalgo County Library System; Joe Garcia, Director, Cameron County Library System; Michael D. Bell, Library Director, South Texas Community College; Eleanor Folger Foster, University Library, University of Texas - Pan American; Jaime Vela (PI), Director of Instructional Technology and Media Services, Ron Pontius, Instructional Technology, and Fabiola Fuentes, Media Services, Education Service Center, Region One; and Sylvia D. Hall-Ellis. Office of Library Media Services, Technology Services, Texas Education Agency. $8,000 (1996-1997)

Developing Leadership Communities for Improving Algebra I for All Students. Developed for a partnership of the Region One Statewide Systemic Initiative Team. Research team: Noel Villarreal (PI), Eduardo Cancino, and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Statewide Systemic Initiative for Reform in Mathematics, Science and Technology Education to The Charles A. Dana Center for Mathematics and Science Education, The University of Texas at Austin. $25,000 (1996-1997)

Academics 2000: First Things First -- The Texas Goals 2000. Developed for Edinburg (Texas) CISD. Research team: Hilda Medrano, Dean, College of Education, University of Texas - Pan American (Edinburg); Helen Jones, Director (PI), Gifted and Talented Education, Edinburg CISD; and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, $750,000 (1996-2001)

Texas Teachers Empowered for Achievement in Mathematics (TEXTEAM) Institute for Algebra I. Developed for Hidalgo ISD, Jim Hogg (Hebbronville) County ISD, La Joya ISD, La Villa ISD, Lyford ISD, Mission CISD, Pharr-San Juan-Alamo ISD, Rio Hondo ISD, San Isidro ISD, San Perlita ISD, Santa Maria ISD, Santa Rosa, Sharyland ISD, Valley View ISD, Webb (Laredo) CISD, Weslaco ISD, and Zapata County (Zapata) ISD. Research team: Noel Villarreal (PI), Chuck McInteer, Ellen M. Gonzalez, Education Service Center, Region One (Edinburg); and Sylvia D. Hall-Ellis. Charles A. Dana Center for Mathematics and Science Education, University of Texas - Austin, $15,975 (1996)

Community Learning Center for La Villa, Texas. Developed for Edcouch-Elsa Independent School District. Research team: Noe Gonzalez (PI), Assistant Superintendent, Edcouch-Elsa Independent School District, and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, $325,000 (1996-1997)

Monte Alto (Texas) Community Learning Center. Developed for Monte Alto Independent School District. Research team: Homero A. Diaz (PI), Superintendent, Monte Alto Independent School District, and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, $300,000 (1996-1997)

Community Learning Center for La Villa, Texas. Developed for La Villa Independent School District. Research team: Sam Gonzalez (PI), Assistant Superintendent, La Villa Independent School District; and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, $325,000 (1996-1997)

Building Project for Taylor Elementary. Developed for Mercedes (Texas) Independent School District. Research team: Mrs. Denise Rivera, Librarian, and Eduardo Infante, Principal, Taylor Elementary School; Ismael S. Cantu (PI), Federal Programs Director, Mercedes Independent School District; and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, $375,000 (1996-1997)

Border Education Network (BEN) - Distance Education through Cable Television. Developed for Edinburg (Texas) Consolidated Independent School District. Research team: Noe Torres (PI), Library Media Specialist, Magdalena
Rosas, Library Media and Technology Coordinator, Edinburg Consolidated Independent School District; and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Edinburg (Texas) Consolidated School District, $250,000 (1996-1997)

Multiservice One-Stop Open Enrollment Charter School. Developed for the Information Referral Resource Assistance, Inc. (McAllen, Texas). Research team: Pablo Perez and Aguie Pena (PI), Executive Director, Information Referral Resource Assistance, Inc.; Roberto Zamora and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, $3,066,000 (1996-2001)

Project OK: A Community Youth Opportunities Grant for Summer, 1996. Developed for McAllen (Texas) Independent School District, St. Joseph the Worker Catholic Church, and the Office of Adult Education, Education Service Center, Region One. Research team: Father Bart Flatt, St. Joseph the Worker Catholic Church; Noe Calvillo (PI), Office of Adult Education; Maria Louisa Garcia, McAllen Independent School District; and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Protective and Regulatory Agency through the Office of the Mayor, City of McAllen, $350,000 (1996-2001).

Early Childhood: a Time of Discovery. Developed for a partnership of Lasara ISD, Rio Hondo ISD, San Perlita ISD, the School of Education, University of Texas - Brownsville, and Education Service Center, Region One (Edinburg). Research team: Hugo Rodriguez, Dean, School of Education, University of Texas - Pan American; Leonel Barrera and Jack Damron, Field Service Agents, Ellen M. Gonzalez (PI), Administrator for Student Instructional Services, Ruth Solis, Education Specialist in Special Education, and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, $722,090 (1996-2001)

Innovative Gifted and Talented Programs for Early Childhood and Elementary Education Students. Developed for a partnership of Edinburg (Texas) CISD, the School of Education, University of Texas - Pan American (Edinburg), and Education Service Center, Region One (Edinburg). Research team: Hilda Medrano, Dean, School of Education, University of Texas - Pan American; Helen de la Garza (PI), Director of Elementary Curriculum and Instruction, Edinburg CISD; and Sylvia D. Hall-Ellis. Texas Education Agency, $750,000 (1996-2001)

Reading Recovery in Early Elementary Grades. Developed for a partnership of La Villa (Texas) ISD the School of Education, University of Texas - Pan American (Edinburg), and Education Service Center, Region One (Edinburg). Research team: Hilda Medrano, Dean, School of Education, University of Texas - Pan American; Marcario Salinas (PI), Supervisor of Elementary Curriculum and Instruction, La Villa ISD; and Sylvia D. Hall-Ellis, Education Service Center, Region One. Texas Education Agency, $750,000 (1996-2001)

Connected Mathematics Project for Middle and Junior High Students. Developed for a partnership of Michigan State University, The Charles A. Dana Center for Mathematics and Science Education, The University of Texas at Austin and Region One Statewide Systemic Initiative Team. Research team: Jack Damron, Chuck McInteer, Noel Villarreal (PI), and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). National Science Foundation through Michigan State University to the Charles A. Dana Center at the University of Texas - Austin, $539,610 (1996-1999)

Sharing Resources: Testing the Interlibrary Loan Potential of the Texas Library Connection -- Integrating Media Resources. Developed under the sponsorship of the Hidalgo County Library System (McAllen) and Education Service Center, Region One (Edinburg). Research team: William H. McGee, Hidalgo County System Coordinator; Fabiola Fuentes, Library Media; Ronald Pontius (PI), Instructional Technology, Education Service Center, Region One; and Sylvia D. Hall-Ellis. Library Media Services Program, Office of Technology Services, Texas Education Agency, $25,000 (1996-1997)

State and Federal Adult Education JOBS Program. Developed for Education Service Center, Region One (Edinburg). Research team: Noe Calvillo (PI), Director, Adult Education Program, and Sylvia D. Hall-Ellis. Adult Education Program, Texas Education Agency, $532,846 (1995-1996)

Creating Safe and Drug-Free Schools and Communities. Developed for a partnership of the Region One Consortium for Safe and Drug-Free Education Environments. Research team: Clara Contreras (PI), Health Specialist, and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, $150,000 (1995-1996)

Developing Leadership Communities for Improving Mathematics Performance for All Students on Title I Campuses. Developed for a partnership of the Region One Statewide Systemic Initiative Team. Research team: Jack Damron, Chuck McInteer, Noel Villarreal (PI), and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Statewide Systemic Initiative for Reform in Mathematics, Science and Technology Education to The Charles A. Dana Center for Mathematics and Science Education, The University of Texas at Austin, $50,669 (1995-1996)

The Impact of Library Resource Centers on Academic Achievement in Selected Public Schools in South Texas. Sylvia D. Hall-Ellis (PI). Developed under the sponsorship of the Department of Library Science, College of Education and Applied Science, Sam Houston State University (Huntsville). Texas Association of School Librarians, Children's Services Round Table, and Young Adults Round Table (Austin, Texas), $2,500 (1995)

School Library Media Specialists Fellowship Program. Sylvia D. Hall-Ellis (PI). Developed under the sponsorship of the Department of Library Science, College of Education and Applied Science, Sam Houston State University (Huntsville, Texas). U.S. Department of Education, HEA Title II-B, Library Education and Human Resource Development Program, $44,000 (1995-1996)

Planning for Educational Technology. Research team: Ruth Ann Riggins (PI), Director of Library Media and Technology Services, Donna (Texas) Independent School District; Noe Torres, Education Service Center, Region One; Patricia G. Bubb, Tech Prep of the Rio Grande Calley, Inc; Michael D. Bell, South Texas Community College; and Sylvia D. Hall-Ellis, Sam Houston State University. Developed under the sponsorship of Donna (Texas) Independent School District, Education Service Center, Region One (Edinburg), Tech Prep of the Rio Grande Valley, Inc. (Harlingen), South Texas Community College (McAllen), and the Department of Library Science, Sam Houston State University (Huntsville). Funded through Infusion of Educational Technology Planning Grant Program (H.B. 18: Models). Texas Education Agency, $18,000 (1993-1994)

The Impact of Library Resource Centers on Academic Achievement in Selected Public Schools in South Texas. Sylvia D. Hall-Ellis (PI) and Mary Ann Berry. Developed under the sponsorship of the Department of Library Science, College of Education and Applied Science, Sam Houston State University (Huntsville). Sam Houston State University Research Enhancement Fund, $7,500 (1993-1994)

Electronic Mail Resource Sharing System: Management and Operation of the Iowa Computer-Assisted Network. State Library of Iowa, $294,000 (1986-1993)

The Iowa Locator: A CD-ROM Resource Sharing Tool. State Library of Iowa, $567,000 (1986-1992)

Statewide Database Development: An OCLC Tape Analysis To Determine Feasibility. State Library of South Dakota, $15,000 (1987)

The Iowa Locator: A Feasibility Study. State Library of Iowa, $50,000 (1986)

Electronic Mail Resource Sharing System: A Feasibility Study for Libraries in the State of Iowa. State Library of Iowa, $5,000 (1985)

Access Pennsylvania: A Feasibility Study. State Library of Pennsylvania, $50,000 (1984)

Automating Library Administrative and Management Tasks: Procurement and Distribution of Microcomputer Systems for District Library Centers in the Commonwealth of Pennsylvania. State Library of Pennsylvania, $495,000 (1982)

Sharing Serial Titles Resources: Procurement and Distribution of Microfiche Readers for 550 Libraries in the Commonwealth of Pennsylvania. State Library of Pennsylvania, $500,000 (1982)

Electronic Mail System: A Pilot Project for Libraries throughout the Commonwealth of Pennsylvania. State Library of Pennsylvania, $125,000 (1982)

Literacy Program for Adults in Rural Upstate New York State: Program Outreach and Evaluation - Phase 3. Appalachian Regional Commission, $50,000 (1981)

Database Building: A Cooperative Project of the Finger Lakes Library System (Ithaca), Four County Library System (Binghamton), and the Southern Tier Library System (Corning). New York State Library, $450,000 (1980-1985)

Faces of the Southern Tier: A Professional Photographer-in-Residence. New York State National Endowment for the Humanities, $25,000 (1980)

Literacy Program for Adults in Rural Upstate New York State: Program Implementation - Phase 2. Appalachian Regional Commission, $50,000 (1980)

Small Business Resources Center: A Pilot Project for Rural Public Libraries. New York State Library, $50,000 (1980)

Media Programming: A Professional Development Program for Public Librarians in Upstate New York: A Program in Allegheny, Chemung, Schuyler, Steuben, and Yates Counties. New York State Library, $35,000 (1979)

Information and Library Resources for Inmates and Prisoners in Selected Upstate New York Facilities: A Cooperative Program in Allegheny, Chemung, Schuyler, Steuben, and Yates Counties. New York State Library, $25,000 (1979)

Library Resources for Homebound Adults in Upstate New York: An Outreach Program in Allegheny, Chemung, Schuyler, Steuben, and Yates Counties. New York State Library, $40,000 (1979)

Literacy Program for Adults in Rural Upstate New York State: Program Initiation and Establishment - Phase 1. Funded by the Appalachian Regional Commission. Awarded to the Corning (New York) Public Library, $50,000 (1979)

Information Reference Services to Homebound Adults. New York State Library, $31,000 (1978)

Books-By-Mail Services to Homebound Adults. New York State Library, $31,000 (1978)

System Headquarters Services and Programs for Public Libraries in District 10. Funded through Library Services and Construction Act Title I. Texas State Library and Historical Commission, $880,000 (1976)

County Library Development Grant for Atascosita County. Funded through Library Services and Construction Act Title I. Texas State Library and Historical Commission, $15,000 (1976)

Spanish Language Materials Collection Development Program. Texas State Library and Historical Commission, $40,000 (1975)

Establishment of System Headquarters for Alamo Regional Library System (District 10) Headquartered at the San Antonio (Texas) Public Library. Texas State Library and Historical Commission, $800,000 (1975)

SELECTED CONSULTANTSHIPS

Project Strategic Planning & Funding Proposal Development

Walden University, 2015.
Pikes Peak Library District, 2014.
Douglas County Public Libraries, 2011-2012.
Denver School for Science and Technology, 2008-2011.
Johnson & Wales University, Denver Campus, 2007-2009.
Challenges, Choices, and Images K-12 Charter School, Denver Public Schools, 2007.
Denver Medical Library, Inc., 2006-2010.
Bemis Public Library (Littleton), Ergonomic Design and Facilities Enhancement Consultant, 2003.
Curtis Park Community Center (Denver), Community Technology Center Evaluation and Proposal Development Consultant, 2003.
Colorado Community Based Research Network (Denver), Funding Research Associate, 2002.
Our Lady of the Rosary Academy (Edgewater), Learning Resource Center Development Project Consultant, 2001-2003
University of Southern Colorado (Pueblo). Technology Integration and Curriculum Enhancement into Higher Education Learning Environment. Proposal Development Consultant, 2000.
Jefferson County Library System (Lakewood), 1999-2000.
Southeastern BOCES (Lamar, CO). Distance Learning Curriculum Content Development Project. Proposal Development Consultant, 1998-2004.
Cheyenne Mountain School District 12 (Colorado Springs, CO). Technology Integration into Elementary Writing Curriculum Project. Proposal Development Consultant, 1998.
Telecommunications Infrastructure Fund Board Round #2 Application, 1997. Technical assistance to the following: La Villa (Texas) Independent School District; Mirando City (Texas) Independent School District; Monte Alto (Texas) Independent School District; San Isidro (Texas) Independent School District.
Telecommunications Infrastructure Fund Board Round #1, 1996. Technical assistance to the following: Brownsville (Texas) Independent School District; Donna (Texas) Independent School District; Edinburg (Texas) Consolidated Independent School District; Harlingen (Texas) Consolidated Independent School District; Jim Hogg County Independent School District (Hebbronville, Texas); La Feria (Texas) Independent School District; La Joya (Texas) Independent School District; La Villa (Texas) Independent School District; Los Fresnos (Texas) Consolidated Independent School District; Progreso (Texas) Independent School District; Raymondville (Texas) Independent School District; Rio Hondo (Texas) Independent School District; San Benito (Texas) Independent School District; Sharyland Independent School District (Mission, Texas); Weslaco (Texas) Independent School District; Zapata (Texas) County Independent School District.
South Texas Community College (McAllen). Strategy Development to Meet the Technology Instructional Needs for Vocational, School-To-Work and Academic Programs, 1994-2000. Development Consultant.
Donna (Texas) Independent School District. Planning for the Infusion of Technology in Middle Schools Serving High At-Risk Students, 1994-1995. Research Associate.
Pettus (Texas) Independent School District. Planning for District-wide Automation in School Library Media Centers: Preparation of Data, and CD-ROM Hardware/Software Configuration Evaluation, 1994. Principal Investigator.
Fort Bend Independent School District (Sugar Land, TX). Planning for District-wide Automation in School Library Media Centers, Preparation of Data, and CD-ROM Hardware/Software Configuration Evaluation, 1994-1995. Principal Investigator.
Northern Waters Library Services (Ashland, WI). Professional Consulting Services to Make Recommendations on the Development of System-Wide Efforts of the Northern Waters Library Service, 1988-1989. Research Associate.
State Library of Iowa (Des Moines). The Iowa Locator Compact Disc to Support Multi-Type Libraries Resource Sharing including Database Design, Building, Production, and Distribution, 1986-1991. Project Director.
State Library of Iowa (Des Moines). Iowa Computer-Assisted Network Development, Enhancement, and Operation, 1985-1992. Technical Director.
State Library of South Dakota (Pierre). Statistical Sampling and Analysis of Multi-Institutional OCLC Archive Tape for Statewide Online Database Building, 1985-1986. Research Associate.
District of Columbia Public Library (Washington, DC). Planning Document for the Retrospective Conversion of Bibliographic Records and Automation Issues in the 1990's, 1984-1985. Research Associate.

State Library of Pennsylvania (Harrisburg). Database Development for High School Libraries, 1984-1985. Research Associate.
MINITEX (Minneapolis, MN). Workshops for Retrospective Conversion, Bar Coding, Library Statistics, and OCLC Serials Format, 1985. Presenter and Research Associate.
ABC Film Consortium (Altoona, Bellefonte, Johnstown, PA). Database Building, System Design, and Implementation of Online Film Booking System, 1983-1985. Database Manager.

Library Automation -- System Design & Implementation

Douglas County Library District (Castle Rock, CO). Library Automation Technical and System Performance Specifications, 2001.
Pharr-San Juan-Alamo Independent School District (Pharr, TX). Library Automation Technical and System Performance Specifications, 1997. Project Development Consultant.
Harlingen (Texas) Independent School District. Planning for District-wide Automation in Junior High School Library Media Centers: Preparation of Data, and CD-ROM Hardware/Software Configuration Evaluation, 1996. Principal Investigator.
Sharyland (Texas) Independent School District. Design and Construction of New Elementary School Library and Technology Resources Center, 1995-1996. Principal Investigator.
South Texas Independent School District (Mercedes, TX). Design and Construction of a New High School Library and Technology Resources Center, 1995-1996. Principal Investigator.
Citizens' Library (Washington, PA). Online Community Resources Files: Design and Implementation, 1984. Research Associate.
Altoona (Pennsylvania) Hospital. Integrated Online System Upgrade Study, 1984. Research Associate.
State Library of South Dakota (Pierre). Automation Plan and State Database Development, 1982-1983. Principal Investigator.
State Library of Pennsylvania (Harrisburg). COM Production and Preparation of the Technical Specifications Document, Procurement, and Distribution of Microcomputers in the Commonwealth of Pennsylvania, 1983-1984. Research Associate.
Altoona (Pennsylvania) Area Public Library. Integrated System (Circulation/Online Catalog) Study, 1982-1983. Principal Investigator.
COPSCAULD (Council of Pennsylvania State College and University Library Directors, Edinboro, PA). Design of Online Media Catalog, 1982. Principal Investigator.
Erie (Pennsylvania) County Library System. Operations Research and Design for Automated Circulation, Hardware Upgrade and Re-Retrospective Conversion, 1982. Research Associate.
Michigan Library Consortium (Lansing, MI). Tape Management System Design and Implementation, 1982-1984. Research Associate.
State Library of Pennsylvania (Harrisburg). Preparation of the Technical Specifications Document, Procurement and Distribution of Microfiche Readers in the Commonwealth of Pennsylvania, 1982. Research Associate.
Community College of Allegheny County, Allegheny Campus (Pittsburgh, PA). Integrated Systems Study, 1981. Principal Investigator.
Community College of Allegheny County, South Campus (West Mifflin, PA). Retrospective Conversion Training Program for Handicapped Students, 1981. Technical Director.
Southern Tier Library System (Corning, NY). OCLC Acquisitions Subsystem Evaluation, 1981. Principal Investigator.
South Central Reference and Research Council (Ithaca, NY). South Central Regional Delivery System, 1980. Principal Investigator.
Southern Tier Library System (Corning, NY). Newspapers on Microfilm in the Chemung-Southern Tier Library System, 1979-1981. Principal Investigator.

Cataloging & Bibliographic Database Building

Challenges, Choices, and Images K-12 Charter School, Denver Public Schools, 2007.
Denver Medical Library, Inc., 2006-2010.
Ricks Gifted and Talented School Library, 2005-
American Humane Society (Englewood), 2004-2006.
Fisher Early Learning Center Library, 2004-

Colorado Community Based Research Network (Denver), 2004-
Boulder Valley School District (Boulder), 2002-2003.
Douglas Public Library District (Castle Rock), 2001-2002.

Bibliographic Center for Research, Inc. (Denver). Original Cataloging, 2001-2003 & 1992-1993. Professional Cataloger. Libraries include Arapahoe Library District (Centennial); Clarke College (Clarke, IA); Kaiser Permanente Center for Health Research (Portland, KS); Douglas County Library System (Carson City, NV); Grinnell College (Grinnell, IA); Kansas State University (Manhattan, KS); Kansas State Library (Topeka, KS); McPherson College (McPherson, KS); Newman University (Wichita, KS); Montana Technical University (Helena, MT); Montana State Library (Helena, MT); University of Texas Southwest Medical Center Library (Dallas, TX); Community College of Southern Nevada (Las Vegas, NV); Pikes Peak Library District (Colorado Springs); Mesa Community College (Grand Junction); Coe College (Cedar Rapids, IA); Briar Cliff College (Sioux City, IA); Tri-Care Health Systems (Aurora); The Penrose-St. Francis Healthcare System (Colorado Springs); Westminster Public Library (Westminster); Lutheran Medical Center Medical Library (Wheat Ridge); American Heritage Center, University of Wyoming (Laramie, WY); National Wildlife Research Center Library (Lakewood); University of Colorado Health Sciences Center, Denison Memorial Library (Denver); Water Resources Library, Denver District Office, Bureau of Land Management (Lakewood); Mesa State Community College Learning Resources Center (Pueblo); Front Range Community College Learning Resources Center (Westminster).

Colorado Historical Society Library (Denver). Original Cataloging of Serials for Multi-Institutional Union Listing Project, 1993. Technical Services Associate. Institutional partners: Denver Art Museum, Denver Museum of Natural History Library, and Denver Botanical Gardens Library.

Arapahoe Library District (Centennial). Original Cataloging of Major Media, 1991.

Original Cataloging Projects: Davis and Elkins College (Elkins, WV), 1989-1990; Waldorf College (Forest City, IA), 1989-1990; Kennametal Corporation (Latrobe, PA), 1984-1985; Pennsylvania Public Libraries Film Center (Harrisburg), 1982-1985.

Retrospective Conversion Projects: North Central Regional Library Service (Mason City, IA), 1987-1988; Southeastern Library Services (Davenport, IA), 1986-1987; Virginia Theological Seminary (Alexandria), 1984-1985; California University of Pennsylvania (California, PA), 1984-1985; Kennametal Corporation (Latrobe, PA), 1984-1985; West Virginia University (Morgantown), 1983-1985; Altoona Area Public Library (Altoona, PA), 1983-1984; George Washington University (Washington, DC), 1983-1984; Indiana University of Pennsylvania (Indiana, PA), 1983-1985; Health Education Center (Pittsburgh), 1983-1984; Central Pennsylvania District Library Center (Bellefonte, PA), 1982-1985; Duquesne University Law School Library (Pittsburgh), 1982-1983; Allegheny County Law Library (Pittsburgh), 1982-1984; Calgon Technical Information Center (Pittsburgh), 1982; Dow Corning Corporation, Technical Information Center (Midland, MI), 1982-1983; Tri-System Public Library Retrospective Conversion Project (Binghamton, Corning, and Ithaca, NY), 1978-1981, Technical Project Director.

Updated June 2023

ATTACHMENT 1A

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246 3 a| Diabetes technology and therapeutics
260 a| Larchmont, NY : b| Mary Ann Liebert, c| c1999-
300 a| v. : b| ill. ; c| 28 cm.
310 a| Bimonthly, b| 2002-
321 a| Quarterly, b| 1999-2001
362 0 a| Vol. 1, no. 1 (spring 1999)-
500 a| Title from cover.
500 a| Published: New Rochelle, NY, <Feb. 2007->
500 a| Latest issue consulted: Vol. 9, no. 1 (Feb. 2007).
510 0 a| Chemical abstracts x| 0009-2258
530 a| Also issued online.
650 0 a| Diabetes v| Periodicals. =| ^A525733
650 0 a| Medical technology v| Periodicals. =| ^A542732
650 12 a| Diabetes Mellitus x| therapy v| Periodicals. =| ^A3153397
650 22 a| Blood Glucose Self-Monitoring v| Periodicals. =| ^A3449516
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999 a| RC660.A1 .D528 v.11 Jan.-June 2009 i| 30000122368016 j| RC 000660 .A1 .D528 V.000011
JAN.-JUNE 002009 l| PERIODICAL m| SBEND n| PERIODICAL w| LC
999 a| RC660.A1 .D528 v.11 July-Dec. 2009 i| 30000122358439 j| RC 000660 .A1 .D528 V.000011
JULY-DEC. 002009 l| PERIODICAL m| SBEND n| PERIODICAL w| LC
999 a| RC660.A1 .D528 v.12 Jan.-June 2010 i| 30000127882011 j| RC 000660 .A1 .D528 V.000012
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ATTACHMENT 1B

LIBRARY OF CONGRESS AUTHORITIES

The Library has opened access to some reading rooms by appointment only. More. The Jefferson Building has reopened to visitors via timed, ticketed entry. More.

LC control no.: sh2009123299
LCCN Permalink: https://lccn.loc.gov/sh2009123299
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667 __ |**a** Record generated for validation purposes.
670 __ |**a** Work cat.: Diabetes technology & therapeutics, c1999-
906 __ |**t** 8888 |**u** tc00 |**v** 0
953 __ |**a** tc00

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LCCN Permalink: https://lccn.loc.gov/sh2010101256
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001 8150264
005 20110729163545.0
008 100120|| anannbabn |n ana
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667 __ |**a** Record generated for validation purposes.
670 __ |**a** Work cat.: Biomedical technology management, c1994-
906 __ |**t** 8888 |**u** tc00 |**v** 0
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ATTACHMENT 1D

Diabetes Mellitus MeSH Descriptor Data 2021

Details | Qualifiers | MeSH Tree Structures | Concepts

MeSH Heading
Diabetes Mellitus
Tree Number(s)
C18.452.394.750
C19.246
Unique ID
D003920
RDF Unique Identifier
http://id.nlm.nih.gov/mesh/D003920
Annotation
general or unspecified; prefer specifics; pregnancy of diabetic patients = PREGNANCY IN DIABETICS but do not confuse with DIABETES, GESTATIONAL: see note there; /diet ther: consider coord with DIET, DIABETIC but see note there; alloxan- & streptozocin-induced diabetes: see note on DIABETES MELLITUS, EXPERIMENTAL
Scope Note
A heterogeneous group of disorders characterized by HYPERGLYCEMIA and GLUCOSE INTOLERANCE.
See Also
Diabetes Insipidus
Diet, Diabetic
Gastroparesis
Glucose Intolerance
Glycation End Products, Advanced
Prediabetic State
Scleredema Adultorum
Entry Combination
complications:Diabetes Complications
Date Established
1966/01/01
Date of Entry
1999/01/01
Revision Date
2017/07/17

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ATTACHMENT 1E

Blood Glucose Self-Monitoring MeSH Descriptor Data 2021

Details | Qualifiers | MeSH Tree Structures | Concepts

MeSH Heading
Blood Glucose Self-Monitoring
Tree Number(s)
E01.370.225.124.100.105
E01.370.374.100
E01.370.520.100
E02.900.950.500
E05.200.124.100.105
Unique ID
D015190
RDF Unique Identifier
http://id.nlm.nih.gov/mesh/D015190
Annotation
usually NIM; coordinate with disease /blood, not /physiopathol
Scope Note
Self evaluation of whole blood glucose levels outside the clinical laboratory. A digital or battery-operated reflectance meter may be used. It has wide application in controlling unstable insulin-dependent diabetes.
Entry Version
BGSM
Entry Term(s)
Blood Sugar Self-Monitoring
Glucose, Blood, Self Monitoring
Glucose, Blood, Self-Monitoring
Home Blood Glucose Monitoring
Monitoring, Home Blood Glucose
Self-Monitoring, Blood Glucose
Previous Indexing
Blood Glucose (1978-1988)
Monitoring, Physiologic (1978-1988)
Self Care (1981-1988)
Public MeSH Note
89
History Note
89
Date Established
1989/01/01
Date of Entry
1988/04/20
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MeSH Heading
Equipment and Supplies
Tree Number(s)
E07
Unique ID
D004864
RDF Unique Identifier
http://id.nlm.nih.gov/mesh/D004864
Annotation
general or unspecified; prefer /instrum
Scope Note
Expendable and nonexpendable equipment, supplies, apparatus, and instruments that are used in diagnostic, surgical, therapeutic, scientific, and experimental procedures.
Entry Version
EQUIPMENT SUPPLIES
Entry Term(s)
Apparatus and Instruments
Device, Medical
Devices
Devices, Medical
Equipment
Inventories
Medical Device
Medical Devices
Supplies
See Also
Catalogs, Commercial as Topic
Date Established
1966/01/01
Date of Entry
1999/01/01
Revision Date
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S/L	0	**Orig**		**EntW**		**Regl**	r	**Alph**	a				
Desc	a	**SrTp**	p	**Cont**		**DtSt**	c	**Dates**	1999	9999			

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042 pcc $a nsdp
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090 $b
210 0 Diabetes technol. ther.
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245 00 Diabetes technology & therapeutics.
246 3 Diabetes technology and therapeutics
260 Larchmont, NY : $b Mary Ann Liebert, $c ©1999-
300 volumes : $b illustrations ; $c 28 cm
310 Bimonthly, $b 2002-
321 Quarterly, $b 1999-2001
336 text $b txt $2 rdacontent
337 unmediated $b n $2 rdamedia
338 volume $b nc $2 rdacarrier
362 0 Vol. 1, no. 1 (spring 1999)-
500 Title from cover.
500 Published: New Rochelle, NY, <Feb. 2007-
510 0 Chemical abstracts $x 0009-2258
530 Also issued online.
588 Latest issue consulted: Vol. 9, no. 1 (Feb. 2007).
650 0 Diabetes $v Periodicals.

650 0 Medical technology $v Periodicals.
650 12 Diabetes Mellitus $x therapy.
650 22 Blood Glucose Self-Monitoring.
650 22 Equipment and Supplies.
650 7 Diabetes. $2 fast $0 (OCoLC)fst00892147
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776 1 $t Diabetes technology & therapeutics (Online) $x 1557-8593 $w (DLC) 2005214266 $w (OCoLC)43498340
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856 4 $u http://firstsearch.oclc.org $z Address for accessing the journal using authorization number and password through OCLC FirstSearch Electronic Collections Online
856 4 $u http://firstsearch.oclc.org/journal=1520-9156;screen=info;ECOIP $z Address for accessing the journal from an authorized IP address through OCLC FirstSearch Electronic Collections Online

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1. I am a Records Request Processor at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.

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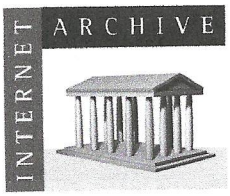
6. Attached hereto as Exhibit A are true and accurate copies of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.



7. Attached hereto as Exhibit B are true and accurate copies of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each file.

8. I declare under penalty of perjury that the foregoing is true and correct.

DATE: Aug 23, 2021

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DexCom™ STS™

Continuous Glucose Monitoring System

User's Guide

Dexcom

Take Control. Live Uninterrupted.

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User's Guide

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DEXCOM™ STS™
CONTINUOUS GLUCOSE MONITORING SYSTEM

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INTRODUCTION

The DexCom™ STS™ Continuous Glucose Monitoring System provides you with real time continuous glucose measurements every 5 minutes for up to 3 days (72 hours). These readings will help you detect trends and patterns in your glucose levels. The DexCom STS System also features adjustable high and low glucose alerts to notify you when you are outside of your target glucose levels. The DexCom STS System consists of three components: the STS Sensor, the STS Transmitter, and the STS Receiver. The DexCom STS System is currently only compatible with the LifeScan OneTouch® Ultra® Blood Glucose meter for calibration using a connection cable (Blood glucose values from the OneTouch Ultra Meter or other blood glucose meters CANNOT be manually entered in to the STS Receiver).

The DexCom STS Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in adults (age 18 and older) with diabetes. The DexCom STS System is intended for use by patients at home and in healthcare facilities. The device is for prescription use only.

The DexCom STS Continuous Glucose Monitoring System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The DexCom STS Continuous Glucose Monitoring System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the DexCom STS System results should be based on the trends and patterns seen with several sequential readings over time.

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The STS™ Sensor is a disposable unit that you insert into your abdomen (belly) to continuously monitor your glucose levels for up to 3 days (72 hours). The STS Transmitter is a reusable device that snaps into the STS Sensor Pod and wirelessly sends glucose information measured by your STS Sensor to the STS Receiver. The STS Receiver is a hand-held device that receives and displays glucose information every 5 minutes sent by the STS Sensor/ Transmitter. The STS Receiver displays your current glucose value and also shows your glucose trend information from the past 1-hour, 3 hours, and 9 hours. These trends allow you to see where your glucose levels have been and which direction your glucose levels are headed. The STS Receiver also vibrates and beeps to let you know when your glucose levels are high or low.

Clinical Studies reported 21 adverse events in 16 of 91 subjects Studied. These events consisted of 2 blisters, 2 reports of edema(swelling) and 17 reports of erythema(redness). All events were mild and required no treatment.

This User's Guide describes how to use your DexCom STS System from start to finish of a continuous glucose monitoring session. Important safety information, warnings, cautions, and contraindications of the DexCom STS System are described in the next few pages and throughout this guide. Be sure to read this entire User's Guide before beginning your glucose monitoring session.

IMPORTANT SAFETY INFORMATION

READ THIS ENTIRE GUIDE BEFORE USING YOUR DEXCOM™ STS™ CONTINUOUS GLUCOSE MONITORING SYSTEM. IF YOU DO NOT UNDERSTAND SOMETHING OR HAVE ANY QUESTIONS, PLEASE ASK YOUR DIABETES MANAGEMENT TEAM OR ANOTHER HEALTH CARE PROVIDER. CONTRAINDICATIONS, WARNINGS PRECAUTIONS, AND OTHER IMPORTANT SAFETY INFORMATION CAN BE FOUND IN THIS SECTION, AND IN BOXES THROUGHOUT YOUR DEXCOM STS SYSTEM USER'S GUIDE. THE TROUBLESHOOTING SECTION (SECTION 8) CONTAINS IMPORTANT INFORMATION ON TROUBLESHOOTING YOUR DEXCOM STS SYSTEM.

CONTRAINDICATIONS

- The DexCom™ STS System must be removed prior to Magnetic Resonance Imaging (MRI).
- Use of acetaminophen-containing medications when the STS Sensor is inserted may affect the performance of the device.

WARNINGS AND PRECAUTIONS

WARNINGS

- This device is not designed to replace a blood glucose meter. The DexCom™ STS System must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the DexCom STS System. You must confirm with a blood glucose meter before making therapeutic adjustments.
- Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use your blood glucose meter to check the STS System results.

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- You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

PRECAUTIONS

- Always wash hands with soap and water before opening the STS Sensor package. After opening the package, avoid touching the adhesive area.
- Before inserting the STS Sensor, always clean the skin at the STS Sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol. Do not apply the STS Sensor until the cleaned area is dry.
- Establish a rotation schedule for choosing each new STS Sensor location. Avoid STS Sensor location that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.
- Avoid injecting insulin within 3 inches of the STS Sensor or 3 inches from an insulin infusion set for pump wearers.
- The STS Sensor must be covered with a water resistant bandage or tape prior to showering or bathing.
- The STS Sensor is sterile in its unopened, undamaged package. Do not use any STS Sensor if its sterile package have been previously damaged or opened.
- The STS System has currently only been tested in adult persons with type 1 and type 2 diabetes. The device has not been tested in children, adolescents or pregnant women.

CAUTION

- U.S. federal law restricts the sale of the DexCom™ STS System to sale by or on order of a physician.

SECTION 1

OVERVIEW OF THE DEXCOM™ STS™ SYSTEM

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1.1 GLOSSARY

The following list of terms will help you while reading though this guide.

BG value – Blood Glucose value. A fingerstick blood glucose value taken on your LifeScan One-Touch Ultra Meter.

BG Meter – Blood Glucose Meter. Currently the only meter compatible with the DexCom™ STS™ System is the OneTouch Ultra Meter.

Calibration – Required for the DexCom STS System to display continuous glucose data and trend information. Performed by uploading One Touch Ultra meter blood glucose values to the STS Receiver. (Do not use alternate site testing for calibration.)

DexCom™ STS™ System – The STS Sensor, STS Transmitter, and STS Receiver.

Glucose Trends – Allows you to see the pattern of your glucose levels; you can see where your glucose levels have been and where your glucose levels are headed. The DexCom STS System has three (3) glucose trend screens: the 1-Hour, 3-Hour, and 9-Hour Screens. Each trend screen shows glucose trends over the specified time.

mg/dL – Milligrams per deciliter. The standard unit of measure for glucose readings in the United States.

mmol/L – Millimoles per liter. The standard unit of measure for glucose readings in many countries outside the United States.

Glucose Data Gaps – When the STS™ Receiver does not display glucose values sent from the STS Sensor to the STS Receiver.

Range – The distance between the STS Receiver and STS Transmitter. The 2 devices should be kept within 5 feet (1.5 meters) from each other for best communication.

RF – Radio Frequency Transmission of the STS Transmitter to the STS Receiver.

Sensor Probe – The portion of the STS Sensor that is inserted under your skin using the STS Applicator. Measures glucose levels in your surrounding tissue fluid.

SN # – STS Transmitter serial number that is programmed into your Receiver for communication.

Start-Up Period – The 2-hour period after you insert a new STS Sensor (Glucose information cannot be provided during this time).

STS™ Applicator – A disposable piece of the STS Sensor that you use to insert the Sensor Probe. There is a needle inside the STS Applicator that you remove once you have inserted the Sensor Probe underneath your skin.

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STS™ Receiver – A pager-like device programmed to collect and process data from the STS Sensor and to display the results as a glucose value (mg/dL or mmol/L).

STS™ Sensor – A device inserted underneath the skin to continuously monitor glucose levels.

STS™ Sensor Pod – The small base adhered to your abdomen that holds the STS Transmitter in place. The STS Sensor Pod and STS Transmitter are all that remain on your skin during each STS Sensor wear period.

STS™ Transmitter – Device that snaps into the STS Sensor Pod and wirelessly sends glucose data to your STS Receiver.

STS™ Transmitter Latch – The small disposable piece that snaps the STS Transmitter into the STS Sensor Pod.

Upload – To transfer BG values from the OneTouch Ultra Meter to your STS Receiver. You transfer BG values directly with the connection cable.

1.2 STS™ SENSOR OVERVIEW

The DexCom™ STS Sensor is a device that continuously measures your glucose levels. You will use a Blood Glucose(BG) meter to calibrate the readings measured by the STS Sensor. The glucose levels measured by the STS Sensor are sent by a wireless, low-powered, radio frequency (RF) to the STS Receiver every 5 minutes for up to 3 days (72-hours).

The STS Sensor consists of an STS Applicator (needle/sensor housing), Sensor Probe and STS Sensor Pod. You will insert the Sensor Probe just beneath the skin (subcutaneous tissue) of your abdomen (belly) using a small needle inside the STS Applicator. The needle is inserted about ½ inches (1.3 cm) beneath your skin and carries the Sensor Probe with it. After you insert the needle and Sensor Probe, you will pull the needle back into the STS Applicator, leaving the Sensor Probe behind to continuously measure your glucose levels. The STS Applicator is then removed from the STS Sensor Pod and should be thrown away.

The Sensor Probe lies ½ inch underneath your skin and will continuously measure your glucose levels for up to 3 days. The STS Sensor and STS Transmitter (once snapped in) are all that remain on your body for the entire wear period. The insertion site looks very similar to an insulin pump infusion site.

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1.3 STS™ TRANSMITTER OVERVIEW

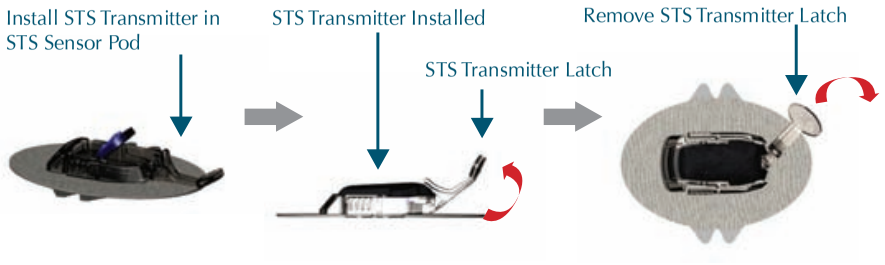
The STS Transmitter wirelessly sends glucose information collected by your STS Sensor to your STS Receiver. Once you insert your STS Sensor, you will snap the STS Transmitter into the STS Sensor Pod, using the STS Transmitter Latch. The STS Transmitter can be used for multiple STS Sensor wear periods (for approximately 6 months).

As your STS Transmitter nears the end of its useful life, it may periodically loose communication with the STS Receiver even if they are within 5 feet(1.5m) of each other. Once your STS Transmitter battery has drained, you will need to replace it.

Your new STS Transmitter can easily be programmed to communicate with your DexCom STS System (see Section 7.2).

NOTE

No warning is given when your STS Transmitter battery is about to die. Contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) to order a new STS Transmitter so you can continue using your DexCom STS System.



1.4 STS™ RECEIVER OVERVIEW

The STS Receiver is similar to a pager or an insulin pump and communicates the glucose information measured by the STS Sensor to you. Your STS Receiver should be kept within 5 feet (1.5 m) of your STS Sensor Pod (with STS Transmitter) at all times for best communication. The best places to keep your STS Receiver are on your beltline in the carrying case provided or in the pocket of your pants. During nighttime use you may want to place the Receiver under your pillow.

The STS Receiver is rechargeable like a cell phone. The re-chargeable battery should last for about 5 days before needing to be charged; however the STS Receiver will alert you when the battery charge is low. The STS Receiver takes 3 hours to fully charge if the battery was completely drained. To charge the STS Receiver, plug the charger cable provided into a standard wall outlet. If you are currently wearing a STS Sensor, remember that you should stay within 5 feet (1.5 m) of your STS Receiver to continue to receive continuous glucose information.

The STS Receiver has 4 buttons to guide you through its screens. The screens display Glucose values and Trend Graphs and allow you to change your STS Receiver settings. You can program your STS Receiver with a specific STS Transmitter Serial Number (SN#) so your STS Receiver and STS Transmitter can “talk” to each other. You will also notify your STS Receiver each time you insert a new STS Sensor.

Each STS Sensor must be calibrated before glucose readings can be displayed on your STS Receiver. To calibrate, you directly connect your STS Receiver to the LifeScan OneTouch Ultra Meter using the connection cable. By connecting the 2 devices, you will

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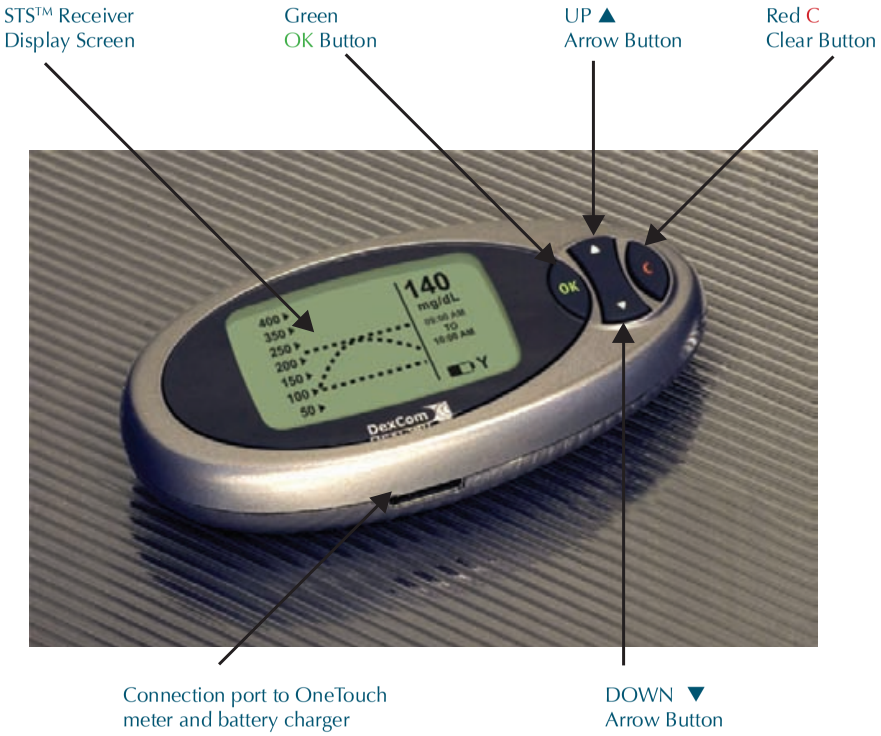
transfer fingerstick blood glucose values taken on your OneTouch Ultra Meter to your STS Receiver. Please note, BG values from the OneTouch Ultra Meter or other blood glucose meters CANNOT be manually entered into your STS Receiver, and you should not use alternate site testing to check your blood glucose.



