Welcome to today’s FDA/CDRH Webinar

Thank you for your patience while we register all of today’s participants

If you have not connected to the audio portion of the webinar, please do so now:

Dial: 888-459-7564
Passcode: 2398303
Why Focus on the Home?

- Faster discharges from clinical facilities
- Elderly population
- Chronic diseases
What is considered “Home”?

Any environment other than a professional healthcare facility or clinical laboratory where a device may be used.
Home Use Devices Are:

- **Disposables & Accessories**
  - Oxygen therapy related devices
  - Needles, syringes, IV catheters, tubing, foley catheters, gloves
- **Implantables**
  - Defibrillators,
  - Hip/knee implants
- **Computerized Medical Systems**
  - Infusion pumps
  - Dialysis
- **Reagents**
  - Fecal occult blood tests
  - Lyme Disease tests
- **Durable Medical Equipment**
  - Wheelchairs
  - Patient Lifts
Home Use Medical Device Initiative 2010

1. Establish guidelines for manufacturers of home use devices;

2. Develop a home use device labeling repository;

3. Partner with home health accrediting bodies to support safe use;

4. Enhance postmarket oversight; and

5. Increase public awareness and education
Three Main Considerations

- Environmental
- User
- Design
A. Environmental Considerations

- **Location**
  - Urban/suburban/rural
  - School/office/retail environments
  - Electromagnetic interference (EMI)
  - Crowded environment
  - Movement from room to room
  - Wireless signal

- **Contaminants**
  - Non-sterile environment
  - Vermin, pets, tobacco, smoke, household chemicals

- **Water Supply**
  - Type of water: ex. well water vs. distilled water
Environmental Considerations (cont.)

- Temperature
  - Fluctuations and extremes in temperature
- Dampness and humidity
  - Static
  - Mold
- Airflow
- Atmospheric pressure changes
  - Low pressures on mountains/air travel

*removed ‘childproofing’ and ‘tampering’ from final guidance*
Environmental Considerations (cont.)

• Travel and International Use
  – Electrical supply/voltage rates
  – Electrical converters
  – Back up batteries
  – Passing through security – pat down, backscatter x-ray

• Fluid Exposure
  – Fluid spills
  – Submersion

• Storage
B. User Considerations

Physical: size, mobility, coordination, flexibility, strength, stamina, dexterity

Sensory/Perceptual: vision/hearing abilities, tactile sensitivities, ambient light conditions, alarm visibility

Cognitive: literacy level, cognitive impairment

Emotional: anxiety, fear

*inappropriate use replaces childproof and tampering
C. Design Considerations

• Lock-out Mechanisms
• Maintenance
• Calibration
  – No calibration/minimal calibration
  – Step-by-step instructions
• Mechanical Strength
  – Portability
  – Withstand transport conditions
Design Considerations (cont.)

Electrical Issues

• Supply Mains
  – Interruption of power supply/supply mains
  – Voltage limitations

• Internal electrical power source
  – Typical operation time
  – Recharging
  – Replacing

• Permanently installed devices
  – Protective grounding

• Outlets and Adapters
  – Surge protection

• Power outages
  – Back-up power
  – Emergency contact information

• Battery life
Design Considerations (cont.)

- Electromagnetic Compatibility (EMC)
  - EMC testing
- Wireless Technology
  - Radio frequency (RF) wireless technology
- Alarm Systems
  - Noise inside/outside the home
  - Hearing impairments
  - Visual, auditory, tactile alarm signals
D. Human Factors

- Human factors validation study
- User training and certification
- Outline responsibilities of care partner, caregiver, and care recipient
- Recertification/retraining
E. Labeling

• Handling the device in an emergency
  – Natural disasters
  – Power outages

• Disposal
  – Regular versus biological waste
  – Sharps disposal

• Hygienic maintenance
  – Cleaning, disinfecting, sterilizing
Post Market Considerations

• Customer service
  – Technical assistance phone numbers, website, email address

• Medical Device Reporting
  – MedWatch

• * removed: Selling/Purchasing used prescription devices
Home Use Devices Should Be:

- Useful
- Usable
- Iterative
- Intentional
- Intuitive
- Integratable
- Informative
- Addressing the risks unique to the home
SAFE AND RELIABLE DEVICES LEAD TO LIVING WELL
Resources

www.fda.gov/homeusedevices

FAQs
Guidance
Resources
Educational materials
Thank you for participating

Please send your questions to:
DICED@fda.hhs.gov

For more information on the regulation of medical devices, visit CDRH Learn and Device Advice in the Medical Device section of FDA.gov