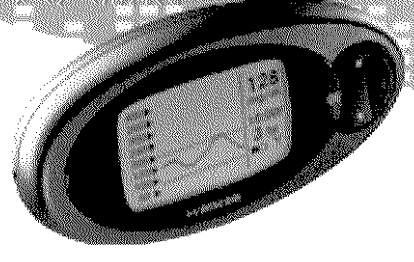
DexCom Comments on MICS/MEDS NPRM

ET Docket Number 06-135

February 27, 2008



dexcom

Meeting Objectives

- Diabetes Overview
  - Overview of DexCom™ STS® Continuous Monitors
  - Update on Seven™
  - Insulin Pump integration agreements
- Problems with proposal to reduce output power
- DexCom needs a rule change consistent with the present waiver

Everyday in the US…

- 1 in 3 children born will develop diabetes
- 4,100 people will be diagnosed
- 55 people with diabetes will go blind
- 230 amputations will be performed
- 120 will enter treatment for kidney failure

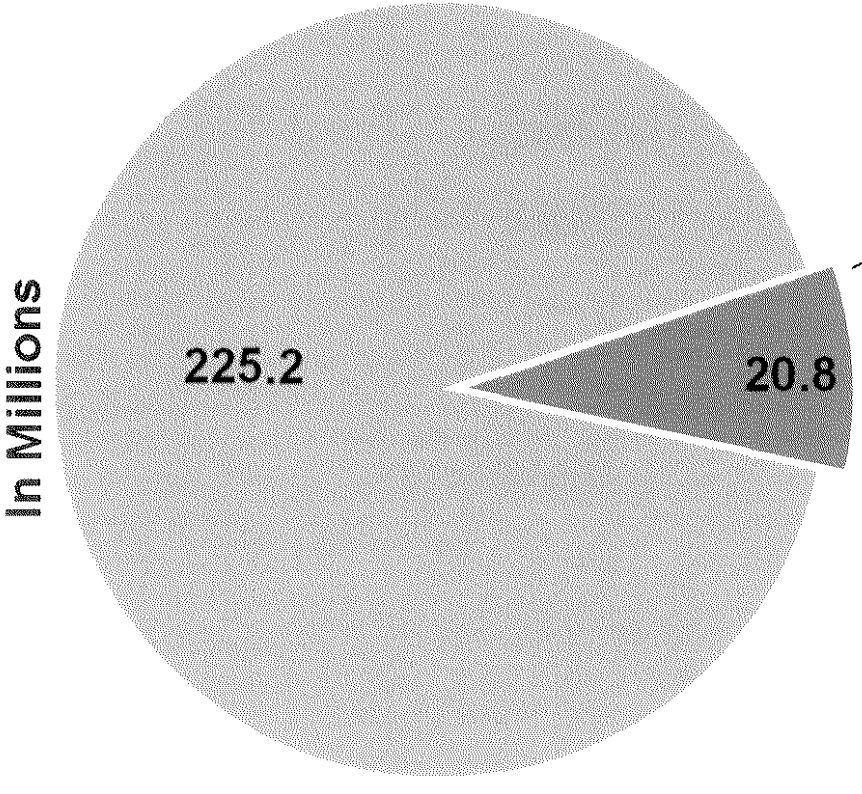
1 in 7 health care dollars is spent treating diabetes

Kleinfeld N.R. NYT, "Diabetes and Its Awful Toll Quietly Emerge as a Crisis" 1/9/2006