1.4.1 STS™ RECEIVER SCREEN SYMBOLS

The following symbols may appear on the STS Receiver display during use:

	ANTENNA: Indicates the STS Receiver and STS Transmitter are "talking" and glucose data has been sent in the last 5 minutes.
	LOW BATTERY ALERT: Indicates the STS Receiver battery is running low and needs to be recharged. Charging should be done as soon as possible.
	CONNECTION: Indicates the BGM is successfully transferring BG values to your STS Receiver.
	CONNECTION FAILURE: Indicates the BGM and your STS Receiver are not connected properly. BG values have not been successfully transferred.
	NEW METER SCREEN: Indicates that a new meter has been plugged into the STS Receiver. This meter has a different serial number from the presently registered meter. You will have to re-take any fingersticks needed for calibration and then connect the 2 devices again for a calibration update.

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	DUAL BLOOD DROP PROMPT: Appears approximately 2 hours after you insert a new STS™ Sensor and indicates that you need to take 2 fingerstick BG values on your BG meter and upload them to get into calibration.
	SHADED-OUT BLOOD DROP PROMPT: Notifies you that only 1 fingerstick BG value has been successfully uploaded from the BG meter to the STS Receiver. You need to take and upload at least 1 more BG value for calibration.
	CALIBRATION UPDATE SCREEN: Indicates you should take a calibration fingerstick on the BG meter and upload it to the STS Receiver.
	OUT OF CALIBRATION SCREEN: Indicates the STS Receiver is out of calibration. You will need to take another BG fingerstick and upload it to your STS Receiver at this time.

	ERROR CODE: Indicates the STS™ Receiver is not functioning properly. If you see this code, use your meter to check your blood glucose readings and notify DexCom Technical Support at 1-877-DEXCOM4 (339-2664).
	6 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 6 hours.
	2 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 2 hours.
	30 MINUTE STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session will end in 30 minutes.
	0 HOUR STS SENSOR EXPIRATION NOTIFICATION: Indicates that your Continuous Glucose Monitoring Session has ended. Once you clear the alert your STS Receiver will be notified that the STS Sensor is removed.

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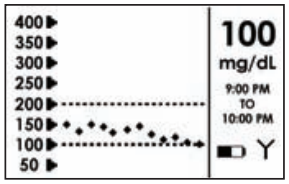
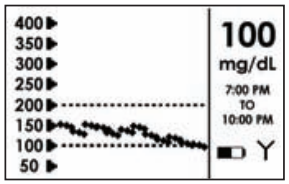
1.4.2 VIEWING THE STS™ RECEIVER SCREENS

By default, the STS Receiver's Liquid Crystal Display (LCD) screen is turned off to save battery power. However, you can press any STS Receiver button to display the 1-hour Trend Screen.

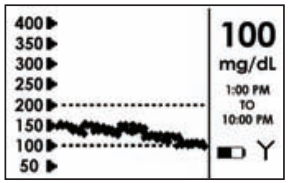
Use the Up ▲ and Down ▼ Arrow Buttons to move through screens. The OK button confirms any change you make to a setting, and the C Button sends you back to the previous screen or to the 1-hour trend screen if you are in the first series of a setting screen. The chart below shows the STS Receiver screens you can navigate through to view glucose readings or set your STS System settings.



1-Hour Glucose Trend Screen



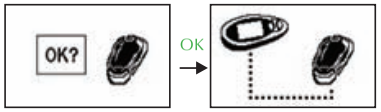
3-Hour Glucose Trend Screen



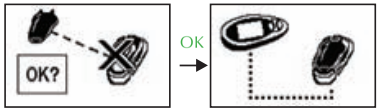
9-Hour Glucose Trend Screen

Glucose Trend Screens (see Section 4.1)

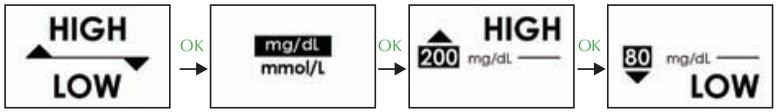
Settings Screens (see Section 7)
To get to these screens, once you get to the 9-hr Screen, you must hold down the Down ▼ arrow for at least 7 Seconds.



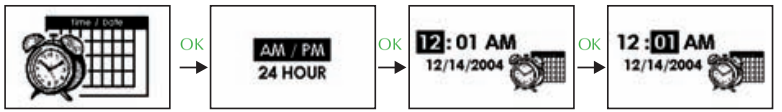
STS Sensor Insertion Screens (see Section 2.4)



STS Sensor Removal Screens (see Section 5.1)



High/Low Alert Screens (see sections 4.2, 7.3)



Time/Date Screens (see Section 7.1)

STS™ Transmitter Serial Number Screens (see Section 7.2)

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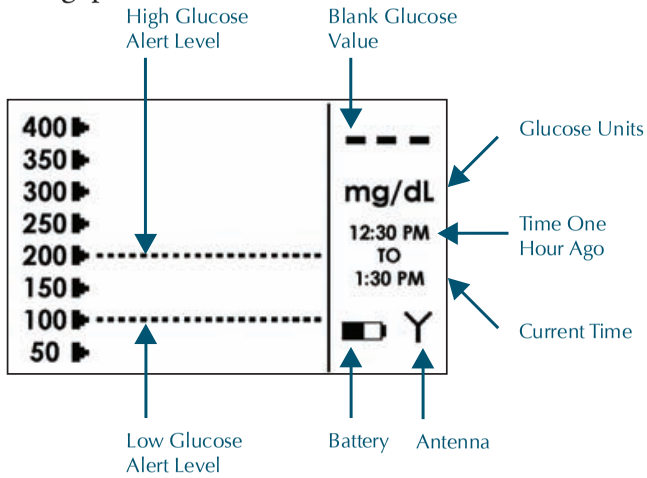
1.4.3 STS™ RECEIVER SCREEN DISPLAYS

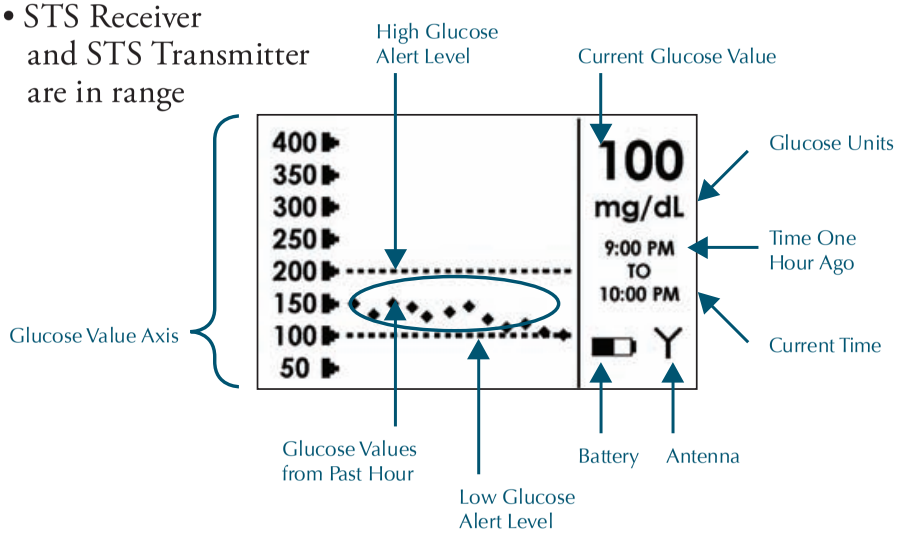
STS Receiver Non-Display Mode:

- During Start-up period
- During Glucose data gaps



STS Receiver Display Mode:

- In Calibration
- STS Receiver and STS Transmitter are in range



SECTION 2

STARTING YOUR STS™ CONTINUOUS GLUCOSE MONITORING SESSION

To use your DexCom™ STS Glucose Monitoring System, you will need a STS Sensor, a STS Transmitter, and a STS Receiver. You will also need a LifeScan OneTouch Ultra meter and OneTouch Ultra test strips for calibration. Once inserted and calibrated, your STS Sensor will continuously measure and display your glucose values for up to 3 days (72 hours).

At the end of the 2-hour Start-Up period, the DexCom STS System will ask for 2 calibration BG values. These two fingersticks must be taken using the OneTouch Ultra meter and uploaded to your STS Receiver using the connection cable. Once calibrated, your STS Receiver will display glucose values, trend graphs, and provide low and high glucose alerts.

BEFORE YOU START

- Wash your hands thoroughly.
- You should fully charge your STS Receiver to avoid the battery dying during use.
- Check that the SN# entered into the STS Receiver is the same SN# number located on the top label of the STS Transmitter, place this information on the STS Transmitter / STS Receiver Card for future reference.

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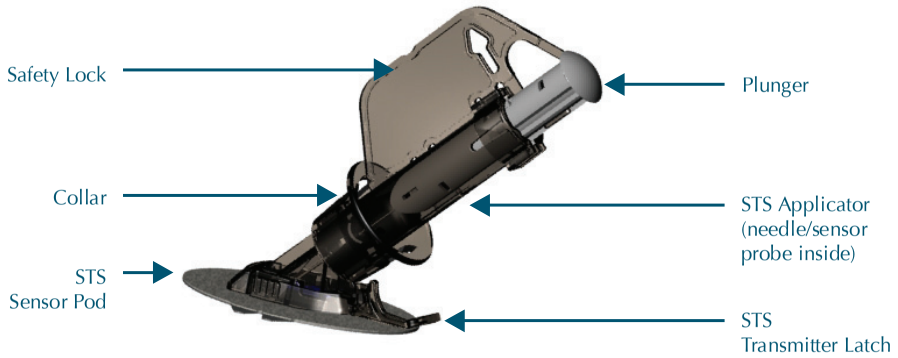
- Place the STS Transmitter and STS Receiver next to each other to make sure they are communicating (you see the Antenna Icon).
- Register your OneTouch Ultra meter to your STS™ Receiver before each session.
- Check the expiration date on the STS Sensor before every time you start a new STS continuous glucose monitoring session.
- You should "QC" your OneTouch Ultra meter per the manufacturer's instructions to make sure it is providing you the best readings for calibration.
- You should clean the bottom of your STS Transmitter with a damp cloth or alcohol wipe before every use.
- Make sure you have enough water resistant bandages or medical tape for showers, bathing, etc..., for three days of use.

2.1 INSERTING A NEW STS™ SENSOR

The following sections will teach you how to insert your STS Sensor and start a new continuous glucose monitoring session. You should become familiar with the STS Applicator diagram below prior to insertion.

NOTE

Always check the expiration date on the STS Sensor packaging before you open the STS Sensor for use.



2.1.1 REMOVING AN STS SENSOR FROM ITS PACKAGING

- Carefully remove your STS Sensor from its packaging and examine it to make sure it is not damaged.
- The STS Applicator is a single use, disposable unit. The safety lock prevents you from accidentally releasing the needle before you are ready.

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2.1.2 CHOOSING AND PREPARING A SITE FOR STS™ SENSOR INSERTION

- Choose a site on fatty area of your abdomen (belly) to put your STS Sensor. You can choose a site above or below your beltline. The best areas are usually flat, "pinchable", and relatively free from where rubbing can occur (i.e. pant line, seatbelts).
- Avoid areas with scarring or rough patches of skin from your insulin injections or pump. The area you choose should be at least 3 inches (7 cm) from where you plan to inject insulin or from where your pump is located.
- Avoid using the same spot repeatedly for STS Sensor insertion.
- You may need to shave the area where you plan to put the STS so the adhesive patch sticks well.
- Make sure there are no traces of lotions, perfumes or medications by using an alcohol swab to clean the area. The area should be clean and dry prior to insertion.

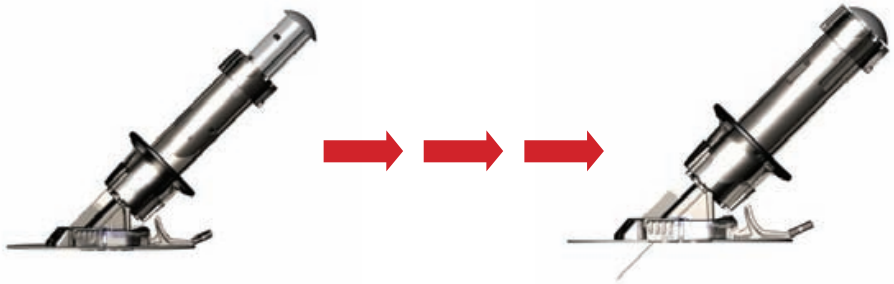
2.1.3 ADHERING THE STS SENSOR

1. After you have cleaned the skin site, remove the adhesive backing from the STS Sensor Pod. Hold the STS Sensor by the STS Applicator area, making sure not to touch the sticky adhesive.
2. Place the STS Sensor on the site you selected, horizontal to your mid-line. You can place the STS Sensor facing towards or away from your belly button. Press firmly on and around the adhesive to make sure it is flat.

3. Once you have stuck the adhesive to your abdomen (belly), pull the Safety Lock out from the STS Applicator. Pull near the arrow on the Safety lock, as shown below:

2.1.4 INSERTING YOUR STS™ SENSOR

1. After adhering the STS Applicator to your abdomen and removing the Safety Lock, place two fingers under the collar (making sure not to squeeze the applicator) and place your thumb on the plunger. Push the plunger down completely. This action inserts the needle and sensor underneath your skin.



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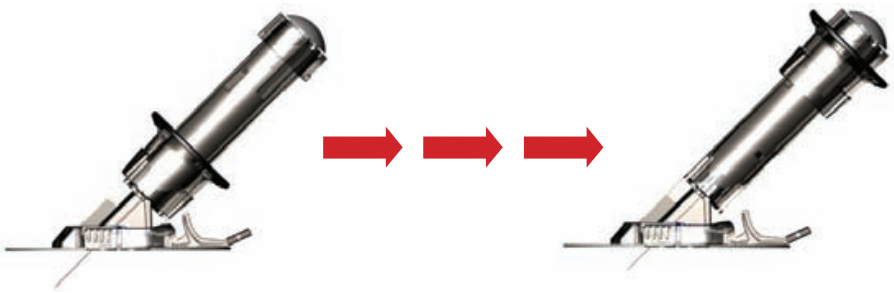
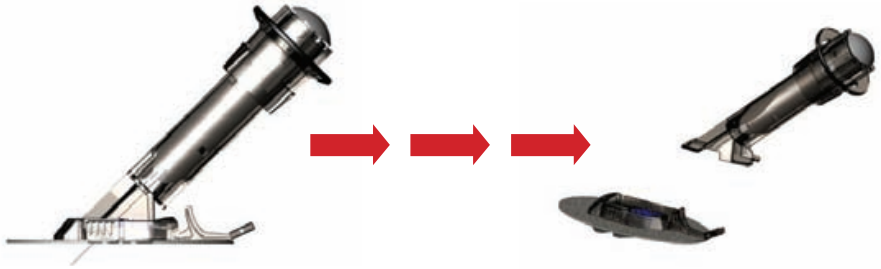
2. After you have pushed the plunger down, pull the collar back until you hear a click or cannot pull back any further. This step pulls the needle back into the STS Applicator and leaves the sensor underneath your skin.



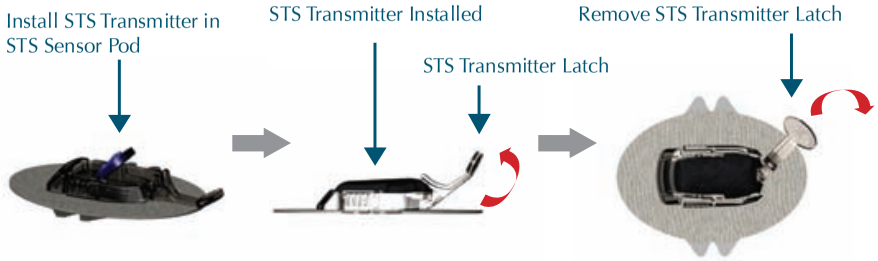
3. Remove the STS Applicator by pressing the tabs on the sides of the STS Sensor Pod. Once you feel the back tabs open, pull off the STS Applicator so that only the STS Pod remains adhered to your body.



2.2 INSTALLING YOUR STS™ TRANSMITTER

The STS Transmitter wirelessly sends your STS Sensor glucose information to your STS Receiver. Once you have inserted the STS Sensor, you will need to snap the STS Transmitter into the STS Sensor Pod. To do this, you must perform the following steps:

1. Clean the bottom of the STS Transmitter with a damp cloth or an alcohol wipe before every use.
2. Place the STS Transmitter in the STS Sensor Pod with the flat side facing down.
3. Pull the STS Transmitter Latch over the STS Transmitter to snap the STS Transmitter into place so it lies flat in the STS Sensor Pod.
4. Remove the STS Transmitter Latch by holding down the STS Sensor Pod with one hand, then holding the latch with your thumb and forefinger and quickly twisting your wrist away from your body.



QUICK TIP

You can place your STS Transmitter next to your STS Receiver before you snap it in to make sure they are communicating before you insert a new sensor. When the STS Transmitter and STS Receiver are next to each other the STS Receiver should display the Antenna Icon.

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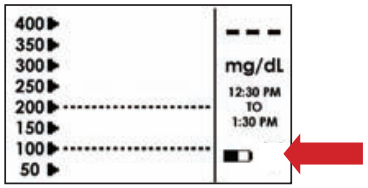
NOTE

Make sure that you have the correct STS Transmitter serial number (SN#) entered into your STS Receiver. The SN# is printed on a sticker located on the top of a STS Transmitter when you first receive it. You should place that sticker on the STS Transmitter / STS Receiver Card provided for future reference. See Section 7.2 for instructions on how to enter the SN# into your STS Receiver.

2.3 CHECKING THAT YOUR STS™ TRANSMITTER AND STS™ RECEIVER ARE COMMUNICATING

You should keep your STS Receiver within 5 feet (1.5 m) of your STS Sensor/STS Transmitter for best communication. To check that your STS Receiver and STS Transmitter are communicating ("talking"), press any STS Receiver button to see the 1-hour Glucose Trend Screen:



If you can see the Antenna Icon (Y), then your STS Transmitter and STS Receiver are communicating. You are ready to notify your STS Receiver that you have inserted a new STS Sensor and begin your continuous glucose monitoring session (Section 2.4). If an antenna has not appeared then you should review the following:

- Is the STS Receiver within 5 feet (1.5 m) of your STS Sensor Pod/STS Transmitter? If the STS Receiver is not close enough, move it within that range and re-check to see if the Antenna appears on the STS Receiver display in 5-10 minutes.
- If you still do not see the Antenna Icon after 5-10 minutes, re-check that the correct STS Transmitter Serial number (SN#) is programmed into your STS Receiver (see Section 7.2 to do this).
- If you make sure that the correct SN# is entered into your STS™ Receiver and you still do not see the antenna icon please contact DexCom Technical Support for further assistance 1-877-DEX-COM4 (339-2664).

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NOTE

The STS Transmitter and STS Receiver may lose communication during the following circumstances:

- Near metallic objects
- While lying on a waterbed
- During use of electric blanket

CONTRAINDICATION

The DexCom™ STS System must be removed prior to Magnetic Resonance Imaging (MRI).

2.4 TELLING YOUR STS™ RECEIVER YOU HAVE INSERTED A NEW STS™ SENSOR

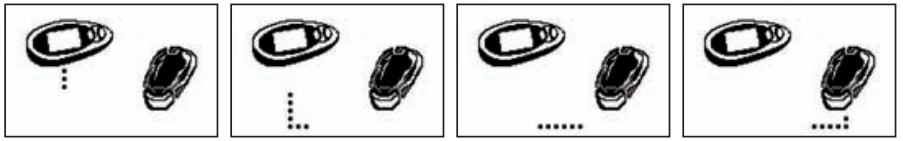
You are now on your way to beginning your continuous glucose monitoring session! After you have checked that your DexCom™ STS System is communicating, you need to tell your STS Receiver that you have inserted a new STS Sensor.

To indicate that you have inserted a new STS Sensor and to begin the Start-Up Period you must do the following:

1. Scroll down through the Receiver Settings Screens to the STS Sensor Insertion Screen by pressing the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen.
2. At the 9-hour Screen, hold the Down ▼ Arrow for at least 7 seconds to see the STS Sensor Insertion Screens, shown below.

STS Sensor Insertion Screen

3. Press the OK button to confirm insertion and then you will see the following series of screens appear:



Confirmation Screen

After completion of the above series of screens the STS Receiver will return to the 1-hour Trend Screen and the Start-Up period will begin.

NOTE

You must tell your STS Receiver each time you insert a new STS Sensor or the STS Receiver will not begin its Start-Up period for calibration.

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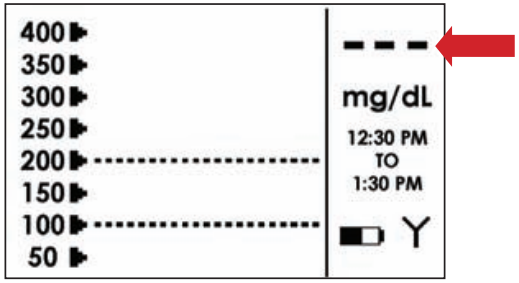
2.5 STS™ SENSOR START-UP PERIOD

The STS Sensor requires a two hour Start-Up period to adapt to its new biological environment (equilibrater). The Start-Up period lasts 2 hours from the current time displayed on the 1-hour Trend Screen once you have confirmed STS Sensor insertion.

During the Start-Up period you should periodically check to see that the Antenna Icon (Y) is visible and that your STS Receiver battery is charged.

Pressing any of the STS Receiver buttons during the Start-Up period will display the following screen:



Blank glucose values indicate your STS Sensor is still in the Start-Up period

At the end of the 2 hour Start-Up period the STS Receiver will provide a vibratory prompt to notify you that it is time to calibrate your STS Sensor. Section 3 describes how to calibrate your STS Sensor.

During the Start-Up period you may see the STS™ Sensor Removal Srceen.

STS Sensor Removal Screen

If you see this screen, the STS Sensor is not working properly or you may have dislodged the STS Sensor. You will need to replace your STS Sensor. In order to replace your STS Sensor, simply remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin, which will pull out the Sensor Probe. Remove the STS Transmitter from the STS Sensor Pod and clean the bottom of the STS Transmitter with a damp cloth or alcohol swab before your next use. To begin a new session, you must insert a new STS Sensor, go through a new Start-Up period and calibrate your STS Sensor.

NOTE

- The STS Receiver is only compatible with the LifeScan One-Touch Ultra Blood Glucose Meter. Please refer to the LifeScan OneTouch Ultra meter Owner's Booklet for complete information about using this meter.
- All BG values used for STS Sensor calibration must be uploaded using the connection cable.
- BG values CANNOT be manually entered into your STS Receiver.
- Alternate site BG testing is not approved for calibration of the DexCom™ STS System.

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2.6 REGISTERING A METER TO YOUR STS™ RECEIVER

If you are connecting the OneTouch Ultra Meter to your STS Receiver for the first time or are using a different meter since your last STS Receiver connection, you will have to register the meter so it can be used for calibration. You can do this by simply connecting the 2 devices as follows:

1. Make sure the OneTouch Ultra meter display is off (screen is blank) before connecting. To turn it off, press the M button once.
2. Plug the meter into your STS Receiver using the connection cable. First plug the cable into the connection port of the meter. (The connection port is at the bottom of the meter). Then connect the wide end of the cable into the STS Receiver. Make sure the raised Push button on the cable is facing down.
3. After a few seconds, "PC" will appear on the OneTouch Ultra meter screen (shown below):

4. Your STS Receiver will vibrate twice and you will see the following screen:

New Meter Screen

5. Press the OK button to accept this new meter. The symbol will then disappear and the STS™ Receiver will return to the 1-Hour Glucose Trend Screen to indicate that registration is complete. (Note: This process may take a few minutes to complete.)
6. BG values uploaded from this meter will now be used to calibrate your STS Sensor. See Section 3 for instructions on how to calibrate your STS Sensor.

NOTE

- Blood glucose information stored in the OneTouch Ultra meter before registering it to your STS Receiver will not be used for calibration. You must always register a meter for the first time before uploading fingersticks intended for calibration.
- If you use more than 1 OneTouch Ultra meter during a continuous glucose monitoring period any fingersticks you take on the non-registered meter will not be used for calibration. You will have to register the meter first, and then take BG values with the new meter for calibration.

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SECTION 3

HOW TO CALIBRATE YOUR STS™ SENSOR

The DexCom™ STS System uses the LifeScan OneTouch Ultra meter to calibrate your STS Sensor readings. You can directly connect these 2 devices using the connection cable.

The DexCom STS System requires 2 fingerstick BG values at the first calibration prompt. The STS Receiver will prompt you for these values about 2 hours after you insert a new STS Sensor (see Section 2.4). The STS Receiver will also request 1 fingerstick BG value if you have not uploaded another BG value within 12 hours. These additional BG values will update the calibration throughout your STS Sensor wear period.

WARNING

You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

NOTE

Always check your STS Receiver for the Antenna Icon while you upload fingerstick BG values.

3.1 RECEIVING THE CALIBRATION PROMPT (THE END OF THE START UP PERIOD)

Two (2) hours after STS™ Sensor insertion (see Section 2.4), your STS Receiver will prompt you to calibrate your STS Sensor by vibrating and displaying the following screen on the STS Receiver:

Dual Blood Drop Prompt

After you see this prompt, press the C Button to clear the display and do the following:

1. Take 2 BG fingersticks using your OneTouch Ultra meter. (Note: If you are not familiar with using this meter, please see the LifeScan OneTouch Ultra meter Owner's booklet for complete instructions).
2. Then upload these 2 BG values from your meter to your STS Receiver.

If you do not upload 2 fingerstick BG values for calibration immediately after you see this prompt, the STS Receiver will vibrate/beep and display the "Dual Blood Drop Screen" every 15 minutes for the next 3 hours. If it is not convenient for you to calibrate at this time you can continue to silence the prompt by pressing the "C" button on the STS Receiver.

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HELPFUL HINTS:

- Prior to taking any fingersticks for calibration, make sure the STS Transmitter and STS Receiver are communicating (the Y is displayed).
- Make sure you have previously registered your OneTouch Meter to your STS Receiver.
- Your blood glucose value must be between 40 mg/dl and 400 mg/dl (2.2 and 22.2 mmol/L) to calibrate. If you take fingersticks outside of this range the STS System will not calibrate. You should treat yourself first and then try calibrating the STS Sensor at a later time.

3. 2 HOW TO UPLOAD BG VALUES TO YOUR STS™ RECEIVER FOR CALIBRATION

Once you have taken at least 2 fingersticks, you can calibrate your STS Sensor by uploading the fingerstick BG values from the One-Touch Ultra meter to your STS Receiver. The following steps will guide you through your upload:

1. Make sure the OneTouch Ultra meter display is off (screen is blank) before connecting. To turn it off, press the M button once. Check your STS Receiver to make sure that your STS Receiver and STS Transmitter are communicating (the Y is visible).
2. Plug the meter into your STS Receiver using the connection cable. First plug the cable into the connection port of the meter. (The connection port is at the bottom of the meter). Then connect the wide end of the cable into the STS Receiver. Make sure the raised Push button on the cable is facing down (toward the back of the STS Receiver).
3. After a few seconds, “PC” will appear on the OneTouch Ultra meter screen (shown below):

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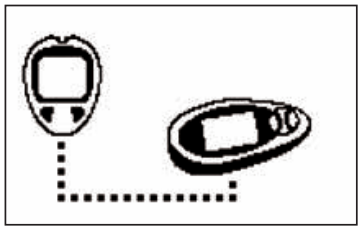
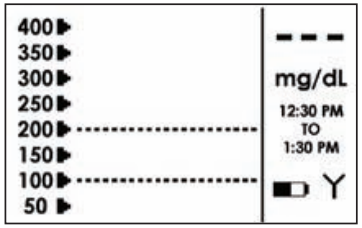
4. The STS™ Receiver will display the Connection Screen below. The following screen indicates that BG values from the meter are successfully being uploaded to your STS Receiver for calibration:



Connection Screen

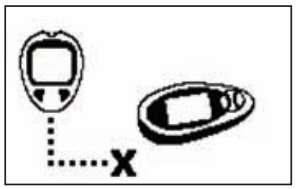
5. The 1-Hour Trend Screen will appear once the upload is complete:



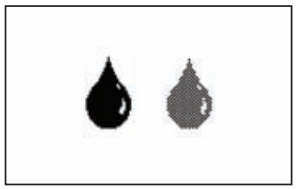
6. Disconnect the cable from the BGM and STS Receiver (The order that you disconnect the cable does not matter).
7. Press the M button on the OneTouch Ultra meter to see that the date and time are the same as the STS Receiver. The current time on the STS Receiver will be displayed on any trend screen at the bottom-most time stamp. If they do not match, re-connect the 2 devices to set the date and time on the meter and take 2 new fingerstick values to upload.
8. A glucose value should appear on the STS Receiver in about 15 minutes, and glucose values will be updated every 5 minutes.

IF YOU SEE ANY OF THE FOLLOWING 3 SCREENS DURING OR AFTER UPLOAD, SEE SECTION 3.3, CALIBRATION TROUBLESHOOTING:

New Meter Screen



Connection Failure Screen



Shaded-Out Blood Drop Prompt

NOTES

- BG values CANNOT be manually entered into the STS Receiver.
- Only BG values between 40 - 400mg/dL (2.2 - 22.2mmol/L) can be used for calibration. If 1 or more of your values are outside this range, you will have to re-calibrate.
- Always make sure the STS Receiver Antennae Icon (Y) is visible.
- Never change the date and time on your OneTouch Ultra meter. Your STS Receiver will do this automatically each time you connect the two devices.

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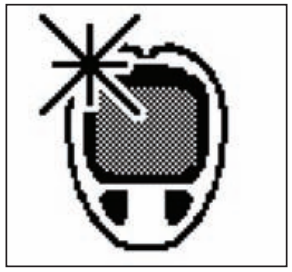
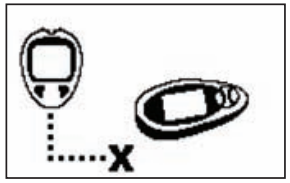
3.3 CALIBRATION TROUBLESHOOTING



NEW METER SCREEN

You will see this screen if you are connecting a new/different OneTouch Ultra Meter to your STS™ Receiver for the first time. Your STS Receiver will vibrate twice.

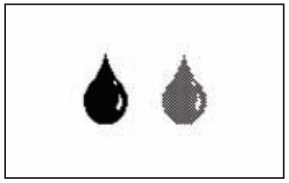
- You will be asked to register the meter with your DexCom STS System. **See Section 2.6 for instructions on how to do this.**



CONNECTION FAILURE SCREEN

If you see this screen (with an "X" between the dotted lines), the BG value upload failed. In this case you should clear the alert by pressing any STS Receiver button and disconnect the devices and review the following:

- Make sure that the OneTouch Ultra meter screen is always blank before you connect the 2 devices.
- Make sure you plug the connection cable into the meter first and the STS Receiver second.
- Do not disconnect the cable while uploading or before you see the 1-Hour Trend Screen appear.



SHADED-OUT BLOOD DROP PROMPT

The Shaded-Out Blood Drop Prompt indicates that you should take one more BG fingerstick and upload it to your STS™ Receiver and may appear for the following reasons:

- One of the BG values you uploaded was outside of the 40-400mg/dL (2.2 -22.2 mmol/L) range required for calibration. (For safety, your STS Sensor will not initially calibrate on extreme glucose values).
- Only one BG value was successfully uploaded to your STS Receiver.
- Your STS Transmitter and STS Receiver may have been out of range. Check to see if you have an Antenna Icon and take another fingerstick.

The STS Receiver will prompt you to remind you a second fingerstick is required for successful calibration every 15 minutes for the next 3 hours.

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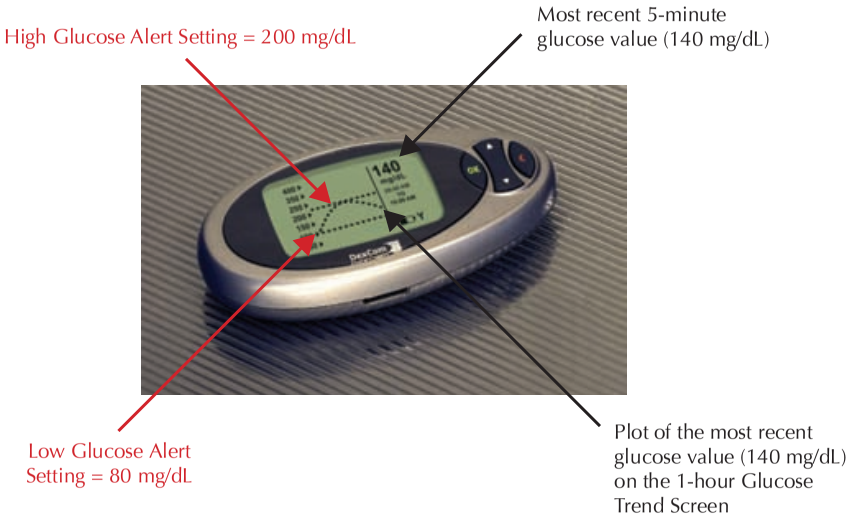
VIEWING YOUR CONTINUOUS GLUCOSE INFORMATION

This section will educate you on how to view and understand Glucose Trend information provided to you by your STS™ System. Once you have uploaded at least 2 BG values (between 40-40mg/dL or 2.2-22.2mmol/L) to your STS Receiver (calibrated), wait at least 15 minutes to check the STS Receiver display for glucose information. If your STS Sensor has successfully calibrated, you should see the following display by pressing any button on the STS Receiver:



After successful calibration, the STS™ Receiver will update your glucose value every 5 minutes. You will be provided with glucose readings from 40 mg/dL (2.2 mmol/L) to 400 mg/dL (22.2 mmol/L) and you can check your STS Sensor glucose value at any time by pressing any STS Receiver button. In addition to discrete glucose values, your STS System will alert you when your glucose levels are outside of your programmed alert levels. The default high and low glucose alerts are set at 80 mg/dL (4.4 mmol/L) and 200 mg/dL (11.1 mmol/L) but can be changed to fit your personal diabetes goals (see Section 7.3.2).

WARNING

You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

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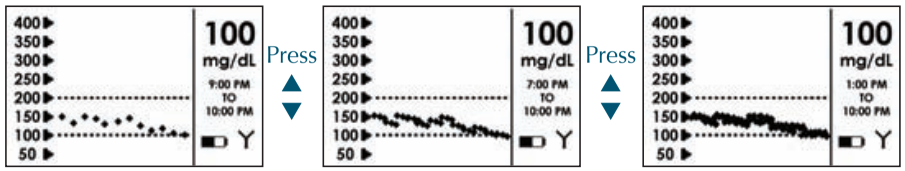
4.1 GLUCOSE TREND SCREENS

You can see glucose trend graphs of your glucose information from the past 1-hour, 3-hour and 9-hour periods by pressing the Down ▼ and Up ▲ Arrows on your STS™ Receiver. The Glucose Trend Screens allow you to see where your glucose levels have been and where your glucose levels are headed.



1-Hour Glucose Trend Screen | 3-Hour Glucose Trend Screen | 9-Hour Glucose Trend Screen

- Each "dot" on a glucose trend graph represents a past glucose reading.
- You can tell which screen you are viewing by looking at the time. The bottom time is always the most current time. The top time is the time the graph starts (e.g., 1 hour earlier, 3 hours earlier, or 9 hours earlier).
- The dashed lines on the graph represent the high and low glucose alert settings (see Section 7.3).
- Glucose values between 40 mg/dL and 400 mg/dL (2.2 mmol/Land 22.2 mmol/L) will be displayed on the STS Receiver.
- For glucose values less than 40 mg/dL (2.2 mmol/L) the value displayed will be "Low"
- For glucose values greater than 400 mg/dL (22.2 mmol/L) the value displayed will be "High"

WARNING

Treatment decisions should not be based solely on results from the DexCom STS System. You must confirm with a blood glucose meter before making therapeutic adjustments.

WARNING

You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

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4.2 RESPONDING TO HIGH AND LOW GLUCOSE ALERTS

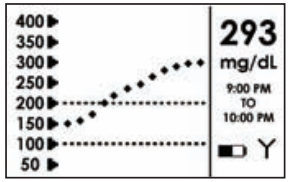
One of the benefits of the DexCom™ STS™ System is your ability to select high and low glucose alerts that will tell you when your glucose values are out of your target range (see Section 7.3). This feature is especially helpful during extended periods of time when you may not test your blood glucose (such as sleeping, driving, exercise, or long meetings).

- When your STS Sensor glucose values are below your Low Alert setting and trending down, the STS Receiver will vibrate and display the Low Alert Screen.
- When the STS Sensor glucose values are above your High Alert setting and trending up, the STS Receiver will vibrate and display the High Alert Screen.
- Examples of the STS Receiver Screens are shown below:

Low Glucose Alert Screen

High Glucose Alert Screen

- Press any button on the STS Receiver to acknowledge the glucose alert and the 1 Hour Glucose Trend Screen will show your current glucose value (outside of the alert setting).



1-Hour Glucose Trend Screen

- If after 5 minutes you do not respond to the first vibratory alert, the STS Receiver will beep once. It will beep loudly again after another 5 minutes if you do not respond to the second alert. You should acknowledge these alerts by pressing any STS Receiver button. The STS Receiver will not re-alert you once you acknowledge the Alert.
- If you do not acknowledge the Alert for any reason, and you are above or below the alert setting and trending up or down, the STS Receiver will re-alert you in 15 minutes.

WARNING

Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use your blood glucose meter to check the STS System results.

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4.3 LOW GLUCOSE ALARM

In addition to your personal glucose alert settings, your STS™ Receiver also has an automatic low glucose alarm set at 55mg/dL (3.1 mmol/L). You cannot change or turn off the Low Glucose Alarm.

- When the STS Sensor detects a glucose level below 55 mg/dL (3.1 mmol/L) your STS Receiver will vibrate to notify you of a very low glucose value by displaying the following screen:

Low Glucose Alarm

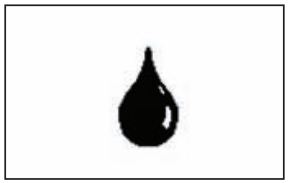
- If you do not acknowledge the vibratory alert, the STS Receiver will then sound a loud beep 5 minutes later. It will continue this vibrating/beeping until you acknowledge the alert.
- To acknowledge and turn off the alarm, press any button on the STS Receiver. If after you turn off the alarm and your glucose is still ≤ 55 mg/dL (3.1 mmol/L) in the next 30 minutes, the STS Receiver will alarm you again and continue to do so until your glucose levels rise above 55 mg/dL (3.1 mmol/L).
- You may want to take a fingerstick at this time to determine if you should make any treatment decisions.
- If the glucose value that initiated the alert is below 40mg/dL (2.2 mmol/L), the STS Receiver will display LOW only (no glucose value displayed).

4.4 MAINTAINING STS™ SENSOR CALIBRATION: 12-HOUR UPDATE

You should upload any fingerstick BG values you take during STS Sensor wear. These BG values will update your STS System calibration.

However, if you have not uploaded any fingerstick BG values for at least 12 hours, the STS Receiver will request a fingerstick BG value to update its calibration as follows:

- The Calibration Update Screen will appear to notify you of the requirement to update the STS System calibration (Note: The STS Receiver will not vibrate at this time.)



Calibration Update Screen

- If you see this reminder symbol, clear this display by pressing any STS Receiver button. The Calibration Update Screen will not go away until you acknowledge it by pressing a button.
- It is recommended that you take a fingerstick at this time using the OneTouch Ultra Blood Glucose meter. Upload this value to your STS Receiver to update your STS Sensor calibration.

WARNING

You should update the STS System's calibration every 12 hours at a minimum to ensure device performance. The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

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4.5 MISSING STS™ GLUCOSE INFORMATION (GLUCOSE DATA GAPS)

At times your DexCom STS System will not display glucose information, or provide alerts. These Glucose Data Gaps can happen if the two devices are out of Range, if the STS Sensor readings are "noisy", or if the STS System determines that another fingerstick is needed for calibration because the STS Sensor values are not matching your current blood glucose value.

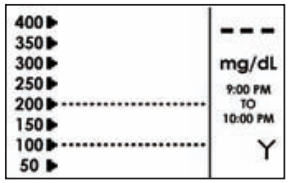
Detailed reasons for Glucose Data Gaps and what you should do to start receiving glucose readings again are described in the sections below.

4.5.1 STS RECEIVER AND STS TRANSMITTER ARE "OUT OF RANGE"

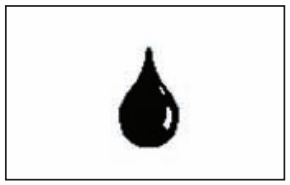
- Anytime you see a "- - -" on the STS Receiver display you should first check to see if the Antenna Icon (Y) is displayed. The STS Transmitter and STS Receiver must be within 5 feet (1.5 meters) of each other.
- If there is no Antenna, move your STS™ Receiver within range and you should receive a glucose value in the next 5 minutes.
- If there is an Antenna on the Display but no glucose values, see sections 4.5.2 and 4.5.3 for other reasons why a Glucose Data Gap may occur.

4.5.2 NOISY STS™ SENSOR GLUCOSE READINGS

- During your continuous monitoring session, your STS Sensor may send the STS Receiver "noisy" glucose readings that the STS Receiver will not display. If this occurs, the antenna will be visible (Y symbol), but you will see a "- - -" on the STS Receiver Display.



- If this happens, you may want to check the placement of your STS Sensor to make sure it is still adhered to your skin properly and that nothing is rubbing the STS Sensor (i.e. clothing, seat belts).
- This may also occur due to rapid increases or decreases in your glucose levels.
- Once the "noisy" stops, your STS Receiver will display glucose values again and provide High and Low Glucose alerts. However, your STS Receiver may also display the following screen:



Calibration Update Screen

- It is recommended when you see this symbol that you take a fingerstick and upload the BG value to the STS Receiver.

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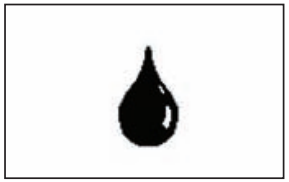
NOTE

Your STS System will count how many "noisy" values you have during your 3-day glucose monitoring session. If it counts 20 "noisy" events, then the STS Receiver will end your glucose monitoring session and you will see the STS Sensor Removal Screen the next time you turn on the STS Receiver display. If you see the STS Sensor Removal Screen, you will have to insert a new STS Sensor and calibrate after the Start-Up period.

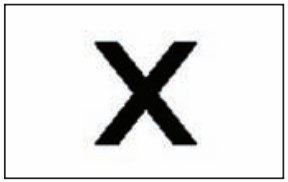
4.5.3 STS™ SENSOR GLUCOSE DATA CHECK & RE-CALIBRATION

- When you update calibration by uploading a fingerstick BG value the Calibration Update Screen may appear.



Calibration Update Screen

- If this screen appears the fingerstick you uploaded was not processed correctly and you should upload another fingerstick. There will be a vibratory alert and beep for this alert.
- If you do not respond to the Calibration Update Screen by uploading a fingerstick BG value, the Out of Calibration Screen may appear in the next 10 minutes.



Out of Calibration Screen

- This screen appears if the last fingerstick you uploaded does not closely match your STS System glucose readings. It prevents you from missing clinically important information (i.e. when your glucose levels are high or low).
- When you see the Out of Calibration Screen, you must take a new fingerstick BG value and upload it to your STS Receiver to continue your glucose monitoring session.

NOTE

- You should check your STS Receiver in 10 minutes any time you upload BG values to make sure the calibration update was successful (no "X").
- If your DexCom STS System goes Out of Calibration, check your BG values on your meter.
- Remember that the STS Receiver will not provide you with glucose values or alerts while it is out of calibration.

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4.6 STS™ SYSTEM EARLY SHUTOFF SCREENS

In some cases your STS System Continuous Glucose Session may end before the end of a full 3-day period. Cases when this may occur are described below.

4.6.1 EARLY SHUT-OFF DUE TO SENSOR NOISE

If your Receiver detects more than 20 incidences of "noise" (see Section 4.5.2), then the STS System will cease displaying glucose values using the current STS Sensor inserted and will display the following screen:

STS Sensor Removal Screen

If you see this screen, then your current STS Continuous Glucose monitoring session has ended. You can simply remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin, which will pull out the Sensor Probe. Remove the STS Transmitter from the STS Sensor Pod and store it for your next glucose monitoring session. To receive anymore continuous information, you must insert a new STS Sensor, go through a new Start-Up period and calibrate the new STS Sensor.

You should also clean the bottom of your STS Transmitter with a damp cloth or alcohol wipe before your next use.

4.6.2 EARLY SHUT-OFF DUE TO RECEIVER ERROR CODE

An error code displayed on the STS Receiver indicates that the STS Receiver is not functioning properly. An example is displayed below:

If you see this screen, then your current STS System Continuous Glucose monitoring session has ended. You should note the code that appears on the screen and contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664).

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SECTION 5

ENDING YOUR STS™ SYSTEM CONTINUOUS GLUCOSE MONITORING SESSION

At the end of your 3-day (72 hour) STS Sensor wear period, you can simply remove your STS Sensor Pod by gently peeling up the adhesive patch from your skin which will pull out your sensor probe. Remove the STS Transmitter from the STS Sensor Pod and keep for your next glucose monitoring session.

