

Frequently Asked Questions

If you have a question or two, chances are others do as well. If you have a question that is not answered here, please let us know! We'll be happy to contact you to answer your specific questions.

Q – What is the FDA status of the device?

A –The MOD has been classified as a Class I device by an FDA ruling in October 2005. The FDA calls the MOD[®] a “daily activity assist device.” It is also 510K exempt which means that no formal FDA approval is required other than documented compliance with the Code of Federal Regulations which requires a certified FDA manufacturer for the device and production to be in accordance with good manufacturing practice regulations and design controls.

Q – Isn't there a ruling that the nurse should observe a patient taking a pain pill?

A – There is no Joint Commission requirement that states that the patient must be observed while taking the medication. The Joint Commission states that under the accreditation standard MM 5.20 that hospitals have a policy for self administered medications to be safely and accurately administered. Under that guideline the patient must receive training and appropriate information regarding the nature of medication, how to administer the medication and the expected action and side effect of the medication. In that policy there should also be a plan as to how to monitor the patient. Patients taking their own medication from the MOD must also be determined to be competent before being allowed to use the medication.

The MOD Hospital Sample Policy provided with the MOD materials addresses these areas. Patients can only use the MOD via a doctor's order. All patients must complete a simple teaching module and demonstrate that they are capable of using the device before the device can be left at the bedside. Nursing is required to reassess the patient's pain for prn pain medications and this will provide an opportunity to monitor the patient. Most patients that begin the MOD have already received intravenous pain medication or they are already on chronic breakthrough oral pain medications.

Under The Joint Commission guideline MM 7.10 for high risk medications which would include pain medications with abuse potential, hospital policies must identify these medications and have policies for safely administering these medications.

Q – Does the MOD record how many attempts have been made to remove a medication from the device? This is recorded in IV PCA devices.

A –The MOD does not have this function. Patients learn very quickly using the MOD that if the bright green ready light is **not** on, then it is futile to try and access a

medication. Since the MOD[®] records the pain score with each dose administered, the staff will have an opportunity with the scores and reassessment visits to determine quickly if the patient is receiving adequate medication for their level of pain.

Q – How do we clean the MOD between different patient uses?

A –The FDA standards require that medical devices be evaluated for proper cleaning procedures as designated in the Association for the Advancement of Medical Instrumentation document AAMI TIR 12:2004. The MOD has been formally reviewed by The North American Science Associates, Inc (NAMSA) for cleaning requirements. The MOD has been judged to be a reuseable device with a disposable clean tray of medications supplied for each patient. Because the tray is disposable, the risk of cross contamination is minimized. Therefore the MOD can be cleaned using a simple wipe down of all the exposed surfaces between patients or when soilage occurs. A low level disinfectant is acceptable. A detailed cleaning protocol is supplied as part of the MOD documents package at the time of first use or purchase.

Q – How will the medication be wasted from the MOD[®] trays if the patient is discharged before the tray contents are used or if the medication is changed from one drug to another during the hospitalization.

A – Each hospital is required to have a waste policy for oral pain medications. The waste procedure would be same for the MOD tray medications that are not fully used prior to disposal.