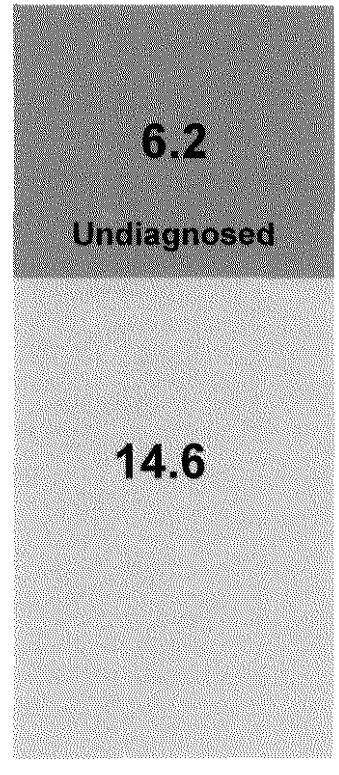
DEXCOM

Diabetes: A Global Epidemic

WW Incidence 246 M



US Incidence 20.8 M



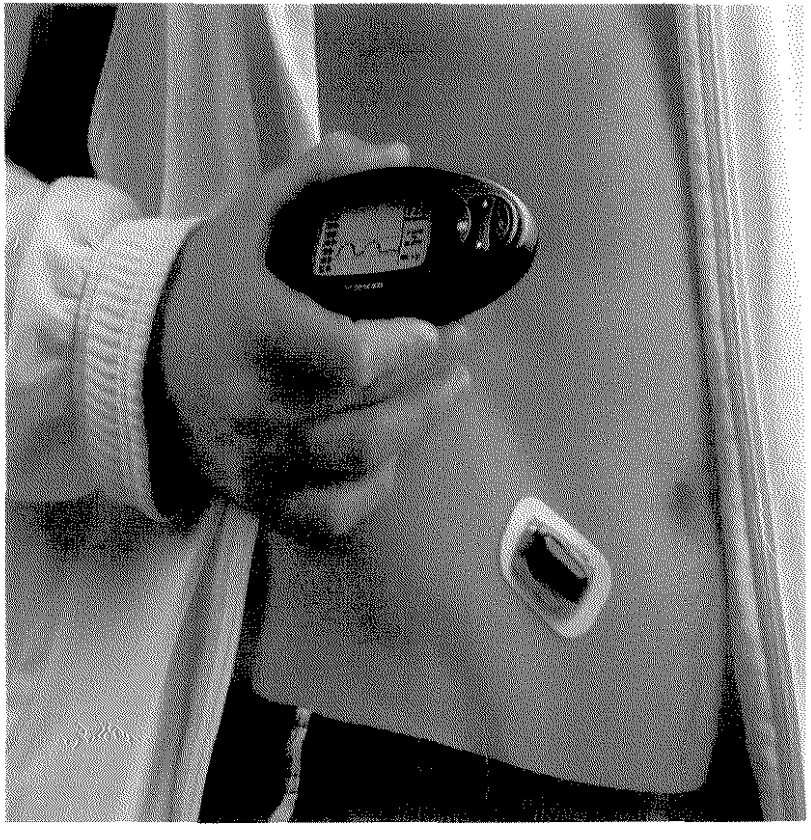
IDF estimates 380M by 2025

ADA estimates 23.9M by 2011

Source: IDF website "Facts & Figures"
ADA website "Diabetes Fact Sheet"