5.1 ENDING YOUR CONTINUOUS GLUCOSE MONITORING PERIOD

5.1.1 AUTOMATIC STS™ SENSOR EXPIRATION NOTIFICATION

Your STS Receiver will notify you how much time you have remaining until your STS Continuous Glucose Monitoring Session is complete. The Expiration Screen will simply appear 6 hours and 2 hours before your 72-hour session ends. At the 30 minute and 0 hour Expiration Screen, the STS Receiver will display the Expiration Screen and will also vibrate. You can clear all of these screens by pressing any button on the STS Receiver. You can remove your STS Sensor when the 0 hour Screen appears.

6 hour STS Sensor Expiration Notification

2 hour STS Sensor Expiration Notification

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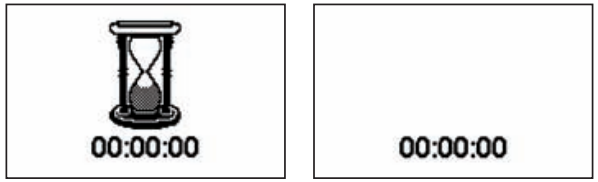
30 minute STS™ Sensor Expiration Notification (+Vibration)



0 hour STS Sensor Expiration Notification (+Vibration)
END OF SESSION

5.1.2 MANUAL STS™ SENSOR SHUT OFF

To manually end your continuous glucose monitoring period, follow the steps below:

1. Press the Down ▼ Arrow 3 times until you see the 9-hour Glucose Trend Screen.
2. Hold the Down ▼ Arrow for at least 7 seconds to get to the STS Receiver Settings screens.
3. Press the Down ▼ Arrow 1 time to arrive at the STS Sensor Removal Screen, shown below. Once you see this screen, press the OK button to indicate removal of your STS Sensor.

STS Sensor Removal Screen

4. After you see the series of screens below, you have successfully removed your STS Sensor.

Confirmation Screen

5. The STS Receiver will clear to the default 1-Hour Trend Screen.

NOTE

If you removed your STS Sensor before telling the STS Receiver, the STS Sensor Removal Screen will appear automatically. You must press OK before inserting a new STS Sensor.

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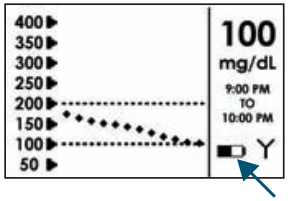
SECTION 6

MONITORING YOUR STS™ RECEIVER BATTERY

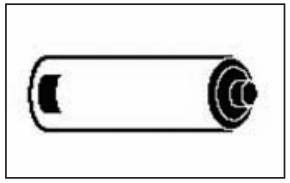
Your STS Receiver battery is rechargeable like a cellular phone. The battery should last for about 5 days before needing to be recharged. The STS Receiver will take 3 hours to fully charge when the battery is completely dead. Periodically check your STS Receiver display to make sure it has enough charge.

6.1 LOW BATTERY ALERT

- The Battery indicator is located next to the Antenna Icon (Y) on the bottom right side of the screen. This indicator tells you how much charge is left in the battery.
- When the STS™ Receiver's battery is low, the STS Receiver will flash a large Low Battery Alert across the screen. Press the C Button to clear the alert.



Battery Indicator



Low Battery Alert

NOTE
You should charge your STS Receiver as soon as possible when you see the Low Battery Alert so you can continue to receive glucose readings.

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6.2 CHARGING YOUR STS RECEIVER BATTERY

- To charge the STS Receiver battery, connect the charger cable provided into the port on the bottom of your STS Receiver. Make sure the "Push" button side of the charger cable is facing down.
- Connect the plug into a standard power outlet.
- The STS Receiver will display the animated symbol below of a battery charging across the STS Receiver Screen:

- After a few seconds, the 1-hour Glucose Trend Screen will reappear with the animated Battery indicator displayed in the lower right corner next to the Antenna Icon (Y).
- The battery will fully charge after 3 hours and should last approximately 5 days before recharging is necessary.

SECTION 7

CHANGING STS™ RECEIVER SETTINGS

You can reach all of the STS Receiver Settings Screens by scrolling down to the 9-Hour Glucose Trend Screen and holding the Down ▼ Arrow for at least 7 seconds. Please refer to Section 1.4.2 for an overview on the order of all STS Receiver screens.

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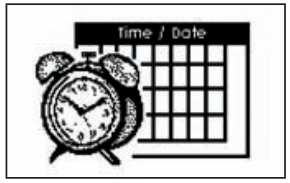
7.1 SETTING THE STS™ RECEIVER TIME

7.1.1 GETTING TO THE STS RECEIVER TIME

- Press the Down ▼ Arrow 3 times to get to the 9-hour glucose trend screen.
- Hold the Down ▼ Arrow again for at least 7 seconds to get to the Settings Screens.
- Press the Down ▼ Arrow 3 more times to view the Time/Date Screen:

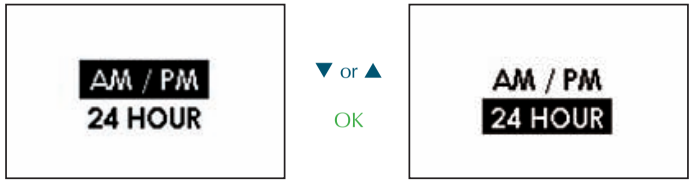


Time / Date Screen

- Press the OK Button on the STS Receiver to begin setting the time.

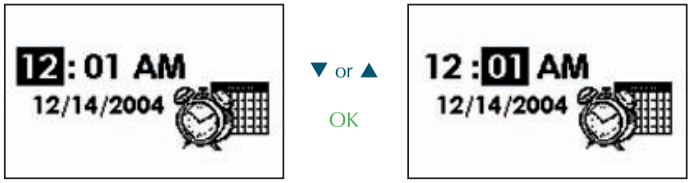
7.1.2 CHOOSING THE TIME MODE

- You can choose what time format you would like displayed.
- Choose an AM/PM (12-hour) format or a 24-hour clock format by pressing the Down ▼ Arrow or Up ▲ Arrow.
- Press the OK Button once you have selected the time format you prefer.



7.1.3 SETTING THE TIME (AM/PM MODE)

- Once you select the time format and press OK, the Time Set Screen will appear in the format you selected.
- Press the Up ▲ or Down ▼ Arrows to choose the hour.
- Press the OK Button to move to the minutes.
- Press the Up ▲ or Down ▼ Arrows to choose the minutes.



- When you choose the hours and minutes, the AM/PM will adjust automatically (e.g. if you go from 11:59 AM to 12:00PM, AM will automatically switch to PM).
- Note: If you pass 11:59 PM the date will automatically update to the next day or the previous day based on the arrow direction you are pressing.
- If you press C at any time, this will not set the time and return you to the STS™ Receiver Time and Date Screen.

NOTE

- The STS Receiver date is pre-programmed at the factory.
- Your STS Receiver time can only be adjusted ± 24 hours from the factory set time/date. If you need to adjust the time more than 24 hours there may be a problem with the STS Receiver. Please contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) to determine if your STS Receiver needs to be replaced.

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7.1.4 SETTING THE TIME (24-HOUR MODE)

• If you chose the 24-hour Time Mode:

OK

•Press the Up ▲ or Down ▼ Arrows to chose the hour.

•Press the OK Button to move to the minutes.

•Press the Up ▲ or Down ▼ Arrows to choose the minutes.

▼ or ▲

OK

•Note: If you pass 23:59 the date will automatically update to the next day or the previous day based on the arrow direction you are pressing.

•If you press C at any time, this will return you to the STS™ Receiver Time and Date Screen and will not set the time.

NOTE

• The STS Receiver date is pre-programmed at the factory.
• Your STS Receiver time can only be adjusted ± 24 hours from the factory set time/date. If you need to adjust more the time more than 24 hours there may be a problem with the STS Receiver. Please contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664) to determine if your STS Receiver needs to be replaced.

7.2 HOW TO ENTER A NEW STS™ TRANSMITTER SERIAL NUMBER (SN#)

Any time you use a new STS Transmitter as part of your DexCom™ STS System, you must enter the STS Transmitter serial number (SN #) into your STS Receiver. This will begin the wireless radio-frequency (RF) communication between the two devices. To do this perform the following steps:

1. Press the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen.
2. Hold the Down ▼ Arrow for at least 7 seconds until you come to the Settings Screens.
3. From this screen, press the Down ▼ Arrow 4 more times until you arrive at the STS Transmitter Serial Number Screen:

STS Transmitter Serial Number Screen

4. Press the OK Button to display the entry screen for the STS Transmitter SN#:

5. The 5-digit SN# is located on the STS Transmitter packaging. The SN# is also printed on a removable label located on top of the STS Transmitter. After entering the SN # into your STS Receiver, remove the sticker and place it on the STS Transmitter / STS Receiver Card for future reference.

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6. To enter your SN#, press the Up ▲ or Down ▼ Arrows until you arrive at the first number.
7. Press the OK Button to enter that number and to move to the next number.
8. Once you have entered all of the numbers, press the OK Button once more to confirm the STS™ Transmitter serial number.
9. If you press C at any time, this will return you to the STS Transmitter Serial Number Screen and not change the SN#.

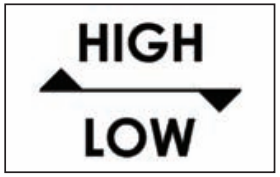
7.3 CHANGING YOUR GLUCOSE ALERT SETTINGS

The default setting for the high glucose alert is 200 mg/dL (11.1 mmol/L). The default setting for the low glucose alert is 80 mg/dL (4.5 mmol/L). These alerts should be set at values that will help monitor when your glucose levels are too high or too low. You should work with your Diabetes Management Team to help you choose your appropriate glucose alert settings.

7.3.1 CHOOSING GLUCOSE VALUE UNITS

Follow the steps below to choose the type of glucose unit (mg/dL or mmol/L) you would like reported to you. Please note that if you change the alerts to the mg/dL or mmol/L units, all glucose values will be reported to you in that way.

1. Press the Down ▼ Arrow 3 times until you come to the 9-hour Glucose Trend Screen.
2. Hold the Down ▼ Arrow for at least 7 seconds until you come to Settings Screens.
3. Press the Down ▼ Arrow 2 more times to get to the Glucose Alert Screens:



Glucose Alert Screen

4. After you press OK, you will see the glucose unit screen which will allow you to choose your glucose unit values:

5. Press the Down ▼ or Up ▲ Arrow to select which kind of glucose unit you would like reported (mg/dL or mmol/L). Once you choose the unit you would like (highlighted unit), press the OK Button.

NOTE

- Your DexCom™ STS™ System can display glucose readings in two different units of measure. In the United States, milligrams per deciliter (mg/dL) are the standard unit used for glucose testing systems (i.e. blood glucose meters). In many other parts of the world, the standard unit for glucose readings is millimoles per liter (mmol/L). Please check with your Diabetes Management Team if you do not know which type of unit your glucose readings are usually displayed in.
- Because the DexCom STS System can be set to display glucose readings in either of these 2 units of measure, it is important to check the unit displayed on the STS Receiver EVERY time you view a glucose reading. This will allow you to make sure that you are receiving readings according to your desired unit setting (mg/dL or mmol/L).

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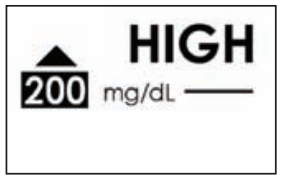
7.3.2 SETTING HIGH AND LOW GLUCOSE ALERT LEVELS (mg/dL UNITS)

- If you choose mg/dL as your glucose units, you will see the following High Glucose Alert Screen:



- Use the Up ▲ or Down ▼ Arrows to increase or decrease the high glucose alert value by 20 mg/dL (i.e. 220, 240, 260 mg/dL).
- You may select high glucose alert values from 140 mg/dL to 400 mg/dL. Select the value recommended by your Diabetes Management Team by pressing the OK Button.

NOTE

If you scroll above 400 mg/dL the display will read NO. If you press the OK Button to select this option, you will turn off the high glucose alert. You will not receive any high glucose alerts, even when your STS™ System is in calibration.

- Once you press OK to select your high glucose alert value, you will see the Low Glucose Alert Screen:

- Use the Up ▲ or Down ▼ Arrows to increase or decrease the low glucose alert value by 10 mg/dL.

- You may select low glucose alert values from 60 mg/dL to 90 mg/dL. Select the value recommended by your Diabetes Management Team by pressing the OK Button.

NOTE

If you scroll below 60 mg/dL the display will read NO. If you press the OK Button to select this option, you will turn off the low glucose alert. You will not receive any low glucose alerts, even when your STS™ System is in calibration. (For safety, there is a low glucose alarm set at 55 mg/dL that you cannot turn off. See section 4.3).

- Press the OK Button after you set the low glucose alert to confirm the both high and low alert settings and then you will return to the Glucose Alert Screen.

7.3.3 SETTING HIGH AND LOW GLUCOSE ALERTS (MMOL/L UNITS) SETTINGS

- If you choose mmol/L as your glucose units, you will see the following High Glucose Alert screens:

and

- Use the Up ▲ or Down ▼ Arrows to increase or decrease the high and low glucose alert values in the same manner as described above (see Section 7.3.2).
- You may select high glucose alert values from 7.8 mmol/L to 22.2 mmol/L. See the following chart to view the high alert level selection options.

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- Select the value recommended by your Diabetes Management Team by pressing the OK Button.
- The chart below displays the high alert level selection options.

mmol/L
Disabled
22.2
21.1
20.0
18.9
17.8
16.6
15.5
14.4
13.3
12.2
11.1
10.0
8.9
7.8

NOTE

If you scroll above 22.2 mmol/L the display will read NO. If you press the OK Button to select this option, you will turn off the high glucose alert. You will not receive any high glucose alerts, even when your the STS™ System is in calibration.

- You may select low glucose alert values 3.3 mmol/L to 5.0 mmol/L. See the following chart to view the low alert level selection options.

mmol/L
5.0
4.4
3.9
3.3
Disabled

NOTE

If you scroll below 3.3 mmol/L the display will read NO. If you press the OK Button to select this option, you will turn off the low glucose alerts, even when the STS System is in calibration. (For safety, there is a low glucose alarm set at 3.1 mmol/L that cannot be turned off. See section 4.3).

- Press the OK Button after you set the low glucose alert to confirm the both high and low alert settings and you will return to the Glucose Alert Screen.

SECTION 8

TROUBLESHOOTING

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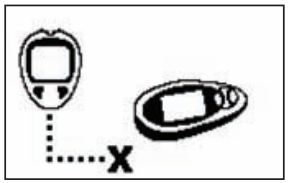
8.1 MISSING ANTENNA

- If you cannot see the Antenna Icon(Y) on your STS™ Receiver, make sure that you have your STS Receiver within 5 feet (1.5 meters) of your STS Sensor Pod and STS Transmitter.
- After checking the position of the STS Receiver wait 5 to 10 minutes to see if the Antenna Icon appears.
- If the Antenna Icon still does not appear, check to see that your STS Transmitter serial number (SN#) is correctly entered into the STS Receiver. Follow the steps found in Section 7.2.
- If none of the above options work, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). You may need a new STS Transmitter.

8.2 PROBLEMS UPLOADING BG VALUES TO YOUR STS RECEIVER

- If the OneTouch Ultra Meter and STS Receiver have trouble communicating with each other, the following symbol will be displayed:



Connection Failure Screen

- Make sure you have done the following during upload:
  - » The meter should be "OFF" prior to performing the upload (no display). If necessary, press the M button once to turn the meter off and reconnect the two devices.
  - » DO not accidentally push meter buttons while performing the upload.
  - » Connection cable is plugged in properly. Remember to plug it into the meter first and then to the STS Receiver.
  - » The Antenna Icon (Y) is present.
- If you are still unable to successfully transfer values to the STS™ Receiver:
  - » Press the M button on the BG meter to view its display and to ensure the meter is functioning.
  - » If the BG meter has no display, replace the meter's battery. (Note: The meter's battery should last at least a year.)
- If the BGM still fails to function after replacing the meter's battery, replace the meter.
- Press one of the STS Receiver buttons and check to see that it is functioning.
- If the STS Receiver's display does not appear, plug the STS Receiver into the charger to make sure that the battery is charged.
- If you still do not see a display, contact DexCom Technical Support 1-877-DEXCOM4 (339-2664) for further help.

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8.3 TIME DIFFERENCE BETWEEN BG METER AND STS™ RECEIVER

- The time on the blood glucose meter is matched to the STS Receiver every time you connect the OneTouch Ultra meter to your STS Receiver.
- If you notice that a time difference between the meter time and the STS Receiver time occurs often, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). Your STS Receiver may need to be replaced.
- DO NOT attempt to change the Ultra Meter time.

8.4 ERROR CODE

The STS Receiver may display Error Codes like the one below. This indicates that the STS Receiver is not functioning properly.

- If an error occurs, note the error code number (if applicable).
- Contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664). You may need to replace your STS Receiver.
- Continue to check BG values on your meter.

SECTION 9

TECHNICAL INFORMATION

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9.1 DEVICE PERFORMANCE CHARACTERISTICS

Performance Characteristics

NOTE

You should have the information in this chapter reviewed by your healthcare provider. We also suggest that you review this information with them in order to understand how well the STS™ System or STS works.

The STS System uses a glucose Sensor to continuously monitor your glucose levels. The STS Sensor is "calibrated" using your OneTouch® Ultra® blood glucose meter. Once calibrated, the STS System reports glucose values every 5 minutes. In a clinical study, STS values were compared to blood glucose measurements in order to assess its performance. Clinical Study findings are presented below.

Although presentations to characterize performance of the STS System are given below, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors such as the STS System. Performance may be best understood by viewing graphs called time-elapsed plots. In these plots, the values from the STS System were recorded over time and were overlaid with values taken at the same time with a reliable laboratory method. Three representative time-elapsed plots are presented on pages 100-102, Figures 2-4. They are examples of good, average and poor STS System performance.

Users and healthcare providers should consider that performance in this study might be idealized. Participants enrolled in the clinical study and certain conditions of the study tend to result in above average glucose control. This, in turn, may result in the appearance that the STS System agrees with blood glucose levels better than it does under typical conditions. Monitors that measure glucose in interstitial fluid often show better agreement to blood glucose levels when glucose levels are not changing rapidly or when glucose levels are not extremely low or high. The following are some examples of why performance of the STS System may be idealized.

- The mean Hemoglobin A1c among the 91 participants was 7.6%. Many people with diabetes have higher A1c levels, indicating poorer control of their glucose levels.
- Subjects saw, on average, 6 to 7 fingerstick results per day. This enables subjects to control their glucose levels better.
- While subjects participated in the clinic portion of the study, they were more limited in their activities than someone at home. They were also provided with all their meals. Subjects who are more active, or with poor eating habits, may create more challenging conditions for the STS System.
- OneTouch Ultra meters used in the study were well maintained. Because the OneTouch Ultra meter is used to calibrate the STS System, performance may be poorer if the meter is not well maintained. It is important to carry out quality-control checks on the meter and code the meter according to the manufacturer's instructions to optimize performance of the STS System.

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Clinical Study Results

To evaluate performance of the STS System, 91 participants were enrolled in a clinical study conducted at 4 centers. All participants had Type 1 or Type 2 diabetes mellitus, and required insulin to manage their diabetes. About 80% of participants had Type 1 diabetes and about 20% had Type 2 diabetes. Subjects ranged in age from 18 to 79 years of age.

Participants used the STS System for approximately nine days (each participant wore 3 Sensors for 3 days.) STS Receivers were calibrated approximately 3 times per day using the Lifescan One-Touch Ultra meter. Approximately half of the participants used the STS System in a controlled clinic environment for 2 of the 9 days. The remainder of the study took place at home.

While using the STS System in the clinic, 14 participants also had their blood glucose measured every 20 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus glucose analyzer. This instrument is referred to as the "YSI". Readings from the STS System were paired with YSI readings in order to characterize how well STS System results agreed with blood glucose results. For the remainder of the study, STS results were paired with OneTouch Ultra blood glucose meter results when participants were at home. (One OneTouch meter was used to calibrate STS, while a second OneTouch meter was used to collect the comparison blood glucose results.)

Agreement and Accuracy

Agreement between the STS System and blood glucose levels is characterized using matched pairs of STS and YSI results. Each YSI measurement was paired with the STS measurement that was closest in time to it. Agreement between matched pairs was estimated by calculating the percent difference between the STS reading and the YSI reading. For example, if the YSI reading is 100 mg/dL and the STS reading is 90 mg/dL, there is a 10% difference between the two. The mean absolute percent difference is the average of all of the “distances” between STS readings and YSI readings viewed as percentages.

The bias was also calculated. Bias is defined as the average difference between the STS System glucose values and the true glucose value provided by YSI values. Agreement and Bias are summarized in Table 1 below:

Table 1. STS Sensor-Meter agreement during 3-day of use

Number of paired glucose measurements	676
Mean Absolute Percent Difference (±SD)	26% (± 21%)
Bias	Approximately +11% across the measuring range

The agreement of the STS System to blood glucose levels was also assessed by calculating the percentage of STS System values that were within 20%, 30%, and 40% of the YSI reading. For values less than 80 mg/dL the difference was calculated according to the percent falling within 20, 30, and 40 mg/dL. The total number of data pairs considered in this analysis 676. Results are shown in Table 2.

Table 2. Percentage of STS Results Falling Within 20, 30, and 40 Percent of the Paired YSI Result, Stratified According to Glucose Concentration

YSI Readings (mg/dL)	Number of Paired Readings	% of STS Readings Within 20%*	% of STS Readings Within 30%*	% of STS Readings Within 40%*
40-80*	140	56	74	88
81-120	133	44	63	75
121-240	314	46	67	86
241-350**	89	65	81	93

* For the 40-80 mg/dL range the difference is presented as the difference in mg/dL between the STS Sensor and YSI, rather than the percent.

** There were no YSI readings above 350 mg/dL observed in these studies.

Performance above 300 mg/dL is characterized by comparing STS results to OneTouch results. This information is presented in Table 3, below:

Table 3. Percentage of STS Results Falling Within 20, 30, and 40 Percent of the Paired OneTouch Meter Result, Stratified According to Glucose Concentration

Blood Glucose Meter Readings (mg/dL)	Number of Paired Readings	% of STS Readings Within 20%*	% of STS Readings Within 30%*	% of STS Readings Within 40%*
>300-350	121	84	98	100
>350-375	32	91	100	100
>375-400	12	83	83	100

The STS System reports glucose concentrations between 40 and 400 mg/dL. When STS determines the glucose level is below 40 mg/dL, it indicates "LOW." If STS determines that the glucose level is above 400 mg/dL, it indicates "HIGH." The ability of the STS System to accurately report these occurrences is assessed by looking at the actual glucose concentrations (as determined by the YSI analyzer) when "LOW" or "HIGH" is reported.

- On 20 occasions STS indicated the glucose level was less than 40 mg/dL. Of these, 4 times the glucose level was below 40 mg/dL. The actual range of glucose concentrations was 18-90 mg/dL compared to YSI.
- There were 37 occasions when STS indicated the glucose level was above 400 mg/dL. Of these, 3 times the glucose level was above 400 mg/dL. The actual range of glucose concentrations was 245-445 mg/dL compared to YSI.

The Clarke Error Grid was used to determine if STS results are "clinically accurate". The Clarke Error Grid divides a correlation plot into 5 zones, which are described in Table 4.

Results in zones A and B are considered clinically acceptable, while results in zones C, D, and E are potentially dangerous. They may result in clinically significant errors. The Clarke Error Grid zones are labeled on a correlation plot in Figure 1

Table 4. Clarke Error Grid Description

Zone	Description
A	Clinically Accurate, would lead to correct treatment decisions
B	Would lead to small corrections that would keep a normal glucose level state or would cause no treatment decision
C	Would lead to overcorrection of normal glucose levels
D	Would lead to failure to be aware of and treatment of high or low glucose levels
E	Would lead to erroneous and "dangerous" treatment decisions

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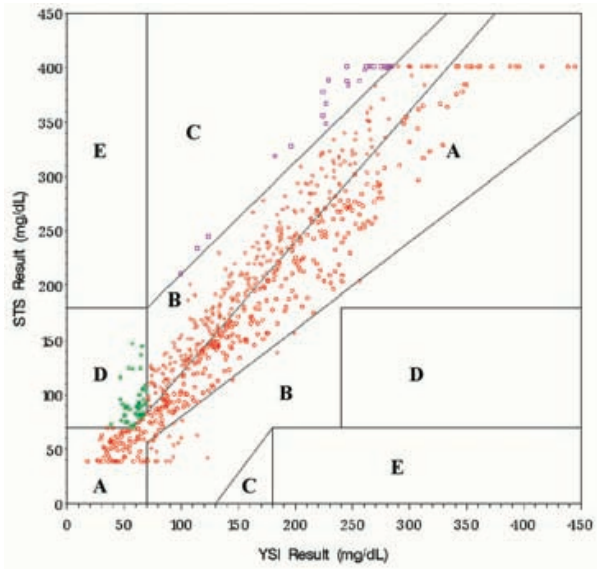
Figure 1 is a correlation plot. Each YSI result (on the horizontal axis) is matched up with its corresponding STS result (on the vertical axis). A point is recorded where the two values intersect. There are 733 paired data points recorded.

The measuring range of the YSI is 0-900 mg/dL while the measuring range of the STS System is 40-400 mg/dL. In the graph below, if STS indicated "LOW" then the reading is recorded as 40 mg/dL. If STS indicated "HIGH" then the reading is recorded as 400 mg/dL.

Figure 1. Clarke Error Grid, STS Results Compared to YSI Results



The percentage of STS System results in the above graph are presented in Table 5 below according to the percentage of points falling within each zone (A-E). Results are further broken down (stratified) according to the range of glucose concentration.

Table 5. Stratified Clarke Error Grid Analysis

YSI Readings (mg/dL)	Number of Paired Readings	A+B %	A %	B %	C %	D %	E %
<=80 mg/dL	156	69%	52%	17%	0%	31%	0%
81-120 mg/dL	137	99%	44%	55%	2%	N/A	N/A
121-240 mg/dL	314	98 %	46%	51%	3%	N/A	0%
>240 mg/dL	126	87%	57%	29%	14%	0%	0%
Total (40-400 mg/dl)	733	90%	49%	41%	4%	7%	0%

*N/A means that the Clarke Error Grid does not consider the possibility of these zones in that concentration range.

Low and High Glucose Alerts

The ability of the STS System to detect high and low glucose levels is assessed by comparing STS results to YSI results at low and high glucose concentrations, and when the alert sounds. There were 733 pairs of matched STS and YSI results evaluated. We suggest that you ask your doctor what settings are best for you.

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The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in the table below. For example, if you set the STS Low Glucose Alert to 70 mg/dL, the STS System will alert when glucose levels drop below 70 mg/dL 57% of the time. Additionally, 24% of the time when the alert sounds, the glucose level will actually be above 70 mg/dL. If you set the STS the Low Glucose Alert to 90 mg/dL, the STS System will alert when glucose levels drop below 90 mg/dL 68% of the time. At this alert level, 9% of the time when the alarm sounds, the glucose level will actually be above 90 mg/dL.

Table 6. Hypoglycemic Alert Evaluation

STS Alert Level	True Alert Rate*	False Alert Rate**
60 mg/dL	54%	36%
70 mg/dL	57%	24%
80 mg/dL	62%	13%
90 mg/dL	68%	9%

*True Alert Rate is the % of time when the glucose level was at or below the alert setting and the alert would have sounded.
**False Alert Rate is the % of time when the device would have sounded but the blood glucose level was above the alert level.

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in the table below. For example, if you set the STS High Glucose Alert to 200 mg/dL, the STS System will alert when glucose levels rise above 200 mg/dL 98% of the time. Additionally, 31% of the time when the alert sounds, the glucose level will actually be below 200 mg/dL.

Table 7. Hyperglycemic Alert Evaluation

STS Alert Level	True Alert Rate*	False Alert Rate**
140 mg/dL	99%	21%
180 mg/dL	98%	24%
200 mg/dL	98%	31%
240 mg/dL	96%	43%
300 mg/dL	97%	67%

*True Alert Rate is the % of time when the glucose level was at or above the alert setting and the alert would have sounded.
**False Alert Rate is the % of time when the device would have sounded but the blood glucose level was below the alert setting.

Calibration Stability

The STS System should be calibrated every 12 hours. To demonstrate performance of the STS System over a 12-hour calibration period 91 Sensors were evaluated to verify that performance remains consistent over the 12 hour calibration period, a portion of STS Systems are evaluated in 3 hour increments after calibration. Performance is assessed by comparing the % of STS Sensor readings falling within 20, 30, and 40 % of the One-Touch reading in each 3 hour period. Minimal deterioration in performance is noted. See Table 8, below.

Table 8. Percentage of STS Readings Falling Within 20, 30, and 40% of OneTouch Readings With Data Stratified in Three Hour Increments After Calibration

Time After Calibration (hours)	% of STS Readings Within 20%*	% of STS Readings Within 30%*	% of STS Readings Within 40%*
0-3	62	79	89
3-6	63	79	88
6-9	59	81	91
9-12	58	74	85

*The difference from the OneTouch is measured in mg/dl if the meter reading is less than 80 mg/dL.

The performance of the STS System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

Sensor Stability

STS Sensors may be worn up to 72 hours. To verify that sensors perform consistently over the 72 hour period, 91 Sensors were evaluated in 12 hour increments after insertion. Performance is assessed by comparing the % of STS results falling within 20, 30, and 40% of the OneTouch result in each 12 hour increment after the STS Sensor is inserted.

Table 9. Percentage of STS Readings Falling Within 20, 30, and 40% of OneTouch Readings With Data Stratified in 12 Hour Increments After Sensor Insertion

Time After Insertion (hours	% of STS Results Falling Within 20%*	% of STS Results Falling Within 30%*	% of STS Results Falling Within 40%*
0-12	64	82	91
12-24	63	79	88
24-36	59	76	86
36-48	63	79	88
48-60	58	77	87
60-72	62	81	91

*The difference from the SMBG reading is measured in mg/dL if the meter reading is less than 80 mg/dL or in percent if the meter reading is 80 mg/dL or higher.

Precision of STS System Readings

A separate study of 20 subjects, wearing two STS Systems each was also conducted. This study was designed to look at how similar two STS Systems on the same person function (Sensor Precision). Precision was evaluated by comparing the glucose readings from the two STS Systems. Results showed that STS Systems generally agreed with each other within 21%.

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Sensor Life

Sensors may be used for up to 72 hours. Ninety-one sensors were evaluated to estimate how many sensors continued to work up to 72 hours. Table 10, below, displays how long you can expect a sensor to last. For example, 75% of the sensors lasted between 65 and 72 hours.

Table 10. Estimated Sensor Life

Hours of Use	Percentage of Sensors
4-18 hours	8%
20-35 hours	6%
45-64 hours	11%
65-72 hours	75%

Of the 24 sensors that did not last beyond 64 hours, approximately two-thirds of them became nonfunctional because of device failure and one-third of them fell off the inserted site. Almost all STS failures occurred in the first two days.

Number of Readings Provided

The STS System is capable of providing a reading every 5 minutes, or 288 readings per day. For a variety of reasons, this does not always happen. Sometimes sensors fail to provide readings after calibration or readings are skipped. Table 11 below, estimates the number of readings you can expect to get from the STS System per day. For example, 47% of STS devices provided between 251 and 288 readings per day.

Table 11. Number of Readings Provided by Each Sensor per Day

Range of Readings Provided per Day	% of STS Devices Providing that number of readings
0-1	10%
36-151	10%
168-220	11%
221-250	22%
251-288	47%

Approximately 17% of readings were lost because the Transmitter was more than 5 feet away from the Receiver. Most other results were lost because an error was detected during calibration, causing a delay in obtaining results. (The error may be operator related or because of an algorithm problem.)

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Time-Elapsed Plots

Example of STS continuous glucose monitoring overlaid with the corresponding YSI readings over time are presented below. The horizontal axis represents time, with the matching STS and YSI readings plotted above the point in time when the measurements were taken. The circles (•) on the graph represent the STS data, connected by a line. The "Y"s represent the YSI reading.

There are three Figures presented. Figure 2 is an example of when the STS System performed well, Figure 3 represents a period when the STS performed in an average manner, and Figure 4 represents when the STS performed poorly.

Figure 2. Example of "Good" STS Performance

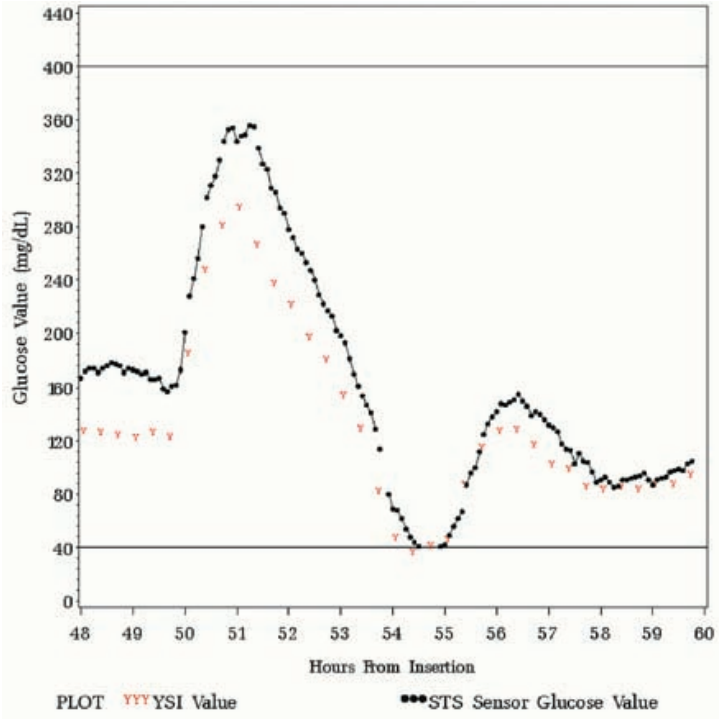


Figure 3. Example of "Average" STS Performance

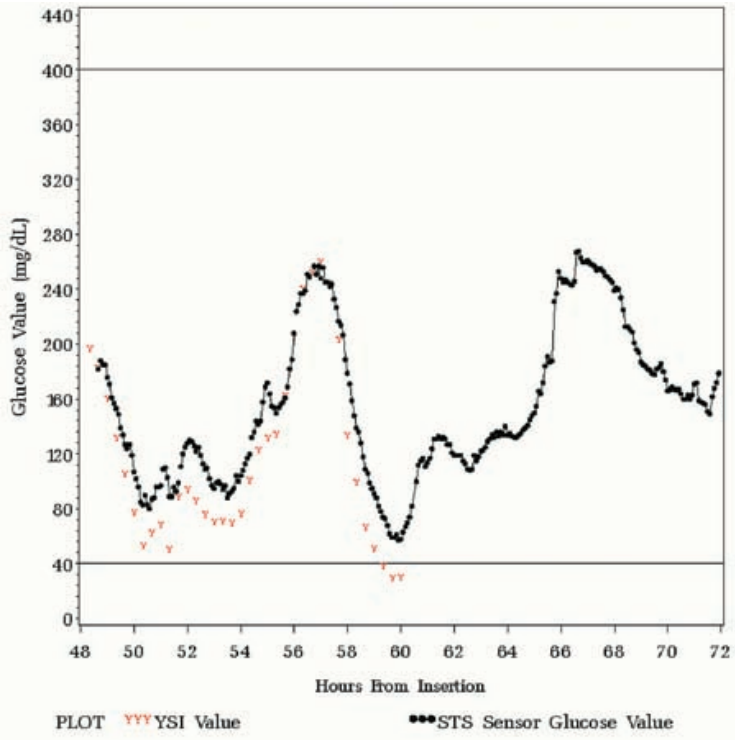
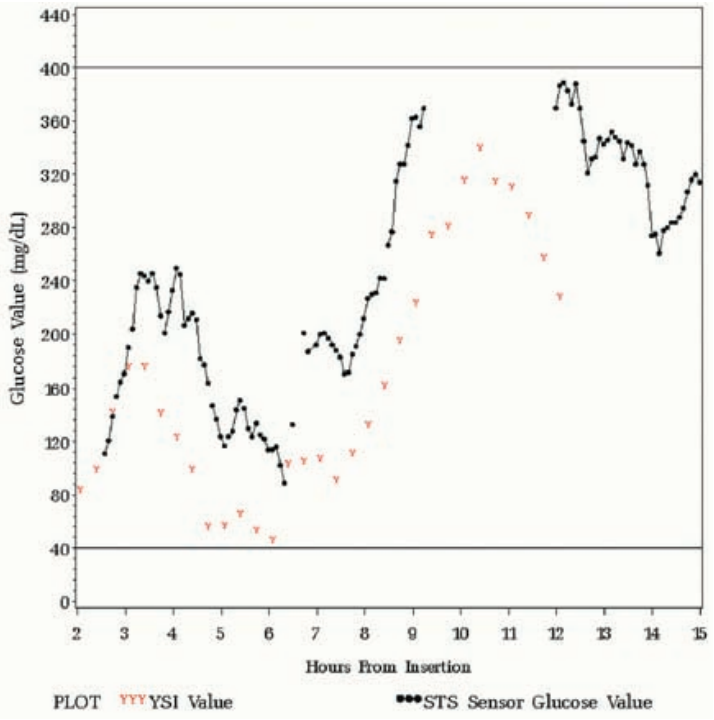


Figure 4. Example of "Poor" STS Performance



Adverse Events

Twenty-one (21) adverse events were reported in 16 of 91 study participants. These events consisted of 2 blisters, 2 reports of edema (swelling), and 17 reports of erythema (redness). All were mild and required no treatment.

9.2 PRODUCT SPECIFICATIONS

STS™ SENSOR

Glucose Range	40-400 mg/dl (2.2 – 22.2 mmol/l)
Sensor Life	Up to 3 days
Calibration	Blood Glucose Measurement-Fingerstick Value
Calibration Range	40-400 mg/dl (2.2 – 22.2 mmol/l)
Operational Conditions Humidity	Humidity: Maximum 95 % Relative
Storage Conditions	Temperature: 2°-25° C (36°-77° F)
Shelf Life	6 Months

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STS TRANSMITTER

Dimensions (including STS Sensor Pod)	Length: 1.8 inches (4.6 cm) Width: 1.2 inches (3.0 cm) Thickness: 0.4 inches (1.0 cm)
Weight (including STS Sensor Pod)	.32 ounces (9 grams)
Communication Range	5 ft (1.5 m)
Frequency	402-405 MHz
Power Supply	Lithium Battery
Display	Liquid Crystal Display (LCD)
Operational Conditions Humidity	Temperature: 10°- 42° C (50°- 108° F) Humidity: Maximum 95 % Relative
Storage Conditions	Temperature: 0°- 45° C (32°- 113° F)
Limited Warranty	6 months

PARAMETER	PERFORMANCE CHARACTERISTICS
Frequency Allocation	MICS Band
TX/RX Frequency	402.142MHz
Bandwidth	300kHz
Maximum Output Power	25uW EIRP
Modulation	On-Off Key
Data Rate	8192 bits/Sec
Total Packet	48 bits
Transmit Duty Cycle	5.86ms every 5 minutes
Data Corruption Detection CRC	
Range	5ft
Probability of Transmission Overlap due to Coexistence - 20 DexCom STS Tramsnitters - within 15 feet	<1% probability of Transmission Overlap; if overlap occurs no glucose value is received.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

The STS™ Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the STS Transmitter should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	STS TRANSMITTER COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electromagnetic Environment-Guidance Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical Fast Transient /burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable-Battery Operated	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not Applicable-Battery Operated	
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	Not Applicable-Battery Operated	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power Frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment

Note: U_T is the a.c. mains voltage prior to application of the test level

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STS™ RECEIVER

Reading Frequency	Every 5 minutes
Dimensions	Length: 4.5 inches (11.4 cm) Width: 2.3 inches (5.8 cm) Thickness: 0.85 inches (2.2 cm)
Weight	3.5 ounces (100g)
Communication Range	5 ft (1.5 m)
Battery Life	5 days
Memory Storage	30 days
Storage/Operating Conditions	Temperature: 0°- 45° C (32°- 113° F) Humidity: 10-85 % Relative Humidity
Power Supply	Rechargeable Battery
Charging Time	3 hours
Limited Warranty	6 months

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

The STS™ Receiver is intended for use in the electromagnetic environment specified below. The customer or the user of the STS Receiver should assure that it is used in such an environment

IMMUNITY TEST	IEC 60601 TEST LEVEL	STS RECEIVER COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT- GUIDANCE
Electromagnetic Environment-Guidance Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical Fast Transient /burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	Main power quality should be that of a typical commercial or hospital environmental.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power Frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment

Note: U_T is the a.c. mains voltage prior to application of the test level

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Guidance and Manufacturer's Declaration- Electromagnetic Immunity

The STS™ Receiver is intended for use in the electromagnetic environment specified below. The customer or the user of the STS Receiver should assure that it is used in such an environment

IMMUNITY TEST	IEC 60601 TEST LEVEL	COM-PLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
			Portable and mobile RF communications equipment should be used no closer to any part of the STS Receiver, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\ P^{1/2}$
Conducted RF IEC 61000-4-6	3 Vrms 150 k Hz to 80 MHz	3 V	$d = 1.2\ P^{1/2}$ 80 MHz to 800 MHz $d = 2.3\ P^{1/2}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measure field strength in the location in which the STS™ Receiver is used exceeds the applicable RG compliance level above, the STS Receiver should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary. Such ad reorienting or relocating the STS Receiver.
[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and STS Receiver

The STS Receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the STS Receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the STS Receiver as recommended below, according to the maximum output power of the communications equipment.

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RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (M)		
	150 kHz to 80 MHz $d = 1.2\ P^{½}$	80 MHz to 800 MHz $d = 1.2\ P^{½}$	800 MHz to 2.5 GHz $d = 2.3\ P^{½}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

BG METER CONNECTION CABLE

Length	6.6 ft (2m)

CHARGING CABLE

Length	6.6 ft (2 m)

9.3 FCC REQUIREMENTS

The DexCom STS™ Transmitter covered by this User's Guide has been certified under FCC ID:

PH29300
PH29400

The STS Transmitter is authorized by rule under the Medical Implant Communications Service (part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation.

The STS Transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although the STS Transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the STS Transmitter will be free from interference.

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1-877-DEXCOM4 (339-2664)

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DEXCOM STS SYSTEM USER'S GUIDE
LBL 9548 REV 03

ATTACHMENT 3A

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210 0 IEEE trans. biomed. eng. $b (Print)
222 0 IEEE transactions on biomedical engineering $b (Print)
245 00 IEEE transactions on bio-medical engineering / $c Bio-medical Engineering Group.
246 3 Institute of Electrical and Electronics Engineers transactions on bio-medical engineering
246 30 IEEE transactions on biomedical engineering
246 30 Transactions on bio-medical engineering
260 New York, N.Y. : $b Institute of Electrical and Electronics Engineers, $c ©1964-
300 volumes : $b illustrations, portraits ; $c 28 cm
310 Monthly, $b <Jan. 1979-
321 Bimonthly, $b <Nov. 1975-
321 Quarterly, $b 1964-<Jan. 1969
336 text $b txt $2 rdacontent
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ATTACHMENT 5

DECLARATION OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.

4. The archived data made viewable and browseable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.

5. The Internet Archive assigns a URL on its site to the archived files in the format http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL] aka an "extended URL". Thus, the extended URL http://web.archive.org/web/19970126045828/http://www.archive.org/ would be the URL for the record of the Internet Archive home page HTML file (http://www.archive.org/) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.

6. Attached hereto as Exhibit B are true and accurate copies of printouts of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.

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7. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE: April 8, 2024

Nathaniel E Frank-White

Nathaniel E Frank-White

EXHIBIT B

https://web.archive.org/web/20101216030536/http:/freestylenavigator.com/static/cms_workspace/document/FSN-User-Guide-ART16072_Rev-A-Web.pdf

Customer Care available 24 hours a day,
7 days a week at: 1-866-597-5520
www.continuousmonitor.com

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5,262,035; 5,264,104; 5,264,105; 5,593,852; 5,899,855; 5,918,603; 5,965,380; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,162,611; 6,175,752; 6,284,478; 6,299,757; 6,329,161; 6,338,790; 6,461,496; 6,484,046; 6,503,381; 6,514,718; 6,560,471; 6,565,509; 6,591,125; 6,592,745; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,676,816; 6,749,740; 6,893,545; 6,932,894; 6,942,518; 6,973,706; 6,990,366; 7,003,340; 7,003,341; 7,074,308; 7,090,756; 7,299,082.

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ART16072 Rev. A 05/08

Abbott

FreeStyle Navigator®

Continuous Glucose Monitoring System

User's Guide

R_x *Only* **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

Abbott

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Indications for Use

The FreeStyle Navigator® Continuous Glucose Monitoring System is indicated for continually recording interstitial fluid glucose levels in people (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management. Readings and alarms about glucose levels from FreeStyle Navigator® Continuous Glucose Monitoring System are not intended to replace traditional blood glucose monitoring. Before adjusting therapy for diabetes management based on the results and alarms from the FreeStyle Navigator® Continuous Glucose Monitoring System, traditional blood glucose tests must be performed. The FreeStyle Navigator® Continuous Glucose Monitoring System provides a built-in blood glucose meter to confirm the continuous glucose result.

The FreeStyle Navigator® Continuous Glucose Monitoring System provides real-time readings, graphs, trends, and glucose alarms directly to the user. The FreeStyle Navigator® Continuous Glucose Monitoring System is intended to be used in home settings to aid people with diabetes in predicting and detecting episodes of hypoglycemia and hyperglycemia and in clinical settings to aid health care professionals in evaluating glucose control. The FreeStyle Navigator® Continuous Glucose Monitoring System is available only by prescription.

