



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
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Medical Devices in the Home: Design Considerations and Guidance for Industry

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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

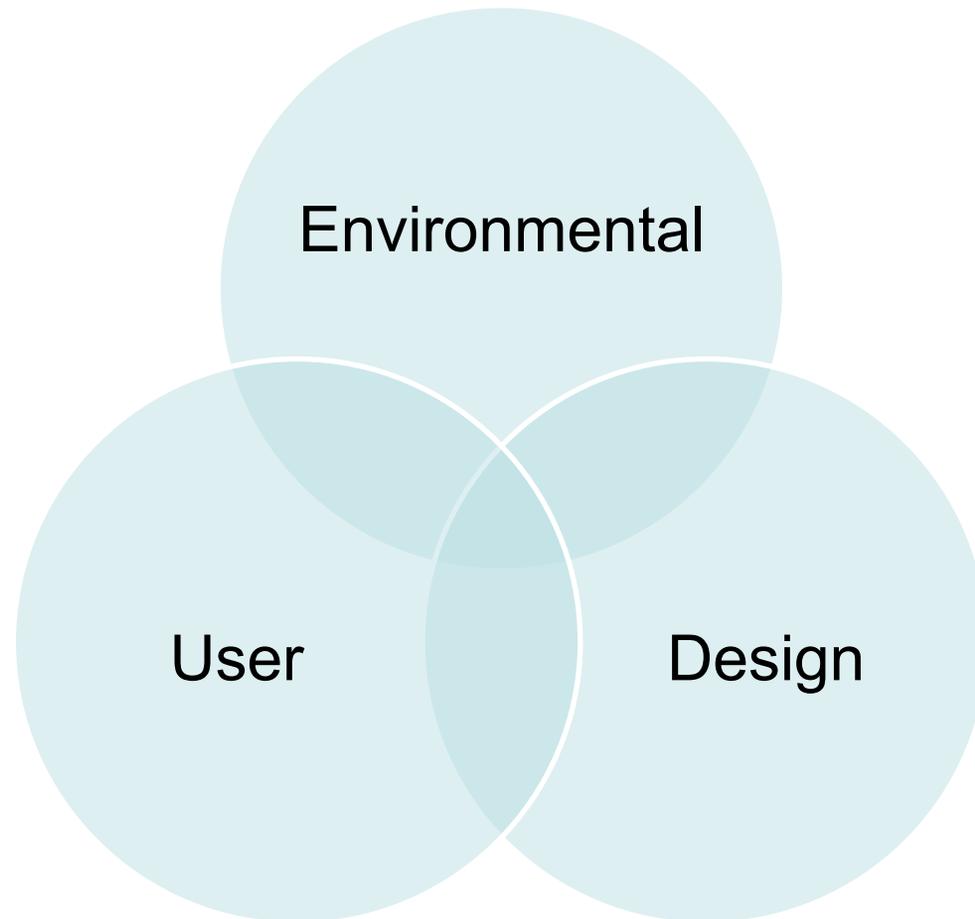


Home Use Medical Device Initiative 2010

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



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



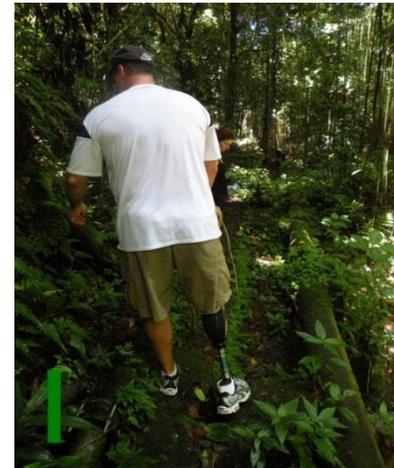
- Water Supply

- 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

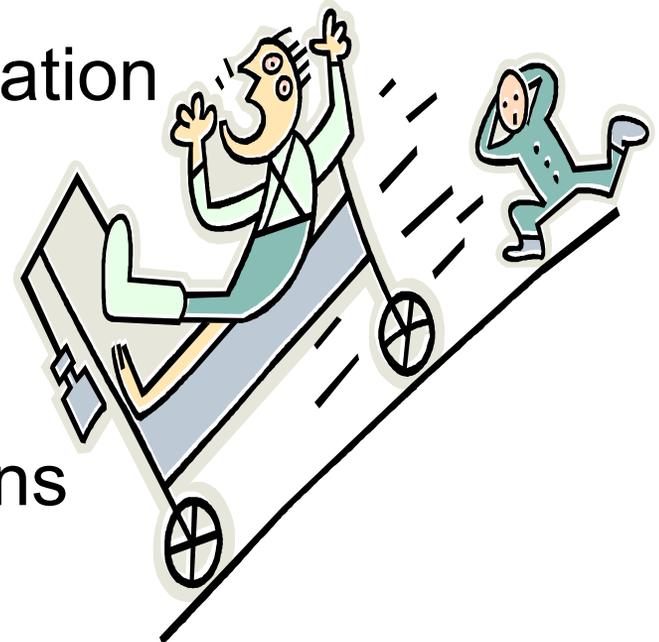
Cognitive: literacy level, cognitive impairment

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:

DICE@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