



Infection Control for Blood Glucose Monitoring Systems – Single vs. Multiple-Patient Use

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Background

- During the week of August 23, 2010, the FDA, CDC, and CMS issued clinical reminders and public health notifications highlighting the risk of transmission of disease from shared use of fingerstick (lancing) devices and point of care blood testing devices.
- These notifications were in response to recent outbreaks of viral hepatitis among patients where these devices were shared between users.

Background

- Accordingly, the FDA modified its regulatory review requirements for all blood glucose monitoring systems (BGMS) to ensure that validated cleaning and disinfection instructions are provided to users so that they may adequately respond to these recommendations.
- Letters to BGMS manufacturers were issued (September 2010) by FDA. New review requirements were applied to submissions that were in house (under review or on hold) or submitted thereafter.

OTC Meters in Healthcare Settings

- Majority of meters are designed for OTC use and are CLIA waived by regulation.
- Many of these meters designed for OTC home use are used in hospitals.

OTC Meters in Healthcare Settings

- Distinguished systems designed to be used at home by a single person from those that were intended to be used on multiple-patients:
 - intended use
 - naming
 - cleaning and disinfection validation testing
 - labeling
- Continue to allow sponsors to obtain “OTC” clearance even for the “multiple-patient, professional use” devices.

Single- vs. Multiple-Patient Use: Intended Use

Distinct products should be created with separate intended uses:

- For home use; single-patient use:
 - intended to be used by a single person and should not be shared
- For healthcare professional use; multiple-patient use:
 - intended for multiple-patient use in professional healthcare settings
 - system should only be used with single-use, auto-disabling lancing devices

Different Naming Schemes

- Device systems should have naming schemes that tie the components (system, meter and test strips) together and differentiate the systems (single- vs. multiple-patient use).
- CLIA categorized separately under the two distinct names.

Infection Control Validation

- EPA registered disinfectant effective against HBV
- Disinfection Efficacy Testing
- Device Robustness Testing

EPA Registered Disinfectant

- EPA registered disinfectant effective against HBV
 - Readily available for purchase by user
 - Acceptable disinfectant time (< 3 min)
 - No personal protective equipment
 - Follow EPA registered label instructions (pre-clean step, contact time...) for all validation testing

<http://oaspub.epa.gov/pestlabl/ppls.home>

Disinfection Efficacy Testing

- Demonstrate that the chosen EPA registered disinfectant is effective against Hepatitis B virus:
 - Using the materials used to make the device
 - EPA registered contact time
 - No cleaning step

Device Robustness Testing

- Demonstrate that the device can withstand the minimum number of expected cleaning and disinfection cycles within a typical use life (3-5 years).
- Should simulate actual use by the user (wiping). Wrapping, soaking, dunking are not acceptable methods
- Criteria to assess potential deterioration of performance and deterioration of external materials

Differences in Cleaning and Disinfection Claims

- Once per week for a single-patient use home device (minimum of 156 cycles to support a 3 year use life).
- After use on each patient for a multiple-patient use device (minimum of 10 cycles per day; minimum 10,950 cycles to support a 3 year use life) .

Labeling recommendations

- Emphasize the risk of disease transmission when using BGMS and reference any relevant public health notifications, standard practice guidelines, or other resources available to users.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Labeling recommendations

- Emphasize Lancing device usage:
 - The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
 - Lancing devices should never be shared. Only single-use, auto-disabling lancing devices can be used with multiple-patient use BGMS.

Labeling recommendations

- Description of disinfectant wipe and instructions on how these products can be purchased need to be clearly outlined.
- Recommended cleaning and disinfection frequency.
- The use life of the device and number of validated cleaning and disinfection cycles.
- A list of what things a user should look for as signs of deterioration (performance and physical).

Labeling recommendations

- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- A statement that users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.