Contraindications

The FreeStyle Navigator® Continuous Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI).

How to Use this Guide?

This guide has many Sections arranged in a logical sequence that will be useful for the first time use and every use thereafter. Most Sections begin with a purpose for that Section, when to perform the steps in that Section, materials required to perform the steps in that Section and important cautions, warnings and helpful information. The first page of each Section will be very useful when you are getting familiar with the system. Once you are familiar with the system and the typical precautions, you may find yourself relying less on the first page of the individual Sections.

The remainder of each Section describes the steps to perform the tasks. The steps are organized in a simple manner to allow you to see what to do based on what you experience and based on where you are in that particular Section. It is important that you go through the steps in the order that they have been presented. Every Section also indicates if you have reached the end of the Section. If you find it difficult to use the guide or if you seem lost or confused, use the table of contents, index, glossary and appendices to help you. The table of contents provides a list of Sections you will find in this guide and what each Section contains. The appendices have useful information that you may want to refer to. The glossary provides a list of terms and what they mean. The index is a tool you could use to quickly find terms and items that you are looking for.

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- OpSite® IV 3000 and Uni-Solve® are trademarks of Smith and Nephew Inc.
- Bluetooth® wireless technology is a trademark of the Bluetooth SIG Inc.
- YSI 2300 STAT Plus™ Glucose Analyzer is a trademark of Yellow Springs Instrument Inc.
- Energizer® Max®, Energizer® e2® Titanium® and Energizer® Industrial Batteries are trademarks of the Eveready Battery Company Inc.

Glossary of Symbols

	Do not re-use		Temperature limitation
$R_{X\ Only}$	Rx only. For use by prescription only		Manufactured by
STERILE	Sterile		Consult operating instructions
	Use by	LOT	Batch code
SN	Serial number	REF	Catalog number

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1 Getting Acquainted

Section 1

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Section 1 – Key Terms

- Alarms
- Blood Glucose Mode
- Continuous Monitoring Mode
- FreeStyle Navigator Continuous Glucose Monitoring System
- FreeStyle Test Strips
- *in vitro*
- Interstitial Fluid
- LEFT/RIGHT Option Buttons
- Receiver
- Receiver Display Screen
- Receiver Test Strip Port
- Reports
- Sensor
- Sensor Delivery Unit
- Sensor Inserter
- Sensor Insertion Button
- Sensor Locking Pin
- Sensor Release Tabs
- Sensor Support Mount
- Transmitter
- Transmitter Tabs
- UP/DOWN Arrow Buttons

1 Getting Acquainted

Introduction

Important: *Read all of the instructions in this User's Guide and the FreeStyle® Test Strip package insert before using your FreeStyle Navigator® Continuous Glucose Monitoring System. Adjustments to your treatment should be done under the guidance of your healthcare team.*

Your FreeStyle Navigator system continuously reads, displays, and records the glucose levels in the fluids found between the cells under your skin (interstitial fluids). It does this by using a small, thin, plastic sensor inserted just under the skin.

Your FreeStyle Navigator system provides you with continuous glucose readings in real time. By having access to more frequent glucose measurements, you can monitor your glucose levels and gain an understanding of patterns in your glucose levels. This will help you and your healthcare team see how factors such as your diet, insulin, exercise, and diabetes medication affect your glucose levels, and to adjust your treatment plan accordingly.

Your FreeStyle Navigator system has a number of helpful features.

- Wireless communication between the transmitter and receiver.
- Disposable sensor that can be worn up to 5 days.
- Alarms to alert you to low or high glucose levels (hypoglycemia or hyperglycemia) ***before*** reaching those low and high glucose levels and ***when*** reaching those glucose levels.
- Graphs and statistics that show your glucose results in easy-to-understand formats.
- Directional glucose trend arrows that show if your glucose values are rising or falling and how fast.
- Memory to hold up to 60 days worth of data.
- Wireless communication capabilities to a personal computer.
- Built-in FreeStyle® Blood Glucose Meter for performing blood glucose measurements.
- Event entry capabilities (like meals, exercise, insulin and other).
- Backlit display.

Important: *Keep this User's Guide for future reference. It will come in handy when you have to do procedures that you do not do often enough to remember.*

OVER

How are the parts packaged?

Your FreeStyle Navigator system comes with two kits:

- A System kit.
- A Sensor kit.

The System Kit

- *1 FreeStyle Navigator Receiver in a Receiver Skin*
- *2 AAA Alkaline Batteries (for the receiver)*
- *1 FreeStyle Navigator Transmitter*
- *1 Silver Oxide 357 HC Battery (for the transmitter)*
- *1 Belt Clip (for the receiver)*
- *1 FreeStyle Lancing Device*
- *1 Finger Cap (for the lancing device)*
- *1 User's Guide*
- *1 Getting Started Guide*
- *1 Quick Reference Card*
- *1 Welcome Card*
- *6 Overbandages*
- *12 Alcohol Prep Pads*
- *30 Sterile Lancets*
- *1 Vial of FreeStyle Control Solution and Insert*
- *1 Vial of 50 FreeStyle Strips and Strip Insert*
- *1 Warranty Registration Card*

The Sensor Kit

- *6 Sterile Sensor Delivery Units (each containing a sensor) and Product Insert*
- *1 Silver Oxide 357 HC Replacement Battery (for the transmitter)*

- In addition, the FreeStyle Navigator system can transfer data to a computer wirelessly using Bluetooth® technology.

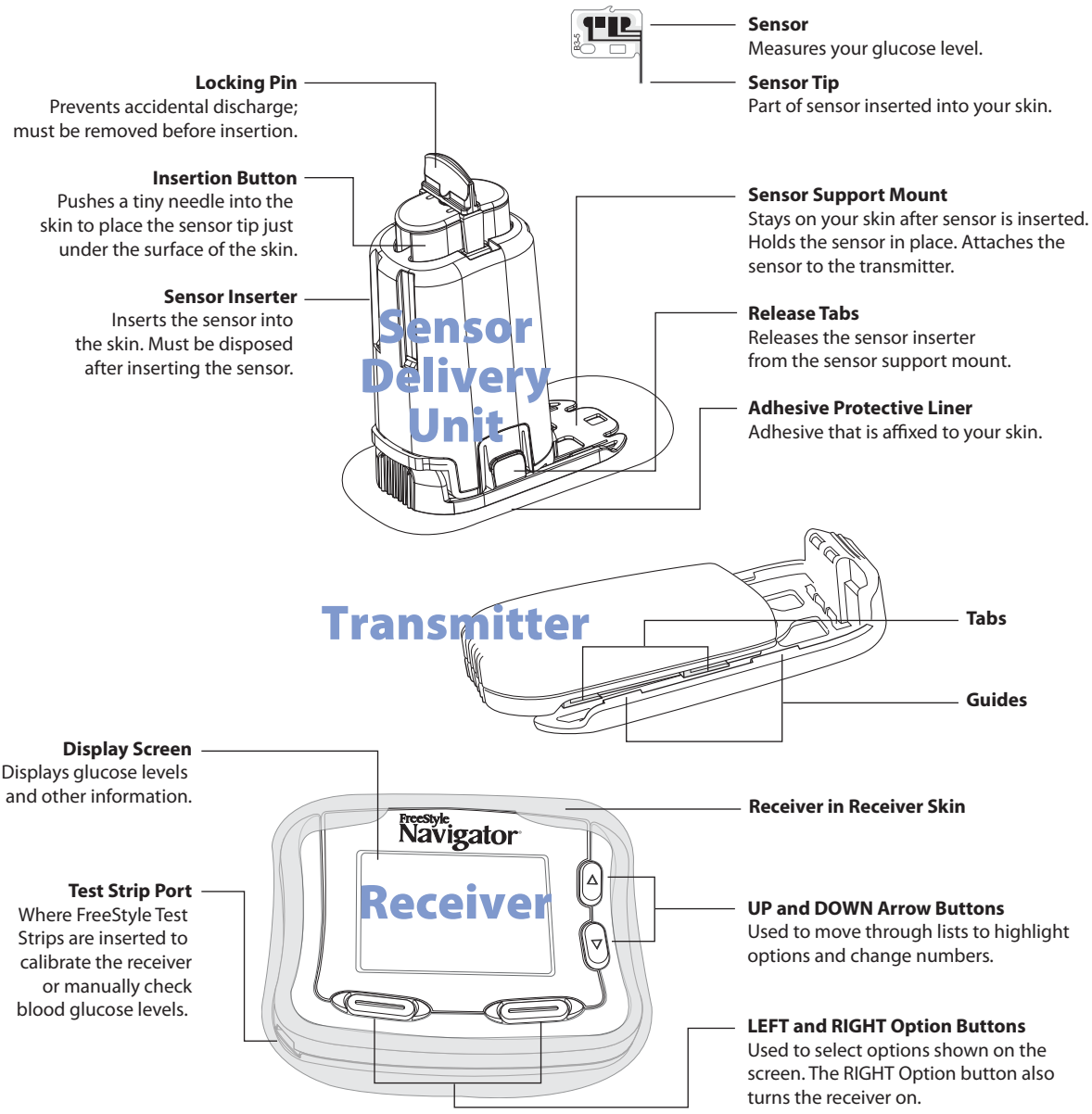
Important Notes:

- The FreeStyle Navigator® Continuous Glucose Monitoring System is designed as a complete system. Use only the FreeStyle Navigator Sensor, the FreeStyle Navigator Transmitter, the FreeStyle Navigator Receiver and FreeStyle Test Strips.
- The system is intended for your personal use; do **NOT** share your system with others.

Abbott Ex. 1027 - 217/400

What are the key parts of my system?

Your FreeStyle Navigator system includes the following major parts:



a. A FreeStyle Navigator Sensor that you insert about 5 mm under your skin. Each inserted sensor is intended to remain in place and provide a continuous glucose reading for up to 5 days. The sensor is contained in the Sensor Delivery Unit.

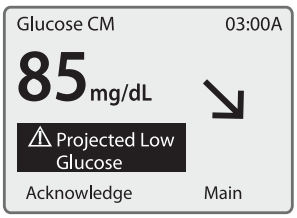
b. A wireless FreeStyle Navigator Transmitter (Tx), a small electronic device that connects to the sensor and sends glucose values to the receiver once every minute.

c. A wireless FreeStyle Navigator Receiver (Rx) that captures and displays glucose measurements. With the press of a button, the receiver displays the glucose measurement taken from the sensor.

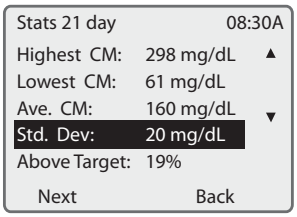
Note: The receiver also has a built-in FreeStyle Blood Glucose Meter that can be used for blood glucose testing. The receiver should always be kept with you on a belt, in a pocket, or in a purse.

OVER

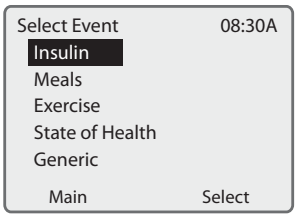
Key features of the System



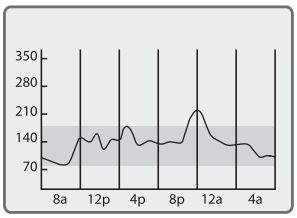
Alarms



Statistics



Event Log



Line Graph

Your receiver comes with backlight capability to see the screen in dark environments. The backlight can be turned on by pressing and releasing the DOWN Arrow button and then pressing and releasing the RIGHT Option button.

For more details on the different symbols and icons on the screen, see Section 9 on “Daily Use”.

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Using your system

For Daily Activities

You will be wearing a sensor and a transmitter at all times while you are using the system. Keep the following in mind as you go about your normal routine.

- Only wear the sensor and transmitter on a flat surface of either your abdomen or the back of your upper arm.
- ***Sleeping*** – The sensor and transmitter should not interfere with your normal sleeping patterns. As you get ready to go to sleep, place the receiver within 10 feet to maintain the transmitter-to-receiver connection.
- ***Bathing*** – Do **NOT** wear the receiver while bathing or showering. Do **NOT** allow the receiver to get wet. However, you can wear the sensor and transmitter while bathing or showering.
- ***Swimming*** – You may swim while wearing the sensor and transmitter. Do **NOT** go deeper than 1 meter (approximately 3 feet).

Note: The connection between the transmitter and receiver is **NOT** maintained when the transmitter is underwater; thus, you will **NOT** receive continuous glucose readings. However, when you take the sensor and transmitter out of the water, the continuous glucose readings will resume.

When Traveling by Plane

Note: Do **NOT** perform the upload data feature when you are on a commercial aircraft.

Follow the guidelines below when traveling. Always check with local authorities prior to departure as rules and regulations may change without notice.

At the airport:
Notify the security personnel of the presence of the device when going through the security systems.

On the plane:
Check with your airline before departure whether the device will be permitted aboard the aircraft. The airline companies set policies regarding the use of medical devices on board their flights.

If you want to disable the transmit function of the transmitter, follow these steps:

1. If you are currently wearing a sensor, remove the sensor.
2. Detach the transmitter from the sensor support mount and remove the battery from the transmitter.
3. Program into the receiver that you have ended a sensor session.
4. By removing the battery from the transmitter, you have broken the connection between the transmitter and receiver. You can set the data loss alarms and system alarms to a short vibration mode in order to prevent the device from sounding alarms. Once you put a new battery into the transmitter, make sure to set the alarms to the original setting.

Note: Insert a fresh battery into the transmitter after travel before inserting a new sensor.

You can always use your receiver to check your blood glucose manually in the Blood Glucose mode.

OVER

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How do I prepare my system for the first time?

When you are setting up your receiver for the first time, perform all of the procedures listed below ***in the order that they are listed***. Check each procedure off when you complete it.

- ❑ Install batteries in the transmitter first and then in the receiver (***see Section 2***).
- ❑ Set the time and date (***see Section 3***).
- ❑ Perform a control solution test (***see Section 4***).
- ❑ Insert your sensor (***see Section 5***).
- ❑ Attach your transmitter (***see Section 6***).
- ❑ Calibrate your receiver when prompted (***see Section 7***).
- ❑ Set the alarms in the receiver (***see Section 8***). **Note:** This can be done while waiting to perform the first calibration.

Result: *Your system is operational.*

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Warnings, Cautions And Important Notes

Important Notes About System Performance

The following items describe situations that could lead to inaccurate or unreliable continuous glucose results.

Cautions:

- *Movement of the sensor support mount or excessive perspiration at the sensor insertion site due to activities like vigorous exercise or bumping against objects may lead to poor adhesion of the support mount to the skin and cause the sensor to dislodge. If the sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable results or no results. The system may not provide a warning in such circumstances. Choose the proper sensor insertion site when inserting the sensor and prepare the site by following the instructions for site preparation.*
- *If your results from the Continuous Monitoring mode seem erroneous, check and make sure that the sensor has not dislodged. If you notice the sensor is dislodged from the skin, or if you see that the adhesive on your overbandage or the sensor support mount is coming loose, discard the old sensor and insert a new sensor.*
- *The FreeStyle Navigator system includes built-in self-checks to detect conditions that may cause the sensor to not function properly. On rare occasions the system may not be able to detect all such conditions (for example if the adhesive peels up from your skin), and you may get inaccurate results in the Continuous Monitoring mode. If you believe your results are not reliable, or are inconsistent with how you feel, perform a Blood Glucose mode test to measure your glucose. If the problem continues, discard the old sensor and insert a new sensor.*
- *You should never reset your user settings when you are wearing a sensor. This will reset parameters that may affect your system performance.*
- *If you accept an incorrect transmitter ID when linking your Transmitter and Receiver, your glucose readings will be incorrect.*
- *Do **NOT** use the sensor delivery unit if the sterile package is open or damaged.*

Important:

- *Once the code has been entered and you have hit the Set button, you will not be able to change the sensor code number. If you have entered the code incorrectly, you will have to replace the sensor and enter the right sensor code. If you choose the wrong sensor code, you may get erroneous results from the sensor. The code numbers MUST match to ensure accurate test results.*
- *Do **NOT** remove or replace the transmitter from the sensor support mount while wearing a sensor. If you notice that the transmitter is not properly attached, replace the sensor with a new sensor and then reattach the transmitter.*

Important Things to Remember About System Calibration

***Caution:** Always calibrate the system using only a finger-stick blood sample. Do **NOT** use alternate site blood glucose measurements to calibrate the system. The receiver contains a built-in FreeStyle® Blood Glucose Meter for performing calibration tests.*

***Important:** Your blood glucose level must be between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) to be able to perform calibration tests. If your blood glucose level is changing rapidly, you may not be able to calibrate the system. For example, during a meal or exercise, your glucose levels may vary rapidly. Try to time your sensor insertion so that your calibration times do not coincide with your regular meal or exercise activities.*

OVER

Important Things to Remember About System Calibration *(con't)*

Important: *In clinical trials, we observed that the sensor signal sometimes temporarily decreases from the true value. This typically happens at night during sleep, and recovers rapidly when the user moves or is awakened. However, in order to avoid being affected by this phenomenon the system should not be calibrated when the wearer is asleep.*

- You may not be able to calibrate the system if your glucose levels are changing rapidly. (e.g. during or after exercise, meals or insulin dosing). Under such conditions, the system may not ask you to calibrate; instead, it will delay its request until conditions are acceptable.
- You **MUST** successfully complete 4 calibration tests. You will calibrate at approximately 10, 12, 24 and 72 hours after sensor insertion. If you do not complete calibration tests successfully in the allotted time periods, your glucose readings will NOT be displayed and alarms will be inactive. The system may ask you to perform additional calibrations between 2nd and 3rd calibrations depending on the sensor signal. In such cases, you will be prompted with a message to do additional BG tests.
- The receiver will beep (or vibrate) to prompt you to do a calibration. The receiver will display a blood drop icon and the message "Do BG Test." The system will prompt you with alarm messages when your calibrations are unsuccessful.
- You will not have continuous monitoring until you have successfully completed the first calibration (at least for the first ten hours after sensor insertion).
- If you get a request for a calibration or expect additional calibration requests during a time when you do not want to be disturbed (e.g. sleep time), you can choose to wait to perform additional BG tests at a later point in time. If you choose to wait and the allotted time window for calibration has expired, please note that you will not get glucose results until you have performed a successful calibration. You can turn off the System Alarms (or set to vibrate) if you do not want to be disturbed by frequent requests for calibration. In order to silence the alarms that warn you when the allotted time window for a calibration has expired, you must turn off the data loss alarms and all the four glucose alarms (Low Glucose, High Glucose, Projected Low Glucose and Projected High Glucose).

Before You Get Started

Installation and operation of the FreeStyle Navigator® Continuous Glucose Monitoring System requires using a specialized introducer needle to insert the glucose sensor into the skin. Infection, inflammation, or bleeding at the glucose sensor insertion site are possible risks of inserting a sensor into your skin. The glucose sensor should be removed if redness, pain, tenderness, or swelling develops at the sensor insertion site.

Cautions:

- *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*
- *Performance of the FreeStyle Navigator system has not been evaluated in pregnant women.*
- *Performance of the system under conditions of fluctuating hydration levels such as during renal dialysis has not been evaluated.*

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Before You Get Started *(con't)*

Cautions:

- *Low or high glucose measurements can indicate a potentially serious medical condition.*
- *If you have hypoglycemia, or hypoglycemia unawareness, then test ONLY on your fingers.*
- *The high and low alarms are intended to assist you in managing your diabetes and should not be exclusively used to detect hypoglycemia or hyperglycemia. The alarms should always be used in conjunction with other indications of glycemic state such as your glucose level, trend, line graph etc.*
- *High and low glucose alarms are DIFFERENT from your glucose targets. Low and high glucose alarms alert you when you've crossed a certain low or high value. Glucose targets allow the reports and line graphs to show how your glucose levels have been performing compared to your set targets.*
- *The Low Glucose alarm cannot be set below 60 mg/dL (3.3 mmol/L). Therefore, it is not intended to notify you of severe hypoglycemia.*
- *The High Glucose alarm cannot be set above 300 mg/dL (16.7 mmol/L). Therefore, it is not intended to notify you of severe hyperglycemia.*
- *It is important to use the correct type of batteries in the receiver, otherwise the battery life may not be accurately monitored.*
- *Do NOT immerse the receiver in water or in any other liquid. Avoid getting water or any other liquid in the test strip port.*
- *Changes or modifications not expressly approved by Abbott Diabetes Care, Inc. could void the user's authority to operate the equipment.*
- *The system should not be used in environments that are oxygen-rich or that contain a combustible gas.*
- *The radio receiver and transmitter of your FreeStyle Navigator system operate on the frequency of 433.6 MHz. Primary users of this frequency band include amateur "HAM" radio transmitters. Because of the coexistence of the FreeStyle Navigator radio connection and HAM transmitters, there may be instances where the connection between your transmitter and receiver may be lost when in proximity to HAM radio equipment. The FreeStyle Navigator system is designed to sense and notify you about a lost connection. If your FreeStyle Navigator system loses the radio connection, increase the separation distance between yourself and the transmitter by moving away from the HAM radio. The FreeStyle Navigator radio connection should re-establish itself. You should note that HAM radio products can be fixed, mobile or portable handheld ("walkie talkie" type) units.*

Important: *Because you must insert a new sensor after each battery replacement, you should replace the batteries just before you insert a new sensor. For example, if you drop your receiver and the batteries fall out, you will have to insert a new sensor.*

Warnings:

Keep your system and its components away from young children because:

- There are small parts that may be dangerous if swallowed.
- The control solution caps are choking hazards.
- The test strip vial and sensor delivery unit packaging may contain a drying agent that could be harmful if inhaled or swallowed and may cause skin and eye irritation.

NEVER point a pre-cocked sensor inserter toward the eyes, face, or any other body part where sensor insertion is not desired.

OVER

Before You Get Started *(con't)*

- If your results from the continuous monitoring mode do not reflect how you feel, test your glucose using the Blood Glucose mode.
- If you observe a significant change in your continuous glucose readings that you think is erroneous, or if you feel the blood glucose measurement in the Blood Glucose mode is erroneous and you are close to an electromagnetic interference source, move away from the source of interference and check to see if the condition fades away.
- If you have a medical appointment that includes X-ray, MRI (Magnetic Resonance Imaging), CT (Computed Tomography) scan, or another type of exposure to radiation, keep your system and sensor away from the area. Before exposure to such radiation, discard any sensor you are wearing and insert a new sensor after the radiation session. The effect of these types of radiation on the performance of the system has not been evaluated.

Helpful health related information:

The following pertain to your health and should always be kept in mind:

- The system is intended to assist you in better managing your diabetes by allowing you to know your glucose levels throughout the day.
- Test results below 60 mg/dL (3.3 mmol/L) mean your glucose levels are low.
- Test results above 240 mg/dL (13.3 mmol/L) mean your glucose levels are high.
- Severe dehydration and excessive water loss may cause false low results. If you believe you are experiencing severe dehydration, consult your healthcare team immediately.
- If you get results below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L) and do not have symptoms of hypoglycemia or hyperglycemia, test your glucose using the Blood Glucose mode.
- If you have symptoms of hypoglycemia or hyperglycemia, or continue to get results below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare team.
- If you are experiencing symptoms that are not consistent with your glucose test results, consult your healthcare team. Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose measurements. Differences in glucose measurement between interstitial fluid and your finger may be observed during times of rapid change in blood glucose, e.g. after eating, dosing insulin, or exercising.
  - Interstitial fluid (ISF) is the fluid between cells in the body. Movement of nutrients, oxygen and glucose from the blood into the cells happen across the ISF. Therefore, if the glucose in the bloodstream rises (e.g. during meals), that rise is not seen in the ISF until later. Similarly, if glucose levels in the ISF drop (for example during exercise, the cells consume glucose rapidly) that drop is not seen in the bloodstream until later.
- When testing your glucose levels in the Blood Glucose mode, differences in the blood circulation in your finger or palm (at the base of your thumb) and other test sites (forearm, upper arm, hand, thigh, or calf) may result in different glucose readings. Differences in blood glucose readings between your finger or palm (at the base of your thumb) and other test sites (forearm, upper arm, hand, thigh, or calf) may be observed after eating, taking insulin, diabetes medication, or exercising.
- Test your finger if you are testing for hypoglycemia or if you have hypoglycemia unawareness (see next page for definition of hypoglycemia unawareness). Changes in glucose levels may be observed in finger blood samples sooner than in samples from alternate sites (forearm, upper arm, hand, thigh, or calf). If an alternate site must be used, vigorous rubbing of the alternate site before lancing can help minimize this difference.
- Do not use the FreeStyle Navigator system for diagnosing diabetes, testing newborns, or testing arterial or venous blood.

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What is Hypoglycemia Unawareness?

Hypoglycemia unawareness is a condition where you are having hypoglycemia but you do not have any of the usual warning symptoms (such as rapid heartbeat, sweating, shakiness, anxiety, or a tingling sensation in your fingers or toes). Those warning symptoms are either absent or greatly reduced. Instead, the first sign may be confusion or impaired thinking, which makes it even more difficult to know if you are experiencing low blood glucose. You could find yourself in the midst of a severe hypoglycemic episode without any warning at all.

Symptoms of Hypoglycemia Unawareness:
Because you would have missed the early warning signs of hypoglycemia, the only signs or symptoms you may have would be due to the effects of low blood glucose on the brain:

- Irritability
- Tiredness
- Confusion
- Forgetfulness
- Pale skin
- Slurred speech
- Loss of consciousness

This condition is potentially dangerous because hypoglycemia confusion can occur without warning.

If you were driving a car or operating heavy machinery, confusion or delayed reaction could cause an accident.

Hypoglycemia unawareness can develop for several reasons:

a. Having frequent hypoglycemic episodes.

b. Having long standing diabetes and autonomic neuropathy (a form of diabetic neuropathy in which your body does not release its usual hormones to warn you of low blood glucose and to tell your liver to release glucose as a protective mechanism).

If you think you have hypoglycemia unawareness, talk to your healthcare team.

OVER

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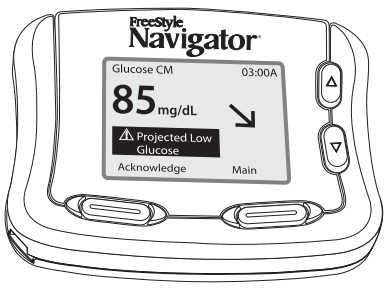
What are the Continuous Monitoring mode and Blood Glucose mode?

Your FreeStyle Navigator system operates in two modes:

- Continuous Monitoring mode (Glucose CM).
- Blood Glucose mode (Glucose BG).



Continuous Monitoring Mode (Glucose CM)

The Continuous Monitoring mode is the mode you will use most of the time. It continuously displays the glucose level in the fluid in the tiny spaces between your tissues (interstitial fluid). This glucose reading comes from the sensor you will place just beneath your skin and is updated every minute.

- "Glucose CM" at the top left of the display.
- The glucose reading is typically accompanied by a directional trend arrow that indicates how fast your glucose is changing and in what direction.
- Most frequently used mode.
- Measures glucose from interstitial fluid detected by a sensor in your skin.
  - Uses a sensor to measure glucose levels.
  - A transmitter sends the glucose readings to the receiver.
  - Should only be used with FreeStyle Navigator system Transmitters and FreeStyle Navigator Sensors.

Blood Glucose Mode (Glucose BG)

You will perform traditional blood glucose testing (BG testing) in the Blood Glucose mode using a FreeStyle Test Strip and a drop of blood. You can use the Blood Glucose mode whenever you wish to perform a traditional blood glucose test. It is also used for calibrating the system. Blood Glucose mode tests used for calibrating the system can also be relied on like traditional blood glucose tests.

- "Glucose BG" at the top left of the display.
  - Built-in FreeStyle Blood Glucose Meter.
- Measures glucose from a blood sample that you supply.
- Uses a FreeStyle Test Strip to measure blood glucose levels.

Note: Use **ONLY** FreeStyle Test Strips and Control Solution. FreeStyle Lite Test Strips will not work in the receiver. Other brands of test strips or control solution can give you inaccurate results.

The system typically works in the Continuous Monitoring mode. It switches to the Blood Glucose mode when you insert a FreeStyle Test Strip into the receiver's test strip port. In order to turn the Blood Glucose mode on, you have to insert the test strip when the receiver is either turned off or when it displays the glucose screen.

END OF Section 1

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2 Install or Replace Transmitter and Receiver Batteries

Section 2

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Section 2 – Key Terms

- Alarm
- Icon
- Receiver
- Transmitter
- Battery Life
- Alkaline Batteries
- 357 HC Silver Oxide Battery
- Reconnect

2 Install or Replace Transmitter and Receiver Batteries

Purpose

To ensure that your FreeStyle Navigator system has power to operate properly.

Start

Do this procedure:

- The first time you use your FreeStyle Navigator system.
- When the receiver displays the Low Battery message and alarm and the battery icon appears on the screen.
- When the receiver sounds an alarm and displays the "Replace TX Battery with Next Sensor" message.

Materials

Gather these materials before you begin:

- 2 new AAA alkaline batteries for the receiver. We recommend Energizer® Max®, Energizer® e2® Titanium®, and Energizer® Industrial batteries. Other batteries may not provide expected battery life.
- 1 Silver Oxide 357 HC battery for the transmitter.
- A coin.
- Your FreeStyle Navigator Receiver.
- Your FreeStyle Navigator Transmitter.

Helpful Information

Caution: *It is important to use the correct type of batteries in the receiver, otherwise the battery life may not be accurately monitored.*

Important:

- *An alarm will sound and a battery icon will appear on the screen when your receiver batteries are running low. You must replace your receiver batteries the next time you replace your sensor. Make sure to replace batteries before inserting your next sensor.*
- *An alarm will sound and a message will appear on the screen when your transmitter battery is running low. You have approximately 4 days of battery power remaining when this first happens.*
- *Because you must insert a new sensor after each battery replacement, you should replace the batteries just before you insert a new sensor. For example, if you drop your receiver and the batteries fall out, you will have to insert a new sensor.*
- *After installing the transmitter or receiver batteries, allow a couple of minutes for the system to recognize new batteries. You may then access the status of the battery life from the System menu in your receiver (see Status Information in Section 10). If the batteries are new, the status screen will show 75-100% as remaining battery life.*

- **If your receiver batteries are low and you fail to replace them, they may run out without a warning and the receiver will neither display your glucose levels nor sound alarms.**
- The transmitter's battery life is estimated to be up to 30 days.
- The receiver's battery life is estimated to be 60 days. However, battery life may be shorter than 60 days if your receiver's alarms are set to vibrate, if you use backlighting frequently, or if the transmitter/receiver connection is broken often.
- If you will not be using your receiver for an extended period of time, remove the batteries from the receiver to preserve battery life.
- To avoid draining the receiver's batteries, be careful not to accidentally press and hold the receiver's buttons for a long period of time.
- After changing the batteries, make sure that you reconnect the transmitter and receiver to establish communication between them.
- If you are replacing batteries on both the transmitter and receiver, replace the battery in the transmitter first.

OVER

Install or Replace the Transmitter Battery

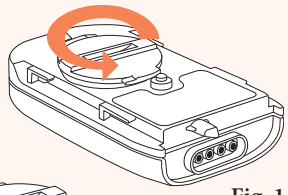

Fig. 1

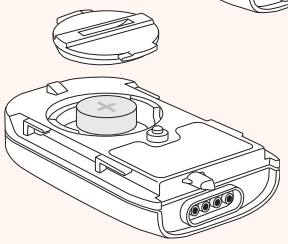

Fig. 2

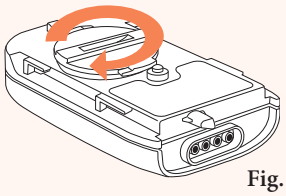

Fig. 3

a. Turn the circular battery door counterclockwise with either a coin or your fingernail. (Fig. 1)

b. Carefully remove the battery door.

c. Remove the old battery, if any, and discard it properly.

d. Insert a NEW silver oxide 357 HC battery with the plus sign (+) facing you. (Fig. 2)

Important: *When inserting the battery in the transmitter, pay special attention to placing the battery straight in rather than at an angle. Do not rock the battery back and forth as this can shorten the battery life.*

e. Replace the battery door and secure it in place by rotating clockwise. (Fig. 3)

Note: The battery door must be closed securely to create a seal. Do not apply excessive force when closing. Excessive force can damage the plastic material of the battery door and the transmitter case. If you are not changing the receiver batteries at this time, reconnect the transmitter and receiver, then go to 'Check your work' at the end of this Section.

Install or Replace the Receiver Batteries

Battery door

Note: The receiver skin must be removed in order to access the receiver's battery door.

a. Locate the battery door on the back of the receiver.

b. Press down on the ridged part of the battery door to slide the battery door completely out.

c. Remove old batteries, if any, and discard them properly.

Note: Be sure to finish within 5 minutes to prevent losing the date and time settings.

d. Insert the new batteries with the positive (+) as shown. Align the + and - signs of the batteries with the signs as shown in the battery compartment.

e. Press each battery into its channel making sure the battery fits tightly.

Note: The receiver will not operate if the batteries are not inserted in the proper direction.

f. Replace the battery door with the tab facing the receiver.

g. Align the edges of the door with the channel in the battery compartment.

h. Slide the door into the receiver until it clicks.

i. Match the screen on your receiver with **ONE** of the screens in the next table and perform the corresponding step.

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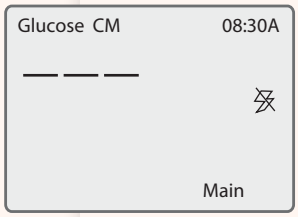
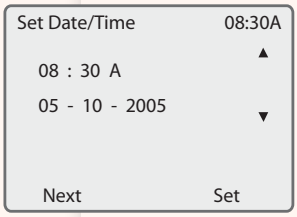
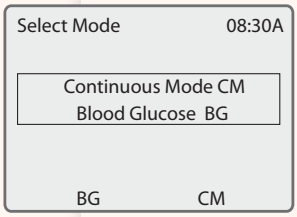
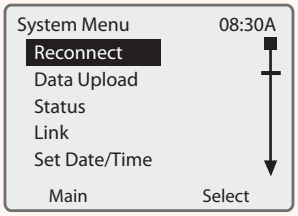
Match what you see on your Receiver with ONE of the screen shots shown below.

If the display is	*Then*
	• Press the RIGHT Option button to see if the screen turns on. • If screen turns on, compare with the screens below and perform the matching steps. • If screen does **NOT** turn on, then repeat this procedure ensuring that the batteries are: – New. – Oriented properly in the battery compartment. – If the problem persists see Section 10 on troubleshooting.
	• The receiver is working properly. Go to "Check your work". You may not see the icon if you have connection between the transmitter and receiver. Reconnect the transmitter and receiver if you see the icon.
	• The time and date need to be set. Go to Step 4 of Section 3. • Set the Time and Date. After setting the time and date, reconnect the transmitter and receiver. Then, "Check your work".
	• Select the mode that you want the system to operate in. • Go to Section 14 to link the transmitter and receiver. • Go to "Check your work".

OVER

Reconnect the Receiver to the Transmitter.



a. Place the receiver within 10 feet of the transmitter.

b. Press the RIGHT Option button twice to display the Main Menu screen.

c. Use the UP or DOWN Arrow button to highlight System.

d. Press the RIGHT Option button (Select) to display the System menu with Reconnect highlighted.

e. Press the RIGHT Option button (Select).

f. Wait for the receiver to beep. If it beeps:

- Twice – The system is connected.
- Three times – The system is not connected. Make sure the battery in the transmitter is new and ensure that the receiver and transmitter are linked (see Section 14).

Note: If the transmitter and receiver are connected properly, the disconnect icon will not appear on the screen.

Check your work.

Result: *An operational system.*

You have done this procedure correctly when:

❑ The batteries have been installed and the battery doors have been closed securely.

❑ The old batteries have been disposed of properly.

❑ The transmitter and receiver have been reconnected.

END OF Section 2

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3 Set the Time and Date

Section 3

Section 3 – Key Terms

- LEFT/RIGHT Option Buttons
- Main Menu
- Receiver
- System Menu
- Transmitter
- UP/DOWN Arrow Buttons

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3 Set the Time and Date

Purpose

To ensure the correct time and date are associated with your data.

Start

Do this procedure:

- The first time you use your FreeStyle Navigator system.
- When you install new batteries.

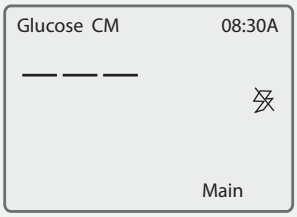
Materials

Your FreeStyle Navigator Receiver.

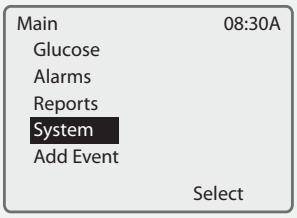
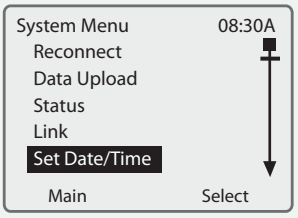
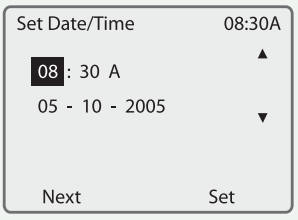
Helpful Information

Important: *Be sure to set the date and time correctly. The correctness of the line graph and statistical reports depends upon the date and the time being correct.*

- The receiver is on whenever batteries with sufficient charge are in the receiver.
- If the batteries are discharged or removed for 5 minutes or more, you must reset the date and time.
- If you make a mistake or want to exit from the Set Date/Time screen, simply leave the receiver alone for 12 seconds. It will automatically turn off, and any changes you made will be cancelled or cleared.
- If you change the time and/or date in the receiver, the line graphs and statistical reports will be affected. For example, if you travel from one time zone to another and change the time to match the local time zone, the appearance of your graph will be affected.

Steps	Do This
1. Go to the Main screen. 	**Note:** When setting the time and date after inserting the batteries, start from Step 4. **a.** Turn the display on. **b.** Press the RIGHT Option button a second time to display the Main screen. If your transmitter and receiver are connected, you will not see the icon.

OVER

Steps	Do This
2. Go to the System screen. 	**a.** Press the DOWN Arrow button to highlight System. **b.** Press the RIGHT Option button (Select) to go to the System Menu screen.
3. Select Set Date/Time from the System Menu screen. 	**a.** Use the UP/DOWN Arrow buttons to highlight Set Date/Time on the System Menu screen. **b.** Press the RIGHT Option button (Select) to display the Set Date/Time screen.
4. Set the time. 	**a.** Use the UP/DOWN Arrow buttons to set the current hour. **b.** Press the LEFT Option button (Next) to move to the minutes digits. **c.** Use the UP/DOWN Arrow buttons to set the current minutes. **d.** Press the LEFT Option button (Next) to move to the AM or PM field. **e.** Use the UP/DOWN Arrow buttons to select A (AM) or P (PM). **f.** To set the date, go to Step 5.

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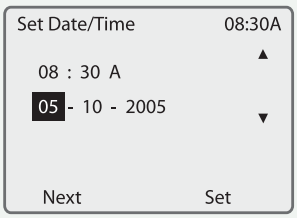
Steps	Do This
5. Set the date.  	**a.** Press the LEFT Option button (Next) to move to the Month field. **b.** Use the UP/DOWN Arrow buttons to set the current month. **c.** Press the LEFT Option button (Next) to move to the Date field. **d.** Use the UP/DOWN Arrow buttons to set the current date. **e.** Press the LEFT Option button (Next) to move to the Year field. **f.** Use the UP/DOWN Arrow buttons to set the current year. **g.** Confirm that your selections are correct: • If **NO**, press the LEFT Option button (Next) and repeat this procedure from Step 5a. • If **YES**, press the RIGHT Option button (Set) to accept your changes. ***Result:*** *The screen displays the System menu.* **h.** Press the LEFT Option button (Main) to return to the Main screen.
6. Check your work.	***Result:*** *Your FreeStyle Navigator Receiver is operating with the correct time and date.* You have done this procedure correctly when: ❑ The time is correct. ❑ The date is correct. **END OF Section 3**

4 Perform a Control Solution Test

Section 4

Section 4 – Key Terms

- Control Solution Test
- FreeStyle Control Solution
- FreeStyle Test Strips
- LEFT/RIGHT Option Buttons
- Receiver
- UP/DOWN Arrow Buttons

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4 Perform a Control Solution Test

Purpose

The purpose of the control solution test is to:

- Ensure that your receiver and test strips are working properly prior to calibration or blood glucose testing.
- Check that you are following the correct testing procedure.
- Practice Blood Glucose mode testing without having to use your own blood. A Control Solution test is not the same as a calibration. See Section 7 for calibrating the system.

Start

Do this procedure when you:

- Set up your receiver for the first time.
- Open and begin using a new vial of test strips.
- Suspect that your receiver or test strips are not working properly.
- Suspect that your glucose test results are not accurate.
- Suspect that your test results are not consistent with how you feel.
- Drop, damage, or expose the receiver to liquids.
- Are advised by your healthcare team to do so.

Materials

Gather these materials before you begin:

- FreeStyle Navigator Receiver.
- FreeStyle Control Solution.
- FreeStyle Test Strips.

Helpful Information

Caution:

- ***Do NOT** use FreeStyle Control Solution for calibration. Do **NOT** perform the control solution test when the system asks you to 'Do BG Test' for calibration.*
- *Results from Control Solution tests do **NOT** reflect your blood glucose level.*

***Important:** The control solution range is a target range for the control solution only. It is **NOT** a target range for your blood glucose levels.*

***Important:** If your control solution test results continue to fall outside of the range printed on the test strip vial, the receiver may not be working properly. Do **NOT** use the system to test your glucose levels. Call Customer Care.*

Ensure accurate control solution results by doing the following:

- Use **ONLY** FreeStyle Control Solution and FreeStyle Test Strips.
- Replace the cap on the control solution vial immediately after using.
- Do **NOT** use your control solution past the expiration date or the discard date.
- Do **NOT** add water or any liquid to the control solution.
- Perform control solution tests only between 59° and 104° F (15° and 40° C).

For important test strip information, including detailed storage and usage information, refer to the FreeStyle Test Strip package insert.

OVER

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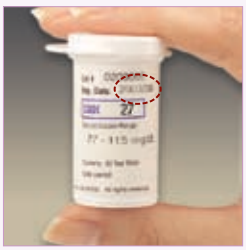
Steps	Do This
1. **Verify that your FreeStyle Control Solution is current.**	**Note:** FreeStyle Control Solution is good for three months after opening the bottle, or until the expiration date printed on the label, whichever comes first. Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle. ***Example:*** *You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.*
2. **Prepare test strip.** 	**a.** Locate the expiration date on the vial of FreeStyle Test Strips. ***If strips are expired, obtain a new vial of strips.*** **b.** Locate the code number (you'll need it in a minute). **c.** Remove a single test strip from the vial. **d.** Close the vial tightly before continuing but do **NOT** put the vial away.

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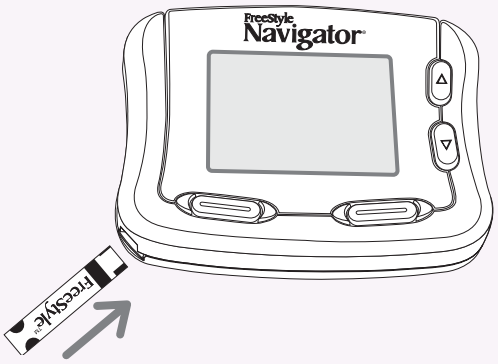
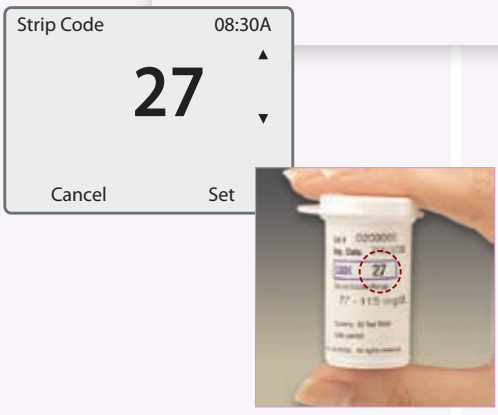
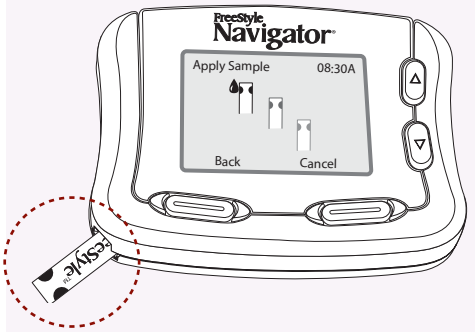
Steps	Do This
3. **Insert test strip into the receiver.** 	**a.** Turn the test strip so "FreeStyle" text faces up. **b.** Grasp the test strip by the end with the two half circles. **c.** Insert the end with the dark rectangle into the receiver at the lower left corner of the receiver. ***Result:*** *The receiver display screen turns on and displays the Strip Code screen.* **Note:** If the screen does not turn on, refer to Section 10 on troubleshooting.
4. **Compare code numbers.**	Compare the code number on the display with the code number on the vial of test strips.

If	*Then*
• The numbers match.	**a.** Press the RIGHT Option button (Set). **b.** Go to Step 5.
• The numbers do **NOT** match.	**a.** Use the UP/DOWN Arrow buttons to change the code to match. **b.** Press the RIGHT Option button (Set). **c.** Go to Step 5.
• The screen changes to the Apply Sample screen.	If the numbers did **NOT** match: **a.** Press the LEFT Option button (Back). **b.** Repeat Step 4. If the numbers match, go to Step 5.