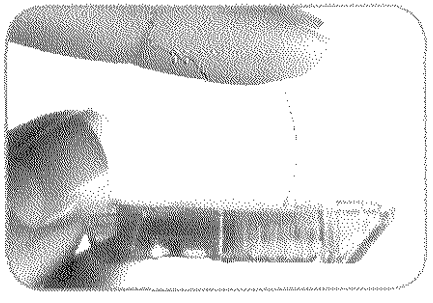
dexcom™

Take control–live uninterrupted.™



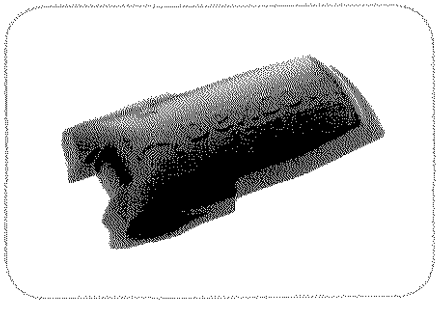
The Sensor

- Small & Comfortable
- Water Resistant
- The Only 7 day Sensor



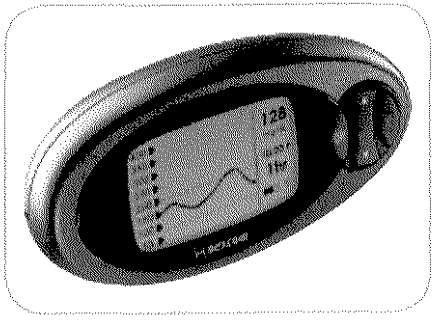
The Transmitter

- Wireless
- Unique Micro-technology



The Receiver

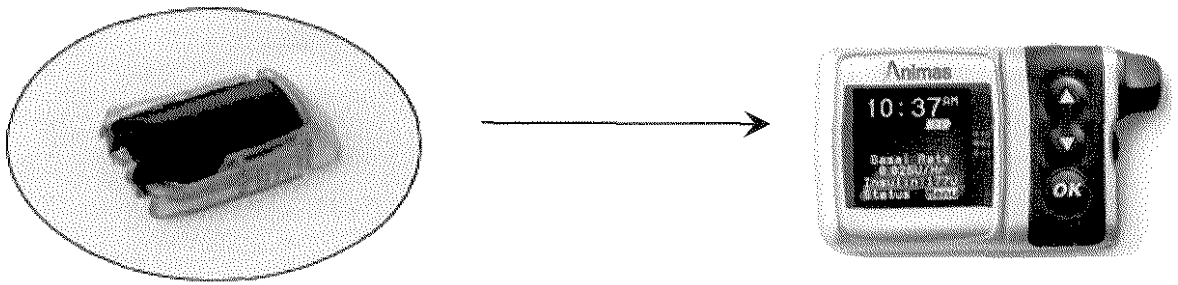
- Portable & Lightweight
- Trending Screens
- High & Low Glucose Alerts



SEVEN System Update

- Outreach efforts continue in approximately 100 largest diabetes centers in the U.S.
  - Continue to see increase in the number of new patients added in these key centers
  - Continue to invest in activities to gain acceptance of CGM as the best standard of care for diabetes management
  - DexCom is actively working with the JDRF (Juvenile Diabetes Research Foundation) on a long term clinical trial to show the benefits of Continuous Glucose Monitoring.
- The next challenge is widespread insurance reimbursement

DexCom Takes First Steps Towards a Closed Loop System



- DexCom has signed two agreements to develop integrated insulin pump-CGM systems with J&J/Animas and Insulet
  - DexCom CGM data to be displayed on Insulin Pump
  - Trended information and glucose alarms included
  - Allows for insulin dosing information and CGM data on same display, therefore, reliable communication is essential
- JDRF is strongly supporting the development of closed loop systems

dexcom

Proposal to Reduce Output Power Will Render DexCom STS Unusable by Patients

	Current MICS Design	Proposed MedRadio Design
Receiver Noise Floor	-97dBm	-97dBm
Receive Antenna Gain	-2dBi	-2dBi
Required SNR	14dB	14dB
Fade Margin	10 dB	10 dB
Excess Loss (Polarization, obstructions)	15 dB	15 dB
Body Absorbtion	4 dB	Accounted for in EIRP Test
EIRP	-20 dBm	-36 dBm
Allowable Free Space Path Loss	32 dB	20 dB
Useful Operating Range	7.5 ft	1.9 ft

- Reducing the output power of the DexCom STS transmitter would dramatically decrease the effectiveness of the system. To require patients to keep the handheld Receiver or integrated Insulin Pump less than two feet from the body worn Transmitter to ensure reliable communication is not realistic.
- Insulin Pump manufacturers require a communication distance of at least five feet.

DexCom Requests that Current Waiver Be Adopted as Rule for MICS Band

- Fixed operation on channel 1 of MICS band
- Standard MICS output power of 25uW
- Non-LBT operation with ultra low duty cycle of 0.003%

DexCom Needs a 5-year Waiver Extension

- 2+ years: DexCom Design Process. Collaborate with insulin pump partners to determine design specifics; develop new transmitter and receiver; design and conduct testing process; internal verification and validation testing; plan and conduct clinical trials on patients.
- Up to 1 year: FDA Approval Process.
- 1 year: Manufacture & market new products.