OVER

Steps	Do This
5. Apply control solution.  	***Important:*** *Do* ***NOT*** *apply control solution to both edges of the test strip.* **Notes:** • Gently touch **ONLY ONE EDGE** of the test strip to the control solution next to one of the dark half-circles. • If progress tones are turned on, the receiver will beep to indicate that enough control solution was applied. ***Result:*** *A stopwatch will appear on the display screen while the receiver measures the control solution.* • The receiver will beep twice when the test results appear.
6. Confirm that you used a control solution. 	Press the LEFT Option button (Yes) to alert the receiver that you used a control solution for this test. **Note:** If you do **NOT** select yes, the system will record the result as a blood glucose result instead of a control solution result, which can result in an incorrect statistical report. ***Go to the next step.***

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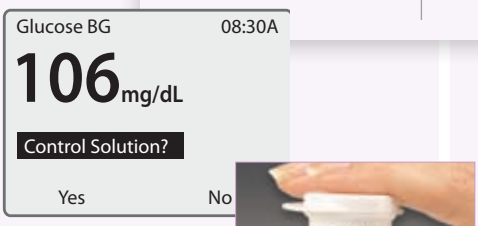
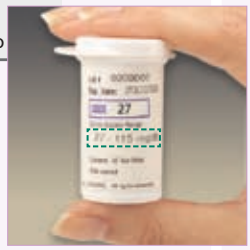
Steps	Do This
7. **Evaluate the test results.**	Compare the test results displayed on the screen to the range printed on the vial of test strips.

If the result	*And*	*Then*
• Falls **WITHIN** the range.	→	Go to Step 8.
• Falls **OUTSIDE** of the range.	You've repeated the test.	Call Customer Care.
	You've **NOT** repeated the test.	Repeat the test from Step 1 with a NEW test strip.
• Is an error message.	→	Go to Section 10 on troubleshooting.





77 – 115 mg/dL

8. **Check your work.**

Result: *Control solution test results displayed on the receiver screen.*

You have done this procedure correctly when:

- ❑ The results are within the normal control solution range.
- ❑ The used test strips have been discarded properly.
- ❑ The control solution tests are marked as control solution tests.

END OF Section 4

5 Insert or Remove Your Sensor

Section 5

Section 5 – Key Terms

- **Calibration**
- **Reconnect**
- **Sensor**
- **Sensor Delivery Unit**
- **Sensor Inserter**
- **Sensor Insertion Button**
- **Sensor Insertion Site**
- **Sensor Locking Pin**
- **Sensor Release Tabs**
- **Sensor Support Mount**
- **Sharps Container**
- **Transmitter Receiver Connection**

Now that you are ready to insert a sensor, here are a few helpful tips.

- Reconnect your transmitter and receiver **BEFORE** inserting a new sensor.
- **BEFORE** inserting a new sensor, program into the receiver that the old sensor has been removed.
- Make sure there are no messages or icons related to low battery conditions on the receiver **BEFORE** inserting a sensor.
- When attaching the transmitter, you may not always hear a click. Place the transmitter about halfway over the sensor support mount and slide the transmitter back and forth to make sure it moves freely before you attach it. You will feel a click as you slide it into place.
- After attaching the transmitter to a new sensor, allow the system a few minutes to recognize a new sensor. Reconnect the receiver and transmitter to make sure they are communicating.
- When responding to messages about sensor insertion and sensor removal, choose the appropriate answer ('Yes' or 'No').
- Do **NOT** use the Link/Unlink feature unless you have received a new transmitter or receiver from the manufacturer. To establish communication between them, **ALWAYS** use the 'Reconnect' feature. {**Note:** Link is **NOT** the same as Reconnect}
- Avoid errors and messages related to calibration by following a few simple guidelines:
  - Do **NOT** calibrate if your blood glucose is higher than 300 mg/dL (16.7 mmol/L) or lower than 60 mg/dL (3.3 mmol/L).
  - If you have just exercised, eaten or taken insulin, your glucose levels may be changing rapidly. Allow about an hour for the glucose levels to reach a relatively steady state before calibrating.
  - The system automatically detects conditions that may not be suitable for calibration. It may delay calibration requests in such instances. Wait for the system to prompt you and **LOOK** for the icon on the screen.
- It is normal during typical usage to get multiple messages about failed calibrations ("Cal Failed") or additional calibration requirements ("Cal Required"). The system automatically evaluates conditions for calibration and displays appropriate messages if those conditions are not met or if the calibrations fail. This helps maintain system accuracy. When you get these messages, simply follow the prompts on the screen or guidelines in the *User's Guide*. If you get too many messages, please call Customer Care.
- Do **NOT** change batteries during a sensor wear. Changing the batteries resets the system and will force you to remove the sensor.

If you need assistance, please call Customer Care.

5 Insert or Remove Your Sensor

Purpose

To insert, remove, or replace a small, thin, plastic sensor under your skin so that your FreeStyle Navigator system can continuously monitor your glucose level.

Start

Do this procedure:

- The first time you use your FreeStyle Navigator system.
- Every 5 days after that.
- Replace your sensor sooner than 5 days when:
  - There is any redness, pain, tenderness, or swelling at the insertion site.
  - An error code displays on your receiver indicating a sensor problem.
- When replacing batteries.

Materials

Gather these materials before you begin:

- Soap and water.
- Alcohol prep pads.
- A sensor delivery unit in its **UNOPENED** package.
- Your transmitter.
- Your receiver.

Helpful Information

Important: *Keep the following in mind when inserting your sensor.*

- *You will not have continuous monitoring data until you have successfully completed the first calibration (at least for the first ten hours after sensor insertion).*
- *You may not be able to calibrate the system if your glucose levels are changing rapidly. For example, during a meal or exercise, your glucose levels may vary rapidly. Try to time your insertion so that your calibration times do not coincide with your regular meal or exercise activities.*

Note: You should ***keep your sensor inserted for 5 days***. See the exceptions listed above under **Start**.

- The system will ask you to perform 4 calibrations at approximately -10, 12, 24 and 72 hours after inserting a new sensor (See Section 7).
- You **MUST** change your sensor every 5 days, to reduce the chance of infection. The system automatically terminates a sensor session after 5 days. Do **NOT** leave the sensor inserted for more than 5 days.
- Taking action at the first sign of irritation or discomfort will keep small issues from turning into larger or ongoing ones.
- You may not be able to perform the calibration after you eat until your glucose levels stabilize.
- See Appendix A: Site Maintenance for additional helpful suggestions.
- Before inserting a new sensor make sure that there are no low battery messages displayed on the receiver. This will help avoid data loss after the insertion if the batteries are running low.

Interferents: *In vitro* and *in vivo* testing suggest that usual pharmacologic levels of ascorbic acid have no effect on the function of the system but salicylic acid has minimal effect. *In vitro* testing suggests that normal physiologic levels of uric acid, lipids, and bilirubin do not affect system function. The impact of oral hypoglycemic agents and other potential interfering substances has not been studied.

OVER

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Important Things to Know About Getting Reliable Results

Caution: *Movement of the sensor support mount or excessive perspiration at the sensor insertion site due to activities like vigorous exercise or bumping against objects may lead to poor adhesion of the support mount to the skin and then cause the sensor to dislodge. If the sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable results or no results. The system may not provide a warning in such circumstances. Choose the proper sensor insertion site when inserting the sensor and prepare the site by following the instructions for site preparation.*

Caution: *If your results from the Continuous Monitoring mode seem erroneous, check and make sure that the sensor has not dislodged. If you notice the sensor is dislodged from the skin, or if you see that the adhesive on your overbandage or the sensor support mount is coming loose, discard the old sensor and insert a new sensor.*

Steps	Do This

1. **Decide what to do.**

If you want to	*Then*
• Change or remove your sensor.	Go to Step 2.
• Insert your sensor.	Go to Step 4.

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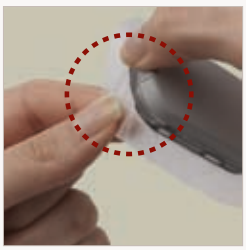
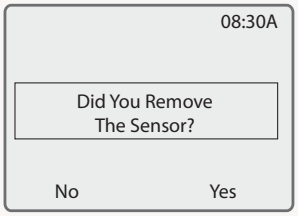
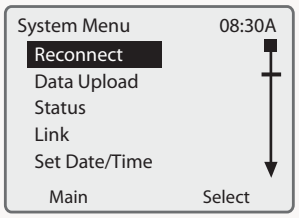
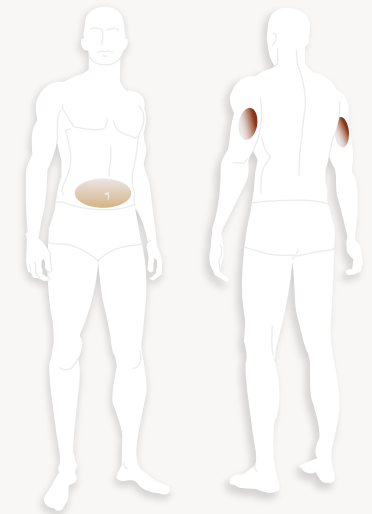
Steps	Do This
2. Remove the sensor. **Fig. 1**  **Fig. 2**	**a.** Wipe a small amount of isopropyl alcohol around the edges of the sensor support mount. **Note:** You can use a regular alcohol prep pad from your local drugstore. **b.** Grasp the top end of the adhesive (the end nearest the sensor, see Fig.1) and slowly peel it off your skin in one continuous motion. **c.** Pull down on the adhesive at the bottom of the support mount (the end farthest from the sensor, see Fig.2). You will hear a click as the transmitter separates from the support mount. **d.** Discard the sensor support mount (with the sensor attached). ***Important:*** • *Do **NOT** discard the transmitter.* • ***NEVER** reuse the sensor support mount and sensor.* **e.** Gently wash the transmitter with soap and water. **f.** Dry the transmitter thoroughly with a clean, soft, lint-free cloth. Be sure that you blot the sensor connector on the end of the transmitter. **g.** If necessary, use an alcohol wipe prep pad, baby oil, or a wet, soapy washcloth to remove any adhesive left on your arm. **h.** Dry your arm with a clean dry towel before continuing. ***Important:*** *Do **NOT** use adhesive remover wipes containing ether or ether-containing components to remove adhesive residue from the transmitter. Adhesive remover solutions such as Uni-Solve® and others that contain ether components can damage the transmitter case. We recommend using regular alcohol pads for cleaning adhesive residues.* **i.** Proceed to next step to end sensor session.

OVER

Steps	Do This
3. **End sensor session.** 	**a.** Press the RIGHT Option button twice to get to the Main menu. **b.** Press the UP/DOWN Arrow button to highlight System. **c.** Press the RIGHT Option button to select System. **d.** Press the UP/DOWN Arrow button to highlight Status. **e.** Press the RIGHT Option button to select Status. **f.** Press the RIGHT Option button to select Removed Sensor. **g.** Press the RIGHT Option button to select Yes. The system now knows you have removed the sensor. If you are going to replace your sensor now, continue to Step 4.
4. **Reconnect the receiver to the transmitter.** 	**a.** Place the receiver within 10 feet of the transmitter. **b.** Press the RIGHT Option button twice to display the Main Menu screen. **c.** Use the UP/DOWN Arrow button to highlight System. **d.** Press the RIGHT Option button (Select) to display the System menu with Reconnect highlighted. **e.** Press the RIGHT Option button (Select). **f.** Wait for the receiver to beep. If it beeps: • Twice – The system is connected. • Three times – The system is not connected. Make sure the battery in the transmitter is new and ensure that the receiver and transmitter are linked (see Section 14). **Note:** If the transmitter and receiver are connected properly, the disconnect icon will not appear on the screen.
5. **Select an insertion site.** 	***Caution:*** *If the sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable or no results. Improper site selection and improper site preparation may cause poor adherence to the skin.* **Notes:** • Select a site **ONLY** on the back of the upper right arm, on the back of the upper left arm, or on your abdomen. • Do **NOT** insert the sensor where another sensor was just removed (See "Site Selection" in Appendix A). • Rotate where you insert your sensor across several sites. • Avoid areas where the edges of clothing may catch or rub against the sensor. • Avoid areas with scars, moles, stretch marks, or lumps. • Select an area of skin that stays flat during your normal daily activities (no bending or creasing). • Avoid areas with excess hair, or consider shaving the area. • Choose a site that is at least 1 inch away from an insulin infusion site.

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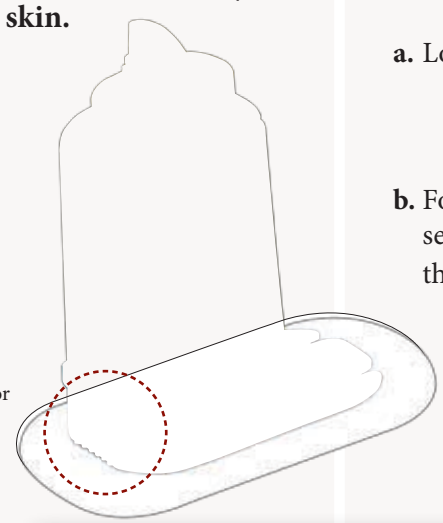
Steps	Do This
6. Prepare the insertion site.	**a.** Wash your hands thoroughly with soap and water. **b.** Clean the selected insertion site area with soap and water. **c.** Rinse the area thoroughly and pat dry. **d.** Wipe the area with an alcohol prep pad. **Note 1:** The insertion area **MUST** be clean and dry. Otherwise: • An infection could occur. • The sensor support mount may not stick to the site. **Note 2:** Do **NOT** place a bandage on the insertion site before inserting the sensor. The sensor may not penetrate the skin and the system will not work with a bandage under the sensor.
7. Remove the sensor delivery unit from package.	***Caution:*** *Do **NOT** use the sensor delivery unit if the sterile package is open or damaged.* **a.** Remove the sensor delivery unit from its sterile package by peeling off the foil on the back of the package. **b.** Save the package. **Note:** You will need the sensor code number on the back of the package, later. ***Important:*** *We recommend that you save the sensor kit carton or the sensor sterile package until the last sensor from your sensor kit has been used and discarded. Saving the package will help you to have sensor lot information, expiration dates and sensor code etc. accessible when you need them.*
8. Remove the protective liner from the sensor support mount. 	**a.** Bend the two-piece protective liner slightly so you can see the seam between the two pieces. **b.** Peel away the smaller section. **c.** Peel away the larger section.

OVER

Steps	Do This
9. **Attach the sensor delivery unit to your skin.**	



a. Locate the top of the sensor support mount.

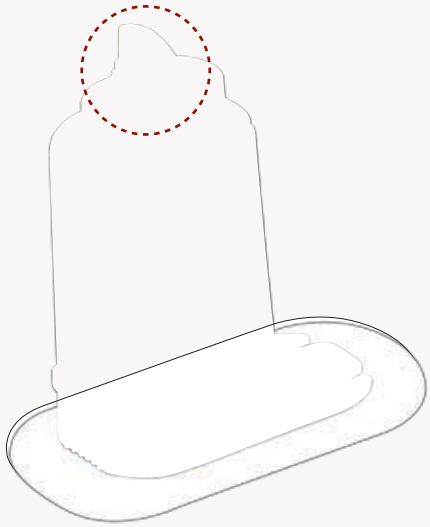
b. Follow the instructions below as you place the sensor support mount, adhesive-side down, on the insertion site:

If you are	*Then*
• Inserting the sensor on the back of your arm.	Place the sensor support mount lengthwise on your arm with the top of the sensor support mount facing your shoulder.
• Inserting the sensor on your abdomen.	Place the sensor support mount horizontally on your abdomen.

10. **Ensure that the adhesive pad is adhered to your skin.**

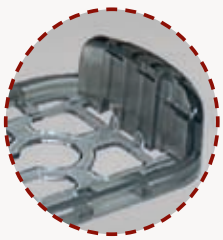
a. Hold the sensor delivery unit firmly in place.
b. Smooth the adhesive pad against your skin.

Abbott Ex. 1027 - 255/400

Steps	Do This
11. **Remove the locking pin.** 	**a.** Grasp the top of the locking pin with your thumb and index finger. **b.** Twist the locking pin a 1/4 turn in either direction until the locking pin clicks. **c.** Pull the locking pin away to remove it. **Note:** The sensor support mount adhesive will help keep the sensor support mount in place.
12. **Insert sensor.** 	***Caution:*** *Do* ***NOT*** *press the button until you are ready to insert the sensor. Doing so may cause unintended results or injury.* **a.** Hold the sensor inserter as shown and press down on both sides of the button at the same time. ***Important:*** *Do* ***NOT*** *press on the blue release tabs while pressing the button on the top of the inserter.* **Note:** You will feel a slight pinch as the sensor is placed just under your skin.
13. **Remove inserter** Blue Release Tab	**a.** Hold the sensor inserter and firmly squeeze the two blue release tabs at the inserter's base, as you lift the inserter away from the sensor support mount. **Note:** Do **NOT** lift the inserter without squeezing the blue release tabs as this may dislodge the sensor support mount.

OVER

Steps	Do This
14. **Check the sensor support mount.**	**a.** Confirm the sensor support mount remains tightly adhered to your skin by sliding your finger along the edges of the adhesive pad and examine for any gaps in adhesion. **b.** Examine the area for a drop of blood. You may see some blood from the insertion site. If there is continuous bleeding that does not stop in a few minutes even after blotting with a clean cloth or swab, repeat the procedure from Step 2 to remove the sensor support mount, select a new site and insert a **NEW** sensor. **c.** Use a mirror to check that sensor is correctly placed.

If	*Then*
	Sensor is ***correctly*** placed. You will see the tip of the sensor is inserted under the skin and the sensor is flush against the top edge of the sensor support mount.
	Sensor is missing. **1.** Remove sensor support mount. **2.** Go to Step 1 to insert a **new** sensor.

Abbott Ex. 1027 - 257/400

Steps	Do This
15. **Discard the sensor inserter safely.**	We recommend a sharps container or a puncture-proof container with a tight lid.
16. **Check your work.**	***Result:*** *An inserted sensor, a removed sensor, or a replaced sensor.* You have done this procedure correctly when: ❑ The system successfully recognized that you removed a sensor (if you removed a sensor). ❑ The site was selected and prepared according to the guidelines given in this procedure. ❑ The receiver and transmitter were reconnected successfully. ❑ The sensor support mount is tightly adhered to either your abdomen or the back of your upper arm. ❑ The sensor is inserted in a site that is different from the site that was used for the last sensor. ❑ The sensor is visible with the tip inserted into your skin. ❑ The sensor inserter is disposed safely. **END OF Section 5**

6 Attach Your Transmitter

Section 6

Section 6 – Key Terms

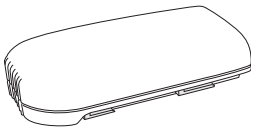
- LEFT/RIGHT Option Buttons
- Receiver
- Sensor Code
- Sensor Support Mount
- System
- Transmitter
- UP/DOWN Arrow Buttons

6 Attach Your Transmitter

Purpose To enable the transmitter to send glucose data to the receiver.

Start Do this procedure after inserting a new sensor.

Materials Your FreeStyle Navigator Transmitter with battery installed.



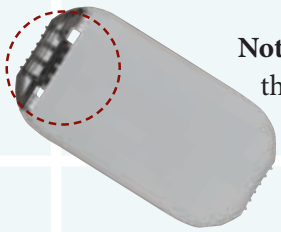
Helpful Information

Important: *Do* ***NOT*** *remove or replace the transmitter from the sensor support mount while wearing a sensor. If you notice that the transmitter is not properly attached, replace the sensor with a new sensor and then re-attach the transmitter.*

- Make sure that you establish communication between the receiver and transmitter by reconnecting them if necessary.
- After you attach your transmitter, you must keep your receiver within 10 feet of the transmitter to maintain a consistent connection. If the connection between the transmitter and receiver is broken you will not receive continuous glucose readings.
- The connection can also be affected by objects getting between the transmitter and receiver, by nearby large metal objects, and by some electronic devices that produce radio frequencies.
- If a connection alarm sounds, move the transmitter closer to the receiver to restore the connection. If you have trouble with the connection between the transmitter and receiver, see Section 10 on troubleshooting.

OVER

Abbott Ex. 1027 - 262/400

Steps	Do This
1. Attach the transmitter to the sensor support mount.	
Fig. 1	**a.** Position the transmitter over the sensor support mount so that the battery side faces the mount. **b.** Lower the transmitter onto the mount. **Note:** It helps to position the transmitter's connector directly over the ***round part of the "keyhole"*** (Fig. 1) as you lower the transmitter. ***Result:*** *The transmitter fits flush against the mount and slides smoothly back and forth on the guide rails.* **c.** Hold the transmitter between your forefinger and thumb and slide the transmitter until it clicks into place. Apply firm pressure as you slide the transmitter into place. (Fig. 2)
Fig. 2	 **Note:** It is normal to see a gap between the transmitter and the support mount towards the top.
2. Confirm the transmitter is correctly attached to the sensor support mount.	
	a. Look at the side of the transmitter where the bottom sits on the guide rails. **b.** Is there a space between the bottom edge of the transmitter and the top edge of the guide rails?

If	*Then*
• No	The transmitter is correctly attached. Go to Step 3.
• Yes	**1.** Go to Section 5 to replace your sensor. **2.** Repeat this procedure to attach your transmitter.

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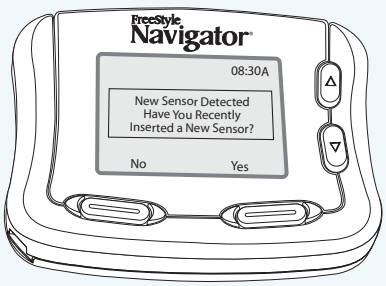
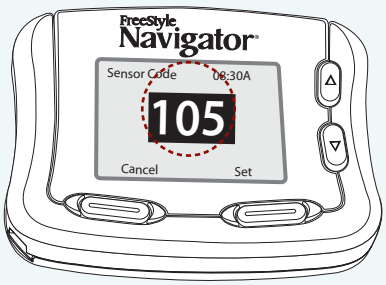
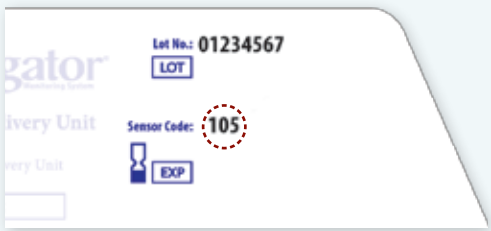
Steps	Do This
3. Apply an over-bandage (Optional).	Apply an over-bandage to hold down the transmitter and sensor support mount. Use an over-bandage if you find that the sensor support mount is not adhering well during daily activities. ***Caution:*** *If your results from the Continuous Monitoring mode seem erroneous, check and make sure that the sensor has not dislodged. If you notice the sensor is dislodged from the skin, or if you see that the adhesive on your overbandage or the sensor support mount is coming loose, discard the old sensor and insert a new sensor.* ***Go to the next step.***
4. Enter the sensor code into your receiver.  **Fig. 1**  **Fig. 2** ***Caution:*** *The code numbers* ***MUST*** *match to ensure accurate test results.*	**a.** When you hear the receiver beep, press the RIGHT Option button **once** to turn the receiver on. ***Result:*** *The receiver screen says, "New Sensor Detected Have You Recently Inserted a New Sensor?"* (Fig. 1) **Note:** Typically, it may take up to 3 minutes after attaching the transmitter before the receiver beeps. See Section 10 to troubleshoot if you do not get the sensor detection message. **b.** Press the RIGHT Option button (Yes). **Note:** If you ever see this message at any other time, press the LEFT Option button (No). **c.** Press the UP or DOWN Arrow button to change the number on the receiver screen to the number on the packaging. (Fig. 2).  ***Important:*** *Once the code has been entered and you have hit the Set button as instructed below, you will not be able to change the sensor code number. If you have entered the code incorrectly, you will have to replace the sensor and enter the right sensor code. If you choose the wrong sensor code, you may get erroneous results from the sensor.* **d.** Press the RIGHT Option button (Set) to accept the number on the screen.

OVER

Steps	Do This
5. Check your work.	***Result:*** *A transmitter ready to send glucose data.* You have done this procedure correctly when: ❑ The transmitter is securely attached to the sensor support mount. ❑ You have applied an over-bandage as necessary to hold down the transmitter and the sensor support mount. ❑ The sensor code has been correctly entered into the receiver. ❑ You see an icon on the top right hand corner of the screen.

END OF Section 6

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7 Calibrate Your System/Test Blood Glucose Manually

Section 7

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Section 7 – Key Terms

- BG Mode
- Calibrate
- Calibration BG
- Control Solution
- FreeStyle Test Strips
- Icon
- Lancet
- Lancing Device
- Lancing Device Cocking Handle
- Lancing Device Depth Indicator Window
- Lancing Device Depth Setting
- Lancing Device Lancet Cup Holder
- LEFT/RIGHT Option Buttons
- Receiver Test Strip Port
- Sharps Container
- UP/DOWN Arrow Buttons

7 Calibrate Your System/Test Blood Glucose Manually

Purpose

To ensure the receiver will calculate your glucose readings accurately.

Start

Do this procedure:

- **Each time** the receiver prompts you with the message, "Do BG Test." You will see a blood drop icon on the screen and you will also hear the system beep (or vibrate).
- When you need to measure your blood glucose manually using the built-in FreeStyle Meter.

Materials

- Soap, water, and a clean towel.
- A FreeStyle Lancing Device.
- Sterile lancets.
- FreeStyle Test Strips.
- Your FreeStyle Navigator Receiver.
- A sharps container.

Helpful Information

Important Things to Remember About System Calibration

- The system is calibrated using a capillary whole blood glucose measurement (performed in the Blood Glucose mode using the built-in FreeStyle Blood Glucose Meter). In order to calibrate, the receiver compares the reading it gets from the blood to the reading the sensor takes from the interstitial fluid. Based on the calibration, the receiver calculates the glucose readings.
- Do not use venous blood for calibrating the system.

> ***Caution:*** *Always calibrate the system only using a finger-stick blood sample. Do* ***NOT*** *use alternate site blood glucose measurements to calibrate the system. The receiver contains a built-in FreeStyle® Blood Glucose Meter for performing calibration tests.*

Important: *Your blood glucose level must be between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) to be able to perform calibration tests. If your blood glucose level is changing rapidly, you may not be able to calibrate the system. For example, during a meal or exercise, your glucose levels may vary rapidly. Try to time your sensor insertion so that your calibration times do not coincide with your regular meal or exercise activities.*

Important: *In clinical trials, we observed that the sensor signal sometimes temporarily decreases from the true value. This typically happens at night during sleep, and recovers rapidly when the user moves or is awakened. However, in order to avoid being affected by this phenomenon the system should not be calibrated when the wearer is asleep.*

- You may not be able to calibrate the system if your glucose levels are changing rapidly (e.g. during or after exercise, meals or insulin dosing). Under such conditions, the system may not ask you to calibrate; instead, it will delay its request until conditions are acceptable.

OVER

Helpful Information *(con't)*

- You **MUST** successfully complete 4 calibration tests. You will calibrate at approximately 10, 12, 24 and 72 hours after sensor insertion. If you do not complete calibration tests successfully in the allotted time periods, your glucose readings will NOT be displayed and alarms will be inactive. The system may ask you to perform additional calibrations between 2nd and 3rd calibrations depending on the sensor signal. In such cases, you will be prompted with a message to do additional BG tests.
- The receiver will beep (or vibrate) to prompt you to do a calibration. The receiver will display a blood drop icon and the message "Do BG Test." The system will prompt you with alarm messages when your calibrations are unsuccessful.
- You will not have continuous monitoring until you have successfully completed the first calibration (at least for the first ten hours after sensor insertion).
- If you get a request for a calibration or expect additional calibration requests during a time when you do not want to be disturbed (e.g. sleep time), you can choose to wait to perform additional BG tests at a later point in time. If you choose to wait and the allotted time window for calibration has expired, please note that you will not get glucose results until you have performed a successful calibration. You can turn off the System Alarms (or set to vibrate) if you do not want to be disturbed by frequent requests for calibration. In order to silence the alarms that warn you when the allotted time window for a calibration has expired, you must turn off the data loss alarms and all the four glucose alarms (Low Glucose, High Glucose, Projected Low Glucose and Projected High Glucose).

When to calibrate the system?

You will calibrate the system at approximately 10, 12, 24 and 72 hours after sensor insertion.

For example:

Insertion at night

If you insert the sensor at 9:00 pm on Day 1,
the first calibration would be at 7:00 am on Day 2,
the second calibration would be at 9:00 am on Day 2,
the third calibration would be at 9:00 pm on Day 2,
the fourth calibration would be at 9:00 pm on Day 4.
Sensor removal would be at 9:00 pm on Day 6.

What happens in the example if the first calibration does not occur until 9 am on Day 2?

The 2 hour delay will add on to the second, third and fourth calibration. Second calibration will now happen at 11 am on day 2 and so on. However, sensor removal will still happen at 9 pm on Day 6.

Although a typical calibration sequence will occur as shown, each calibration has to be performed in a specific window of time.

- 1st calibration: Must be performed at approximately 10 hours after a new sensor has been inserted. The first calibration can be performed after the 10 hours. Continuous glucose readings will NOT be reported until the 1st calibration is performed successfully.
- 2nd calibration: Must be performed between 2 and 4 hours after the 1st calibration or continuous glucose will not be reported. The 2nd calibration can be performed after 4 hours; continuous glucose reporting will resume after completing the 2nd calibration successfully.
- 3rd calibration: Must be performed between 12 and 20 hours after the 2nd calibration or continuous glucose will not be reported. The 3rd calibration can be performed after 20 hours; continuous glucose reporting will resume after completing the 3rd calibration successfully.
- 4th calibration: Must be performed between 48 and 56 hours after the third calibration or continuous glucose will not be reported. The fourth calibration can be performed after 56 hours; continuous glucose reporting will resume after completing the 4th calibration successfully.

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Helpful Information *(con't)*

Some common reasons for unsuccessful calibrations

- Your BG test result is below 60 mg/dL (3.3 mmol/L) or above 300 mg/dL (16.7 mmol/L). Perform the calibration test when your blood glucose is within the above range.
- Your blood glucose is changing too rapidly. This can happen during a meal or exercise activities or if you have taken insulin. Give yourself an hour before you try to perform a calibration test again. Do not perform a Blood Glucose mode test for calibration if you do not see the blood drop icon on the screen.
- The skin temperature may be out of range (the skin temperature has to be between 77° F (25° C) and 104° F (40° C).
- The sensor signal may be out of range or has changed relative to the last successful calibration.
- Improper Blood Glucose mode testing. Carefully follow the instructions in this Section to perform a BG test (keep your hands clean, enter the right strip code and choose finger for calibration tests) to avoid errors from the Blood Glucose mode test.

  The system will prompt you with alarm messages when your calibrations are unsuccessful. See Section 10 for more information or call Customer Care. You will have to perform additional Blood Glucose mode tests (BG tests) if your calibrations are unsuccessful.

OVER

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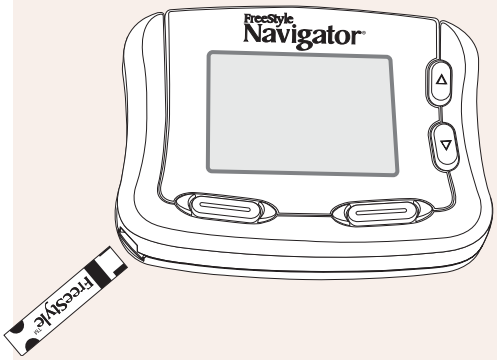
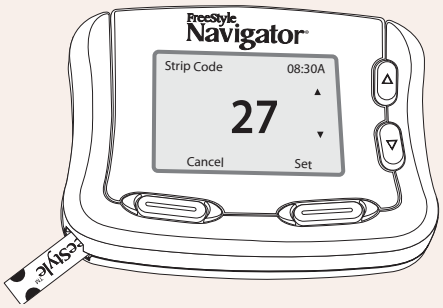
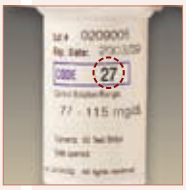
Steps	Do This
1. **Insert a FreeStyle Test Strip into the receiver's test strip port.** 	**a.** Insert the end with the dark rectangle. **b.** Gently push until the test strip stops. ***Result:*** *The receiver will display the most recently used test strip code number.*
2. **Ensure that the code number on the screen matches the code number on the test strip vial.**  	***Caution:*** *The code numbers **MUST** match to ensure accurate test results.* Compare the code number on the display with the code number on the vial of test strips.

If	*Then*
• The numbers match.	**a.** Press the RIGHT Option button (Set). **b.** Go to Step 3.
• The numbers do **NOT** match.	**a.** Use the UP/DOWN Arrow buttons to change the code to match. **b.** Press the RIGHT Option button (Set). **c.** Go to Step 3.
• The screen changes to the Apply Sample screen.	*If the numbers do **NOT** match:* **a.** Press the LEFT Option button (Back). **b.** Repeat Step 2. *If the numbers match, go to Step 3.*

Result: *The receiver will prompt you to "Apply Sample."*

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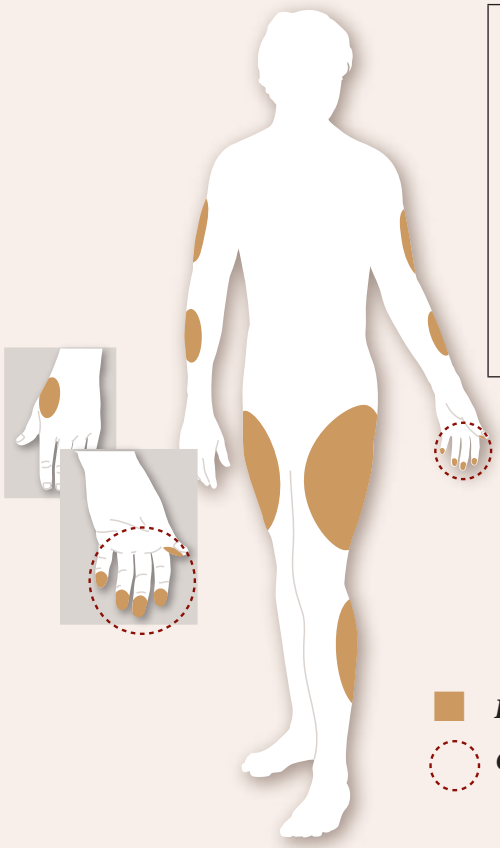
Steps	Do This
3. Select a test site.	

Caution: *If you have hypoglycemia, or hypoglycemia unawareness, then test* **ONLY** *on your fingers.*

Note 1: Vary the sites from test to test to avoid tenderness and to avoid creating calluses.

Note 2: Avoid moles, veins, bones, and tendons.



Caution: *Always calibrate the system using only a finger-stick blood sample. Do* ***NOT*** *use alternate site blood glucose measurements to calibrate the system. The receiver contains a built-in FreeStyle® Blood Glucose Meter for performing calibration tests.*

If	*Then*
• You are calibrating the system.	Select **ONLY** a finger for testing (see red circles).
• You are simply doing a manual glucose test and **NOT** calibrating.	Select from among the sites shown including the circled areas.

OVER

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Steps	Do This
4. Prepare for lancing.	
	a. Wash your hands and the selected test site with soap and water. Make sure there is no lotion on the test site. **b.** Thoroughly dry your hands and the test site. **c.** Snap the cap off the lancing device. ***Important:*** *Use a new sterile lancet for every test.* ***NEVER*** *use a lancet for more than one person.*
	d. Insert a new FreeStyle Lancet firmly into the white lancet cup holder. ***Important:*** *Do not touch the exposed needle on the lancet.*
	e. Hold the lancet firmly in place with one hand and use your other hand to twist off the rounded top.
	f. Replace the cap until it snaps or clicks into place.

If your test site is	*Then*
• A finger.	Use the grey cap.
• Your forearm or a test site other than the finger.	Use the clear cap.

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Steps	Do This
4. Prepare for lancing. *(con't)*	**g.** Select the lancing device depth setting.

If you are lancing	*Then*
• A finger.	Set the depth setting to its shallowest depth (1).
• Your forearm.	Start at Level (2) or higher if your experience with setting 2 does not produce a usable sample.

- The FreeStyle® Lancing Device offers four different depth settings. Move the dial to the desired setting as shown in the depth indicator window. Level 1 is the shallowest depth; Level 4 is the deepest. To lance parts of the body other than the finger, we recommend that you start at Level (2) and use the clear cap.

  To lance your finger, we recommend that you set the depth setting to its shallowest depth (1) and use the grey cap.

h. Pull the dark grey cocking handle out until it clicks.

Note: You may have already cocked the device in Step 4d.

i. Prepare the site:

If you are using	*Then to stimulate blood flow*
• A finger.	Warm your hand, lower it to waist level, and gently massage the finger.
• Your forearm.	Rub the test site vigorously until you feel it getting warm (three to five seconds).

OVER

Steps	Do This
5. Lance the site.	**To lance your finger (grey cap):** **a.** Lightly touch the lancing device against the side of your fingertip. **b.** Press the release button. **c.** Put the lancing device down. **d.** Gently squeeze your finger, if needed, until a drop of blood the size of a pinhead forms. **To lance your forearm (clear cap):** **a.** Hold the lancing device against the test site. **b.** Press the release button. **c.** Continue to hold the lancing device against the test site as you: **i)** Inspect the test site through the clear cap. **ii)** Gradually increase pressure until the sample is the size of this dot: • ***Important:*** *Do* ***NOT*** *smear the sample as you do the next step.* **d.** Lift the lancing device ***straight up***.

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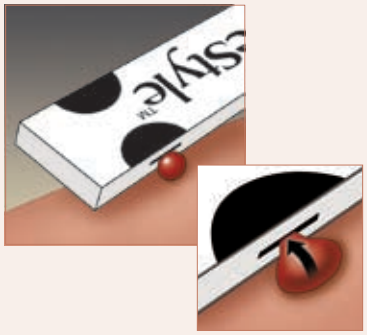
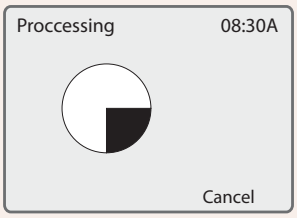
Steps

6. **Test the sample.**





Do This

Do Not:

- Use test strips more than once. Discard used test strips.
- Scrape the blood.
- Apply blood to the flat side of the test strip.
- Apply blood to the test strip when the test strip is out of the receiver.
- Apply blood to both edges of the test strip.
- Put blood or foreign objects into the receiver's test strip port.

a. Holding the receiver at a slight angle to the sample, gently touch the half-circle on the test strip to the sample.

Important: Your blood glucose level must be between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) to be able to perform calibration tests. If your blood glucose level is changing rapidly, you may not be able to calibrate the system.

b. Observe the receiver:

If	*Then*
• The stopwatch icon does **NOT** appear within 5 seconds.	Continue adding blood sample to the **SAME** half-circle for up to 60 seconds.
• The receiver **BEEPS ONCE** (only if Progress Tones are turned on).	Enough blood has been used.
• The stopwatch icon appears.	The receiver is measuring your blood glucose level.
• The receiver **BEEPS TWICE** (only if Progress Tones are turned on).	The test is done. Go to Step 7.
• Your blood glucose results appear in the display (takes an average of 7 seconds).	
• The receiver beeps three times.	The test has failed. Repeat the test. Refer to Section 10 for error messages and troubleshooting.
• You get an error message.	

OVER

Steps	Do This

7. **Interpret the blood glucose results.**

Caution: *Low or high glucose measurements can indicate a potentially serious medical condition.*

If	*And*	*Then*
• Lo appears in the display. Lo appears when the measured glucose result is less than 20 mg/dL (1.1 mmol/L).	You do **NOT** have low blood glucose symptoms.	Repeat the test from Step 3 using: • Your finger. • A new test strip.
	You have any of these symptoms: • Weakness • Headache • Sweating • Confusion • Nervousness	Follow your healthcare team's recommendations for treating hypoglycemia.
	This is your second test.	
• Hi appears in the display. Hi appears when the measured glucose result is more than 500 mg/dL (27.8 mmol/L).	You do **NOT** have high blood glucose symptoms.	Repeat the test from Step 3 with a new test strip.
	You have any of these symptoms: • Fatigue • Excess urination • Thirst • Blurry vision	Follow your healthcare team's recommendations for treating hyperglycemia.
	This is your second test.	
• The receiver displays results from 20 to 500 mg/dL (1.1 mmol/L to 27.8 mmol/L).		Continue to Step 8.

8. **Confirm you did NOT use Control Solution.**

Press the RIGHT Option button to indicate that you did **NOT** use a Control Solution.

Press the RIGHT Option button to select 'No' and press the RIGHT Option button again to view the continuous glucose results. See Section 10 to respond to alarm messages if there are any.

Note: *If you do not select 'No' for the "Control Solution?" question in this step within two minutes, the system automatically considers it a blood test.*

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Steps	Do This
9. **Remove and discard the test strip.**	***Important:*** *Test strips may be used only once. Discard used test strips.*
10. **Discard the lancet.**	**Note:** Use a sealed container such as a sharps container to avoid biohazards. **a.** Snap off the cap from the lancing device. **b.** Hold the lancet over a sharps container or other puncture-proof container with a lid. **c.** Pinch the white clip that holds the lancet until the lancet falls into the container.
11. **Check your work.**	***Result:*** *A properly calibrated receiver. You have done this procedure correctly when:* ❑ Your hands and the test site have been cleaned with soap and water and thoroughly dried with a clean towel. ❑ The code number in the receiver matches the code number for the test strips. ❑ The test site for calibration was a finger. ❑ The test site for manual blood glucose testing was selected from any of the other test sites shown in Step 3 of this Section. ❑ You used your finger, if you have hypoglycemia unawareness. ❑ You used the grey cap on the lancing device for a finger site. Or, you used the clear cap on the lancing device for a forearm site. ❑ The lancing produced an adequate amount of blood without smearing. ❑ You followed all of the notes in Step 6 when testing the blood. ❑ You interpreted the test results according to Step 7. ❑ You selected **NO** in response to the receiver's inquiry, "Control Solution?" ❑ You disposed the lancet in a sharps container or in a puncture-proof sealed container. **END OF Section 7**

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8 Set, Review, or Change the Alarm Settings

Section 8

Section 8 – Key Terms

- Alarm Menu
- Alarm Sensitivity
- Alarm Type
- Data Loss
- High Glucose Alarm
- High Glucose Threshold
- LEFT/RIGHT Option Buttons
- Low Glucose Alarm
- Low Glucose Threshold
- Main Menu
- Progress Tones
- Projected High Alarm
- Projected Low Alarm
- Receiver
- System
- System Alarms
- UP/DOWN Arrow Buttons

8 Set, Review, or Change the Alarm Settings

Purpose

To set the receiver to:

- Alert you when your glucose conditions change.
- Notify you when the receiver needs attention.
- Notify you when the receiver begins or completes certain activities.

Start

Do this task:

- Immediately after you finish the first set up of your FreeStyle Navigator system.
- When your healthcare team gives you new glucose threshold numbers.
- Anytime you get a "Preferences Lost Reconfigure" alarm message on the receiver.
- Anytime you replace your receiver.
- Anytime you want to change your alarm settings.
- Anytime you want to review your alarm settings.

Materials

- Your FreeStyle Navigator Receiver.
- Low and high glucose threshold values (from your healthcare team).

Helpful Information

Caution: *The high and low alarms are intended to assist you in managing your diabetes and should not be exclusively used to detect hypoglycemia or hyperglycemia. The alarms should always be used in conjunction with other indications of glycemic state such as your glucose level, trend, line graph etc.*

Caution: *High and low glucose alarms are* ***DIFFERENT*** *from your glucose targets. Low and high glucose alarms alert you when you've crossed a certain low or high value. Glucose targets allow the reports and line graphs to show how your glucose levels have been performing compared to your set targets.*

Caution: *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

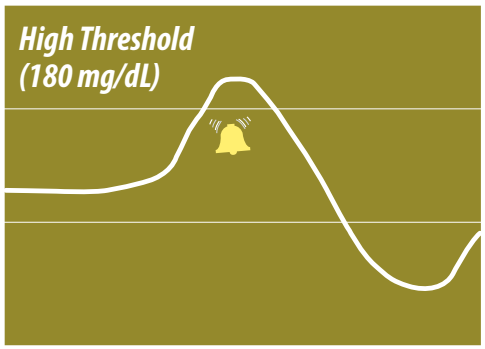
- ***High and low glucose alarms*** let you know when your glucose levels are above or below your low and high glucose ***threshold*** values. You will decide the low and high glucose threshold values based on input from your healthcare team. If there is no glucose data, you will not get glucose alarms.
- A ***projected alarm*** is an alarm that provides an ***early warning*** of an event that is likely to occur if the current trend continues. Projected alarms use the low and high glucose ***threshold*** values regardless of whether or not the low and high glucose alarms are turned on.

  For example, a projected low alarm lets you know when you are approaching your low glucose ***threshold*** *value. You will decide the amount of notice required (whether you should be notified approximately 10 minutes, 20 minutes or 30 minutes in advance of reaching your* ***threshold*** *value) based on the input from your healthcare team.*
- A data loss alarm warns you when glucose results are no longer available. They occur when the sensor has expired, when the transmitter-receiver connection is broken, when a calibration has expired or when the sensor is not working properly. The data loss alarm cannot be turned off without turning off the glucose alarms (Low Glucose, High Glucose, Projected Low Glucose and Projected High Glucose).
- ***System alarms*** notify you of events like low battery or time to calibrate.
- ***Progress tones*** notify you of errors, results, and successful completion of steps in activities like Blood Glucose mode testing.

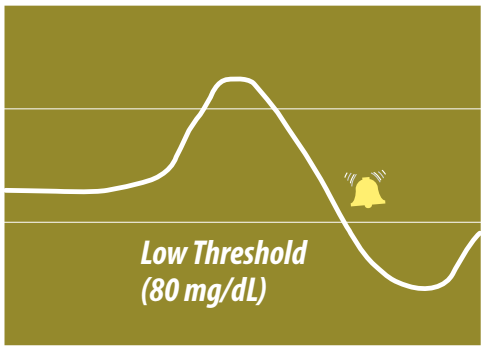
OVER

About Glucose Alarms

The FreeStyle Navigator® system is designed to alert you when your glucose levels reach preset low or high values. These values or 'threshold values' can be programmed in the receiver for any individual. These high and low glucose alarms or the threshold alarms are designed to alert you ***when*** your glucose levels cross these threshold values.

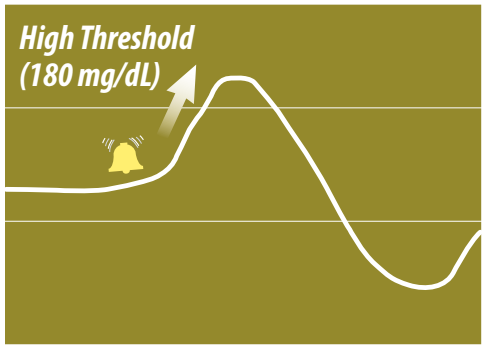


Example of a High Glucose Threshold Alarm - The alarm sounds ***when*** the glucose level crosses the preset threshold value.

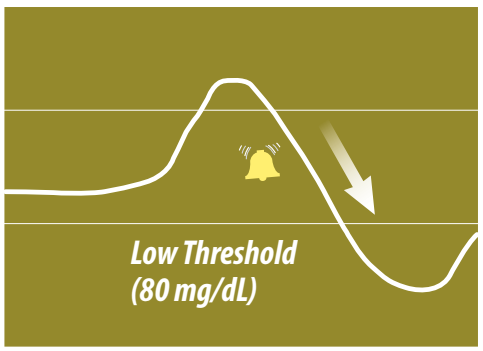


Example of a Low Glucose Threshold Alarm - The alarm sounds ***when*** the glucose level crosses the preset threshold value.

In addition to alerting you of a high or low glucose condition, the system can also alert you ***before*** you reach such a high or low glucose condition. These alarms are called the projected high and projected low glucose alarms. They can be set at low, medium and high sensitivities to alert you approximately 10, 20 or 30 minutes before your glucose levels reach the high or low threshold values, assuming your glucose keeps changing at the same rate. You can turn all glucose alarms ON or OFF. If the alarms are turned OFF, you will not get any alarms.



Example of a Projected High Glucose Alarm - The alarm sounds ***before*** the glucose level reaches the preset threshold value.



Example of a Projected Low Glucose Alarm - The alarm sounds ***before*** the glucose level reaches the preset threshold value.

These alarms are designed to help you take action as soon as you are notified. Projected low and projected high glucose alarms increase the overall ability to detect a condition of low or high glucose. However, they cannot be relied on exclusively for notification of all low and high glucose conditions.

High and low glucose threshold alarms can detect a low or high glucose condition more often than projected high and projected low glucose alarms (see alarm performance under performance characteristics for more information). Therefore, do **NOT** turn off the low and high glucose threshold alarms to rely just on the projected high and projected low glucose alarms.

In order to get maximum notification of low and high glucose conditions, use both the low and high glucose threshold alarms ***AND*** the projected low and projected high glucose alarms.

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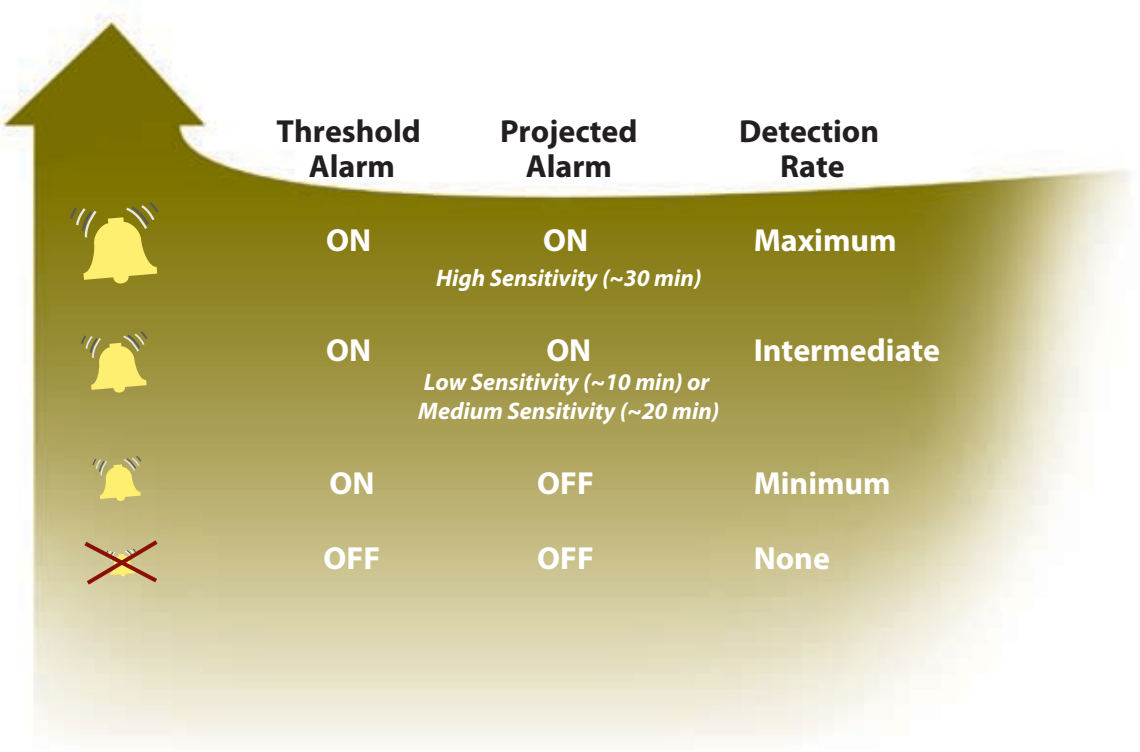
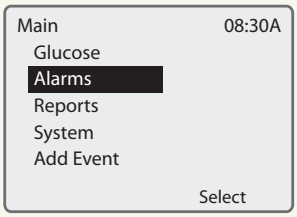
About Glucose Alarms *(con't)*

Follow the guidelines below when selecting your alarm settings for detection of high and low glucose conditions. When the detection rate is maximum, you will get the greatest number of alarms. When the detection rate is minimum, you will get the fewest number of alarms.



Caution: *Do* ***NOT*** *rely solely on the projected glucose alarms for detection of low or high glucose conditions. Always use both the low glucose and high glucose threshold alarms* ***AND*** *the projected low and projected high glucose alarms for maximum notification of low or high glucose conditions.*

OVER

Steps	Do This
1. Access the Alarms menu from the Main menu. 	**Note:** If you don't press any buttons within 12 seconds, the receiver screen will go blank and the last change will be lost if you haven't pressed the Select button. **a.** Press the UP Arrow button or the DOWN Arrow button to highlight Alarms. **b.** Press the RIGHT Option button (Select) to go to the Alarms Setting screen.
2. Decide what to do.	

If you want to	*Then*
• Set, review or change the Low glucose alarm.	Go to Step 3.
• Set, review or change the High glucose alarm.	Go to Step 4.
• Set, review or change the PROJECTED Low glucose alarm.	Go to Step 5.
• Set, review or change the PROJECTED High glucose alarm.	Go to Step 6.
• Set, review or change the Data loss alarms.	Go to Step 7.
• Set, review or change the System alarms.	Go to Step 8.
• Set Progress tones.	Go to Step 9.
• Mute all audible alarms.	Go to Step 10.

Note: In all the subsequent steps choosing the Next button will allow you to go from one field to another. For example, you can go from the ON/OFF field to the Glucose threshold field to the alarm setting field. Choosing the UP/DOWN Arrow button will allow you to choose the value you want for the field.

For example, choose ON or OFF for the alarm, choose a number for the threshold like 70 mg/dL or choose medium beep or long beep for the alarm setting.

Review the alarm performance data in Section 18 for a detailed analysis of the effectiveness of the glucose alarms.

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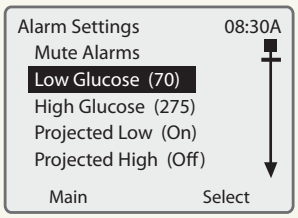
Steps

Do This

3. **Set, review, or change the Low Glucose alarm.**



Decide what settings you want:

- Alarm on or off.
- Your threshold value.

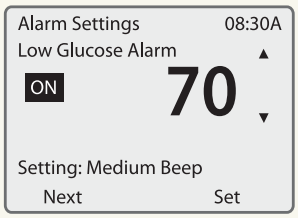
Note: The alarm can only be set between 60 and 139 mg/dL (3.3 mmol/L and 7.7 mmol/L).

- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

Caution: *The Low Glucose alarm cannot be set below 60 mg/dL (3.3 mmol/L). Therefore, it is not intended to notify you of severe hypoglycemia.*

a. Select Low Glucose from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Low Glucose.
- Press the RIGHT Option button to select Low Glucose.



b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

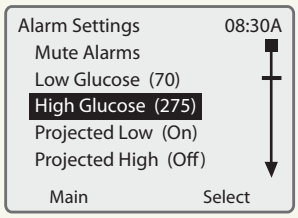
c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

OVER

Steps	Do This

4. Set, review, or change the High Glucose alarm.



Decide what settings you want:

- Alarm on or off.
- Your threshold value.

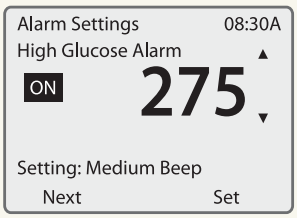
Note: The alarm can only be set between 140 and 300 mg/dL (7.8 mmol/L and 16.7 mmol/L).

- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

Caution: *The High Glucose alarm cannot be set above 300 mg/dL (16.7 mmol/L). Therefore, it is not intended to notify you of severe hyperglycemia.*

a. Select High Glucose from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight High Glucose.
- Press the RIGHT Option button to select High Glucose.



b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

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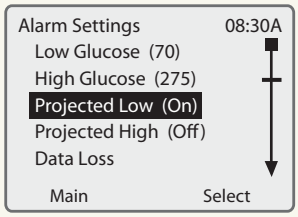
Steps	Do This

5. Set, review, or change your Projected Low glucose alarm.

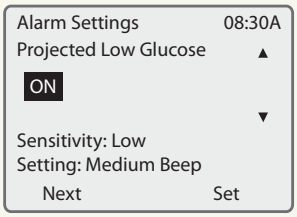


Decide what settings you want:

- Alarm on or off.
- Sensitivity.
- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

a. Select Projected Low from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Projected Low.
- Press the RIGHT Option button to select Projected Low.



If you want this much notice before reaching your Low glucose level:	Then set the **Sensitivity** to:
• Maximum detection (most alarms, approximately 30 minutes in advance of events)	**High**
• Intermediate detection (intermediate alarms, approximately 20 minutes in advance of events)	**Medium**
• Low detection (fewest alarms, approximately 10 minutes in advance of events)	**Low**

b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

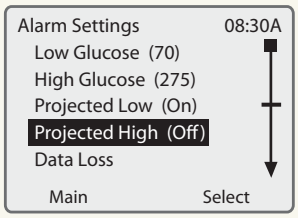
c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

OVER

Steps	Do This

6. Set, review, or change your Projected High glucose alarm.

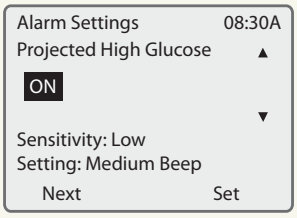


Decide what settings you want:

- Alarm on or off.
- Sensitivity.
- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

a. Select Projected High from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Projected High.
- Press the RIGHT Option button to select Projected High.



If you want this much notice before reaching your High glucose level:	Then set the **Sensitivity** to:
• Maximum detection (most alarms, approximately 30 minutes in advance of events)	**High**
• Intermediate detection (intermediate alarms, approximately 20 minutes in advance of events)	**Medium**
• Low detection (fewest alarms, approximately 10 minutes in advance of events)	**Low**

b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

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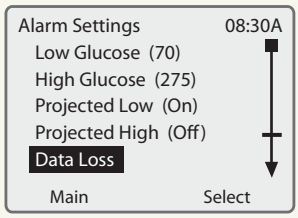
Steps

Do This

7. Set, review, or change the Data Loss alarms.



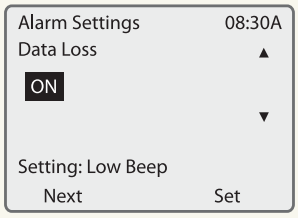
Decide what settings you want:

- Alarm on or off.
- Alarm type (Setting).
  - – Low, medium, or high beep.
  - – Short, medium, or long vibration.

Important: *If you turn off your Data Loss alarms, you must also turn off your Low Glucose, High Glucose, Projected Low and Projected High alarms.*

a. Select Data Loss from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Data Loss.
- Press the RIGHT Option button to select Data Loss.



b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

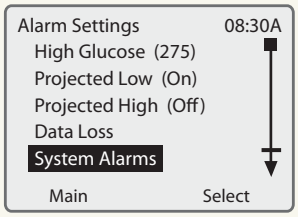
c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

OVER

Steps	Do This

8. Set System Alarms.

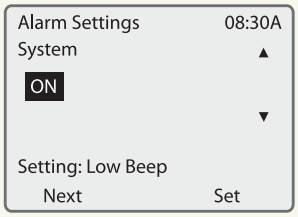


Decide what settings you want:

- Alarm on or off.
- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

Important: *If you turn off the System Alarms, the receiver will* ***NOT*** *prompt you to do the calibration tests after you insert a new sensor.*

a. Select System Alarms from the Alarms menu.



b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

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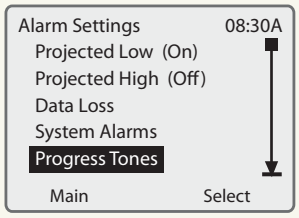
Steps

Do This

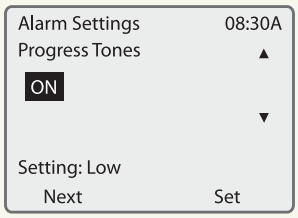
9. Set Progress Tones.



Decide what settings you want:

- Turn progress tones on or off.
- Set progress tones volume low or high.

a. Select Progress Tones from the Alarms menu.



b. Review or change your settings.

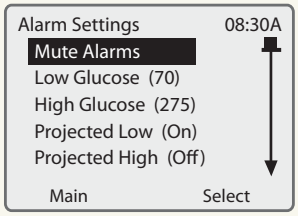
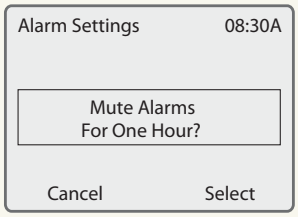
- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in either field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You want to mute alarms.	Go to Step 10.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

OVER

Steps	Do This
10. Mute all audible alarms for 1 hour.	**Note 1:** You will still get vibration, visual alarms will still be displayed and you will continue to get Low Glucose alarms. **Note 2:** If you want to turn off all alarms for more than one hour, you should turn off each alarm individually. Exercise caution when turning off or muting alarms. For example, if you turn off the low and high glucose alarms, you will **NOT** get low and high glucose alarms.
	**a.** Select Mute Alarms from the Alarms menu.
	**b.** Press the RIGHT Option button (Select) to mute alarms for 1 hour. **Note:** If you change your mind before you press the RIGHT Option button (Select), press the LEFT Option button (Cancel) to return to the Alarm screen without muting the alarms. If the alarms are muted, you will see a symbol indicating that the alarms are muted. Once the alarms have been muted, they cannot be turned on before the 1 hour expires. ***Important:*** *Muting the alarms is not recommended during times when you are unable to interact with your receiver (for instance, when you are asleep). Interacting with your receiver includes activities such as pressing the buttons, viewing the screen, or inserting a strip to do a BG test.* *If no buttons are pressed during the 1 hour muting period during which an alarm is active, the alarm response period will elapse during the mute time and no further alarms will sound until the display has been activated.*
11. Return to the main menu.	Press the LEFT Option button (Main) on the Alarms menu to return to the main menu.
12. Check your work.	***Result:*** *The result will be a receiver set up to alert you to your glucose conditions, to system events, and to activity progress in a way that you prefer.* You will have done this procedure correctly when the receiver provides alarms as you want it to.

END OF Section 8

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9 Daily Use

Section 9

Section 9 – Key Terms

- BG Mode
- CM Mode
- Directional Glucose Trend Arrows
- Icon
- Receiver
- Transmitter
- Transmitter Receiver Connection

9 Daily Use

Purpose To read and understand your display screen.

Start Do this procedure:
- Anytime you are using your system in the Continuous Monitoring mode.

Materials Your receiver.

Helpful Information

- Your receiver and transmitter must be linked, connected, and calibrated in order to use the system in the Continuous Monitoring mode.
- When you sleep, place the receiver on a high headboard or on a nearby dresser rather than clipping it to your bed clothing or taking it to bed. Be aware that if the receiver is set to vibrate and if you place it too far from you, you may not hear it vibrate.
- You must keep your receiver within 10 feet of the transmitter to maintain a consistent connection. If the connection between the transmitter and receiver is broken you will not receive continuous glucose readings.
- The connection can also be affected by objects getting between the transmitter and receiver, like nearby large metal objects, and by some electronic devices that produce radio frequencies.
- As a periodic check, turn your receiver on a few times everyday to make sure that it is still producing glucose results.
- As a periodic check, turn on the low glucose alarm everyday to make sure that it sounds an alarm (or vibrates) based on your settings.
- If a connection alarm sounds, adjust the placement of the receiver, to restore the connection. Step 2 of this Section describes how to maintain connection between the receiver and transmitter. For general troubleshooting, refer to Section 10 as well.
- If the display turns off, press the RIGHT Option button to turn it back on.

OVER

Steps	Do This

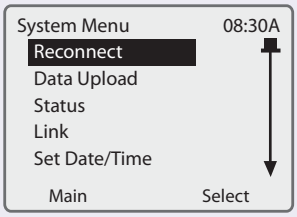
1. **Decide what to do.**

If you want to	*Then go to this Step*
• Connect your receiver and transmitter.	2
• Reconnect your receiver and transmitter.	2
• Interpret the CM screen.	3
• Interpret icons on the CM screen.	4
• Interpret icons on the Main screen.	4
• Turn the receiver backlight on.	5

2. **Reconnect the receiver to the transmitter.**

a. Place the receiver within 10 feet of the transmitter.

b. Decide what to do next.

If the receiver has lost connection	*Then*
• For less than 30 minutes.	**1.** Wait for the connection icon to disappear automatically from the display to confirm connection. **2.** Go back to Step 1 of Section 9.
• For 30 minutes or more. 	**1.** Press the RIGHT Option button twice to display the Main Menu screen. **2.** Use the UP/DOWN Arrow button to highlight System. **3.** Press the RIGHT Option button (Select) to display the System menu with Reconnect highlighted. **4.** Press the RIGHT Option button (Select). **5.** Wait for the receiver to beep. If it beeps: • Twice – the system is connected. Go back to Step 1 of Section 9. • Three times – the system is not connected. Make sure the battery in the transmitter is new and ensure that the receiver and transmitter are linked (see Section 14).

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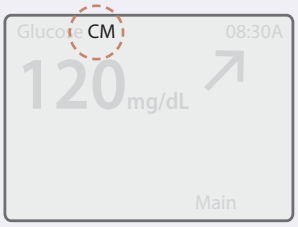
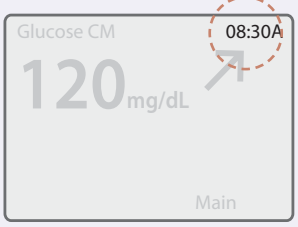
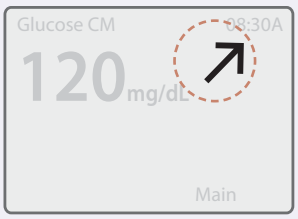
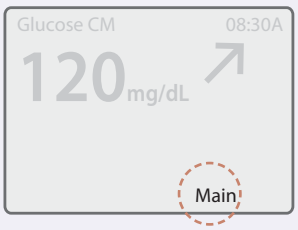
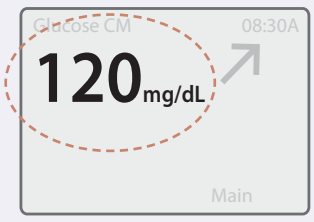
Steps	Do This
3. Interpret the CM screen.	Press the RIGHT Option button to turn the display on. ***Result:*** *The Glucose CM screen is displayed.*

Location	*Description*
	If CM appears here, the receiver is operating in the Continuous Monitoring mode. If BG appears here, the receiver is operating in the Blood Glucose mode.
	The current time of day.
	The directional glucose trend arrow tells you the direction that your glucose levels are trending and how fast (see Step 4). The system uses 15 minutes of continuous glucose data to display the arrow. Occasionally, the arrow may not be displayed temporarily. Refer to the Line Graph for recent glucose history.
	Tells you what pressing the RIGHT Option button will do – in this case, it takes you to the Main screen.
	Your current glucose level. Follow the recommendations of your healthcare team to treat low glucose (hypoglycemic) and high glucose (hyperglycemic) episodes.

Caution: *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

OVER

Steps	Do This
4. Interpret the icons.	**Note:** The directional trend arrows are different from the projected glucose alarms (Section 8). For example, you can have a projected low glucose alarm and still have a relatively stable trend arrow.

This Icon	*Means*
	Your glucose is changing gradually, changing at a rate of less than 60 mg/dL/hr (3.3 mmol/L/hr).
	Your glucose is increasing moderately, at a rate between 60 mg/dL/hr and 120 mg/dL/hr (3.3 mmol/L/hr and 6.7 mmol/L/hr).
	Your glucose is decreasing moderately, at a rate between 60 mg/dL/hr and 120 mg/dL/hr (3.3 mmol/L/hr and 6.7 mmol/L/hr).
	Your glucose is increasing rapidly, at a rate of greater than 120 mg/dL/hr (6.7 mmol/L/hr).
	Your glucose is decreasing rapidly, at a rate of greater than 120 mg/dL/hr (6.7 mmol/L/hr).
	The system is processing a control solution or blood glucose sample in the Blood Glucose mode.
	It is time to do a calibration. See Section 7.
	The system is waiting until it is time to do something (for example, waiting to do the 1st calibration after inserting a sensor). You don't need to do anything.
	There is a problem with the transmitter-receiver connection. See Step 2.
	The alarm is muted.
	It is time to replace the batteries in the receiver. Install the new batteries just before you insert a new sensor. See Section 2.
	This icon shows up for Blood Glucose mode test results that happened when the operating temperature was beyond the system's specified operating temperature range and may be less accurate. Discard the test and repeat another test within the operating temperature range of the system.

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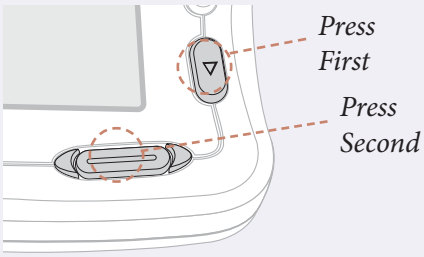
Steps	Do This
5. Turn the Backlight on.  	**a.** In order to turn the backlight on, your receiver has to be turned off. If the receiver is on, wait for 12 seconds to allow the receiver to turn off. **b.** Press and release the **DOWN** Arrow button. Then immediately press and release the **RIGHT** option button. Your receiver will turn on with a backlight.
6. Check your work.	***Result:*** *You are aware of your glucose levels and trends. You have done this procedure correctly when:* ❑ You correctly interpret the directional glucose trend arrows. ❑ You can tell your current glucose level at a glance. ❑ You maintain the connection between your transmitter and receiver or can reconnect the transmitter and receiver when the connection is lost. ❑ You can correctly interpret the icons that appear on the receiver screen. END OF Section 9

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10 Respond to Alarms, Errors, and Problems

Section 10

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Section 10 – Key Terms

- Alarms Menu
- Calibration BG
- CM Status
- Calibration
- High Glucose Alarm
- Icon
- Low Glucose Alarm
- Projected High Alarm
- Projected Low Alarm
- Receiver Status
- Sensor
- Sensor Support Mount
- Status Information
- Transmitter
- Transmitter Receiver Connection
- Transmitter Status

10 Respond to Alarms, Errors, and Problems

Purpose To resolve alarm messages, error codes, or problems.

Start Do this any time you:

- Receive either an alarm or an error code in the Continuous Monitoring mode or the Blood Glucose mode.
- Experience problems with your FreeStyle Navigator system.

Materials Your FreeStyle Navigator system.

Helpful Information

Caution: *For ALL alarms, if you do not turn on the display of the receiver within the first hour of the notification of an alarm, the receiver will stop beeping (or vibrating). No further alarms will sound (beep or vibrate) until the display has been activated.*

Important: *Muting the alarms is not recommended during times when you are unable to interact with your receiver (for instance, when you are asleep). Interacting with your receiver includes activities such as pressing the buttons, viewing the screen, or inserting a strip to do a BG test.*

If no buttons are pressed during the 1 hour muting period during which an alarm is active, the alarm response period will elapse during the mute time and no further alarms will sound until the display has been activated.

- Press the RIGHT Option button to respond to a vibration or audio alarm.
- Press the LEFT Option button to turn off a text display message.
- See Section 8, Step 10 to mute all audible alarms for 1 hour.
- Alarms are given a level of urgency based on how soon you must respond. Alarms act differently depending upon the level of urgency:

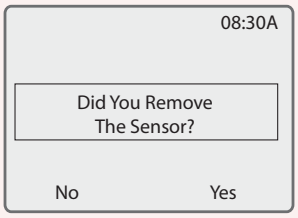
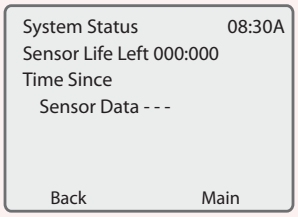
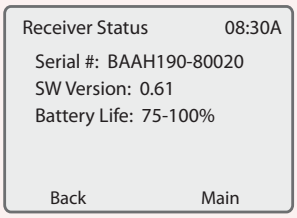
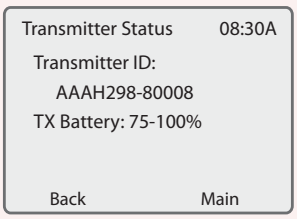
If the level of urgency is	*Then the alarm*
High – **H**	• **Must <u>never</u> be ignored**. • Cannot be muted. • Is the same as a medium urgency alarm in all other respects.
Medium – **M**	• Can be muted. • Sounds three short beeps every 6 seconds for 1 minute or until you activate the display. • Repeats every 5 minutes until acknowledged or fixed. • Repeats every 15 minutes after acknowledged until fixed.
Intermediate – **I**	• Is the same as the medium urgency alarm except the intermediate alarm will stop and will not sound again: – After 1 hour. – When acknowledged. – Can be muted.
Low – **L**	• Does not need to be addressed right away. • It is a single beep that does not repeat. Can be muted. • Is turned off when acknowledged.

- The level of urgency is indicated in some of the following tables with H for high, M for medium, I for intermediate, and L for low.
- The alarms are alphabetized in the following tables.
- If you cannot find the information you need, call Customer Care.

OVER

Status Information

The receiver can provide you with a number of different types of Status Information. Available Status Information is listed in the following table. To access the Status information, press the RIGHT option button twice to get to the Main menu and use the UP or DOWN arrow button to highlight System. Select System by pressing the RIGHT option button. Highlight and select Status from the System menu.

Status Information	*Description*
Removed Sensor 	Allows you to indicate you are removing a Sensor so the Data Loss Alarm will not set off. Use this only if you are removing a sensor. **Note:** Once you select this option, the system will terminate any active sensor.
System Status 	Shows information about the System, including Sensor life remaining (in hours) and time since valid data was transmitted (in hours).
Receiver Status 	Shows information about the receiver, including serial number and software version (may be useful when calling Customer Care), as well as battery life remaining.
Transmitter Status 	Shows the transmitter's serial number. You may need to verify the serial number after linking to a new transmitter. This unique value is used by the receiver to accept data from only the transmitter the receiver is linked to. It also shows battery life remaining. After replacing the battery, once the system has recognized the new battery, it will display battery life as 75-100%. If there is no connection between the transmitter and receiver, you will see 3 dashes, "- - -", instead of the battery life.

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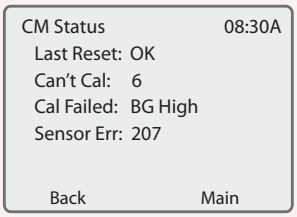
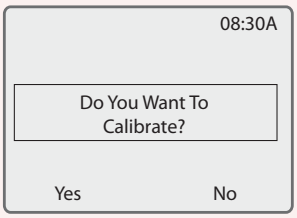
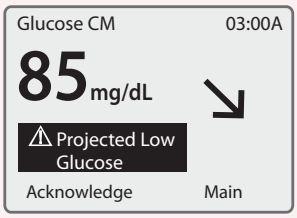
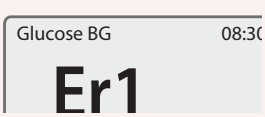
Status Information *(con't)*

Status Information	*Description*
CM Status. 	Stores recent error codes related to the Continuous Monitoring mode (may be useful when calling Customer Care). **Note:** The CM Status screen shows information about calibration and sensor errors. You can get information about why the system did not prompt you to perform a calibration ("Can't Cal: xxx") or why a calibration failed ("Cal Failed: xxx") or why continuous glucose readings are not displayed ("Sen Err: xxx"). These numbers and information help troubleshoot your system performance. The Customer Care representative may ask you to access the CM Status information.
Calibration BG. 	Allows you to add a new blood glucose reading used for calibration. Use this selection **ONLY** at the request of a Customer Care representative. **Note:** Once you use this feature to successfully perform an additional calibration, the system discards the parameters from the previous calibrations. It begins to calculate glucose results based on this calibration. When using the Calibration BG feature, always perform an additional Blood Glucose mode test to confirm the first test. This feature cannot be used in the first ten hours after sensor insertion. Using this feature does not change the regular scheduled times for calibration.

Alarms and Errors

Display	*Description*
 Fig. 1	The system will notify you of any conditions that may need your attention through messages that will be displayed on your receiver screen. You can find out what those messages mean and how to respond to them. For example, see Fig. 1. The messages are arranged alphabetically in the table titled "Respond to alarm message".
 Fig. 2	When you use your built in FreeStyle Meter to make measurements, you may receive error codes on the receiver. You can find out how to respond when you get those codes. For example, see Fig. 2.

OVER

Respond to alarm message:

Alarm Message	Urgency	What It Means	What to Do
___ ___ ___	N/A	• System is not producing continuous glucose results. • This is normal for new sensors before the first calibration (Blood Glucose mode test) is performed. Low and High Glucose alarms cannot function while this appears on the display. • Problem with the connection between the receiver and transmitter. • Sensor problem (or sensor no longer in your skin). • Transmitter failure. • Sensor is expired.	Wait for the receiver to prompt you with an alarm message.
"_____" A Flashing line on the bottom of the screen.	N/A	You are in one of the menu items and a new alarm message has just been triggered.	By using the RIGHT and LEFT option and UP/DOWN buttons on the receiver go to the Glucose screen and read your alarm.
Flashing light at the test strip port.	N/A	Receiver has reset.	Call Customer Care.
⚠ Alarms Inactive Insert New Sensor.	I	Alarms are not operating because the 5-day life of the sensor has ended.	Remove the sensor and insert a new one (see Section 5).
⚠ Alarms Inactive Replace Receiver.	I	Receiver malfunction. Problem has persisted for an hour.	Call Customer Care.
⚠ Alarms Inactive Replace Sensor.	I	The sensor is not functioning properly. The alarms are not working.	Remove the sensor and insert a new one (see Section 5).
⚠ Alarms Inactive Replace Transmitter.	I	Transmitter problem for an hour. Alarms are not active.	Replace the transmitter, and insert a new sensor.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

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Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Alarms Inactive Skin Temp Range.	I	Skin temperature at the insertion site is either too low or too high for the system to produce correct readings. Condition has been persistent for up to one hour. The alarms are not working.	Remove the sensor and insert a new one (see Section 5). If problem persists, then replace transmitter.
⚠ Cal Failed: High BG Redo BG Later.	I	Calibration failed because the Blood Glucose mode test reading was too high. The system needs a blood glucose level between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) for proper calibration.	If your glucose level is high, follow your healthcare professional's advice for a high glucose level (hyperglycemic) episode. Perform another Blood Glucose mode test for calibration.
⚠ Cal Failed: Low BG Redo BG Later.	I	Calibration failed because the Blood Glucose mode test reading was too low. The system needs a blood glucose level between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) for proper calibration.	If your glucose level is low, follow your healthcare professional's advice for a low glucose level (hypoglycemic) episode. Perform another Blood Glucose mode test for calibration.
⚠ Cal Failed: Receiver Temp Redo BG Later.	I	Calibration failed because the receiver was too warm or too cold.	Bring the receiver to room temperature, and then perform another Blood Glucose mode test for calibration.
⚠ Cal Failed: Redo BG in 1 hr.	I	The Blood Glucose mode test showed the sensor may not be working properly.	Wait 1 hour and perform a Blood Glucose mode test for calibration.
⚠ Cal Failed: Redo BG Later.	I	Calibration failed because the information from the transmitter was incomplete or there is no connection between the transmitter and receiver or your glucose levels have been changing rapidly.	Make sure that the receiver and transmitter are connected. Wait 1 hour and perform a Blood Glucose mode test for calibration.
⚠ Cal Failed: Redo BG Test.	I	Calibration test was very different from the previous calibration.	Perform another Blood Glucose mode test for calibration.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

OVER

Abbott Ex. 1027 - 308/400

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Cal Required: Redo BG in 2 hrs.	I	Sensor signal is settling. The system requires another calibration in 2 hours. You will continue to get glucose results during that time.	Wait for the "Do BG test" prompt and perform another Blood Glucose mode test for calibration. You will have half hour to perform the calibration after which you will not get glucose results or alarms until the calibration is completed successfully.
⚠ Cool Down Skin.	L	Unable to calibrate the system because the skin temperature is too warm.	Cool the skin at the insertion site and wait for the "Do BG Test" prompt and perform another Blood Glucose mode test for calibration. You can cool down your skin temperature by moving to a cooler environment. If you are wearing warm clothing (like a sweater or jacket), try taking them off.
⚠ Cool Down Skin Redo BG Later.	I	Calibration failed because your skin temperature is too warm.	Cool the skin at the insertion site. Wait for half an hour and perform another Blood Glucose mode test for calibration. You can cool down your skin temperature by moving to a cooler environment. If you are wearing warm clothing (like a sweater or jacket), try taking them off.
⚠ Did You Remove The Sensor?	L	• The system has detected that the sensor was just removed. • If this message appears and you did not remove the sensor, there may be a faulty connection between the sensor and the transmitter.	• If you did not just remove the sensor, select No. • Ensure that the transmitter is attached firmly to the sensor support mount. • Ensure that the sensor support mount is attached firmly to the skin. • If the alarm persists, remove the sensor and insert a new one (see Section 5).

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
Do BG Test.	**M**	A Blood Glucose mode test is needed for calibration. The receiver will prompt you to perform this test approximately 10 hours after the sensor insertion, 2 to 4 hours after the first successful calibration, 12 to 20 hours after the second successful calibration and 48 to 56 hours after the third successful calibration.	Perform a Blood Glucose mode test for calibration See Section 7.
Do BG Test Alarms Inactive.	**I**	Calibration was not performed within the required time; therefore, readings will not be displayed and the alarms are not working.	Perform a Blood Glucose mode test for calibration.
High Glucose.	**M**	Your glucose has reached your preset high glucose threshold.	Follow the recommendations of your healthcare team for treating a high glucose level (hyperglycemic) episode.†
Link.	**L**	The receiver is not linked to the transmitter. The link is necessary for the system to operate in the Continuous Monitoring mode.	Place the receiver within 10 feet of the transmitter. Select System from the receiver's Main menu, then select Link. If the transmitter ID that appears on the display screen is correct, select Yes. See Section 14.
Log Cleared.	**L**	History log has been successfully cleared.	Acknowledge the alarm.
Log Corrupted Some Data Lost.	**L**	History log is corrupt.	The receiver detected a corrupt sector in the log and erased it. The data in this sector is lost. Your reports will not contain this lost data. If the error occurs, call Customer Care.

† ***Caution:*** *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

OVER

Abbott Ex. 1027 - 310/400

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Low Glucose.	**H**	Your glucose has reached your preset low glucose threshold.	Follow the recommendations of your healthcare team for treating a low glucose level (hypoglycemic) episode.†
⚠ New Sensor Detected Have You Recently Inserted a New Sensor?	**L**	• The system has detected a new sensor. • If this message appears and you did not insert a new sensor, there may be a faulty connection between the sensor and the transmitter.	If you just inserted a new sensor, select Yes. If you did not insert a new sensor, select No. Ensure that the transmitter is attached firmly to the sensor support mount. If the alarm persists, the sensor may have failed. Remove the sensor and insert a new one (see Section 5). This message can appear during or after cleaning the transmitter. Ensure that the transmitter is thoroughly dry before inserting a new sensor (see Section 13).
⚠ Preferences Lost Reconfigure.	**L**	An error occurred with the receiver configuration. The receiver has reset. Your stored preferences may be lost.	Review your alarm settings and other user-settable items like the country settings.
⚠ Projected High Glucose.	**M**	This is an early warning that your glucose level and the rate at which it is changing indicate that you may soon reach your high glucose threshold. When set to **High** sensitivity, you have approximately 30 minutes before reaching your high glucose threshold. When set to **Medium** sensitivity, you have approximately 20 minutes before reaching your high glucose threshold. When set to **Low** sensitivity, you have approximately 10 minutes before reaching your high glucose threshold.	Follow the recommendation of your healthcare team for treating or stopping the rise in glucose that you are experiencing.†

† ***Caution:*** *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Abbott Ex. 1027 - 311/400

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Projected Low Glucose.	**M**	This is an early warning that your glucose level and the rate at which it is changing indicate that you may soon reach your low glucose threshold. When set to **High** sensitivity, you have approximately 30 minutes before reaching your low glucose threshold. When set to **Medium** sensitivity, you have approximately 20 minutes before reaching your low glucose threshold. When set to **Low** sensitivity, you have approximately 10 minutes before reaching your low glucose threshold.	Follow the recommendations of your healthcare team for treating or stopping the drop in glucose that you are experiencing.†
⚠ Receiver Error Alarms Inactive.	**I**	Receiver error.	The problem could go away in 50 minutes or less. If problem persists, call Customer Care.
⚠ Reconnect.	**L**	The receiver has not been receiving signals sent by the transmitter for 5 minutes. The receiver is either too far from the transmitter or there are materials or signals causing interference.	Be sure the receiver and transmitter are within 10 feet of one another. If the alarm persists, select System from the Main menu, then select Reconnect. See Section 9, Step 2.
⚠ Reconnect–Alarms Inactive.	**M**	The receiver has not been receiving signals sent by the transmitter for 8 minutes. The receiver is either too far from the transmitter or there are materials or signals causing interference.	Be sure the receiver and transmitter are within 10 feet of one another. If the alarm persists, select System from the Main menu, then select Reconnect. See Section 9, Step 2.
⚠ Remove Any Sensor Alarms Inactive.	**I**	Alarms are not operating. The receiver thought the sensor was inserted when the receiver was reset.	Remove the sensor and insert a new one (see Section 5). Ignore the message if there is no sensor inserted.

† ***Caution:*** *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

OVER

Abbott Ex. 1027 - 312/400

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Replace Receiver Battery Within 1 Week.	**L**	The batteries in your receiver will lose power in approximately 1 week.	Replace the receiver batteries before you insert a new sensor (see Section 2). Replacing the batteries before a sensor has expired will require you to insert a new sensor.
⚠ Replace Sensor Soon.	**L**	The sensor will reach the end of its life within 2 hours.	Replace the sensor within the next 2 hours (see Section 5).
⚠ Replace TX Batt With Next Sensor.	**L**	The transmitter battery monitor indicates there are only 4 days of battery left.	Replace the transmitter battery prior to inserting the next sensor. Be sure to reconnect the transmitter and receiver. Replacing the batteries before a sensor has expired will require you to insert a new sensor.
⚠ Sensor Error Alarms Inactive.	**I**	Unstable sensor signal. Unable to calculate glucose. Alarms are not working.	Wait for 50 minutes for the problem to go away. Ensure that the sensor is firmly attached and that the transmitter and the sensor support mount are not loose. If the problem persists, remove sensor and insert new one.
⚠ Sensor Error Replace Sensor.	**I**	Sensor failure. No more BG alarms will occur.	Remove and insert a new sensor (see Section 5) if this message appears within the first 10 hours after sensor insertion. Otherwise, please call Customer Care before removing the sensor.
⚠ Skin Temp Range Alarms Inactive.	**I**	Skin temp out of range (too warm or too cold). Condition has been persistent for 10 minutes. Alarms are not working.	Bring skin temperature within range. Ensure that the sensor support mount is firmly attached to the skin. If the problem persists after 50 minutes, remove the sensor and insert a new one (see Section 5). If the problem still persists, replace transmitter.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Abbott Ex. 1027 - 313/400

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Transmitter Error Alarms Inactive.	**I**	Transmitter problem. Alarms are not working.	Wait for the problem to go away. If the problem persists after 50 minutes, you will get the alarm. "Alarms Inactive. Replace Transmitter".
⚠ TX Battery Exhausted Replace Battery.	**L**	Transmitter battery power loss is imminent.	Remove sensor, replace transmitter battery, reconnect transmitter and receiver, and insert a new sensor.
⚠ Warm Up Skin.	**L**	Unable to calibrate the System because the skin temperature is too cold.	Warm the skin at the insertion site and wait for the "Do BG Test" prompt and perform another Blood Glucose mode test for calibration. You can warm up the skin temperature by moving to a warmer environment or by putting on some warm clothing.
⚠ Warm Up Skin Redo BG Later.	**I**	Calibration failed because your skin temperature is too cold.	Warm the skin at the insertion site. Wait for the blood drop icon to appear in about half an hour and perform another Blood Glucose mode test for calibration. You can warm up the skin temperature by moving to a warmer environment or by putting on some warm clothing.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

OVER

Abbott Ex. 1027 - 314/400

Respond to Blood Glucose Mode error codes. *(Note: There is no Error 5)*

If error code is	And you have any of these symptoms	Then
Er1	• Weakness • Sweating • Nervousness • Headache • Confusion	Follow your healthcare team's advice for treating a low glucose level (hypoglycemic) episode.
	→	Perform a control solution test using a new test strip: • If results are within the range printed on the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care.
Er2	• Thirst • Fatigue • Excess urination • Blurry vision	Follow your healthcare team's advice for treating a high glucose level (hyperglycemic) episode.
	→	Perform a control solution test using a new test strip: • If results are within the range printed on the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care
Er3	→	Be sure you see Apply Sample on the receiver screen before you apply blood or control solution. Perform a control solution test using a new test strip: • If results are within the range printed on the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care.
Er4	→	Perform a control solution test using a new test strip: • If results are within the range printed on the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care.
Er6	→	**Note:** Do **NOT** touch the RIGHT Option button while applying blood or control solution to the test strip. **1.** Retest using a new test strip. **2.** If error persists, call Customer Care.

OVER

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Troubleshoot problems

The problems you can troubleshoot in this Section are listed below and are arranged in the order of appearance.

Receiver

- The receiver will not turn on.
- The blood glucose test won't start after you apply a sample.
- Unexpected characters on the receiver display screen, unusual or unexpected receiver screen appearance.
- There is no glucose value on the screen.

Sensor Insertion

- There is skin irritation at the sensor insertion site.
- The sensor support mount is not sticking to your skin.
- Discomfort when inserting the sensor.
- The system does not recognize a new sensor after attaching the transmitter to the sensor support mount.

  Note: Also see Appendix A on Site Maintenance.

Receiver and Transmitter

Connection

- You are not sure whether your receiver and transmitter are connected.

Calibration

- The receiver does not prompt you to do a BG test for calibration.

OVER

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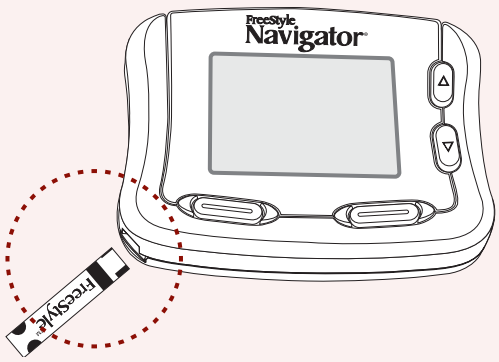
The receiver will not turn on.



a. Was the test strip inserted correctly (the "FreeStyle" side was up as you inserted the end with the dark rectangle)?

If **YES**, go to Step c.

If **NO**, repeat the test with a new strip taking care that the "FreeStyle" side is up as you insert the end with the dark rectangle until it stops.

b. Did this solve your problem?

If **YES**, stop.

If **NO**, continue with Step c.

c. Are the batteries installed correctly?

If **YES**, go to Step d.

If **NO**, Install the batteries correctly and reset time and date.

d. The batteries may be dead, replace existing batteries and reset time and date.

e. Repeat the test with a new test strip.

If this did not resolve your problem call Customer Care.

Note: Whenever batteries are removed and replaced or re-installed in the receiver, you will have to reconnect the transmitter and receiver and insert a new sensor.

The Blood Glucose test won't start after you apply a sample.

Note: Ensure that you apply your sample when the Apply Sample message appears on the display.

a. Repeat the test using a LARGER sample on a **new** test strip.

b. If this did not resolve your problem call Customer Care.

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Unexpected characters on the receiver display screen, unusual or unexpected receiver screen appearance.

If	*Then*
The batteries are installed correctly.	If you are close to a source of electromagnetic interference (see Appendix C for further details), move away from the interfering source and see if the problem goes away. If there is consistent interference from a source, contact the manufacturer of the source or a certified electrician for help. The batteries may have to be replaced. Replace batteries with fresh ones and reset date and time.
The batteries are installed incorrectly.	Install batteries correctly and reset date and time.

a. Reconnect the transmitter and receiver.

b. Insert a new sensor.

c. If this did not solve the problem, call Customer Care.

OVER

There is no glucose value on the screen.

If	*And*	*Then*
You are waiting for the first calibration.	It has been less than 10 hours after the insertion of the sensor.	You will see an icon on the screen. Wait for the system to prompt you to do a BG test for calibration.
It has been more than 10 hours after insertion of the sensor.	You see an icon on the screen.	Allow the system up to 2 hours to prompt you to do a BG Test for calibration.
It has been more than 10 hours after insertion of the sensor.	You receive alarms (for example, skin temperature related alarms or connection alarms).	Acknowledge the alarm, take appropriate action (for example, bring the skin temperature within range or establish connection between the transmitter and receiver) and allow the system up to 2 hours to prompt you to do a BG test for calibration.
The time window for calibration (for example, you have 2 hours to perform the second calibration, see Section 7) has expired.	You have not performed a BG Test for calibration.	Perform a BG test for calibration. (see Section 7).
You have performed all the appropriate calibrations successfully.	You see an icon on the screen.	Follow the guidelines for trouble-shooting connection between the transmitter and receiver.
You have performed all the appropriate calibrations successfully.	→	Allow the system up to 1 hour to start displaying the glucose values on the screen.

If none of the above helps solve the problem, replace the sensor (Section 5) or call Customer Care.

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Skin irritation at sensor insertion site.

a. Ensure that seams, waistbands, or other constrictive clothing or accessories do not cover the site causing friction.

b. Inspect the site.

If the irritation is	*Then*
Around the edges of the adhesive or tape.	Lift the edges slightly all around the dressing.
Wherever the adhesive touches skin.	You may be sensitive to the adhesive or material, consult your healthcare team to identify the best solution.

c. If none of the above works, consult your healthcare team for other suggestions.

The sensor support mount is not sticking to your skin.

Note: Do Step a through Step c **BEFORE** placing the sensor support mount on your skin.

a. Clean the insertion site by washing with soap and water.

b. Dry the site thoroughly with a clean towel.

c. Wipe the area with an alcohol prep pad.

d. If your skin-type requires more adhesive than provided on the sensor support mount, or if you anticipate an activity level that may require more adhesive, place an over-bandage over the transmitter **AFTER** connecting the transmitter to the sensor support mount.

OVER

Discomfort when inserting the sensor.

a. Rub the insertion site with ice before inserting the sensor.

b. If that doesn't work, call Customer Care.

The system does not recognize a new sensor after attaching the transmitter to the sensor support mount.

If	*Then*
Your transmitter and receiver are not connected.	You will see the icon on the screen. Try establishing connection between the receiver and transmitter. If the system still does not recognize a new sensor in about 3 minutes, remove the sensor and insert a new sensor (Section 5).
Your receiver and transmitter are connected. Contact Points	**a.** Make sure that the transmitter is firmly attached to the sensor support mount and wait for 3 minutes to allow the system to recognize the sensor. **b.** If the system still does not recognize the sensor, remove the sensor (Section 5), establish connection between the transmitter and receiver (Section 9), insert a new sensor, and attach the transmitter to the sensor support mount (Section 6). Make sure that the contact points on the transmitter are dry, clean, and not excessively worn.
Your system is not linked and you see the "Link" message on your screen.	Your system may not be linked. Perform the steps to link the system (Section 14). Make sure you reconnect the system after linking (Section 9). Remove and insert a new sensor.

If none of the above solves the problem, there may be something wrong with your transmitter. Call Customer Care.

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You are not sure whether your receiver and transmitter are connected.

If	*Then*
You do not see the icon on the screen.	Your system is connected.
You see the icon.	There is no connection between the receiver and transmitter. Reconnect the transmitter and receiver, see Section 9.
You see the icon and the reconnect procedure was unsuccessful.	Check and make sure that the transmitter battery is not old or exhausted. If the battery is old or exhausted, then **a.** Remove the sensor. **b.** Change the battery. **c.** Establish connection between transmitter and receiver. **d.** Insert a new sensor.
You continue to see the icon even after replacing the battery in the transmitter.	Wait for a couple of minutes after inserting the new battery to allow the system to recognize the new battery. If after two minutes, the system still does not recognize the new battery, there is probably something wrong with your transmitter. Call Customer Care.
You see the "Link" message on the screen.	Your system is not linked. Perform the steps to link the system (Section 14). Make sure you reconnect the system after linking (Section 9).

OVER

The system does not prompt you with a message to do BG test for calibration.

If	*And*	*Then*
The system did not prompt you with a message recognizing a new sensor after you attached the transmitter to the sensor support mount.	→	Follow the troubleshooting guidelines on sensor recognition.
It has been less than 10 hours after insertion of the sensor.	→	Wait for the 10 hour time period to end and allow the system to prompt you to do a BG Test for calibration.
It has been more than 10 hours after the insertion of the sensor.	There is a icon on the screen.	Reconnect the transmitter and receiver (Section 9) and allow the system up to 2 hours to prompt you to do a BG Test for calibration.
It has been more than 10 hours after the insertion of the sensor.	You have received alarm messages on the receiver.	Acknowledge the alarm message, take appropriate action and allow the system up to 2 hours to prompt you to do a BG Test for calibration.

If none of the above helps solve the problem, replace the sensor (Section 5) or call Customer Care.

Check your work.

Result: *Information on what to do in the event of alarm messages, error codes, or other common problems.*

You will have done this task correctly when you have resolved the problem or contacted either your healthcare team or Customer Care for additional suggestions or help.

END OF Section 10

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11 Add Events

Section 11

Section 11 – Key Terms

- Events
- Exercise Event
- Generic Event
- Insulin Event
- LEFT/RIGHT Option Buttons
- Meal Event
- State Of Health Event
- UP/DOWN Arrow Buttons

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11 Add Events

Purpose To create a record of events that may affect your glucose levels.

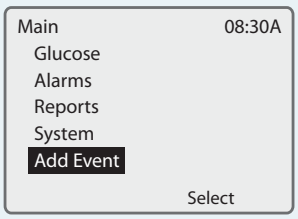
Start Do this procedure any time you observe anything that may affect your glucose levels, including your state of health and daily activities such as meals, exercise, and insulin dosages.

Materials
- Your FreeStyle Navigator Receiver.
- Data and details about the event that you want to record.

Helpful Information

Important: *To edit an event, go to Section 12, Review Your Reports and Edit Events.*

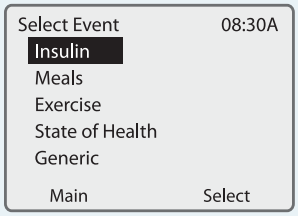
- Pressing the RIGHT Option button (Set) completes the entry of your event regardless of how much or how little detail you have provided.
- The current date and time are automatically recorded when you enter an event. If you enter the event at a later time, you must change the date and time of the event to when it actually occurred before you press the RIGHT Option button (Set) to save the event.
- If you change your mind about saving the event, use the UP/DOWN Arrow button to change **SAVE** to **CANCEL** before you press the RIGHT Option button (Set).

Steps	Do This
1. Access the Add Event screen from the Main menu. 	**Note:** If you don't press any buttons for 12 seconds, the receiver screen will go blank and the last change will be lost if you haven't pressed the Select button. **a.** Press the UP Arrow button or the DOWN Arrow button to highlight Add Event. **b.** Press the RIGHT Option button (Select) to go to the Select Event screen.

OVER

Steps	Do This

2. **Select the type of event you want to record.**

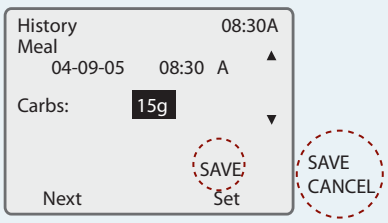


Use the UP Arrow button or the DOWN Arrow button to highlight the type of event:

If the event deals with	*Then*
• Meals or snacks.	1. Highlight Meals. 2. Press the RIGHT Option button (Select). 3. Go to Step 3.
• Details of an insulin dose. (injection or pump)	1. Highlight Insulin. 2. Press the RIGHT Option button (Select). 3. Go to Step 4.
• Exercise.	1. Highlight Exercise. 2. Press the RIGHT Option button (Select). 3. Go to Step 5.
• Your state of health. • Symptoms. • Other health related observations.	1. Highlight State of Health. 2. Press the RIGHT Option button (Select). 3. Go to Step 6.
• Other events.	1. Highlight Generic. 2. Press the RIGHT Option button (Select). 3. Go to Step 7.

Note: For all the steps below, make sure that you have entered the correct date and time.

3. **Record meal events.**



a. Use the LEFT Option button (Next) to select which item to enter or change (Carbohydrate grams, SAVE/CANCEL, Date, Time).

b. Use the UP Arrow button or the DOWN Arrow button to change the selected item.
Note: You can change the carbohydrate grams from 0 to 350 grams in 1 gram increments.

c. When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.

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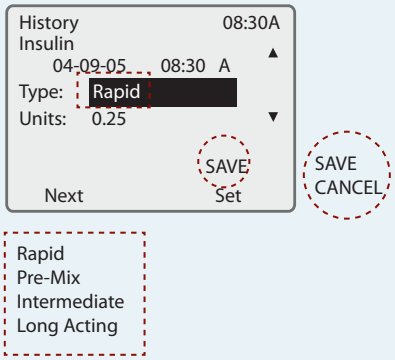
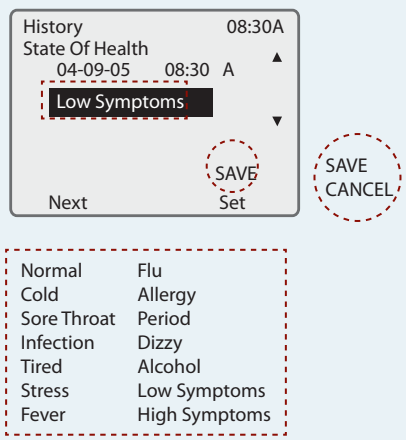
Steps	Do This
4. Record insulin events. 	**a.** Use the LEFT Option button (Next) to select which item to enter or change (Type, Units, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **Note:** Your insulin choices are Rapid, Intermediate, Long Acting, or Pre-mix. **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.
5. Record exercise events.	**a.** Use the LEFT Option button (Next) to select which item to enter or change (Type, Duration, Intensity, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **Note:** Your exercise choices are: • **Type:** Aerobics, Walking, Jogging, Running, Swimming, Biking, Weights, or Other. • **Duration:** 0:00 to 2:30 (hrs:minutes) in 15 minute increments. • **Intensity:** None, Low, Medium, or High. **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.
6. Record state of health events. 	**a.** Use the LEFT Option button (Next) to select which item to enter or change (State of health, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **Note:** Your state of health choices are Normal, Cold, Sore Throat, Infection, Tired, Stress, Fever, Flu, Allergy, Period, Dizzy, Alcohol, Low Symptoms, or High Symptoms. **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.

OVER

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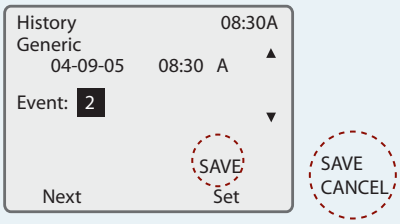
Steps	Do This
7. Record generic events. 	**a.** Use the LEFT Option button (Next) to select which item to enter or change (Event, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **Note 1:** There are eight generic event numbers that you or your healthcare team can assign to specific events (For example, #1 can refer to "Dining Out," #2 to "Shopping," #3 to "Inactive Day, #4 to "Party," etc.) **Note 2:** Write down the meanings for each number as you assign them so you don't forget what they represent (you don't have to assign meanings to all the numbers). **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.
8. Check your work.	***Result:*** *An electronic record of all events that may affect your glucose levels.* You have done this procedure correctly when the event records are complete and accurate.

END OF Section 11

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12 Review Reports and Edit Events

Section 12

Section 12 – Key Terms

- Event History Reports
- Events
- Exercise Event
- Generic Event
- Glucose Targets
- Insulin Event
- LEFT/RIGHT Option Buttons
- Line Graph
- Main Menu
- Meal Event
- Multi-Day Statistics
- Reports
- Single-Day Statistics
- State Of Health Event
- Statistical Reports
- UP/DOWN Arrow Buttons

12 Review Reports and Edit Events

Purpose

- To review your glucose levels.
- To help you and your healthcare team detect patterns in your glucose levels relative to your targets.
- To review a history of events that are important to your treatment plan.
- To edit event history.

Start

- When you or your healthcare team want to know about your glucose levels or about events that may either explain your glucose levels or influence your treatment plan.
- When you need to make changes to your event history.

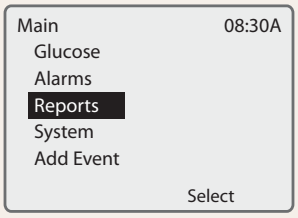
Materials

Gather these materials before you begin:

- Your glucose targets (your healthcare team can help determine these).
- Your receiver.

Helpful Information

- Your healthcare team will usually give you glucose targets. Compare your actual glucose levels with these targets to see how you are doing. Ask your healthcare team to tell you how your levels should compare to each target.
- Glucose targets are **DIFFERENT** from the thresholds for low and high glucose alarms. Low and high glucose alarms alert you when you've reached the low or high threshold value. Glucose targets allow the reports and line graphs to show how your glucose levels have been performing compared to your set targets.

Steps	Do This
1. Access the Reports menu from the Main menu. 	**a.** Press the UP Arrow button or the DOWN Arrow button to highlight Reports. **b.** Press the RIGHT Option button (Select) to go to the Select Reports screen.

OVER

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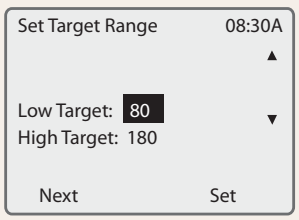
Steps	Do This
2. Decide what you want to do.	**Note:** Your reports will be more meaningful if you set glucose targets. Glucose targets give you something to compare your actual glucose levels with. Decide what to do:

If you want to	*Then*
• Set glucose targets.	Go to Step 3.
• See a line graph showing a history of your glucose levels.	Go to Step 4.
• See a statistical summary of your glucose levels over time.	Go to Step 5.
• Review or edit the events you have recorded in your receiver.	Go to Step 7.
• Quit and return to the Main menu.	Press the LEFT Option button (Main) on the Reports menu.

3. Set your glucose targets.



a. Select Glucose Targets from the Select Report menu.
  i) Press the UP Arrow button or DOWN Arrow button to highlight Glucose Targets.
  ii) Press the RIGHT Option button (Select) to go to the Glucose Targets screen.

b. Enter your low glucose target using the UP or DOWN arrows.

c. Press the LEFT Option button (Next) to move to the High Glucose target setting.

d. Enter your high glucose target using the UP or DOWN arrows.

e. Press the RIGHT Option button (Set) to save the settings.

Result: *The settings are saved and the Select Report screen appears.*

f. Return to Step 2 to decide what to do next.

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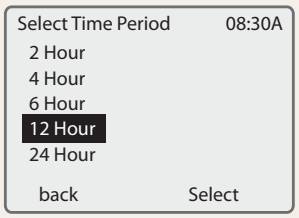
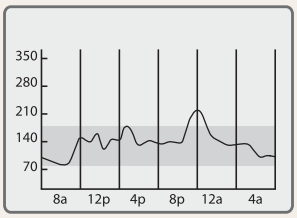
Steps

Do This

4. **View a line graph of your glucose level history.**





Note: The line graph display range is between 20 mg/dL (1.1 mmol/L) and 350 mg/dL (19.4 mmol/L).

Glucose values exceeding 350 mg/dL (19.4 mmol/L) will be plotted as 350 mg/dL (19.4 mmol/L).

Glucose values ***falling below*** 20 mg/dL (1.1 mmol/L) will be plotted as 20 mg/dL (1.1 mmol/L).

a. Select Line Graphs from the Select Report menu.
  i) Use the UP Arrow button or DOWN Arrow button to highlight Line Graph.
  ii) Press the RIGHT Option button (Select) to go to the Select Time Period screen.

b. Select the time period (2, 4, 6, 12, or 24 hours) using the UP Arrow button or the DOWN Arrow button.

c. Interpret the graph:
- Notice your glucose target range (the shaded horizontal band).
- Notice your glucose level (in mg/dL along the left hand side) at different times (bottom line).
- Notice the trends and the times that your glucose level is outside of your target range.
- Notice how different events that you entered are located in relation to your glucose profile. Events entered will be shown on the line graph with letters indicating the event - "I" for Insulin, "M" for meals, "E" for exercise, "H" for state of health and the number (1 thru 8) for a generic event.

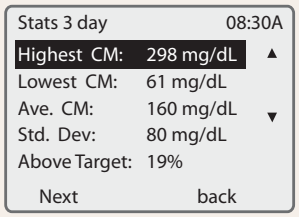
Note: The line shows both your continuous readings (plotted every 10 minutes) and your blood glucose readings (the "+" symbols on the line graph).

When viewing the line graph, you can scroll forward on the time axis by pressing the UP Arrow button and you can scroll backward on the time axis by pressing the DOWN Arrow button. You will not be able to see the date on the time axis.

d. Decide what to do next.

If you want to	*Then*
• View a line graph for another time period.	**1.** Press the RIGHT Option button to return to the Select Time Period screen. **2.** Go to Step 4b.
• End viewing line graphs.	**1.** Press the RIGHT Option button to return to the Select Time Period screen. **2.** Press the LEFT Option button (Back) to return to the Select Reports screen. **3.** Go to Step 2 to decide what to do next.

OVER

Steps	Do This
5. View a statistical summary of your glucose levels. 	**a.** Select Statistics from the Select Reports menu. i) Use the UP Arrow button or DOWN Arrow button to highlight Statistics. ii) Press the RIGHT Option button (Select) to go to the Statistics screen. **Note:** The Stats screen shows you a summary of glucose results relative to your glucose targets. **b.** Press the LEFT Option button (Next) to advance to the desired period. **Note:** You can view statistical reports for 1, 3, 7, 14, 21, or 28 day periods, in that order. (Continue to Step 6)

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Steps	Do This
6. Select the desired statistical reading.	**Note:** Statistics include **ONLY** continuous glucose results. Glucose readings that were taken in the Blood Glucose mode are **NOT** included in the statistics. **a.** Use the UP Arrow button or DOWN Arrow button to highlight the statistic you want to review ***for the selected period***.

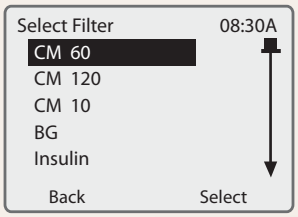
If you want to know	*Then highlight*
• Your highest glucose reading.	Highest CM.
• Your lowest glucose reading.	Lowest CM.
• Your average glucose reading.	Ave. CM.
• How well you are maintaining your levels near the average value.	Std. Dev. **Note:** A **small** number indicates that most of your glucose readings are close to your average value. A **large** number indicates that many of your glucose levels vary considerably from your average value.
• The percentage of readings that are above your high glucose target.	Above Target.
• The percentage of readings that are within your glucose targets (between the high and low targets).	Within Target.
• The percentage of readings that are below your low glucose target.	Below Target.
• The average number of low glucose alarm events per day.	Low/Day.
• The average number of high glucose alarm events per day.	High/Day.
• The average number of projected low alarm events per day (early warnings).	Proj Low/Day.
• The average number of projected high alarm events per day (early warnings).	Proj High/Day.

b. Press the LEFT Option button (Next) to view other periods.
Note: You can view reports for 1, 3, 7, 14, 21, or 28 day periods, in that order.
c. Press the RIGHT Option button (Back) to return to the Select Reports screen.
d. Go to Step 2 to determine what to do next.

OVER

Steps	Do This

7. **Review or change your event history.**



a. Select Event History from the Select Reports menu.

b. Use the UP or DOWN Arrow button to highlight the event you want to review or edit.

If you want to review/edit your	*At*	*Then highlight*
• Continuous glucose measurements.*	10 minute intervals	CM 10
	60 minute intervals	CM 60
	120 minute intervals	CM 120
• Blood glucose readings.*	→	BG
• Insulin events.	→	Insulin
• Meal events.	→	Meals
• Exercise events.	→	Exercise
• State of health.	→	State of Health
• Miscellaneous events.	→	Generic
• Alarms history.*	→	Alarm history
• All events.	→	User Events

(* = Cannot be edited)

c. Use the RIGHT Option button (Select) to go to the highlighted report.

d. Decide what to do next.

If you want to	*Then*
• Edit the event.	Go to Step 9.
• Interpret the event.	Go to Step 8.
• Review other events.	**1.** Select the LEFT Option button (Back) to go to the Select Filter screen. **2.** Go to Step 7b.
• Stop reviewing events.	**1.** Select the LEFT Option button (Back) to go to the Select Filter screen. **2.** Select the LEFT Option button to go to the Select Report screen. **3.** Go to Step 2 to decide what to do.

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Steps	Do This
8. **Interpret your events.**	**a.** Interpret the events using the notes about each type of event in the table below:

Event	*Notes*
CM (CM 60, CM 120, and CM 10)	• Each recorded measure is displayed on one screen with its date and time. • Displays actual measures at the indicated intervals. • Does **NOT** display averaged measures. • Use the RIGHT Option button (Next) to move to the next recorded CM reading.
BG	• Each BG measure is displayed on one screen with its date and time. • All BG measures are displayed. • A check mark ✓ indicates that the measure was marked as a control. • Use the RIGHT Option button (Next) to move to the next recorded BG screen.
Insulin	Each recorded insulin event is displayed with type, dosage in units, date, and time.
Meals	Each recorded meal event is displayed with its carbohydrate value in grams, date, and time.
Exercise	Each recorded exercise event is displayed with its description, duration in hours and minutes, intensity, date, and time.
State of Health Generic Alarm History User Events	• Each recorded event is displayed with its description, date, and time. **Note:** Generic events do **NOT** include a description, just a number that represents the event.

b. Go to Step 7d.

OVER

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Steps	Do This
9. Edit the event.	**Note:** You **CANNOT** edit your glucose measurements. **a.** Press the RIGHT Option button (Edit). **b.** Use the LEFT Option button (Next) to select the item you want to change. **c.** Use the UP or DOWN Arrow button to change the selected item. **d.** Repeat this process from Step 9b until you've changed every item that you wanted to change. **Note:** If you change your mind about saving your edits, change SAVE to CANCEL. **e.** Press the RIGHT Option button to save or cancel your edits.
10. Check your work.	***Result:*** *The result will be an increased awareness of your glucose level history, glucose level patterns, and events that could affect your treatment plan.* You will have done this procedure correctly when: ❑ Your glucose targets are set correctly. ❑ You view and correctly interpret line graphs for any available period. ❑ You correctly select and view any desired statistical summary for any of the available time periods. ❑ You can review any of the available event history reports. ❑ Your events have been edited to your satisfaction.

END OF Section 12

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13 Clean Your System

Section 13

Abbott Ex. 1027 - 340/400

Section 13 – Key Terms

- Receiver
- Transmitter
- Contact Points

13 Clean Your System

Purpose To maintain the appearance of your system.

Start Do this procedure:

- Every time you change your sensor (transmitter).
- Any time the system needs cleaning.

Materials Make sure you have access to these materials before you begin:

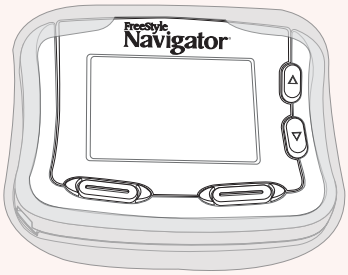
- Mild soap.
- Running water.
- A clean, soft, lint-free towel for cleaning and drying. For example, a dish towel.
- 70% isopropyl alcohol.

Helpful Information

- Your FreeStyle Navigator system needs minimal maintenance aside from cleaning and battery replacement.
- Avoid getting dust, dirt, blood, control solution, water, or any other substance in the receiver's test strip port.
- Keep your receiver in its protective carrying case when you are not using it.

  Note: Your transmitter and receiver cannot be repaired when broken.
- The transmitter should be removed from the sensor support mount and cleaned each time you remove a used sensor (every 5 days).
- Contact your healthcare team or Customer Care when you need to replace your transmitter or receiver. They will suggest a proper way to dispose of the old parts.
- Your transmitter has a life of 2 years from the date of first use. Replace the transmitter after that time period.
- Do **NOT** use adhesive remover wipes or solutions containing ether or ether-containing components for cleaning or removing residual adhesive from the transmitter or receiver. These solutions can damage the casing of the receiver and transmitter.

OVER

Steps	Do This
1. Clean your transmitter. Contact Points	**a.** Wash the transmitter with mild soap and water. **b.** Rinse the transmitter thoroughly under running water. **c.** Dry the transmitter thoroughly with a clean, soft, lint-free towel. **d.** Shake any water out of the transmitter's contact points and blot on a clean, dry, lint-free towel. **e.** Make sure that the contact points are clean, dry, and not excessively worn.
2. Clean your receiver skin. 	Before cleaning the receiver skin, remove it from the receiver. Wash the receiver skin in mild soap and water.
3. Clean your receiver. 	***Caution:*** *Do* ***NOT*** *immerse the receiver in water or in any other liquid. Avoid getting water or any other liquid in the test strip port.* Wipe the outside of your receiver with a clean, soft, lint-free towel dampened with either a mild soapy solution or 70% isopropyl alcohol.
4. Check your work.	***Result:*** *A clean transmitter, receiver and receiver skin.* You have done this procedure correctly when: ❑ All visible dust, dirt, grime, and other foreign substances have been removed. ❑ The transmitter is thoroughly dry, including the contact points.

END OF Section 13

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14 Link and Unlink Your Transmitter and Receiver

Section 14

Abbott Ex. 1027 - 344/400

Section 14 – Key Terms

- BG Mode
- CM Mode
- Link/Unlink
- Receiver
- Transmitter

Abbott Ex. 1027 - 345/400

14 Link and Unlink Your Transmitter and Receiver

Purpose To enable secure communication between your transmitter and your receiver.

Start Do this procedure:

- When you replace either your transmitter or your receiver.

Materials Gather these materials before you begin:

- Your receiver.
- Your transmitter.

Note: Your system may need fresh batteries if it cannot establish communication.

Helpful Information

Important: *You will **NOT** receive continuous glucose data while the transmitter and receiver are unlinked and all alarms associated with the Continuous Monitoring mode will be turned off.*

- You **MUST** unlink your receiver from your old transmitter and link your receiver to your new transmitter whenever you replace your transmitter.
- Once the transmitter and receiver are linked, they don't have to be re-linked or unlinked unless you want to link the receiver to a new transmitter. If you attempt to link your receiver to a new transmitter, you must replace the current sensor with a new sensor.
- You can still perform blood glucose measurements in the blood glucose mode while the transmitter and receiver are unlinked.
- Link is **NOT** the same as Reconnect. Typically, when you receive the system kit, your receiver and transmitter are already linked – your receiver knows which transmitter it is paired with. The receiver will then accept data only from that transmitter. Once your receiver and transmitter are linked, you do not need to link them again unless you have had to unlink them (if changing transmitter). "Reconnect" (see Section 9 Step 2) establishes connection if your receiver and transmitter have been temporarily moved beyond the normal range of communication (10 feet).

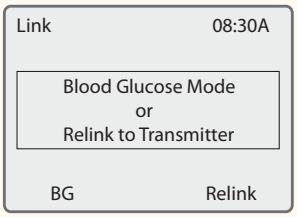
OVER

Steps	Do This

1. **Decide what you want to do.**

If you want to	*Then go to Step*
• Unlink your receiver from your transmitter.	**2**
• Link your receiver to your transmitter.	**3**
• Check your work.	**4**

2. **Unlink your receiver from your transmitter.**



a. Press the RIGHT Option button twice to display the Main menu.

b. Use the UP or DOWN Arrow button to highlight System.

c. Press the RIGHT Option button (Select) to display the System menu.

d. Use the UP or DOWN Arrow button to highlight Link.

e. Press the RIGHT Option button (Select) to display the Link screen.

f. Press the LEFT Option button (Unlink) to unlink your transmitter from your receiver.

Note: Unlinking your receiver from your transmitter will terminate your sensor. If you proceed, you will need to insert a new sensor after linking to your new transmitter. A warning screen is displayed if you have a sensor in progress. Press the button labeled "Yes" to continue unlinking.

g. Press the LEFT Option key (BG) to operate your system in the Blood Glucose mode. By choosing this option, you have shut off the Continuous Monitoring mode.

Note: You can now use your receiver to perform blood glucose measurements (See Section 7).

h. Go to Step 1 to decide what to do next.

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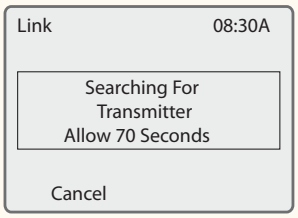
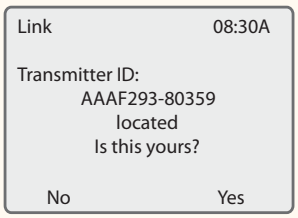
Steps

Do This

3. Link your receiver to your transmitter.





a. Place the receiver within 10 feet of the transmitter.
b. Press the RIGHT Option button twice to display the Main menu.
c. Use the UP or DOWN Arrow button to highlight System.
d. Press the RIGHT Option button (Select) to display the System menu.
e. Use the UP or DOWN Arrow button to highlight Link.
f. Wait while the receiver searches for the transmitter.

Note: It may take the receiver up to 70 seconds to find the transmitter.

Result: *The receiver displays the transmitter's ID number.*

Verify that the ID number displayed on the screen is the same as the ID number on the bottom of your transmitter.

If the ID numbers	*And this is your*	*Then*
• Are the same.	→	**1.** Press the RIGHT Option button (Yes). ***Result:*** *The Main menu is displayed.* **2.** Go to Step 4.
• Are **NOT** the same.	1st attempt	Press the Left Option button (No). The receiver will continue to search for another transmitter in the vicinity.
	2nd attempt	Call Customer Care.

Caution: *If you accept an incorrect transmitter ID when linking your Transmitter and Receiver, your glucose readings will be incorrect.*

4. Check your work.

Result: *A linked or unlinked transmitter and receiver. You have done this procedure correctly when:*

- ❑ Your system is linked when you wanted it linked.
- ❑ Your system is unlinked when you wanted it unlinked.
- ❑ You called Customer Care after your 2nd attempt to link failed.
- ❑ The ID number of the transmitter displayed by the receiver (under the Transmitter Status menu item) matches the ID on the transmitter label.

END OF Section 14

15 Reset User Settings

Section 15

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15 Reset User Settings

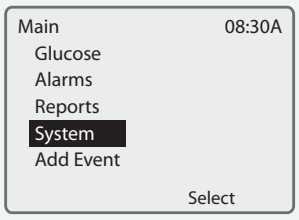
Purpose To reset the user settings to the default values.

Start Do this procedure anytime you feel a need to return your settings to the factory defaults.

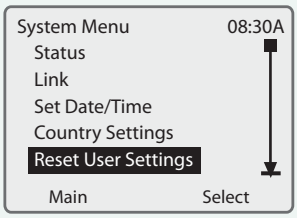
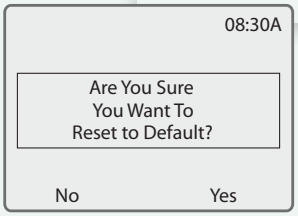
Materials Your FreeStyle Navigator Receiver.

Helpful Information

- If you don't press any button within 12 seconds, the receiver screen will go blank and the last change will be lost if you haven't pressed the Select button.
- Be careful to avoid making unintentional changes to the system settings and configuration.
- Resetting user settings resets the following items to their default. **Note:** The units of glucose cannot be changed. [*The default values are shown in brackets*]:
  - High Glucose Target. *[180 mg/dL (10 mmol/L)]*
  - Low Glucose Target. *[80 mg/dL (4.4 mmol/L)]*
  - Alarm Settings: *[Med Beep]*
    - On/Off
    - Low beep
    - Medium beep
    - High beep
    - Short vibe
    - Medium vibe
    - Long vibe
    - Alarm Thresholds
  - Country Settings: *[Local settings]*
    - Date format
    - Time format
    - Language
    - Decimal format
  - Displays for the items in the Add Event menu:
    - Insulin type *[Rapid]*
    - Insulin dose *[1 unit]*
    - Exercise type *[Walking]*
    - Exercise duration *[30 min.]*
    - Exercise intensity *[Medium]*
    - State of Health *[Normal]*
    - Generic Event *[1]*
  - Strip Cal code. *[18]*
  - Sensor Code. *[109]*
  - Low Glucose Alarm. *[65 mg/dL (3.6 mmol/L)]*
  - High Glucose Alarm. *[300 mg/dL (16.7 mmol/L)]*

Steps	Do This
1. Access the System menu from the Main menu. 	**a.** Press the UP or DOWN Arrow button to highlight System. **b.** Press the RIGHT Option button (Select) to go to the System Menu screen.

OVER

Steps	Do This
2. Access the Reset User Settings screen. 	**a.** Press the UP or DOWN Arrow button to highlight Reset User Settings. **b.** Press the RIGHT Option button (Select) to go to the Reset User Settings Screen.
3. Reset your settings. 	Confirm what you want to do: *If you want to* / *Then* • Return your system to its default settings. — Press the RIGHT Option button (Yes). **Note**: You will lose your personal settings. • Change your mind. — Press the LEFT Option button (No). **Note:** Your personal settings will be retained. ***Caution:*** *You should never reset your user settings when you are wearing a sensor. This will reset parameters that may affect your system performance.*
4. Check your work.	***Result:*** *Your receiver with the settings you want.* You have done this procedure correctly when the receiver's settings match your desired settings: ❑ Default settings OR, ❑ Your personal settings (if you changed your mind).

END OF Section 15

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16 Change Country Settings

Section 16

Section 16 – Key Terms

- LEFT/RIGHT Option Buttons
- Receiver
- System Menu
- UP/DOWN Arrow Buttons

Abbott Ex. 1027 - 355/400

16 Change Country Settings

Purpose To set the date and time formats, the language, and the decimal format.

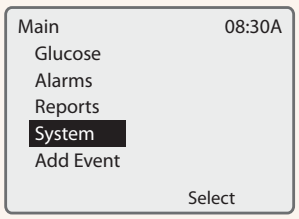
Start Do this procedure when your requirements differ from the country setting currently being used by the system.

Materials Gather these materials before you begin:

- Your requirements for displaying date, time format and the other items mentioned in the purpose statement.
- Your FreeStyle Navigator Receiver.

Helpful Information

- Check with your healthcare team if you have any questions about your requirements.
- If you don't press any button within 12 seconds the receiver screen will go blank and the last change will be lost if you haven't pressed the RIGHT Option button (Select).

Steps	Do This
1. Access the System menu from the Main menu 	**a.** Press the UP or DOWN Arrow button to highlight System. **b.** Press the RIGHT Option button (Select) to go to the Select System screen.

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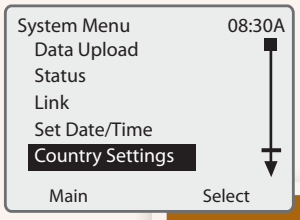
Steps	Do This

2. **Access the Country Settings menu.**



a. Press the UP or DOWN Arrow button to highlight Country Settings.

b. Press the RIGHT Option button (Select) to go to the Country Settings screen.

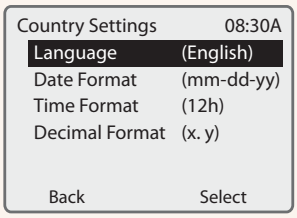
c. Decide what you want to do:

If you want to change how this is displayed	*Then go to Step*
• Language.	**3**
• Date.	**4**
• Time.	**5**
• Decimals.	**6**
• None of the above. (you are done changing the country settings.)	**2d**

d. Press the LEFT Option button (Back) twice to return to the Main menu.

e. Go to Step 7 to check your work.

3. **Change the Language.**



a. Use the UP or DOWN Arrow button to highlight Language.

b. Press the RIGHT Option button (Select) to go to the Select Language screen.

c. Use the UP or DOWN Arrow button to highlight the language that you want to use.

d. Press the RIGHT Option button (Set) to accept your selection.

Result: *The Country Settings screen is displayed.*

e. Go to Step 2c to decide what to do next.

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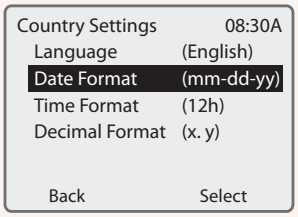
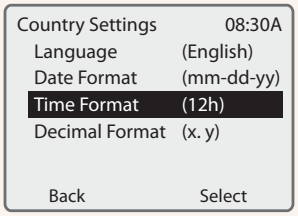
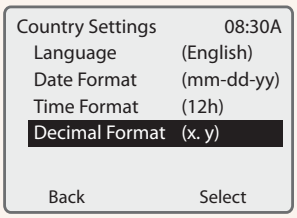
Steps	Do This
4. Change the Date Format.  	**a.** Use the UP or DOWN Arrow button to highlight Date Format. **b.** Press the RIGHT Option button (Select) to go to the Select Date Format screen. **c.** Use the UP or DOWN Arrow button to select either the mm-dd-yy or the dd-mm-yy format. **d.** Press the RIGHT Option button (Set) to accept your choice. ***Result:*** *The Country Settings screen is displayed.* **e.** Go to Step 2c to decide what to do next.
5. Change the Time Format.  	**a.** Use the UP or DOWN Arrow button to highlight Time Format. **b.** Press the RIGHT Option button (Select) to go to the Select Time Format screen. **c.** Use the UP or DOWN Arrow button to select either the 12h or the 24h format. **d.** Press the RIGHT Option button (Set) to accept your choice. ***Result:*** *The Country Settings screen is displayed.* **e.** Go to Step 2c to decide what to do next.

OVER

Steps	Do This
6. Change the Decimal Format.  	**a.** Use the UP or DOWN Arrow button to highlight Decimal Format. **b.** Press the RIGHT Option button (Select) to go to the Select Decimal Format screen. **c.** Use the UP or DOWN Arrow button to select either the x.y or the x,y format. **d.** Press the RIGHT Option button (Set) to accept your choice. ***Result:*** *The Country Settings screen is displayed.* **e.** Go to Step 2c to decide what to do next.
7. Check your work.	***Result:*** *A display that presents information in the format that you prefer.* You have done this procedure correctly when you are satisfied with the format the system uses to display information.

END OF Section 16

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17 Appendix A: Site Maintenance

Appendix A

Section 17 – Appendix A

- Adhesive Enhancers
- Antiseptics
- Dressings
- Site Rotation
- Skin Barriers

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17 Appendix A: Site Maintenance

Introduction

Careful site selection, preparation, and maintenance can help to lower the risk of infection and improve sensor adhesion. In addition to site selection, a number of helpful products are available.

Site Selection

Site rotation helps prevent discomfort, irritation, bruising, skin rashes, and sensitivity to adhesives. It is important for you to rotate across several sites and to insert sensors only in the abdomen or in the back of the upper arm. ***ALWAYS*** change the insertion site each time a new sensor is used.

Rotating the sites in a predictable pattern may help you remember to rotate them evenly. For example, you may want to start in the upper-right corner of your abdomen, and then move one inch to the left when you insert a new sensor, continuing in a circular direction. Or, you may want to start on the right arm at a high position, move to a low position on the right arm, then repeat on the left arm.

Helpful products

Choose from the list of products below as needed.

- Antiseptics – If you tend to develop infections at the sensor insertion site, consider prepping the skin with an antiseptic. Ask your healthcare team to recommend which antiseptic is best for you.
- Dressings – If you are having trouble with the sensor support mount sticking to your skin, consider applying a bandage over the transmitter. A variety of such bandages are available at your local pharmacy. Ask your healthcare team to recommend which type of bandage is best for you.
- Adhesive enhancers – If you're having trouble getting the sensor support mount to stick to your skin, you may want to try an adhesive enhancer. Adhesive enhancers help the adhesive pad on the sensor support mount stick to your skin. After applying this type of product, be sure that the sensor insertion site is thoroughly dry before placing the sensor support mount on your skin. Ask your healthcare team to recommend which adhesive enhancer is best for you.
- Skin barriers – If you experience sensitivity to adhesives, there are products that may help prevent irritation or sensitivity by placing a barrier between your skin and the sensor support mount's adhesive pad. These products may also help the adhesive stick better. Be sure to allow the skin to dry thoroughly before inserting the sensor or applying another tape or dressing. Ask your healthcare team to recommend which skin barrier product is best for you.

END OF Section 17

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18 Appendix B: Specifications

Appendix B

Section 18 – Appendix B

- Calibration
- Hematocrit
- Interstitial Fluid
- Receiver
- Transmitter

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18 Appendix B: Specifications

System Specifications

Your FreeStyle Navigator system specifications are listed in the following table:

Operating Temperature	40° F to 104° F (4° C to 40° C).
Storage Temperature	Store the transmitter and receiver between 14° F (-10° C) and 113° F (45° C). Store the test strips and sensor delivery units between 37° F (3° C) and 86° F (30° C). Control solution should be stored between 50° F (10° C) and 86° F (30° C).
Operating Humidity (Receiver)	5% to 90% (non-condensing).
Operating and Storage Altitude	Sea level to 10,000 feet (3,048 meters).
Operating Pressure	14.7 psia (sea level) to 10.1 psia (10,000 feet).
Sensor Life	Up to 5 days.
Sensor Operating Skin Surface Temperature	77° F (25° C) to 104° F (40° C).
Glucose Result Range	20 to 500 mg/dL (1.1 to 27.8 mmol/L).
Glucose Assay Method (for CM mode)	Amperometric electrochemical sensor using WIRED ENZYME™ technology. Continuous subcutaneous measurement of glucose in interstitial fluid by a sensor inserted approximately 5mm under the skin.
Power Source	Transmitter: One silver oxide 357 HC battery (small coin cell battery), replaceable (battery life is ~ 30 days). Receiver: Two AAA alkaline batteries, replaceable (battery life is ~ 60 days). We recommend Energizer® MAX®, Energizer® e2® Titanium®, and Energizer® Industrial batteries. Other batteries may not provide expected battery life.
Transmitter Size	Height: 2.05 in. (5.2 cm). Width: 1.23 in. (3.1 cm). Depth: 0.43 in. (1.1 cm).
Transmitter Weight	0.48 oz. (13.61 grams) – including battery.
Transmitter Battery Life	Up to 30 days.
Wearing Transmitter Under Water	Up to 1 meter under water for no more than 30 minutes.

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18 Appendix B: Specifications *(con't)*

Receiver Size	Height: 2.5 in. (6.3 cm). Width: 3.24 in. (8.2 cm). Depth: 0.88 in. (2.2 cm).
Receiver Weight	3.5 oz. (99.2 grams) – including batteries.
Receiver Battery Life	Up to 60 days.
Automatic Shutoff	Built-in blood glucose meter: 2 minutes after last user action. Receiver: 12 seconds after last user action.
Receiver Memory	• 60 days of normal use including continuous glucose readings (stored every 10 minutes) and daily blood glucose readings. • Date/time will be remembered for 5 minutes after receiver battery removal.
Calibration	Plasma equivalent.
Calibration Time	• 1st calibration: Must be performed at approximately 10 hours after a new sensor has been inserted. The first calibration can be performed after the 10 hours. Continuous glucose readings will NOT be reported until the 1st calibration is performed successfully. • 2nd calibration: Must be performed between 2 and 4 hours after the 1st calibration or continuous glucose will not be reported. The 2nd calibration can be performed after 4 hours; continuous glucose reporting will resume after completing the 2nd calibration successfully. • 3rd calibration: Must be performed between 12 and 20 hours after the 2nd calibration or continuous glucose will not be reported. The 3rd calibration can be performed after 20 hours; continuous glucose reporting will resume after completing the 3rd calibration successfully. • 4th calibration: Must be performed between 48 and 56 hours after the third calibration or continuous glucose will not be reported. The fourth calibration can be performed after 56 hours; continuous glucose reporting will resume after completing the 4th calibration successfully.
Blood Glucose Test Time (for BG mode)	Average of 7 seconds.
Blood Glucose Assay Method (for BG mode)	Coulometric electrochemical sensor.
Blood Sample Type (for BG mode)	Whole blood, capillary.
Hematocrit (for BG mode)	15% to 65%.

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18 Appendix B: Specifications *(con't)*

Performance Characteristics

Note: Please consult your healthcare team on how to use the information in this section.

Performance of the FreeStyle Navigator® Continuous Glucose Monitoring System was evaluated in a controlled clinical study. The study was conducted in 3 centers and included a total of 58 subjects with diabetes. Each subject wore two FreeStyle Navigator Sensors over a 5-day period. The subjects wore one sensor on the back of the upper arm and one on their abdomen. The FreeStyle Navigator system was calibrated with capillary fingerstick measurements using the built-in FreeStyle Blood Glucose Meter at approximately 10, 12, 24 and 72 hours after insertion of the sensor.All measurements were performed by a trained clinic study staff or the subject.

During the study, subjects came to the clinical center for frequent glucose samples measured once every 15 minutes on the YSI (Yellow Springs Instrument) STAT Plus™ Glucose Analyzer. YSI measurements were performed in duplicate on venous whole blood and the FreeStyle measurements were performed in duplicate on capillary blood from the finger. All YSI whole blood measurements were adjusted by applying a +12% correction factor (based on a normal hematocrit value of 45%).

Users and healthcare providers should consider that performance in this study might be idealized. Participants enrolled in the clinical study and certain conditions of the study tend to result in above average glucose control. This, in turn, may result in the appearance that the FreeStyle Navigator Continuous Glucose Monitoring System agrees with blood glucose levels better than it does under typical conditions. Monitors that measure glucose in interstitial fluid often show better agreement to blood glucose levels when glucose levels are not changing rapidly or when glucose levels are not extremely low or high. The following are some examples of why performance of the FreeStyle Navigator Continuous Glucose Monitoring System may be idealized.

- Subjects saw, on average, 15 fingerstick results per day in the clinic and 8 fingerstick results per day at home. This enables subjects to control their glucose levels better.
- While subjects participated in the clinic portion of the study, they were more limited in their activities than someone at home. They were also provided with all their meals. Subjects who are more active, or with poor eating habits, may create more challenging conditions for the FreeStyle Navigator Continuous Glucose Monitoring System.
- The built-in FreeStyle glucose meters used in the study were well maintained. Because the built-in FreeStyle meter is used to calibrate the FreeStyle Navigator Continuous Glucose Monitoring System, performance may be poorer if the system is not well maintained. It is important to carry out quality-control checks on the system and code the system according to the manufacturer's instructions to optimize performance of the FreeStyle Navigator Continuous Glucose Monitoring System.

OVER

18 Appendix B: Specifications *(con't)*

Accuracy

Table 1 below shows the distribution of all the data from the In-Clinic study on the Clarke Error Grid. Accuracy was assessed by comparing the differences between the FreeStyle Navigator system and the YSI laboratory reference. The Clarke Error Grid Analysis evaluates the clinical relevance of the differences by dividing a correlation plot (Figure 1) into five zones as described in Table 1. The YSI results and the corresponding glucose results from the FreeStyle Navigator system together (called a 'data pair' or 'matched data points') determine what zone of the error grid the results fall into. Table 1 also shows that glucose data measured by FreeStyle Navigator system on the arm and on the abdomen have similar distribution on the error grid. This demonstrates that there is no difference in the performance of the system when worn on the abdomen or on the back of the upper arm.

Table 1. Clarke Error Grid Analysis. Continuous glucose results from FreeStyle Navigator System (mg/dL) vs. the YSI (mg/dL)

Zone in the Clarke Error Grid	N (pairs of data)	Percentage in the different zones (%)	Sensor Insertion Site	
			Abdomen %	Arm %
A	16627	81.7	81.5	81.8
B	3398	16.7	16.8	16.6
C	19	0.1	0.1	0.1
D	316	1.6	1.6	1.5
E	2	0.0	0.0	0.0
Total	20362	There is no difference between the performance of the system on the arm and the performance of the system on the abdomen.		

Error Grid Explanation

A – Clinically accurate; would lead to correct and safe treatment

B – Benign; would lead to benign decisions or no treatment decisions

C – Overcorrection; would lead to over-correction of normal glucose levels

D – Failure to detect; would lead to failure to detect and treat high or low glucose levels

E – Erroneous readings; would lead to erroneous treatment decisions

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18 Appendix B: Specifications *(con't)*

Table 2 is a summary of the statistics that describe how well data from the FreeStyle Navigator system correlates to the results from the reference method. Glucose results from the FreeStyle Navigator system and the corresponding results from the YSI (a total 20362 pairs of data points) in the In-Clinic study were used to determine the correlation.

Figure 1.

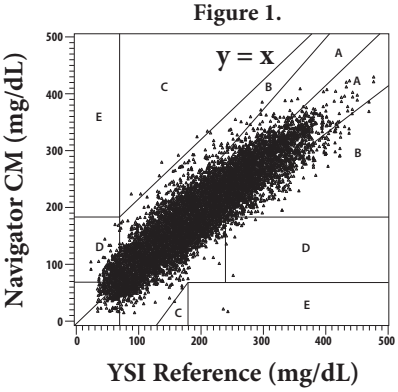

Table 2. Regression Analysis. FreeStyle Navigator System (mg/dL) vs the YSI (mg/dL)

Slope	0.92
Intercept	14.3 mg/dL
Correlation Coefficient (r)	0.93
N	20362
Range	25 – 533 mg/dL
Overall mean bias	+0.8 mg/dL

Table 3a displays the distribution of all the data from the In-Clinic study on the Clarke Error Grid. It breaks the data set into smaller groups based on the glucose value reported by the YSI. For each of these smaller groups, the table shows what percentage of data fall into different zones of the grid.

Table 3a. Accuracy performance at different glucose levels using the Clarke Error Grid Analysis

Reference Glucose Level (mg/dL)	Number of Paired Readings	A and B (%)	A (%)	B (%)	C (%)	D (%)	E (%)
20-40	22	54.5	54.5	N/A*	N/A*	45.5	0.0
41-80	1295	77.7	55.2	22.5	0.0	22.3	0.0
81-120	3820	99.9	69.5	30.4	0.1	N/A*	N/A*
121-240	11430	99.9	85.4	14.4	0.1	N/A*	0.0
241+	3795	99.5	91.7	7.8	0.0	0.4	0.1
Overall	**20362**	98.3	**81.7**	**16.7**	**0.1**	**1.6**	**0.0**

*N/A means that the Clarke Error Grid does not consider the possibility of these zones in that concentration range.

Table 3b displays the same data as in table 3a on the Continuous Glucose-Error Grid. This is a modified error grid that is designed to evaluate the clinical accuracy of continuous glucose monitoring systems based on both glucose data points in time and the rate of change of glucose.

Table 3b. Accuracy performance at different glucose levels using the Continuous Glucose-Error Grid Analysis

Zone	YSI ≤ 70 mg/dL		70 mg/dL < YSI ≤180 mg/dL		YSI > 180 mg/dL		All	
	N	%	N	%	N	%	N	%
Accurate Readings	369	59.5	10407	98.9	8364	98.6	19140	97.5
Benign Errors	5	0.8	99	0.9	74	0.9	178	0.9
Erroneous Readings	246	39.7	22	0.2	41	0.5	309	1.6
ALL	620	100.0	10528	100.0	8479	100.0	19627	100.0

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Performance Relative to the Reference (YSI)

Error grid analysis (like the Clarke Error Grid Analysis and Continuous Glucose-Error Grid Analysis) is one way to evaluate the accuracy of the FreeStyle Navigator system. The accuracy can also be assessed by analyzing the difference in the glucose results from the FreeStyle Navigator system when compared to the results from the YSI. Table 4a shows an analysis of the measure of closeness of the FreeStyle Navigator system to the YSI. It breaks the data into smaller groups based on the glucose value reported by the YSI. The table reports the mean absolute difference for the data pairs in each of the smaller groups. Table 4b shows the same data at different levels of glucose and further groups them by the amount of difference from the YSI. Table 5 breaks out the overall performance relative to the YSI for the two sites of sensor insertion.

The overall median absolute relative difference for all the data pairs is **9.3%**.

Table 4a. Performance relative to YSI at different glucose levels

Glucose (mg/dL)	Performance
20-40	Mean Absolute Difference = 32.3 mg/dL
41-80	Mean Absolute Difference = 18.1 mg/dL
81-120	Mean Absolute Difference = 16.3 mg/dL
121-240	Mean Absolute Relative Difference = 11.0%
>240	Mean Absolute Relative Difference = 9.5%

Table 4b. Performance relative to YSI at different levels of glucose – grouped by amount of difference from the YSI

Glucose Range (mg/dL)	Number of Paired Readings	Percent Within 20% of the YSI	Percent Within 30% of the YSI	Percent Within 40% of the YSI
20-40*	22	31.8	54.5	72.7
41-80*	1295	65.9	82.0	90.7
81-120	3820	69.5	85.2	92.7
121-240	11430	85.4	95.1	98.3
>241	3795	91.7	98.8	99.9
Overall	20362	82.3	93.1	97.0

*The absolute difference from the YSI reading is measured in mg/dL if the YSI reading is 20-80 mg/dL.

Table 5. Performance relative to YSI at different insertion sites

Overall MeanAbsolute RelativeDifference	MARD by Insertion Site	
	Abdomen	Arm
12.8% (Std. Dev. = 13.6%)	13.1%	12.6%

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Performance Over the Duration of Wear

This section presents the performance data in a variety of ways to demonstrate the performance of the system over time during the entire sensor wear period. The sensor is worn on the body for up to 5 days, during which time the system has to be calibrated 4 times. Typically, the system has to be calibrated at 10, 12, 24 and 72 hours after sensor insertion. Data presented in this section demonstrates how the sensor performs as a function of time.

Sensor Stability

Tables 6a-6b show there is little difference in accuracy over the five days of sensor wear according to the Clarke Error Grid Analysis (Table 6a) and the Continuous Glucose-Error Grid Analysis (Table 6b).

Table 6a. Clarke Error Grid Analysis by day of wear

Zone	Day 1	Day 2	Day 3	Day 4	Day 5
	%	%	%	%	%
A	82.5	82.4	79.4	84.0	80.9
B	16.4	16.6	18.3	14.2	16.9
C	0.2	0.1	0.0	0.0	0.0
D	0.9	0.9	2.2	1.8	2.1
E	0.0	0.1	0.0	0.0	0.0
Overall Mean Absolute Relative Difference (%) MARD0	12.6	12.3	14.1	11.9	13.0

Table 6b. Continuous Error Grid Analysis by day of wear

Zone	Day 1	Day 2	Day 3	Day 4	Day 5
	%	%	%	%	%
Accurate Readings	97.9	97.8	97.1	97.4	97.3
Benign Errors	1.0	1.2	0.7	0.8	0.8
Erroneous Readings	1.1	1.0	2.2	1.8	1.9

Table 6c groups the difference between glucose results from the FreeStyle Navigator system and the YSI into different blocks (within 20%, within 30% and within 40% from the YSI). It shows there is little change in the difference from YSI over time, thus demonstrating sensor stability.

Table 6c. Difference from the YSI at different times after sensor insertion

Time After Insertion (hours)	Percent Readings Within 20% of the YSI*	Percent Readings Within 30% of the YSI*	Percent Readings Within 40% of the YSI*
10-12	86	92	96
12-24	82	93	97
24-72	81	92	97
72-122	82	93	97

*The absolute difference from the YSI reading is measured in mg/dL if the YSI reading is at or below 75 mg/dL.

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Stability of Sensor Calibration

FreeStyle Navigator system typically requires a calibration at 10, 12, 24 and 72 hours after insertion of the sensor. This section presents information about the performance of the system by the 4 calibration periods. The table (Table 6d) breaks each calibration period into smaller slots and summarizes the difference from YSI in each slot. The data below demonstrates that there is little change in the system performance within each period.

Table 6d. Distribution of the difference from the YSI in the different calibration windows

Calibration Period		Percent Readings Within 20%* of the YSI	Percent Readings Within 30%* of the YSI	Percent Readings Within 40%* of the YSI
Cal 1 (typically occurs 10 hrs after sensor insertion)	First Calibration Period	80	88	94
Cal 2 (typically occurs 12 hours after sensor insertion)	First Third of Second Calibration Period	83	94	98
	Second Third of Second Calibration Period	83	94	98
	Final Third of Second Calibration Period	84	95	98
Cal 3 (typically occurs 24 hours after sensor insertion)	First Third of Third Calibration Period	84	94	98
	Second Third of Third Calibration Period	80	92	97
	Final Third of Third Calibration Period	80	91	95
Cal 4 (typically occurs 72 hours after sensor insertion)	First Quarter of Final Calibration Period	86	93	96
	Second Quarter of Final Calibration Period	84	92	96
	Third Quarter of Final Calibration Period	80	93	98
	Final Quarter of Final Calibration Period	82	93	97

* The absolute difference from the YSI reading is measured in mg/dL if the YSI reading is at or below 75 mg/dL.

Sample Glucose Traces

The following figures show examples of glucose traces from the In-Clinic study. These traces are representative examples of excellent, average and poor performance of the system. These traces show an overlay of the continuous glucose readings from the FreeStyle Navigator system and the blood glucose measurements made using the laboratory YSI reference. The blood glucose measurements that were used to calibrate the system are marked with 'x' in the traces. Glucose results from the FreeStyle Navigator system are shown using circles and the glucose results from the laboratory reference (YSI) are shown using triangles. Time (hours since sensor insertion) is on the horizontal axis, and glucose value in mg/dL is on the vertical axis.

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Figure 2. Sample of a Representative 'Excellent' Glucose Trace

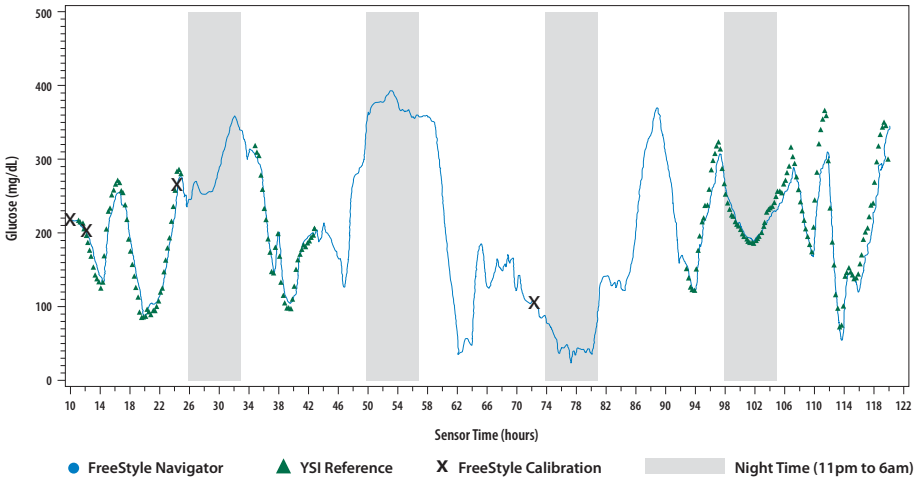


Figure 3. Sample of a Representative 'Average' Glucose Trace

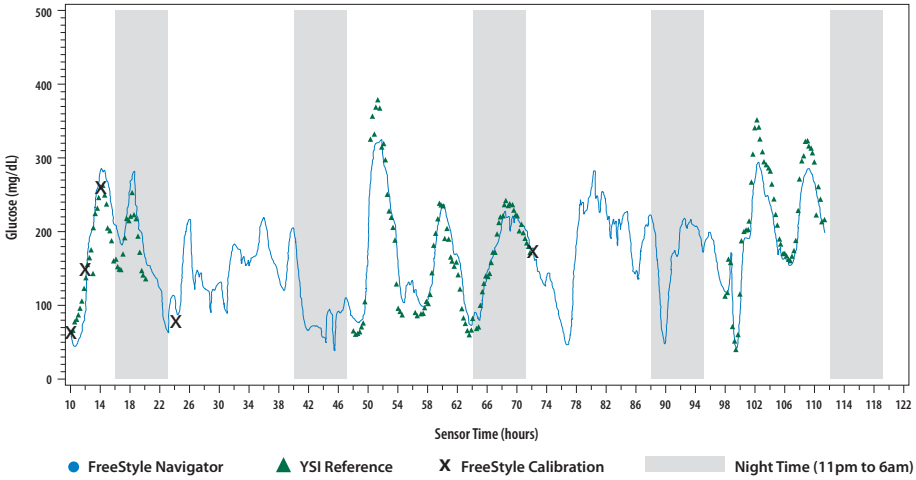
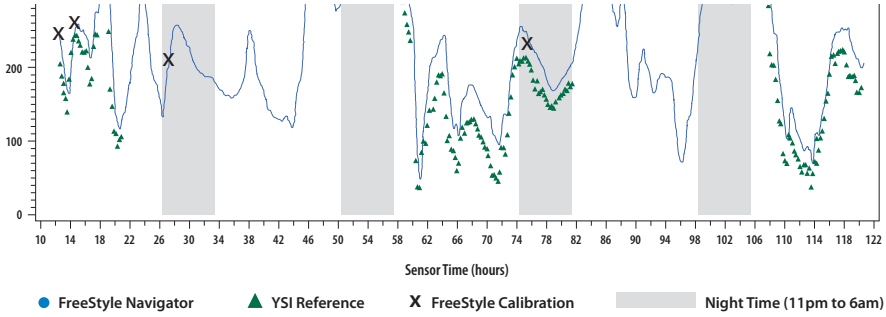


Figure 4. Sample of a Representative 'Poor' Glucose Trace



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Determination of Alarm Performance

The threshold alarm is characterized below. The projected alarm performance has not been established.

The performance of low and high glucose alarms was assessed in an in-clinic study using 58 subjects with type 1 diabetes wearing one FreeStyle Navigator sensor on the arm and one sensor on the abdomen. FreeStyle Navigator continuous data were masked from the subjects and investigators and the alarms were not turned on. During 50 hours the subjects' venous glucose was tested with a YSI 2300 Stat Plus glucose analyzer at 15 minute intervals. Arm and abdomen data were pooled in the alarm analysis. Alarm performance was evaluated in a retrospective analysis of the study data. As alarm performance was developed retrospectively, your results may vary from those reported below.

Definitions:

Hypoglycemic event – two or more successive YSI measurements below the alarm threshold or one YSI measurement 6 mg/dL below the alarm threshold.

Hyperglycemic event – two or more successive YSI measurements above the alarm threshold or one YSI measurement 6% above the alarm threshold.

True Threshold Alarm – a threshold alarm that occurred ± 30 minutes from the start of a hypoglycemic or hyperglycemic event

True Alarm Rate – the percentage of time the glucose level was beyond the threshold and an alarm was activated

$$\frac{\textit{Events Detected by True Threshold Alarms}}{\textit{Total Events}} \textit{ X 100}$$

Missed Alarm Rate – the percentage of time the glucose level was beyond the threshold and an alarm was not activated

$$\frac{\textit{Events Not Detected by True Threshold Alarms}}{\textit{Total Events}} \textit{ X 100}$$

False Threshold Alarm – a threshold alarm that occurred when a YSI measurement within ± 30 minutes was not beyond the threshold setting

False Alarm Rate – the percentage of time an alarm occurred when glucose level was not beyond the threshold setting

$$\frac{\textit{False Threshold Alarms}}{\textit{Total Threshold Alarms}} \textit{ X 100}$$

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Detection of Low Glucose

See Table 7 below for detection of low glucose. As an example, when the threshold alarm was set at 70 mg/dL (during the day), 56 % of the low glucose events were detected by FreeStyle Navigator.

Table 7. Low Glucose Detection

	DAY			NIGHT		
Low Alarm Setting (mg/dL)	**Day True Alarms***	**Day Missed Alarms****	**Day False Alarms*****	**Night True Alarms***	**Night Missed Alarms****	**Night False Alarms*****
	% (n/N†)	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
65	46 (56/121)	54 (65/121)	19 (18/95)	80 (12/15)	20 (3/15)	41 (11/27)
70	56 (98/176)	44 (78/176)	16 (21/132)	79 (19/24)	21 (5/24)	40 (14/35)
75	59 (130/219)	41 (89/219)	9 (15/161)	72 (23/32)	28 (9/32)	37 (14/38)
85	61 (189/308)	39 (119/308)	7 (17/228)	65 (22/34)	35 (12/34)	33 (14/43)

* True Alarms are the percentage of time the glucose level was below the threshold and an alarm was activated.
** Missed Alarms are the percentage of time the glucose level was below the threshold and an alarm was not activated.
*** False Alarms are the percentage of time an alarm occurred but the glucose level was not below the threshold setting.
†n/N is the (n)umber of observations divided by the total (N)umber.

Detection of High Glucose

See Table 8 for detection of high glucose. As an example, when the threshold alarm was set at 240 mg/dL (during the day), 78 % of the high glucose events were detected by FreeStyle Navigator.

Table 8. High Glucose Detection

	DAY			NIGHT		
High Alarm Setting (mg/dL	**Day True Alarms***	**Day Missed Alarms****	**Day False Alarms***	**Night True Alarms****	**Night Missed Alarms*****	**Night False Alarms*****
	% (n/N†)	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
180	89 (561/630)	11 (69/630)	11 (68/628)	69 (29/42)	31 (13/42)	7 (3/44)
240	78 (295/376)	22 (81/376)	12 (47/393)	41 (12/29)	59 (17/29)	25 (7/28)
270	70 (193/274)	30 (81/274)	12 (32/265)	21 (3/14)	79 (11/14)	36 (5/14)
300	61 (117/192)	39 (75/192)	12 (20/161)	12 (1/8)	88 (7/8)	33 (1/3)

* True Alarms are the percentage of time the glucose level was above the threshold and an alarm was activated.
** Missed Alarms are the percentage of time the glucose level was above the threshold and an alarm was not activated.
*** False Alarms are the percentage of time an alarm occurred but the glucose level was not above the threshold setting.
†n/N is the (n)umber of observations divided by the total (N)umber.

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Measuring Glucose in Interstitial Fluid

FreeStyle Navigator system measures glucose in the interstitial fluid (ISF) by means of a sensor that is inserted about 5 mm under the skin. Interstitial fluid is the fluid between the body's cells. Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose measurements. Differences in glucose measurement between interstitial fluid and your finger may be observed during times of rapid change in blood glucose, e.g. after eating, dosing insulin, or exercising. Movement of nutrients, oxygen and glucose from the blood into the cells happen across the ISF.

Therefore, if the glucose in the bloodstream rises (e.g. during meals), that rise is not seen in the ISF until later. Similarly, if glucose levels in the ISF drop (for example during exercise, the cells consume glucose rapidly) that drop is not seen in the bloodstream until later.

On average, glucose levels in the ISF lag the glucose levels in capillary blood by 14 minutes. This is a physiological phenomenon that can vary from one person to another.

Precision

Data from two sensors inserted at different insertion sites was used to calculate the between sensor reproducibility. Based on 312953 pairs of data sets, the average between sensor reproducibility was 10%.

Sensor Insertion, Calibration and Sensor Wear

Home Use Study: Sensor insertion, calibration and sensor wear were evaluated in a Home Use Study where 137 participants used the product on their own in a home environment. The participants wore 8 sensors during the study period of 40 days. They wore the sensors either on the arm or abdomen. During the first 20 days of the study, continuous glucose results were not visible to the participants. During the following 20 days, participants had access to the glucose measurements. In addition to required calibration tests, the participants performed 4 finger stick measurements a day using the built-in FreeStyle meter. The following information is based on the findings from this study.

When used as directed, 96.8% of the total sensor insertions were successful. 92.6% of the sensors were calibrated successfully and began producing glucose results within 12 hours after sensor insertion. The median time for a successful first calibration was 10.1 hours. The median duration of wear of calibrated sensors was 120 hours. 83% of sensor wears lasted at least 108.3 hours. The median wear time for sensors inserted on the arm was 0.4 hours longer than for sensors inserted on the abdomen.

Skin Interaction

Based on the examination of 124 study participants at a 21-day follow up, the following incidence of skin issues were observed in 304 site exams.
Moderate to severe itching – 1.6% of the time
Moderate bruising – 0.3% of the time
Moderate erythema – 1.0% of the time
Moderate pain – 0.3% of the time
Rate of mild incidences for any individual category of skin issues above including edema, rash, induration, bleeding and others was less than 5%.

END OF Section 18

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19 Appendix C: FCC Compliance Information

Appendix C

19 Appendix C: FCC Compliance Information

Electromagnetic Interference and Your FreeStyle Navigator® Continuous Glucose Monitoring System

Important Information about Electromagnetic Interference

The FreeStyle Navigator® Transmitter and Receiver communicate using radio frequency waves. The FreeStyle Navigator system has been designed to be reliable and immune to common electromagnetic interference so that it is not influenced by such interference. However, under rare circumstances, if you happen to be in an environment of strong electromagnetic radiation, there may be some interference. Examples of possible sources of interference are: store doorways, store checkout counters, metal detectors like those used in airport security systems or electronic surveillance devices, and radio transmitting devices such as cellular phones, 2-way radio and cordless phones.

Interference may occur in the vicinity of equipment marked with symbol.

If such interference happens, it tends to be temporary. This makes it unlikely that you will experience any noticeable difference in the performance of the system. In the event of electromagnetic interference, you may experience loss of communication between the receiver and transmitter, you may see unrecognizable characters on the receiver display screen, or you may not see continuous glucose results. The system is designed to alert you of these conditions through audio (beep or vibrate) or visual (icons, unrecognizable characters on the screen or lack of glucose results) means.

If you observe a significant change in your continuous glucose readings that you think is erroneous, or if you feel the blood glucose measurement in the Blood Glucose mode is erroneous and you are close to an electromagnetic interference source, move away from the source of interference and check to see if the condition fades away. Always maintain a minimum separation distance from potential sources of electromagnetic interference (see Tables 3 and 4 in this section for guidance).

Depending on your distance from the source of interference, the strength of the interfering signal, and the relative orientation between you and the source of interference, you may or may not see or experience these conditions. ***When in doubt, move away from any likely source of electromagnetic interference***. If you experience consistent interference from any source, contact the manufacturer or dealer for that source and have a trained technician assess the situation. In addition, please report any consistent interference issues to Abbott Diabetes Care Customer Care.

If you have a medical appointment that includes X-ray, MRI (Magnetic resonance Imaging), CT (Computed Tomography) scan, or another type of exposure to radiation, keep your system and sensor away from the area. Before exposure to such radiation, discard any sensor you are wearing and insert a new sensor after the radiation session. The effect of these types of radiation on the performance of the system has not been evaluated.

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Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Table 1. The FreeStyle Navigator system is intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle Navigator system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The FreeStyle Navigator system uses RF Energy only for its Intended function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The FreeStyle Navigator system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Table 2. The FreeStyle Navigator system is intended for use in the electromagnetic environment specified below. The customer or user of the FreeStyle Navigator system should assure that it is used in such an environment.

Immunity test	Test Level	FreeStyle Navigator System Compliance Level	Electromagnetic Environment– Guidance
Tx/Rx Electrostatic Discharge (ESD) IEC60601-1-2	±8 kV Contact Discharge ±15 kV Air Discharge	±8 kV Contact Discharge ±15 kV Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Tx/Rx Electrostatic Discharge (ESD) EN 300 489-3	±4 kV Contact Discharge ±8 kV Air Discharge	±4 kV Contact Discharge ±8 kV Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Magnetic Field Immunity IEC 60601-1-2	3A/m @ 50Hz and 60Hz 5 min dwell time	3A/m @ 50Hz and 60Hz 5 min dwell time	Power frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial or hospital environment.
Transmitter Radiated Emissions FCC CFR 47 Part 15.231(e)	Must be below 72.9 dBuV/m @433.56MHz	67.9 dBuV/m @ 433.56MHz	

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Guidance and Manufacturer's Declaration - Electromagnetic Immunity. ***(con't)***

Transmitter Radiated Emissions for EN EN 300 220-3	Must be below 107.5 dBuV/m @433.56MHz	83.1 dBuV/m @ 433.56MHz	
Transmitter Intentional Radiation Occupied Bandwidth for FCC EN 300 220-3	Less than 1084 kHz @433.56MHz	253 kHz @ 433.56MHz	
Transmitter Unintentional Radiation CISPR 11 Class B	Less than 30 dBuV/m @ 203.48MHz	12.6 dBuV/m @ 203.48MHz	
Receiver Unintentional Radiation CISPR 11 Class B Sec 5	Below 30 dBuV/m (30-230Mhz 37dBuV/m) (230Mhz -1GHz)	21.1 dBuV/m @ 429.79MHz	
Tx/Rx Radiated Immunity IEC 60601-1-2	80Mhz-3000MHz 10V/m @ 80% 1kHz AM Modulation 108 second dwell time	80Mhz-3000MHz 10V/m @ 80% 1kHz AM Modulation 108 second dwell time	
Tx Radiated Immunity IEC 60601-1-2 EN 300 220-3	80Mhz-2500MHz 3V/m @ 80% 1kHz AM Modulation 2.874 msec dwell time	80Mhz - 2500MHz 3V/m @ 80% 1kHz AM Modulation 2.874 msec dwell time	
Tx Frequency Stability EN 300 220-3	80Mhz-2500MHz 3V/m @ 80% 1kHz AM Modulation 2.874 msec dwell time	Within 433.05-434.79MHz operating range and < 100ppm Frequency Error	
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	Not Applicable Battery Operated	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV for Differential mode ±2 kV for common mode	Not Applicable Battery Operated	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips on Power Supply input lines IEC 61000-4-11	<5% for 0.5 cycle 40% Ut* for 5 cycles 70% Ut* for 25 cycles < 5% Ut* for 5 sec	Not Applicable Battery Operated	Mains power quality should be that of a typical commericial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery pack.

* Ut is the a.c. mains voltage prior to application of the test level.

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Recommended separation distance between portable and mobile RF Communications equipment and the FreeStyle Navigator system.

Table 3. The FreeStyle Navigator system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FreeStyle Navigator system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FreeStyle Navigator system as recommended below, according to the maximum output power of the communications equipment.

Radiated maximum power of Transmitter W	Separation distance according to frequency of transmitter (m)	
	80 – 800MHz $d = 1.2\sqrt{P}$	800MHz - 3GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.20	2.30
10	3.79	7.27
100	12.00	23.00

For Transmitters rated a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800MHz the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: 1 meter = 3.28 feet.

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Guidance and Manufacturers' Declaration – Electromagnetic Immunity.

Table 4. The FreeStyle Navigator system is intended for use in the electromagnetic environment specified below. The Customer or the user of the FreeStyle Navigator system should assure that it is used in such an environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment – Guidance
Tx/Rx Radiated Immunity Test	80MHz -3000MHz 10V/m @ 89% 1kHz AM Modulation 108 second dwell Time	80MHz -3000MHz 10V/m @ 89% 1kHz AM Modulation 108 second dwell Time	Portable and mobile RF Communications equipment should be used no closer to any part of the FreeStyle Navigator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$ (m) @ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ (m) @ 800 MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measurement field strength in the location in which the FreeStyle Navigator system is used exceeds the applicable RF compliance level above the FreeStyle Navigator system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FreeStyle Navigator system.

[b] Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

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Caution: *The radio receiver and transmitter of your FreeStyle Navigator system operate on the frequency of 433.6 MHz. Primary users of this frequency band include amateur "HAM" radio transmitters. Because of the coexistence of the FreeStyle Navigator radio connection and HAM transmitters, there may be instances where the connection between your transmitter and receiver may be lost when in proximity to HAM radio equipment.*

The FreeStyle Navigator system is designed to sense and notify you about a lost connection. If your FreeStyle Navigator system loses the radio connection, increase the separation distance between yourself and the transmitter by moving away from the HAM radio. The FreeStyle Navigator radio connection should re-establish itself. You should note that HAM radio products can be fixed, mobile or portable handheld ("walkie talkie" type) units.

Classification

The transmitter and receiver are classified as follows:

- Internally-powered equipment.
- Type B equipment.
- Mode of operation for the receiver is "continuous operation".
- Mode of operation for the transmitter is "continuous operation with intermittent loading".

FCC Compliance Information

Transmitter

Model Number: PRT03831-xxx.

FCC Rules: Tested to comply with FCC Part 15, Class B, Security/Remote control Transmitter. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or locate the receiving antenna.
- Increase the separation between the equipment and transmitter.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: *Changes or modification to the device not expressly approved by Abbott Diabetes Care Inc. could void the user's authority to operate this equipment.*

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19 Appendix C: FCC Compliance Information *(con't)*

Receiver

Model Number: PRT03410-xxx.

Operating Environment: For Home or Office Use.

DECLARATION OF CONFORMITY

We, Abbott Diabetes Care Inc.

1360 South Loop Road
Alameda, California 94502
510-749-5400

Declare under our sole responsibility that the product
FreeStyle Navigator Receiver

Part Number: PRT03410-xxx

Complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or locate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: *Changes or modification to the device not expressly approved by Abbott Diabetes Care Inc. could void the user's authority to operate this equipment.*

END OF Section 19

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20 Glossary

Glossary

20 Glossary

Adhesive Enhancers	Products that can help the adhesive pad on the sensor support mount stick better to your skin
Alarms	Sounds, vibrations, or text that are used by the receiver to notify you of certain conditions.
Alarms Menu	A menu you can access from the Main menu. From the Alarms menu, you can turn an alarm on or off, set its sensitivity, and select alarm type.
Alarm Sensitivity	A setting that you can adjust to trigger the Projected Low/High Glucose alarms (early warning alarms) sooner or later. The higher the sensitivity, the sooner the alarm will sound.
Alarm Type	Refers to the sound or vibration of the alarm. Alarm types include low, medium, or high beeps and short, medium, or long vibrations.
Antiseptics	Products that you can use at the sensor insertion site if you tend to develop infections.
Backlighting	A light inside the receiver that lets you see the display screen in the dark.
Blood Glucose Mode	One of two modes in which the system functions (the other is Continuous Monitoring mode). In the Blood Glucose mode, you can perform traditional blood glucose testing manually using a FreeStyle Test Strip and a drop of blood. Although you can use the Blood Glucose mode whenever you wish, its main use is for calibrating the system.
Calibration	The system must be calibrated at approximately 10, 12, 24 and 72 hours after sensor insertion. The system is calibrated using a blood glucose measurement (performed in the Blood Glucose mode using the built-in FreeStyle Blood Glucose Meter). The receiver compares the reading it gets from the blood to the reading the sensor takes from the interstitial fluid. Based on the calibration, the receiver calculates real-time glucose readings.
Calibration BG	Allows you to add a new blood glucose measurement that is used for sensor calibration. Use this feature only under the direction of a Customer Care representative or your healthcare team. Use of this feature will discard all the earlier calibrations. The sensor life will not be reset.
Capillary Blood	Blood from the tiny blood vessels in your body (such as in the tip of your finger or alternate sites) used to measure glucose levels in the Blood Glucose mode. Capillary blood is also used for measuring glucose levels with traditional glucose meters.
CM Status	Lets you view recent error codes related to the Continuous Monitoring mode. These codes appear only when the system is not functioning properly. Use this option only under the direction of a Customer Care representative or your healthcare team.
Contact Points	Conductive points that connect the transmitter to the sensor support mount.

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Continuous Monitoring Mode	One of two modes in which the system functions (the other is Blood Glucose mode). You will use this mode most of the time. It displays the glucose level in your interstitial fluid continuously, as measured by the sensor you place just beneath your skin. Along with the glucose numbers, this mode also displays a directional glucose trend arrow.
Control Solution Test	A test done with FreeStyle Control Solution in the Blood Glucose mode using the built-in FreeStyle Blood Glucose Meter to ensure that the system is working properly in the Blood Glucose mode.
Data Loss Alarm	An alarm that tells you when you are about to lose data, or when your alarms are about to stop working. Data Loss alarms sound when the transmitter-receiver connection is broken or when the sensor has expired.
Data Upload	The act of transferring data from your FreeStyle Navigator system to a computer.
Dressings	Products that can be used as over-bandages to cover the transmitter. These can help the sensor support mount adhesive stick to your skin.
Events	Activities and observations that can affect your glucose levels that you record in your system. Reviewing events may help you to see patterns in your glucose levels and how you manage your diabetes. Once entered into the system, events may be viewed in several ways, including Event History reports or Line Graph reports.
Event History Reports	A type of report that incorporates the event information you enter (For example, histories of recent glucose results, insulin doses, carbohydrate content of meals, exercise, state of health, etc.).
Exercise Event	A record of many popular forms of exercise. You may also specify the intensity and duration of each exercise event.
FreeStyle Control Solution	A solution containing a known amount of glucose. Used to perform Control Solution tests to make sure your receiver and test strips are working properly prior to calibration or blood glucose testing.
FreeStyle Navigator® Continuous Glucose Monitoring System	Also referred to as the system, this device is designed to give people with diabetes a continuous reading of their glucose levels in real-time.
FreeStyle Test Strips	A small strip into which you place a drop of blood to perform Blood Glucose mode tests. You must use **ONLY** FreeStyle Test Strips with the system.
Generic Event	A record of any event that you or your healthcare team thinks is useful in evaluating glucose patterns. You may assign up to eight generic events to observations of your choosing.
Glucose Targets	The high and low levels that you would like your glucose to stay between. Used to make reports more meaningful. Glucose targets are separate from – and independent of – the levels you may be using for high and low glucose alarms.

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20 Glossary *(con't)*

Glucose Trend Arrows	Arrows shown on the receiver that let you know whether your glucose levels are stable, increasing, or decreasing, and how quickly they are changing.
Hematocrit	A measure of the amount of red blood cells in your body.
High Glucose Alarm	Notifies you when you go above your high glucose threshold (a number you and your healthcare team will set).
High Glucose Threshold	The level you do not want your glucose level to rise above. You and your healthcare team choose the level that is right for you, and you set in the system. The High Glucose alarm and the Projected High Glucose alarm use the high glucose threshold.
Icons	Simple graphic symbols that appear on the receiver display screen to alert you to system conditions or actions required.
Insulin Event	A record of insulin doses (injection or pump) that you enter in the system to help you evaluate current therapy. The time and date of an Insulin event are always recorded. You may also enter the type of insulin and dose amount (units).
Interstitial Fluid	The fluid in the tiny spaces between the cells in your body. The system uses this fluid to measure your glucose levels.
in vitro	The measuring of something out of the body. For example, in a test tube.
in vivo	The measuring of something in the body.
Lancet	A tiny, sharp-pointed, disposable component used with the lancing device to obtain a drop of blood for a Blood Glucose mode test.
Lancing Device	A handheld piece of equipment that is used with a lancet to obtain a drop of blood for a Blood Glucose mode test.
Lancing Device Cocking Handle	A part of the lancing device that you pull to position the lancet for pricking the test site.
Lancing Device Depth Indicator Window	A window on the lancing device that shows you the depth setting you have chosen.
Lancing Device Depth Setting	A part of the lancing device that lets you to adjust how deep the lancet pricks your skin. A higher number means a deeper penetration of the lancet.
Lancing Device Lancet Cup Holder	A part of the lancing device that holds the lancet in place when pricking your skin.
LEFT/RIGHT Option Buttons	Buttons on the bottom of the receiver face that allow you to select options shown on the display screen. The RIGHT Option Button also turns the receiver display screen on.

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20 Glossary *(con't)*

Line Graph Reports	Show continuous glucose lines (plotted at 10-minute intervals) for several different periods (2, 4, 6, 12, or 24 hours).
Link	This procedure is performed so that the receiver can be paired with a transmitter. Once linked, the receiver would know to accept information from that transmitter alone. When shipped out of the factory, the receiver and transmitter are already linked.
Low Glucose Alarm	An alarm that tells you when you go below your low glucose threshold (a number you and your healthcare team will set).
Low Glucose Threshold	The level that you do not want your glucose level to fall below. You and your healthcare team choose the level that is right for you, and you set it in the system. The Low Glucose alarm and the Projected Low Glucose alarm use the low glucose threshold.
Main Menu	Displays a list of options that allow you to perform many functions and view specific information.
Meal Event	A record of a meal and snack that you enter in the system to help you see patterns in your glucose levels. The time and date are always recorded. You may also record carbohydrate grams to help you count carbohydrates or determine insulin/carbohydrate ratios.
Multi-Day Statistics	A type of statistical report that shows a summary of glucose results in relation to your glucose targets over a specified number of days. You can choose 3, 7, 14, 21, or 28-day periods.
Progress Tones	Communicate progress, errors, and successful completion of system activities such as Blood Glucose mode testing.
Projected High Alarm	Provides an early warning when you are approaching your high glucose threshold.
Projected Low Alarm	Provides an early warning when you are approaching your low glucose threshold.
Receiver (Rx)	Also called Rx. A wireless component of the system that looks and feels much like a traditional blood glucose meter. However, unlike traditional blood glucose meters, the receiver can provide you with continuous glucose readings from the sensor. The receiver also has a built-in FreeStyle Blood Glucose Meter that works as a traditional blood glucose meter when a FreeStyle Test Strip is inserted into the test strip port. You can wear the receiver on your belt or carry it in your pocket or purse.
Receiver Display Screen	The rectangular window on the center of the receiver that displays glucose levels and other important information.
Receiver Skin	The receiver skin is an optional accessory for use with your FreeStyle Navigator Receiver.
Receiver Status	Provides you with information regarding the receiver, including serial number, software version, and remaining battery life. This information can be accessed from your System menu item in the Main menu.
Receiver Test Strip Port	The slot on the lower left edge of the receiver where you insert the FreeStyle Test Strips to calibrate the system or perform Blood Glucose mode tests.

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Reports	Information about your glucose levels shown in a way to help you and your healthcare team analyze changes in your glucose levels and your treatment plan (such as changes in insulin doses, carbohydrate intake, etc.) Several types of reports are available.
Sensor	The part of the system that you insert under your skin. Each inserted sensor is intended to remain in place and provide a continuous glucose reading for up to 5 days.
Sensor Code	A number that you will find on the sensor delivery unit packaging. This code number must be entered into the receiver after you insert a new sensor and before you complete the system calibration.
Sensor Delivery Unit	The sensor delivery unit is designed and packaged to enable safe insertion of the sensor into your skin. The sensor delivery unit has 2 parts assembled and packaged together: the sensor inserter with pre-installed sensor (which puts the tip of the sensor under your skin) and the sensor support mount (which stays on your skin to hold the sensor in place and which attaches the sensor to the transmitter).
Sensor Inserter	The sensor inserter is a cylindrical-shaped, plastic-cased device. A pre-cocked, coiled spring is connected to a stainless steel needle, used to guide the sensor for insertion. With a single push of the insertion button, the needle guides the sensor into the skin and is quickly withdrawn from the skin. The Locking Pin is designed to avoid accidental discharge of the sensor inserter. Do not remove the locking pin until the sensor support mount is adhered to the skin.
Sensor Insertion Button	With a single push of the insertion button, the needle guides the sensor into the skin and is quickly withdrawn from the skin.
Sensor Insertion Site	The place on your body where you insert a sensor, on either the abdomen or the back of the upper arm. Always change the sensor insertion site each time a new sensor is used. The sensor should be inserted at least 1 inch from the previous site.
Sensor Locking Pin	A pin on the sensor delivery unit that was designed to prevent accidental release of the sensor. This pin must be removed before the sensor can be inserted.
Sensor Release Tabs	Parts of the sensor delivery unit that release the sensor inserter from the sensor support mount.
Sensor Support Mount	The sensor support mount is designed to stay on your skin to hold the sensor in place and attach the sensor to the transmitter. The blue release tabs release the sensor inserter from the sensor support mount after the sensor is inserted into the skin.
Sharps Container	A safe place for disposal of sensor inserters and lancets.
Single-day Statistics	A type of statistical report that shows a summary of glucose results in relation to your glucose targets over a one-day period.
Site Rotation	The practice of using a different location on the body each time you insert a new sensor. The new Sensor should be inserted at least 1 inch from the previous site.
Skin Barriers	Products that can help prevent irritation or sensitivity problems at the sensor insertion site.

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State of Health Event	A record of health-related events, symptoms, and other observations that may help you see patterns in your glucose levels.
Statistical Reports	A comprehensive summary of glucose results relative to your glucose targets. You can view statistical reports for 1, 3, 7, 14, 21, or 28-day periods. Viewing this kind of information can help you see patterns in your glucose levels.
Status Information	Information about the system and how it is working, such as sensor time or battery life remaining.
System	A short name for the FreeStyle Navigator Continuous Glucose Monitoring System.
System Alarms	System messages (For example, low battery life, time for calibration).
System Menu	A menu available from the Main menu that is used to access status information and other functions.
Transmitter (Tx)	Also called Tx. A small electronic device that makes an electrical connection to the portion of the sensor that extends above the skin. The transmitter processes the very low current signals it receives from the sensor and sends the glucose data to the receiver once every minute.
Transmitter/ Receiver Connection	The wireless connection needed for the system to function. The transmitter and the receiver must be within 10 feet of each other for the connection to be valid.
Transmitter Sensor Support Mount Latch	A connector that helps secure the transmitter to the sensor support mount.
Transmitter Status	Allows you to view the transmitter serial ID number and battery life remaining.
Transmitter Tabs	Connectors that help secure the transmitter to the sensor support mount.
Unlink	The process of removing the transmitter ID from the receiver. Once unlinked, the receiver will no longer be paired with a specific transmitter. Before beginning to use the system, the receiver and transmitter have to be linked.
UP/DOWN Arrow Buttons	Buttons on the right face of the receiver that allow you to move through lists to highlight options. Also used to change numbers.

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